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Module Catalogue

Regulatory Affairs and Compliance E-learning Solutions

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Module Catalogue Contents

About Us:

Zenosis is an Internet-based, regulatory and compliance learning-on-demand provider. Zenosis is available as a remote or integrated solution for life science organisations with contrasting sizes of user base. This almost instantly deployable solution is a continually updated resource providing vital knowledge that will enable your staff to comply with regulatory requirements and increase productivity. This is offered at a cost substantially less than that of conventional training methods, resulting in increased return on investment.

Zenosis modules are accredited with Continuing Professional Development (CPD) points by the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom.

ESS01	Essentials of EU and US Regulatory Affairs for Human Medicinal Products
ESS02	Essentials of Monoclonal Antibodies
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SUB02	The European Centralised Procedure (CP)
SUB03	The Mutual Recognition Procedure (MRP)
SUB04	Preparing Submissions in the Common Technical Document (CTD) Format
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SUB11	The Decentralised Procedure (DCP)
SUB12	Registration of Medicinal Products Based on Monoclonal Antibodies
SUB13	How to Gain Approval to Market a Generic Drug in the USA
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CT01	How to Gain and Maintain Approval for Clinical Research Under the EU Clinical Trials Directive
CT03	ICH Good Clinical Practice
CT04	An Introduction to Clinical Trial Preparation and Design
CT06	Clinical Trial Monitoring: Site Evaluation and Set-up
CT07	An Introduction to Clinical Trials and Drug Development
CT08	Clinical Trial Monitoring: Study Monitoring, Documentation and Closure
CT09	Good Clinical Practice Inspections and Audits
CT10	The Investigational New Drug Application (IND) to Conduct FDA-regulated Clinical Trials
CT11	How to Gain Authorisation for Clinical Research Under the EU Clinical Trials Regulation
CT12	How to Conduct Clinical Research Under the EU Clinical Trials Regulation
CT13	Safety Reporting in Clinical Trials
CT14	Clinical Trial Safety Reporting Requirements in the EU and USA

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Module catalogue contents continued

PKPD01	An Introduction to Pharmacokinetics and Pharmacodynamics in Drug Development and Registration
PKPD02	Conducting Pharmacokinetic and Pharmacodynamic Studies
GXP01	Good Practices (GxP) in Drug Development and Manufacturing
GMP01	An Introduction to Good Manufacturing Practice for Medicinal Products
GMP02	Good Documentation Practice
GMP03	Good Manufacturing Practice in Cleaning and Sanitation
GMP04	Good Manufacturing Practice for the Warehouse
GMP05	Good Manufacturing Practice in Processing Medicinal Products
GMP06	Good Manufacturing Practice in Packaging Medicinal products
GMP07	Corrective and Preventive Action (CAPA) in Medicinal Products Manufacture
PV03	An Introduction to Drug Safety and Pharmacovigilance
PV04	Signal Detection and Management in Pharmacovigilance
PV05	Risk Management Planning for Medicinal Products
PV06	Urgent Safety Restrictions
PV07	Good Pharmacoepidemiology Practice
ICT01	Compliance with Regulation 21 CFR Part 11 on Electronic Records and Electronic Signatures
MD01	An Introduction to the Regulation of Medical Devices
VAL01	Introduction to Validation
VAL02	Validation Plans and Documentation
VAL03	Commissioning and Installation Qualification
VAL04	Operational and Performance Qualification
VAL05	Equipment Cleaning Validation
VAL06	Computer Systems Validation, Part 1: Planning
VAL07	Computer Systems Validation, Part 2: Implementation
SAM01	Legal and Regulatory Framework for Advertising and Promotion of Prescription Drugs in the USA
SAM02	Regulatory Requirements and Guidance on Advertising and Promotion of Prescription Drugs in the USA
SAM03	Consumer-directed Advertising and Online Promotion of Prescription Drugs in the USA
SAM04	Marketing of Prescription Drugs in the USA — Interactions with Healthcare Professionals

Essentials

ESS01: Essentials of EU and US Regulatory Affairs for Human Medicinal Products

ESS02: Essentials of Monoclonal Antibodies

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ESS01 Essentials of EU and US Regulatory Affairs for Human Medicinal Products

Approximate study time: 3 hours

Level: Foundation

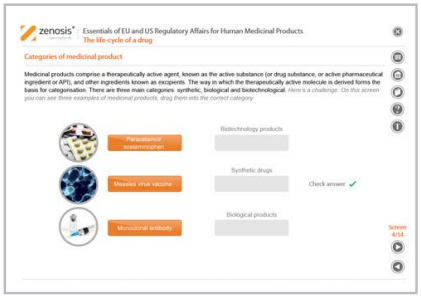
Audience: Regulatory

Category: Preclinical, Clinical, Pharmacovigilance, Manufacturing and QC, IT, Regulatory Submissions, Commercial, Chemistry and Pharmacy

Region: USA, Europe

CPD Points: 3

Module outline
- Regulatory affairs primer
- The life-cycle of a drug
- Registering a drug
- After marketing approval
- Assessment



This foundation-level module is the ideal introduction for new entrants to the field of pharmaceutical regulatory affairs and compliance. It describes the principal requirements that must be satisfied to gain and maintain approval to market medicinal products in the USA and Europe. The legal framework and the roles of major players in regulation are presented. The life-cycle of a drug is outlined. The various procedures available for assessment and approval of products are described and their requirements outlined. Obligations to be fulfilled after marketing approval are discussed.

Who will benefit from this module?

All staff in the pharmaceutical and biotechnology industries who are inexperienced in regulatory affairs and compliance will find the module an invaluable introductory training course. More experienced personnel will find it a useful reference tool. It will also be of benefit to healthcare professionals who contribute to the development of medicinal products.

Learning objectives

- Describe the role and responsibilities of regulatory affairs within the pharmaceutical industry in both the EU and the USA.
- Identify the main legislative instruments relating to medicinal products in both the EU and USA.
- Understand the main phases of the drug development process and be aware of the regulatory requirements that apply.
- Describe the requirements for applications for marketing approval and the procedures to be followed in both the EU and USA.
- Identify post-marketing regulatory activities in both the EU and USA.

Module outline

Regulatory affairs primer
This session gives a definition of regulatory affairs and outlines the function and evolution of regulation in the pharmaceutical industry as well as providing a source of key legislation and guidelines. National and international regulatory authorities are introduced including the legal frameworks in the USA and EU.

The life-cycle of a drug
This session looks at the main differences between types of medicinal products, outlines the discovery phase and nonclinical studies and gives a basic introduction to Good Laboratory Practice. It also identifies the four phases of clinical development and introduces some of the special difficulties associated with paediatric trials.

Registering a drug
This session looks at the regulatory requirements during the nonclinical studies phase as well as the salient points of Good Clinical Practice. It also introduces the regulatory processes involved in gaining marketing authorisation in the EU and the USA. The session also introduces the learner to orphan drugs, line extensions, generics, naming conventions and compassionate use.

After marketing approval
This session explores post-marketing approval activities, including variations and supplements, line extensions and pharmacovigilance, GMP, basic patent law in the EU and USA, marketing issues, advertising and generics.

Assessment
Multiple-choice mastery assessment.

ESS02 Essentials of Monoclonal Antibodies

Approximate study time: 1 hour

Level: Introductory

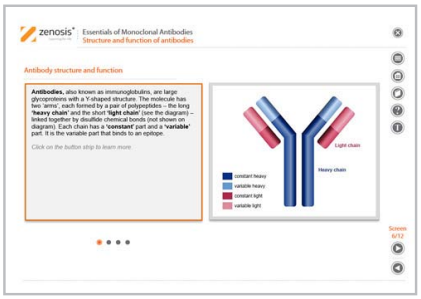
Audience: Research, Regulatory, Manager

Category: Chemistry and Pharmacy, Preclinical, Clinical, Manufacturing and QC

Region: USA, Europe, Other

CPD Points: 1

Module outline
- Module overview
- Structure and function of antibodies
- Production of mAbs
- Uses of mAbs
- Assessment



Monoclonal antibodies (mAbs for short) are the leading products of biotechnology. Drugs based on mAbs dominate the list of top-selling medicines worldwide. In addition, mAbs have many uses in medical diagnosis, in laboratory analysis, and in the biotechnology industry itself.

This module will introduce you to monoclonal antibodies, explaining how they work, how they are made, and the many uses to which they are put.

Who will benefit from this module?

This module will benefit anyone educated in science to high school level or beyond who wants an introduction to the basics of monoclonal antibodies.

Learning objectives

- Describe the structure and function of antibodies in the body
- Distinguish types of monoclonal antibody by their source and constitution
- Outline important factors in the production of mAbs
- Identify major uses of mAbs

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Structure and function of antibodies
In this session we discuss the role of natural antibodies and outline how the dream of creating 'magic bullets' to fight disease has been realised. We identify the structural components of antibodies and describe their actions. We distinguish types of monoclonal antibody by their non-human and human components. Finally, we sketch how some therapeutic mAbs can be linked to cell-killing agents to increase their effectiveness against cancer.

Production of mAbs
Production of a mAb proceeds from the generation of a cell line possessing the mAb's gene sequence, through bulk cell culture, to isolation and purification of the antibody. In this session we describe options for generation of the cell line, we outline the downstream production processes, and we identify important issues for the assurance of product quality.

Uses of mAbs
In this session we describe the wide range of uses for mAbs in laboratory analysis, in-vivo diagnosis and therapy, and purification in the biotechnology industry. We give examples of mAb products in each category of application.

Assessment
Multiple-choice mastery assessment.

Regulatory Submissions

SUB01: Orphan Drug Designation in the USA and Europe
SUB02: The European Centralised Procedure (CP)
SUB03: The Mutual Recognition Procedure (MRP)
SUB04: Preparing Submissions in the Common Technical Document (CTD) Format
SUB05: Electronic Common Technical Document (eCTD)
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SUB01 Orphan Drug Designation in the USA and Europe

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

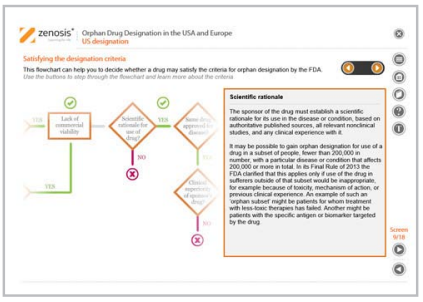
Audience: Regulatory, Other

Category: Regulatory Submissions

Region: USA, Europe

CPD Points: 1.5

Module outline
- Module overview
- Rare diseases and orphan drugs
- US designation
- European designation
- Assessment



Medicines for the prevention, diagnosis, or treatment of rare diseases have become known as 'orphan drugs' because of their commercial unattractiveness. Development of such products is successfully encouraged through incentives offered by regulatory authorities. To qualify for important incentives, the sponsor of a drug must gain 'orphan designation' for its use in an indication. This module describes the requirements for orphan designation and how to apply for it in the USA and the European Economic Area.

Who will benefit from this module?

This module is intended primarily for regulatory affairs professionals. Staff inexperienced in regulatory affairs and compliance will find the module an invaluable introductory training course; more-experienced personnel will find it a useful reference tool. More generally, it will be of interest to all those involved in the development and registration of medicinal products.

Learning objectives

- Explain why and how governments encourage the development of medicines for rare human diseases, and identify important sources of information
- Specify incentives offered for the development of medicines for rare diseases in the USA and in Europe
- State the criteria for orphan drug designation in the USA and in Europe
- List the contents of an application for orphan designation in the USA and in Europe, describe how to make an application in each case, and outline the process of review by the regulatory authority
- Outline the sponsor's obligations and options after orphan designation in the USA and in Europe.

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Rare diseases and orphan drugs
Development of medicines for prevention, diagnosis, or treatment of rare diseases is commercially unattractive, so governments offer incentives to encourage it. In this session, we introduce the concept of orphan drug designation, discuss how it fits within a product development strategy, and identify some important sources of information on rare diseases and orphan drugs.

US designation
Legislation to encourage research and development of drugs for rare diseases was introduced first in the USA. In this session we describe the US legal framework for orphan drug designation and specify the incentives offered. We set out the criteria for orphan designation and how they should be satisfied. We list the contents of an application for designation and outline how to apply. Finally we identify the sponsor's obligations and options after designation.

European designation
In this session we describe the European Union's legal framework for orphan medicine designation and specify the incentives offered. We set out the criteria for orphan designation and how they should be satisfied. We specify the contents of an application for designation, describe how to apply, discuss the procedures for validation and evaluation of the application, and outline the provisions for appeal against refusal of designation. Finally we identify the sponsor's obligations and options after designation.

Assessment
Multiple-choice mastery assessment.

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SUB02 The European Centralised Procedure (CP)

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

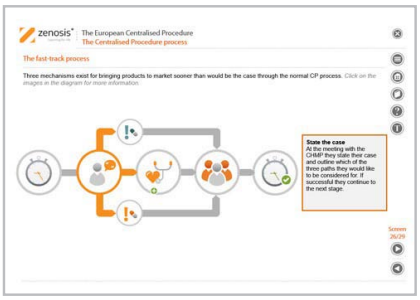
Audience: Regulatory

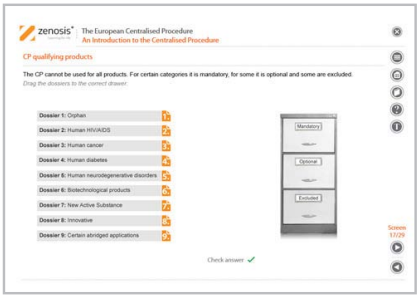
Category: Regulatory Submissions

Region: Europe

CPD Points: 1.5

Module outline
- Module overview
- An introduction to the CP
- The Centralised Procedure Process
- Assessment





The Centralised Procedure is one of three routes available to applicants to gain multinational marketing authorisation within the European Economic Area (EEA) on the basis of a single application. In the CP, one successful application leads to a marketing authorisation being issued by the European Commission that applies throughout the EEA. The CP is mandatory for certain types of products.

This module describes the various players in the procedure, the sequence and duration of the stages involved, and the requirements on content, format and timing of submissions.

Who will benefit from this module?

This module is primarily aimed at regulatory affairs professionals dealing with marketing authorisation applications and related submissions for regulatory approval in Europe. More generally, it will also be of interest to all those involved in the development and registration of medicinal products.

Learning objectives

- Provide an overview of the CP process.
- Identify which products may/must use the CP
- For products for which the CP is optional, outline the advantages and disadvantages of the CP compared with other routes to marketing authorisation.
- Describe requirements on content, format and timing of submissions.
- Specify the sequence and duration of the stages of the CP and the responsibilities of the participants.
- Describe the role of the European Medicines Agency and its relevant competent committee.
- Outline fast-track provisions.
- Describe the appeals procedure.

Module outline

Module overview
Provides an overview of the content of the module and outlines related Zenosis modules

An introduction to the Centralised Procedure
This session provides background information. It specifies the types of product for which the CP is mandatory and those for which it is optional. It discusses the types of Marketing Authorisation Application, and characteristics of the application procedure.

The Centralised Procedure process
This session takes you through the entire process from pre-submission to what happens after an Opinion has been received.

Assessment
Multiple-choice mastery assessment.

SUB03 The Mutual Recognition Procedure (MRP)

Approximate study time: 2 hours

Level: Introductory/Intermediate

Audience: Regulatory

Category: Regulatory Submissions

Region: Europe

CPD Points: 2

Module outline
- Module overview
- Introduction
- The MRP process
- Generics and the MRP
- Assessment

The Mutual Recognition Procedure is one of three routes available to applicants to gain multinational Marketing Authorisation within the European Economic Area (EEA) on the basis of a single application. A national authorisation is converted to harmonised authorisations issued in a number of other member states chosen by the applicant.

The MRP is similar to the Decentralised Procedure but with later involvement of the Concerned Member States in the assessment by the Reference Member State. The Coordination Group for Mutual Recognition and Decentralised Procedures provides guidance and acts to facilitate agreement among the participating states.

This module describes the roles of the various players in the procedure, the sequence and duration of the stages involved, and the requirements on content, format and timing of submissions. It discusses the special issues that apply to generic products in the MRP.

Who will benefit from this module?

This module is primarily aimed at regulatory rffairs professionals dealing with marketing authorisation applications and related submissions for regulatory approval in Europe. More generally, it will also be of interest to all those involved in the development and registration of medicinal products.

Learning objectives

- Provide an overview of the MRP process.
- Describe the pre-submission and submission actions in relation to timeline deadlines.
- Specify the responsibilities of the Reference Member State (RMS), the Concerned Member States (CMSs) and the applicant.

Module outline

Module overview
Provides an overview of the content of the module and outlines related Zenosis modules.

Introduction
This session provides background information. It covers products for which the MRP can be used, the types of Marketing Authorisation Application, and characteristics of the application procedure.

The MRP process
This session takes you through the entire process from initial national authorisation by the RMS to the issuing of national licences by the CMSs. Referral of issues to the CMD, and the arbitration process, are also covered.

Generics and the MRP
This session gives a brief introduction to generics and the special issues that apply to generic products in the MRP.

Assessment
Multiple-choice mastery assessment.

SUB04 Preparing Submissions in the Common Technical Document (CTD) Format

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

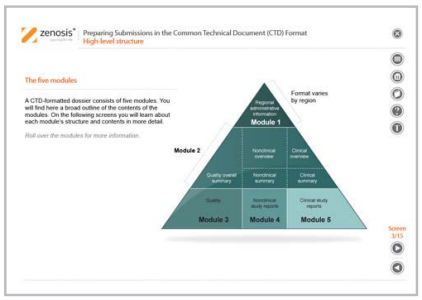
Audience: Regulatory

Category: Regulatory Submissions

Region: USA, Europe, Other

CPD Points: 1.5

Module outline
- Introduction
- High-level structure
- Fine structure and format
- Using the CTD
- Conversion tools
- Assessment



The CTD is the internationally recognised standard format for submissions to medicines regulatory authorities. In the European Economic Area, the USA and Canada, the CTD, in its electronic format (eCTD), is mandatory for all applications for marketing approval and all subsequent related submissions. The CTD is accepted in many other countries, being mandatory for new prescription medicines in some. This module explains the rationale for the CTD and provides guidance on its structure and formatand the ways in which it is used.

Who will benefit from this module?

Regulatory affairs and compliance staff, and all those involved in drug development and who contribute to regulatory submissions, will find the module an invaluable introductory training course and/or a useful reference tool. Specialists in data handling, knowledge management or documentation will also wish to familiarise themselves with its contents.

Learning objectives

- Explain the rationale for the CTD, and describe the ways in which it is used.
- Identify regional differences in regulatory requirements for information in a CTD-formatted submission.
- Describe the structure of the CTD.
- Access guidance on detailed structure and content of the CTD.
- Outline formatting requirements for a CTD dossier.

Module outline

Introduction
This session introduces you to the nature of the Common Technical Document (CTD), a global standard designed by the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) The composition of a regulatory submission team is outlined.

High-level structure
In this session you will become more familiar with the five modules of the CTD.

Fine structure and format
You will be given access to guidelines that specify in detail the structure of each module of the CTD and the relationship between their sections and the documents that make up a dossier. Recommendations are also given on how to segregate and paginate documents and how to format pages, tables of contents and cross-references.

Using the CTD
Different ways in which you can use the CTD in practice are described.

Assessment
Multiple-choice mastery assessment.

SUB05 Electronic Common Technical Document (eCTD)

Approximate study time: 2.5 hours

Level: Introductory/Intermediate

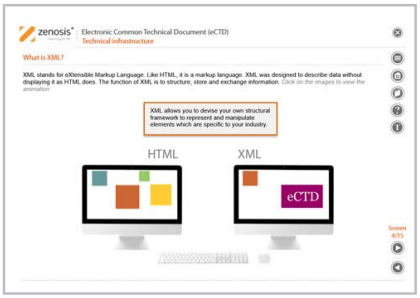
Audience: Regulatory

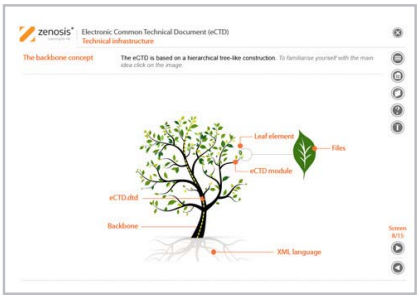
Category: Regulatory Submissions, ICT

Region: USA, Europe, Other

CPD Points: 2.5

Module outline
- Introduction
- Technical infrastructure
- Directory structure
- Creating an eCTD submission
- Special components
- Tools
- Assessment





The eCTD is mandatory for all applications for marketing approval and all subsequent related submissions in the European Economic Area, the USA and Canada. Other countries intend to make its use mandatory. The eCTD specification has been developed to facilitate the global electronic submission, review and lifecycle management of medicinal product dossiers for regulatory applications. It broadens the scope of the CTD to include information on variations, renewals and amendments, so that it is no longer a static document but is updatable throughout the life of the product. This module outlines the eCTD specification, discusses the approach to regional differences in dossiers, and provides guidance on creation of an eCTD submission. The module provides a training and reference tool that will be of particular value to those new to the use of the format.

Who will benefit from this module?

This module is an essential tool for regulatory affairs and compliance staff and specialists in data handling, knowledge management or documentation. All those involved in drug development and who contribute to regulatory submissions will also wish to familiarise themselves with its contents.

Learning objectives

- Describe the structure, requirements and functionality of the eCTD.
- Outline XML basics and the architecture of the eCTD.
- Discuss Document Type Definitions (DTDs) and schemas.
- Explain how to build an eCTD.
- Specify regional differences.
- Discuss life cycle and change management.
- List criteria that will make an electronic application technically valid.
- Initiate electronic transfer to a regulatory authority.
- Create, submit and maintain an eCTD dossier throughout the life of a drug product.

Module outline

Introduction
This session defines the eCTD and identifies advantages of using this submission format.

Technical infrastructure
This session gives information on XML specification and style sheets and describes the eCTD backbone.

Directory structure
This session looks at the eCTD hierarchy, life cycle management and structure of the five modules.

Creating an eCTD submission
This session explores the workflow around planning, creating and submitting an eCTD – particularly setting up the modules, and migrating and validating the data.

Special components
Features of the Canadian, EU, Japanese and US DTDs/schemas and the STF specification are outlined.

Tools
This session includes a case study and an eCTD checklist to assist learners when compiling an eCTD submission.

Assessment
Multiple-choice mastery assessment.

SUB06 Variations to Marketing Authorisations in Europe

Approximate study time: 3.5 hours

Level: Intermediate

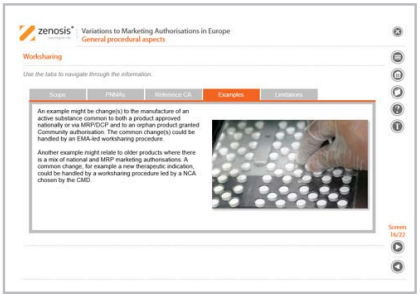
Audience: Regulatory

Category: Regulatory Submissions

Region: Europe

CPD Points: 3.5

Module outline
- Defining variations
- Determining variation types
- General procedural aspects
- Variations via the Centralised Procedure
- Variations via the Mutual Recognition Procedure
- Case study
- Assessment



Changes to the terms of marketing authorisations for medicinal products, called variations in Europe, must be notified to or approved by the relevant regulatory authorities. Variations include changes to the composition of products, their manufacturing processes, the way they are used, or the indications for which they are authorised. Common approaches are adopted within the European Economic Area to variations to marketing authorisations approved through the Centralised, Decentralised or Mutual Recognition Procedures. Recent legislation has substantially modified the regulatory requirements and extended them to purely national authorisations by member states. This module, which is fully up to date with the new legislation, covers the classification of variations into their several types and the regulatory requirements, guidance and procedures to be followed for each type.

Who will benefit from this module?

Regulatory affairs and compliance staff, and all those who contribute to regulatory submissions, will find the module an invaluable introductory training course and/or a useful reference tool.

Learning objectives

- Define the concept of variations to marketing authorisations in the EEA.
- Identify which type of variation is appropriate for each kind of change to be made.
- Identify the documentation required to support the variation.
- Describe how to prepare and submit variation notifications or applications appropriate for each type of variation and route of regulatory approval, including options for grouping of variations and for work sharing of assessment.

Module outline

Defining variations
This session identifies and characterises the different types of variation.

Determining variation types
This session looks at the reasons for variations and describes how to identify the type of variation appropriate for each change required.

General procedural aspects
This session describes the different routes to regulatory approval of variations, identifies which is appropriate for a given product, specifies the supporting documentation necessary, and describes the provisions for grouping multiple variations into a single submission and for work sharing of regulatory assessment among member states.

Variations via the Centralised Procedure
This session describes the processes specific to the submission and processing of variations notifications and applications through the Centralised Procedure.

Variations via the Mutual Recognition Procedure
This session describes the processes specific to the submission and processing of variations notifications and applications through the Mutual Recognition Procedure.

Case study
A case study of a flawed submission process.

Assessment
Multiple-choice mastery assessment.

SUB09 The New Drug Application (NDA) for Marketing Approval in the USA

Approximate study time: 3.5 hours

Level: Introductory/Intermediate

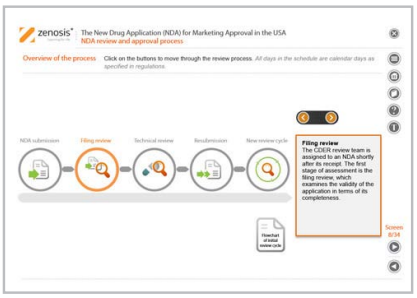
Audience: Regulatory

Category: Regulatory Submissions

Region: USA

CPD Points: 3.5

Module outline
- Module overview
- Introduction
- High-level content and formatting
- Quality information
- Nonclinical information
- Clinical information
- Administrative information and summaries
- NDA review and approval process
- Expedited development and review
- Assessment



The New Drug Application (NDA) is the regulatory vehicle through which sponsors formally propose that the Food and Drug Administration (FDA) approve a new pharmaceutical for marketing and sale in the USA.

This module sets out the FDA's requirements for content and formatting of the NDA, details the process by which the agency reviews and approves an application, and describes the applicant's actions in that process.

Mechanisms for expedited drug development and review, including breakthrough therapy designation, are also outlined. The module is up to date with the sixth reauthorisation of the Prescription Drug User Fee Act (PDUFA VI) for fiscal years 2018 to 2022.

Who will benefit from this module?

This module is intended primarily for regulatory affairs professionals who are new to the NDA or who seek a refresher course. It will also be of interest to others involved in drug development and/or who interact with the FDA.

Learning objectives

- Summarise the content and format requirements for a New Drug Application
- Outline the procedural requirements for an NDA submission to the FDA.
- Describe the role of the FDA in the NDA review and approval process.
- List the principal provisions available from the FDA for expedited drug development and review, and summarise the criteria that apply to them.

Module outline

Overview
Provided in this session is information on the module: the scope, the areas not covered, module objectives and US legislative framework. The background and history of NDAs is also included in this session.

Introduction
This session defines the NDA, outlines the history of related legislation, describes desirable interaction with the FDA, and introduces the US regulatory framework.

High-level content and formatting
This session provides an overview of the fundamental content and format requirements of an NDA for submission to the FDA.

Quality information
The CMC information that must be detailed in the application is described in this session.

Nonclinical information
The nonclinical information that must be provided in an NDA is summarised in this session.

Clinical information
This session sets out the components of the clinical information required in an NDA.

Administrative information and summaries
The administrative and prescribing information and the summaries required in an NDA are outlined.

NDA review and approval process
Details of the FDA's review and approval process are provided.

Expedited development and review
This session describes priority review, accelerated approval, fast track development, and breakthrough therapy designation.

Assessment
Multiple-choice mastery assessment.

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SUB11 The Decentralised Procedure (DCP)

Approximate study time: 2 hours

Level: Introductory/Intermediate

Audience: Regulatory

Category: Regulatory Submissions

Region: Europe

CPD Points: 2

Module outline
- Module overview
- An introduction to the DCP
- DCP Step 1
- DCP Step 2
- Generics and the DCP
- Assessment

The Decentralised Procedure is one of three routes available to applicants to gain multinational marketing authorisation within the European Economic Area (EEA) on the basis of a single application. It can be used only for a product which has no existing marketing authorisation in any member state. It is similar to the Mutual Recognition Procedure (MRP) but with earlier involvement of the Concerned Member States in the assessment by the Reference Member State. The Coordination Group for Mutual Recognition and Decentralised Procedures (CMD) provides guidance and acts to facilitate agreement among the participating states.

This module describes the roles of the various players in the procedure, the sequence and duration of the stages involved, and the requirements on content, format and timing of submissions. It discusses the special issues that apply to generic products in the DCP.

Who will benefit from this module?

This module is primarily aimed at regulatory affairs professionals dealing with marketing authorisation applications and related submissions for regulatory approval in Europe. More generally, it will also be of interest to all those involved in the development and registration of medicinal products.

Learning objectives

- Provide an overview of the DCP process.
- Describe the pre-submission and submission actions in relation to timeline deadlines.
- Specify the responsibilities of the Reference Member State (RMS), the Concerned Member States (CMSs) and the applicant.

Module outline

Module overview
Provides an overview of the content of the module and outlines related Zenosis modules.

An introduction to the Decentralised Procedure
This session provides background information. It covers products for which the DCP can be used, the types of Marketing Authorisation Application, and characteristics of the application procedure.

The DCP Step 1
This session takes you through the pre-procedural step and the first assessment stage of the DCP, as far as day 120.

The DCP Step 2
This session takes you through the second assessment stage and the final step of issuing national licences. Referral of issues to the CMD, and the arbitration process, are also covered.

Generics and the DCP
This session gives a brief introduction to generics and the special issues facing generics in the DCP.

Assessment
Multiple-choice mastery assessment.

SUB12 Registration of Medicinal Products Based on Monoclonal Antibodies

Approximate study time: 1.5 hours

Level: Intermediate

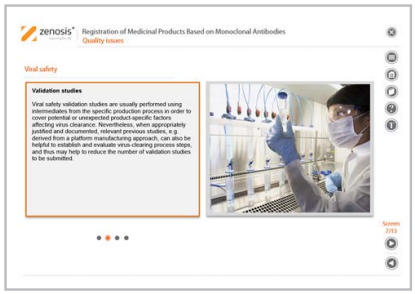
Audience: Regulatory, other

Category: Regulatory Submissions, Preclinical, Clinical, Manufacturing and QC

Region: USA, Europe, Other

CPD Points: 1.5

Module outline
- Module overview
- Quality issues
- Nonclinical issues
- Clinical issues
- Radiolabelled antibodies
- Regulatory submissions
- Assessment



This module addresses characteristic issues influencing the registration of medicinal products based on monoclonal antibodies (mAbs), for use in humans. Regulatory requirements for the registration of biological medicinal products such as those based on mAbs differ in certain respects from those for small-molecule products. This is because of the distinct characteristics of biologics, such as complex structure and susceptibility to variation during manufacture.

In this module, we focus on distinctive issues in the production and testing of mAbs, in the context of relevant regulatory guidance. We discuss manufacturing quality, nonclinical, and clinical issues. We address aspects specific to radiolabelled mAbs. Finally, we identify the pathways for applications to conduct clinical trials and to market mAb-based products in Europe and the USA.

Who will benefit from this module?

This module will benefit regulatory affairs staff and others concerned with the registration of medicinal products based on monoclonal antibodies.

Learning objectives

- Discuss key quality issues in the manufacture of mAb-based products
- Discuss key issues in nonclinical studies of mAb-based products
- Discuss key issues in the clinical investigation and use of mAb-based products
- Identify specific considerations for radiolabelled mAb-based products
- Identify the pathways for applications to conduct clinical trials and to market mAb-based products in Europe and the USA

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Quality issues
Quality information requirements for the registration of mAb-based products focus on characterisation and specifications in areas such as identity, purity, and potency. Information must be provided on the origin and history of the starting materials, and the manufacturing process and its validation must be thoroughly described. Measures taken and validated to control impurities and to clear viruses and other contaminants need to be set out.

Nonclinical issues
Like other drugs, mAb-based products must undergo laboratory and animal testing to define their pharmacological and toxicological effects before they can be studied in humans. The regulatory framework for nonclinical testing of mAb-based products is essentially similar to that for non-biological drugs. Nevertheless, mAbs present special issues, requiring an adaptable, ad hoc scientific approach to nonclinical testing.
In this session, we discuss issues such as studies of cross-reactivity with human tissues, choice of species for nonclinical studies, exposure level, and recipient antibody responses.

Clinical issues
MAbs present issues for clinical development and use, such as assessment of immunogenicity, which typically do not arise for small-molecule medicinal products. This session addresses such characteristic issues.

Radiolabelled antibodies
Monoclonal antibodies may form the basis of radiopharmaceuticals for in-vivo diagnostic use or for radiotherapy. In this session we address characteristics of radiolabelled mAbs.

Regulatory submissions
In this session, we identify the pathways for applications to conduct clinical trials and to market a mAb-based product in Europe and the USA, along with relevant legal statutes, regulations, and regulatory guidance.

Assessment
Multiple-choice mastery assessment.

SUB13 How to Gain Approval to Market a Generic Drug in the USA

Approximate study time: 3 hours

Level: Introductory/Intermediate

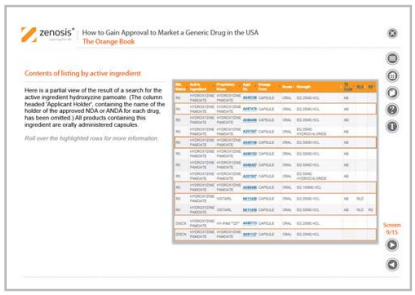
Audience: Regulatory

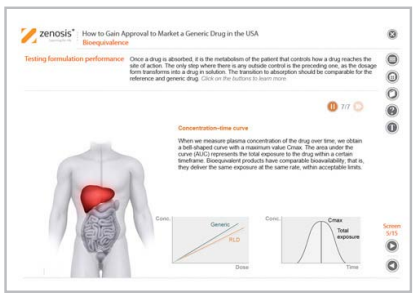
Category: Regulatory Submissions

Region: USA

CPD Points: 3

Module outline
- Module overview
- Generic drugs and the ANDA
- Patent certification
- The Orange Book
- Bioequivalence
- ANDA compilation and submission
- ANDA review and approval
- The Generic Drug User Fee Amendments
- Assessment





This module outlines the legislative and regulatory context for the development of generic drugs and describes the essential role of the Abbreviated New Drug Application (ANDA) in gaining marketing approval. The use of information in the 'Orange Book' is explained, as is the role of patent certification in the application. The importance of establishing bioequivalence between a generic and its reference product is emphasised. The module specifies the content and format requirements for an ANDA submission and describes the FDA's review and approval process. An outline is given of the Generic Drug User Fee Amendments (GDUFA) and the law's effects on industry players.

The module is up to date with the many final and draft publications, recently released by the FDA, that provide guidance for industry on applications for approval of generic drugs. It is also up to date with the provisions of the third authorisation of GDUFA, applicable in US fiscal years 2023 to 2027.

Who will benefit from this module?

This module will benefit staff working in regulatory affairs, medical affairs, clinical development, CMC, analytical methods, and quality assurance departments, and other personnel who contribute to the development and registration of generic drugs.

Learning objectives

- List the criteria for therapeutic equivalence of drugs
- Outline the types of patent classification for an ANDA submission
- Explain how to use the Orange Book in the development of a generic drug
- Describe methods for determining bioequivalence of drug products
- Outline the content and format requirements for an ANDA submission
- Describe the ANDA review and approval process
- Outline the provisions of the Generic Drug User Fee Amendments and summarise their effects on generics sponsors

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Generic drugs and the ANDA
An overview of the legislative and regulatory context for the development and approval of generic drugs, particularly the Hatch-Waxman Act; a summary of the criteria for therapeutic equivalence of drugs; obtaining guidance from the FDA; controlled correspondence.

Patent certification
The role of patent certification in an ANDA submission, the different types of certification, what happens when a patent is challenged, and the circumstances under which marketing exclusivity may be afforded to a generics sponsor.

The Orange Book
The use of the Orange Book in generic drug development, the format and content of the Book's listings, and how to extract information for an ANDA.

Bioequivalence
The crucial importance of establishing bioequivalence with a reference listed drug; tests of bioavailability and bioequivalence; the statistical criteria for bioequivalence; waivers of in-vivo studies.

ANDA compilation and submission
Planning and managing an ANDA project; regulatory requirements on content and format; quality (CMC), labeling, and bioequivalence information; submitting an ANDA to the FDA's Office of Generic Drugs.

ANDA review and approval
The process of review by the FDA; review duration and success rate; communication between applicant and FDA; expedited review; petitions; amendments and easily correctable deficiencies; outcomes of review, and the applicant's options in response to those outcomes.

The Generic Drug User Fee Amendments
The types of fees that the generics industry must now pay to the FDA; requirements for self-identification of generics industry players; the FDA's performance goals for review and inspection; changes brought about by GDUFA II.

Assessment
Multiple-choice mastery assessment.

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SUB14 The Regulatory Pathway to Licensure of Follow-on Biologics (Biosimilars) in the USA

Approximate study time: 30 minutes

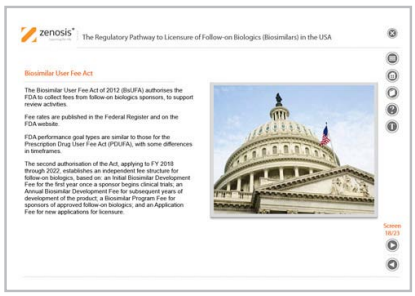
Level: Introductory/Intermediate

Audience: Regulatory

Category: Regulatory Submissions

Region: USA

CPD Points: 0.5



The regulation of biological medicinal products is governed by different laws from those that apply to small-molecule synthetic drugs. Producing faithful copies of therapeutic proteins is more challenging than producing generic drugs. The US legal framework for the licensure of follow-on biologics, and accompanying regulatory guidance from the Food and Drug Administration (FDA), have been established only in recent years.

We describe the provisions of the Biologics Price Competition and Innovation Act, identify criteria for licensing a follow-on biologic as 'biosimilar' or 'interchangeable', specify periods of market exclusivity that apply, and discuss patent infringement issues.

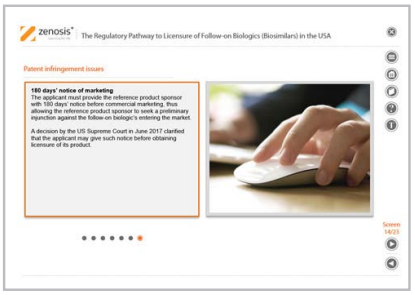
Finally, we describe the provisions of the Biosimilar User Fee Act, which authorises the FDA to collect fees from follow-on biologics sponsors, to support review activities.

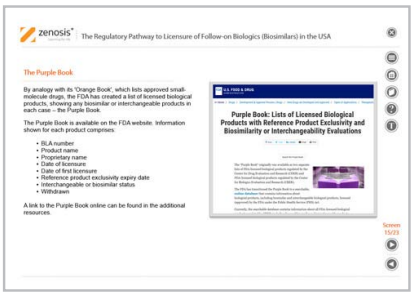
Who will benefit from this module?

This module will mainly benefit regulatory affairs staff concerned with the licensure of follow-on biological products.

Learning objectives

- Outline the provisions of the Biologics Price Competition and Innovation Act
- Identify criteria for licensure of a follow-on biologic as biosimilar or interchangeable
- Specify periods of market exclusivity applicable to biological medicinal products
- Outline patent infringement issues relevant to biological medicinal products
- Access FDA guidance on development and licensure of follow-on biologics
- Outline the provisions of the Biosimilar User Fee Act





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Clinical Trials

CT01: How to Gain and Maintain Approval for Clinical Research Under the EU Clinical Trials Directive

CT03: ICH Good Clinical Practice

CT04: An Introduction to Clinical Trial Preparation and Design

CT06: Clinical Trial Monitoring: Site Evaluation and Set-up

CT07: An Introduction to Clinical Trials and Drug Development

CT08: Clinical Trial Monitoring: Study Monitoring, Documentation and Closure

CT09: Good Clinical Practice Inspections and Audits

CT10: The Investigational New Drug Application (IND) to Conduct FDA-regulated Clinical Trials

CT11: How to Gain Authorisation for Clinical Research Under the EU Clinical Trials Regulation

CT12: How to Conduct Clinical Research Under the EU Clinical Trials Regulation

CT13: Safety Reporting in Clinical Trials

CT14: Clinical Trial Safety Reporting Requirements in the EU and USA

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CT01 How to Gain and Maintain Approval for Clinical Research Under the EU Clinical Trials Directive

Approximate study time: 3 hours

Level: Intermediate

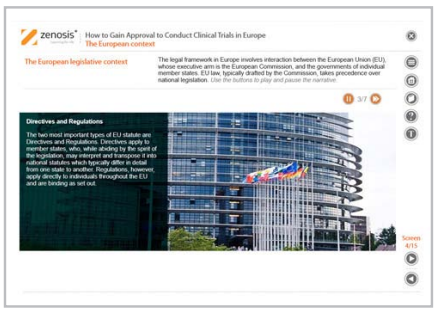
Audience: Regulatory, Compliance, Manager, Other

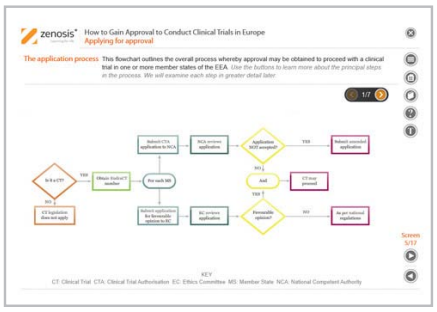
Category: Clinical, Regulatory Submissions

Region: Europe

CPD Points: 3

Module outline
- Module overview
- The European context
- Applying for approval
- Application for clinical trial authorisation
- Application for ethics committee favourable opinion
- Maintaining authorisation
- The Clinical Trials Regulation
- Assessment





To conduct a clinical trial in the European Economic Area under the Clinical Trials Directive the sponsor must apply for authorisation from the national competent authority (i.e. medicines regulator), and favourable opinion must be obtained from a research ethics committee, in each member state in which the trial is to take place. This module sets out the requirements for successful compilation, submission and maintenance of the applications.

During the first year of transition to the Clinical Trials Regulation, sponsors have the option of applying for approval under the Directive, and they can continue trials under that regime until 31 January 2025.

Who will benefit from this module?

The module will benefit:

- regulatory affairs professionals and other staff of pharmaceutical or biotechnology companies involved in clinical development of medicinal products; and
- healthcare professionals conducting clinical research as sponsor-investigators.

It will be of particular value to those who are new to European regulatory affairs, but familiarity with the basics of Good Clinical Practice is assumed.

Learning objectives

- Outline the legal and regulatory framework that governs clinical trials in the European Economic Area.
- Summarise the procedures that must be carried out to gain approval to proceed with a trial under the Directive.
- Identify the principal components of an application to a national competent authority for clinical trial authorisation and describe their contents.
- Discuss the principal areas of concern to an ethics committee and describe the information to be submitted to one.
- Specify what measures must be taken to maintain the authorisation of a trial in progress under the Directive.
- Outline the changes to regulatory requirements that are brought about by the implementation of the Clinical Trials Regulation, and describe the arrangements for transition from the Directive to the Regulation

Module outline

Module Overview
An outline of the module's scope and objectives, and notes on terminology.

The European context
This session explains the legal and regulatory framework for clinical trials in Europe.

Applying for approval
This session outlines the application procedures for clinical trial authorisation (CTA) and for ethics committee (EC) favourable opinion. It provides a decision tree through which you can determine whether your prospective investigation is a clinical trial. It describes how to register a trial with the EudraCT database and obtain a EudraCT number. It summarises the contents of applications and the processes and outcomes of reviews.

Application for clinical trial authorisation
The contents of a CTA application are discussed in more detail, focusing on the investigator's brochure, investigational medicinal product (IMP) dossier, circumstances in which a simplified IMPD or Summary of Product Characteristics may be substituted, and other IMP-related data. Online compilation of the application form is explained.

Application for ethics committee favourable opinion
Significant features of an application for EC favourable opinion are discussed in more detail, including the clinical protocol, informed consent form, and subject recruitment materials.

Maintaining authorisation
This session deals with the regulatory compliance activities that have to be carried out once a clinical trial has been approved. It examines the procedure for submitting substantial amendments, safety reporting requirements, and declaration of the end of a trial.

The Clinical Trials Regulation
This short session outlines the changes brought about by the implementation of the Clinical Trials Regulation, and it sets out the provisions that apply during the 3-year period of transition from the Directive to the Regulation.

Assessment
Multiple-choice mastery assessment.

CT03 ICH Good Clinical Practice

Approximate study time: 3 hours

Level: Foundation

Audience: Research, Regulatory, Compliance

Category: Clinical, Regulatory Submissions

Region: USA, Europe, Other

CPD Points: 3

Module outline
- Module overview
- ICH, harmonisation, and principles of GCP
- Clinical research teamwork
- Documentation
- Investigator responsibilities
- Informed consent
- Monitor responsibilities
- Assessment

Good Clinical Practice (GCP) is a set of internationally recognised ethical and scientific quality requirements for designing, conducting, recording and reporting clinical trials. Compliance with GCP principles is required by regulatory authorities in many countries for the authorisation of clinical trials and the acceptance of their data. The International Council for Harmonisation's guideline E6, often referred to as ICH GCP, is the international standard specification for Good Clinical Practice.

This module introduces GCP and sets it in the context of typical collaborative work in clinical research. We discuss the role and goals of the International Council for Harmonisation and the principles of GCP. We describe the roles of members of a team working on a clinical trial. We set out the documentation that must be created and maintained. We specify the responsibilities of trial sponsors, clinical investigators and monitors. We explain the rationale and execution of the informed consent process, and discuss issues that arise in practice.

The module is fully up to date with Revision 2 of ICH GCP.

Who will benefit from this module?

This module will benefit all those who participate in clinical research, whether they work in the pharmaceutical or biotechnology industry or as healthcare professionals. A sound knowledge of GCP is essential for clinical research associates / monitors, project managers, clinical investigators, clinical research coordinators / study nurses, data managers, pharmacists, and others contributing to clinical trials.

Learning objectives

- Explain why and how the ICH influences clinical research practice through its guideline on GCP, and summarise the principles of GCP.
- Identify the major roles in a clinical trial team, outline the responsibilities of each, and discuss how they work together.
- Describe the responsibilities of a trial sponsor.
- Describe the responsibilities of a clinical investigator.
- Explain the rationale and execution of the informed consent process, and discuss issues that arise in practice.
- Describe the responsibilities of a trial monitor.

Module outline

Module overview
Sets out the module's scope, objectives and notes on terminology.

ICH, harmonisation, and principles of GCP
Describes the ICH's role in the harmonisation of regulations, introduces its guideline E6, and sets out the principles of GCP.

Clinical research teamwork
Introduces the major roles in a typical clinical research project and outlines their duties and relationships.

Documentation
Identifies the documents designated by ICH GCP as essential to the conduct of a clinical trial, describes important examples, and outlines how they should be maintained.

Sponsor responsibilities
Duties and functions discussed in this session include risk-based quality management, selection of investigators, trial management, data handling and record keeping, finance and compensation, regulatory submissions, management of investigational product(s), safety reporting, monitoring, audit, dealing with noncompliance, and clinical trial reports.

Investigator responsibilities
Duties and functions discussed in this session include: provision of adequate resources and oversight of delegatees; liaison with institutional review boards / independent ethics committees; compliance with protocol; management of investigational product(s), informed consent and data records; and safety reporting.

Informed consent
Sets out the principles and requirements of informed consent, describes the process, and provides examples of practical issues confronting healthcare professionals and subjects.

Monitor responsibilities
Explores the responsibilities of the monitor and provides insight into key challenges. Describes assessment of investigators and investigational sites, education and trial initiation, risk-based monitoring of clinical conduct, including CRF review and source document verification, and trial close-out. Discusses noncompliance and how to deal with it

Assessment
Multiple-choice mastery assessment.

CT04 An Introduction to Clinical Trial Preparation and Design

Approximate study time: 4 hours

Level: Introductory/Intermediate

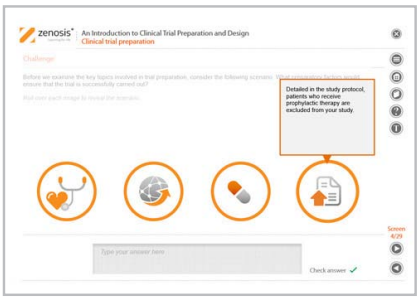
Audience: Research, Regulatory, Manager, Other

Category: Clinical

Region: USA, Europe, Other

CPD Points: 4

Module outline
- Overview
- Clinical trials in drug development
- Protocol design
- Clinical trial preparation
- Endpoints
- Statistical elements
- Study design
- Data capture and management
- Assessment



Worldwide expenditure on R&D by the pharmaceutical industry is continually increasing. Most of the financial investment in the production of a new drug is allocated to clinical trials.

Given the financial risk involved, it is crucially important that clinical trials be designed and set up efficiently to obtain adequate and accurate data in compliance with regulatory requirements.

This module aims to provide you with effective strategies for the preparation and conduct of a clinical trial, while adhering to regulatory safety standards. Management of data for submission is also covered.

Who will benefit from this module?

This module is intended for all those involved in the preparation, design, conduct or analysis of clinical trials. It will be useful to new entrants to the field or as a refresher for staff, including clinical research associates and data managers, in the clinical/medical departments of pharmaceutical or biotechnology companies or in contract research organisations. It will also be of interest to clinical investigators, study coordinators, and other healthcare staff working on clinical trials.

Learning objectives

- Outline the role of clinical trial design in clinical research.
- Identify the relevant legal documents and guidelines relating to clinical trial design.
- Recognise the essential statistical components for clinical trial design and how these affect design choice.
- Define the general principles and concepts for trial design, and describe the implications of design choice on regulatory acceptance.
- Identify the strategies to improve data capture and management.
- Describe how electronic data capture can improve clinical trial development.

Module outline

Overview
This session briefly describes the relevant legal documents and guidelines relating to clinical trial design.

Clinical trials in drug development
The crucial role of clinical trials in the drug development cycle is examined. Regulatory requirements and financial pressures, and their interaction with trial design, are discussed.

Protocol design
This session provides an overview of clinical trial protocols. Opportunities to improve a clinical trial protocol for regulatory approval are also discussed.

Clinical trial preparation
This session provides an overview of the role of the sponsor in supporting and improving quality in the conduct of clinical trials.

Endpoints
This session focuses on clinical trial endpoints. The purpose of endpoints and the types are discussed in this part.

Statistical elements
This session covers the role of statistics in clinical trial design and analysis, as acknowledged in the International Council for Harmonisation (ICH) guideline for Good Clinical Practice (GCP).

Study design
This session provides an overview of the main types of study design.

Data capture and management
This session describes the purpose of data capture and explores efficiencies in data management as part of the evolving regulatory landscape.

Assessment
Multiple-choice mastery assessment.

CT06 Clinical Trial Monitoring: Site Evaluation and Set-up

Approximate study time: 1.5 hours

Level: Intermediate

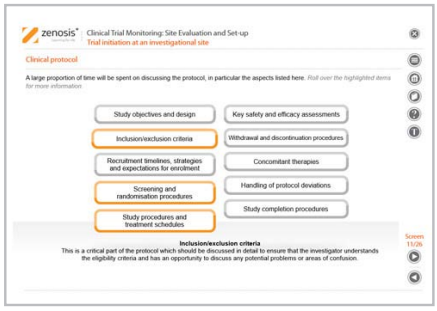
Audience: Compliance, Other

Category: Clinical

Region: USA, Europe, Other

CPD Points: 1.5

Module outline
- Module overview
- Investigational site qualification
- Preparation for trial initiation
- Trial initiation at an investigational site
- Assessment



The sponsor of a clinical trial needs to reach agreement with clinical investigators to conduct the trial. The suitability of investigators and their institutional sites, typically hospitals, has to be evaluated, and the trial has to be set up at each site. This module describes the processes involved, focusing particularly on the role of a Clinical Research Associate (CRA) employed or contracted by the sponsor to monitor the trial.

The purpose of investigational site evaluation and set-up is to ensure that the site has access to the required patient population, has appropriately qualified, trained and committed staff with adequate time and facilities, and that it is fully prepared for the safe and successful conduct of the clinical trial. In this module we set out the criteria, procedures and documentation for evaluating a site and setting up a trial there.

Who will benefit from this module?

The module is intended for those involved in clinical research and development, in particular the monitoring of clinical trials, and those who require an understanding of what this entails. It and its companion module CT08 provide a comprehensive introduction to monitoring for new CRAs, or additional training and professional development for those already working in the field. It will also be of value to clinical research coordinators, clinical investigators and other healthcare professionals involved in clinical studies.

Learning objectives

- State the objectives of an investigational site qualification visit and describe how to carry one out.
- Describe how to prepare for initiation of a clinical trial at an investigational site.
- State the objectives of a trial initiation visit and describe how to carry one out.

Module outline

Module overview
Sets out the module's scope, objectives and notes on terminology.

Investigational site qualification
Each candidate investigational site needs to be assessed for its suitability for the trial. A CRA and/or other representatives of the sponsor will typically visit the site to discuss the trial with the potential investigator and learn about the resources that can be deployed there. In this session we describe the objectives of the visit, preparation for it, and its conduct. We set out factors that should be assessed and give examples of the sorts of issues that may arise.

Preparation for trial initiation
When one or more investigational sites are approved by the sponsor, various activities are carried out concurrently in preparation for the start of a trial. In this short session we outline the tasks leading up to site initiation.

Trial initiation at an investigational site
An initiation visit is made to ensure that the participating site is ready for the conduct of the clinical trial and that the relevant personnel have a clear and accurate understanding of how the study is to be conducted. The CRA will review the clinical protocol and procedures with the team, check that all study materials are in place and that facilities and equipment are ready, ensure that the investigator's trial master file is in order, and confirm the monitoring plan and provisions for audit and inspection. We describe the actions that should be carried out.

Assessment
Multiple-choice mastery assessment.

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CT07 An Introduction to Clinical Trials and Drug Development

Approximate study time: 1.5 hours

Level: Foundation

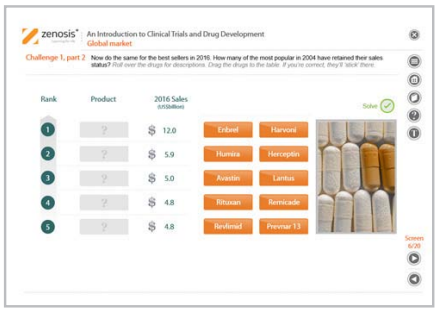
Audience: Research, Regulatory, Compliance, Other

Category: Clinical, Regulatory Submissions

Region: USA, Europe, Other

CPD Points: 1.5

Module outline
- Overview
- History
- Codes and regulations
- Drug development
- Global market
- Assessment



This module provides an understanding of how clinical trials fit into the drug development process. It outlines the key historical events leading to the development of controlled clinical trials. It specifies the purpose of trials, describes their characteristics, and identifies codes of practice and regulations that apply to them. Finally, it discusses the environment of cost control in which the modern pharmaceutical industry operates.

Who will benefit from this module?

This introductory module is an ideal primer for those new to the fields of clinical research or regulatory affairs. It will also provide valuable background information for administrative, sales and other staff in the pharmaceutical and biotechnology industries, enabling them to understand better the context in which they work.

Learning objectives

- Describe the key events in the historical development of the modern pharmaceutical industry
- Outline the key codes of practice and regulatory processes
- Explain how clinical trials fit within the drug development process
- Describe the economic environment within which pharmaceutical companies operate

Module outline

Overview
The context of the pharmaceutical industry and modern medicine is established. The module's four perspectives on clinical trials are set out.

History
Factors that gave rise to the modern framework of regulation of clinical trials are traced.

Codes and regulations
The principal elements of regulation of clinical trials are set out. The regulatory frameworks of the USA, Europe and Japan are outlined. International harmonisation of requirements through the work of ICH is discussed, with particular reference to Good Clinical Practice.

Drug development
The long and financially risky process of developing a drug is described. The various stages of discovery, nonclinical and clinical development are detailed.

Global market
Commercial considerations in drug development are described. Issues such as financial risk, pharmacoeconomics, patent life and generics are discussed.

Assessment
Multiple-choice mastery assessment.

CT08 Clinical Trial Monitoring: Study Monitoring, Documentation and Closure

Approximate study time: 2 hours

Level: Intermediate

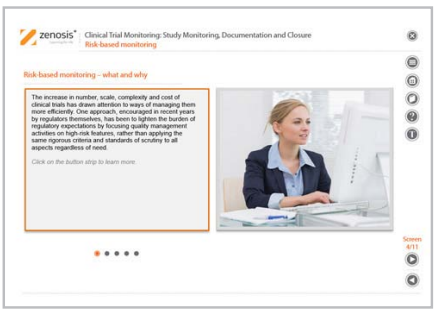
Audience: Compliance, Other

Category: Clinical

Region: USA, Europe, Other

CPD Points: 2

Module outline
- Module overview
- Site monitoring visits
- Data checking
- Close-out visit
- Risk-based monitoring
- Fraud and scientific misconduct
- Assessment



The sponsor of a clinical trial must arrange for it to be monitored throughout its duration to ensure that the rights and wellbeing of subjects are protected, the trial data are accurate, complete and verified from source documents, and the conduct of the trial complies with the study protocol, Good Clinical Practice and regulatory requirements. In this module we describe how a Clinical Research Associate (CRA) monitors an ongoing trial to its conclusion.

Who will benefit from this module?

The module is intended for those involved in clinical research and development, in particular the monitoring of clinical trials, and those who require an understanding of what this entails. It and its companion module CT06 provide a comprehensive introduction to monitoring for new CRAs, or additional training and professional development for those already working in the field. It will also be of value to clinical research coordinators, clinical investigators and other healthcare professionals involved in clinical studies.

Learning objectives

- Describe how to prepare for and carry out regular monitoring visits to investigational sites
- Describe how to review case report forms (CRFs) and verify consistency of data with source documents
- Describe how to close out a trial at a site
- Discuss the concept and implications of risk-based monitoring
- Identify warning signs that raise suspicion of scientific misconduct or fraud

Module outline

Module overview
Sets out the module's scope, objectives and notes on terminology.

Site monitoring visits
Regular visiting of investigational sites by a CRA is the front line of clinical trial monitoring. The visits allow face-to-face interaction with study site personnel and direct access to source records and site resources, providing the best opportunity for the CRA both to assess and to influence the progress and quality of a trial. In this session, we discuss monitoring tasks, the frequency and duration of visits, preparation for a visit, the kinds of deficiencies that may be found at the site, interaction with study staff, assessment of protocol compliance in a variety of areas, investigational product and subject recruitment issues, review of findings, and report and follow-up.

Data checking
Review and verification of data in CRFs and source documents is considered by many to be the CRA's principal task. It takes up most of his or her time on a monitoring visit and constitutes the primary measure taken on behalf of the sponsor to assure the quality of the data provided by the investigator. In this session, we describe how to carry out CRF review and source document verification (SDV). We discuss the extent of SDV required, outline differences between paper and electronic CRFs, identify aspects of trial conduct for which CRFs and source records should be checked, discuss on-site corrections and resolution of discrepancies, and outline data retrieval and data query procedures.

Close-out visit
Almost all clinical trials require an on-site visit to close the study at a site, irrespective of whether routine monitoring visits have been made. In addition to completing tasks typically carried out at a routine visit, the CRA will be required to perform some actions specific to the end of the trial, such as retrieving or authorising the destruction of unused supplies, retrieving some essential documents, and reminding the investigator of continuing responsibilities. In this session we describe the close-out of a trial at an investigational site.

Risk-based monitoring
Monitoring of clinical research by traditional methods, particularly as regards data checking, is time consuming and laborious. In recent years, regulatory authorities have focused attention on ways of making quality management in general, and monitoring in particular, more efficient through a risk-based approach. Implications of this approach include: increased emphasis on centralised monitoring rather than site visits; and a move away from 100% source document verification toward risk-based and statistically directed sampling of data. In this session we provide a brief introduction to principles of risk-based monitoring.

Fraud and scientific misconduct
The great majority of healthcare professionals undertaking clinical research act with honesty and integrity. However, cases of scientific misconduct and downright fraud do occur. Besides damaging the reputations of those who commit them, such actions have potentially serious consequences for the research and might even affect public health. In this session we distinguish error, misconduct and fraud, discuss the CRA's role in detecting them, and describe their consequences.

Assessment
Multiple-choice mastery assessment.

CT09 Good Clinical Practice Inspections and Audits

Approximate study time: 2.5 hours

Level: Intermediate

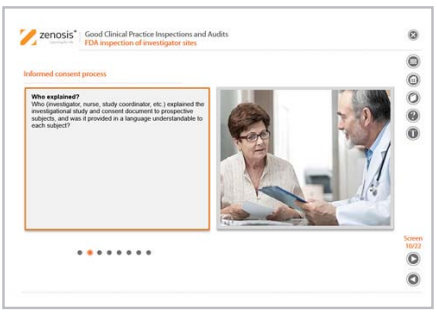
Audience: Research, Compliance, Manager, Other

Category: Clinical

Region: Europe, USA

CPD Points: 2.5

Module outline
- Module overview
- Principles of GCP inspections and audits
- Preparing for an inspection
- European regulators' inspection of sponsor and CRO sites
- European regulators' inspection of investigator sites
- FDA inspection of sponsor and CRO sites
- FDA inspection of investigator sites
- Action after an inspection or audit
- Assessment



Good Clinical Practice (GCP) inspections and audits are carried out to provide assurance that: the rights, safety and welfare of clinical trial subjects are protected; the data that constitute the results of the trials are accurate and reliable; and the trials are carried out in compliance with relevant legal requirements.

This module describes what investigational medicinal product sponsors, contract research organisations and clinical investigators can expect when they undergo inspection or audit. It focuses in particular on inspection by European and US regulators.

The module describes general principles of GCP inspection and audit, discusses preparation for an inspection, and sets out in detail what European and US FDA inspectors will examine. Finally it describes post-inspection actions by the regulator and the inspected party.

Who will benefit from this module?

This module will benefit all those involved in clinical research who already understand the basics of GCP. It will be of value to staff working in clinical, medical and QA departments of pharmaceutical companies and CROs, to independent clinical research associates, and to healthcare professionals conducting clinical studies.

Learning objectives

- Discuss principles of GCP inspections and audits
- Specify activities to be carried out in preparation for an inspection
- Describe what happens when a European regulator inspects the site of a sponsor or contract research organisation
- Describe what happens when a European regulator inspects the site of a clinical investigator
- Describe what happens when the US Food and Drug Administration inspects the site of a sponsor or contract research organisation
- Describe what happens when the US Food and Drug Administration inspects the site of a clinical investigator
- Specify post-inspection actions by the regulator and the inspected party

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Principles of GCP inspections and audits
Principles, applicable in any regulatory jurisdiction, of inspections and audits: their purpose, who carries them out, in what circumstances, and their possible consequences; routine versus targeted inspections; system versus study-specific inspections.

Preparing for an inspection
Actions you can take to prepare your site for a GCP inspection, whether you work for a sponsor or CRO or as a clinical investigator.

European regulators' inspection of sponsor and CRO sites
Procedure for inspection of the site of a sponsor or CRO by the regulatory authority of a member state of the European Economic Area: pre-inspection provision of an inspection request and plan to the inspectee; quality system inspection; study-specific inspection.

European regulators' inspection of investigator sites
Inspection of legal and administrative aspects, organisational aspects, informed consent provisions, subject data, and management of investigational medicinal products.

FDA inspection of sponsor and CRO sites
An outline of pre-inspection activity among the relevant FDA offices is followed by detailed description of what the inspectors examine as regards organisation and personnel, study registration, selection and monitoring of investigators, study monitoring, quality assurance, safety and adverse event reporting, data collection and handling, record retention, financial disclosure, computer systems, electronic records and signatures, and investigational product.

FDA inspection of investigator sites
An outline of investigators' legal obligations and the possible scope of an inspection is followed by detailed description of what the inspectors examine as regards authority and administration, clinical protocol, institutional review board, informed consent, source documents, CRFs, financial disclosure, investigational product control, records retention, reports to sponsor, and monitoring.

Action after an inspection or audit
This session describes post-inspection actions by regulators, and responses by inspected parties, with particular reference to European and US regulators: meetings at the close of inspections, inspection reports, classification of findings, responses and action plans, post-inspectional correspondence, and possible consequences of serious deficiencies.

Assessment
Multiple-choice mastery assessment.

CT10 The Investigational New Drug Application (IND) to Conduct FDA-regulated Clinical Trials

Approximate study time: 3 hours

Level: Intermediate

Audience: Regulatory, Compliance, Manager, Other

Category: Clinical, Regulatory Submissions

Region: USA, Other

CPD Points: 3

Module outline
- Module overview
- Introduction to Investigational New Drug Applications (INDs)
- IND content and format requirements
- Filing and FDA review
- Maintenance of an IND
- Expanded-access use
- Assessment

An Investigational New Drug Application (IND) is a submission to the US Food and Drug Administration (FDA) for permission to conduct a clinical trial of a medicinal product. This module describes regulatory requirements that sponsors or sponsor-investigators must meet for successful compilation, filing and maintenance of INDs. The IND and its role are defined, and the contexts in which it is required are specified.

The information that must be included and the format in which it needs to be presented are outlined. The process of review by the FDA is described, and the outcomes and sponsor's responses are discussed. The actions necessary to maintain an open IND are set out.

Finally, the regulatory provisions for expanded-access use of investigational drugs are described.

Who will benefit from this module?

- Regulatory affairs professionals and other staff of pharmaceutical or biotechnology companies involved in clinical development of medicinal products; and
- Healthcare professionals conducting clinical research as sponsor-investigators or who wish to treat patients under an expanded-access scheme.

Learning objectives

- Specify the role of an IND and the contexts in which it is required
- Access key regulatory documents relating to INDs
- Describe the contents and format of an IND submission
- Describe the process of FDA review of an IND, the possible outcomes and sponsor's responses
- Identify actions necessary to maintain an active IND
- Specify options for expanded-access use of investigational drugs

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Introduction to Investigational New Drug Applications (INDs)
This session explains the role and legal status of an IND, sets out the contexts in which one must be filed, summarises the responsibilities of sponsors and investigators, and outlines the pre-submission process.

IND content and format requirements
This session sets out IND contents required by regulations and describes how these are incorporated in a CTD-formatted submission. The significance of the FDA forms 1571 and 1572 are discussed. The major components of an application are outlined: general investigational plan, investigator's brochure, clinical protocol, Quality/CMC information, nonclinical data, and clinical information.

Filing and FDA review
Options and requirements for submission of an IND are set out, and the review procedure and its outcomes are described. The roles of FDA reviewers are outlined. The significance of a clinical hold and the sponsor's response to a hold are discussed.

Maintenance of an IND
This session identifies the various types of IND amendments and reports: protocol amendments, IND safety reports, annual reports, and information amendments. It explains when they need to be made and outlines the regulations that govern them. The responsibilities of sponsors and investigators to report safety findings are described, as are requirements for financial disclosure and record retention.

Expanded-access use
This session describes the various types of expanded-access use of investigational drugs to treat patients outside of clinical trials and sketches a scenario of emergency use.

Assessment
Multiple-choice mastery assessment.

CT11 How to Gain Authorisation for Clinical Research Under the EU Clinical Trials Regulation

Approximate study time: 2 hours

Level: Introductory/intermediate

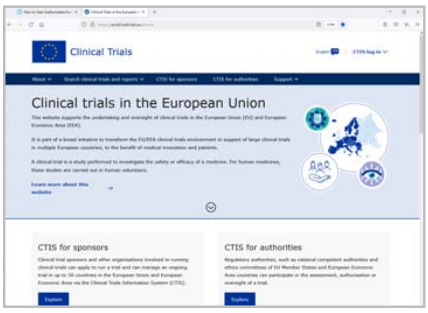
Audience: Regulatory affairs professionals, clinical development staff, healthcare professionals

Category: Clinical, regulatory affairs

Region: Europe

CPD Points: 2

Module outline
- The Clinical Trials Regulation and its context
- Making a clinical trial application
- Assessment of application
- Assessment



To conduct a clinical trial in one or more member states (MSs) of the European Economic Area (EEA) a sponsor must first gain the approval of each relevant national regulator and the favourable opinion of research ethics committees relevant to the investigational sites. The European Union (EU) Clinical Trials Regulation ensures that the rules for assessing clinical trial applications and for conducting clinical trials are identical throughout the EEA. It establishes a harmonised procedure for gaining and maintaining authorisation for trials in up to 30 countries on the basis of a single electronic application per trial, and subsequent interactions, via a single EU online information system. MSs concerned in a trial collaborate on, and coordinate, its evaluation and supervision, and each MS returns a single decision on authorisation. The Regulation also mandates greater transparency of information on trials. The Regulation applies from 31 January 2022 and, after a grace period of one year, sponsors of all new clinical trials in the EEA must comply with it.

This course sets out the procedures that sponsors need to follow to gain authorisation to conduct clinical trials under the Regulation, and it summarises and links to the extensive guidance available from the European Commission and the European Medicines Agency. Its companion course CT12 sets out the procedures that sponsors need to follow to conduct authorised clinical trials in compliance with the Regulation. The two courses therefore provide an ideal foundation for understanding and complying with the new law.

Who will benefit from this module?

Regulatory affairs professionals, clinical development staff, and healthcare professionals who sponsor or participate in clinical trials will benefit from this module.

Learning objectives

- Outline the legal and regulatory framework for clinical trials in the European Economic Area
- Describe the characteristics and applicability of the Clinical Trials Regulation
- Identify online portals and databases essential to authorisation and oversight of clinical trials under the Regulation
- Specify the timeline for transition to the Regulation from the Clinical Trials Directive
- Identify the contents of a clinical trial application (CTA) dossier as required by the Regulation
- Describe how to compile and submit a CTA dossier via the Clinical Trials Information System
- Describe how a CTA is validated and assessed, and how decisions are reached, by the reporting member state and other member states concerned

Module outline

The Clinical Trials Regulation and its context
This session describes how medicines are regulated in the EEA, identifies key characteristics of the Clinical Trials Regulation (CTR), and specifies its applicability to clinical investigations. It identifies EU online portals and databases relevant to clinical trials and describes the Clinical Trials Information System (CTIS), which is essential to the authorisation and supervision of trials under the CTR. It discusses the concept of low-intervention clinical trial. Finally, it explains how requirements vary during the period of transition from the Clinical Trials Directive to the CTR.

Making a clinical trial application
This session explains how to register to use the CTIS, the distinction between Parts I and II of an application, how a reporting member state (RMS) is appointed, and how to make a full or partial submission of a clinical trial application (CTA). It identifies the contents of a CTA dossier and explains how to apply for deferral of publication of certain contents. It describes relationships among the clinical protocol, investigator's brochure, and investigational medicinal product dossier, and explains where the reference safety information should appear. It also specifies requirements that must be met by clinical and nonclinical data in applications.

Assessment of application
This session explains how each part of a CTA is validated and assessed by the RMS and other member states concerned (MSCs) in the application. It specifies the sequence of procedures and the deadlines that have to be met by the MSCs and, in the case of requests for information, by the sponsor. It sets out the various decisions on authorisation that may be the outcome of assessment.

Assessment
Multiple-choice mastery assessment.

CT12 How to Conduct Clinical Research Under the EU Clinical Trials Regulation

Approximate study time: 1 hour

Level: Introductory/intermediate

Audience: Regulatory affairs professionals, clinical development staff, healthcare professionals

Category: Clinical, Regulatory affairs

Region: Europe

CPD Points: 1

Module outline
- Substantial modifications
- Adding an MSC
- Notifications
- Notices, alerts, and RFIs
- Ad hoc assessments
- Corrective measures
- Reporting adverse events
- Reporting SUSARs
- Annual safety report
- Submitting trial results
- Assessment

The European Union (EU) Clinical Trials Regulation ensures that the rules for assessing clinical trial applications and for conducting clinical trials are identical throughout the European Economic Area (EEA). It establishes a harmonised procedure for gaining and maintaining authorisation for trials on the basis of a single electronic application per trial, and subsequent interactions, via a single EU online information system. Member states concerned in a trial (MSCs) collaborate on, and coordinate, its evaluation and supervision. The Regulation also mandates greater transparency of information on trials. The Regulation applies from 31 January 2022 and, after a grace period of one year, sponsors of all new clinical trials in the EEA must comply with it.

This course describes the requirements that must be met by, and options available to, the sponsor during the conduct of an authorised clinical trial. It identifies the various interactions with MSCs that occur via the Clinical Trials Information System (CTIS), and it summarises and links to the extensive guidance available from the European Commission and the European Medicines Agency. Its companion course CT11 sets out the European legal and regulatory context for clinical trials and describes how to apply via the CTIS for authorisation to conduct trials. The two courses therefore provide an ideal foundation for understanding and complying with the new law.

Who will benefit from this module?

Regulatory affairs professionals, clinical development staff, and healthcare professionals who sponsor or participate in clinical trials will benefit from this module.

Learning objectives

- Access the relevant information on the Clinical Trials Regulation's requirements for good clinical practice, product manufacture and importation, and product labelling
- Identify the types of change that can be made to a clinical trial under the Regulation
- Describe how to apply for authorisation of a substantial modification to a trial
- Outline how to extend a trial to an additional member state of the EEA
- Identify the types of interactions between sponsor and MSCs that are possible via the Clinical Trials Information System in the management of a trial, and describe circumstances in which the sponsor must respond to requests for information
- Specify requirements for safety reporting
- Specify requirements for reporting of trial results

CT13 Safety Reporting in Clinical Trials

Approximate study time: 2 hours

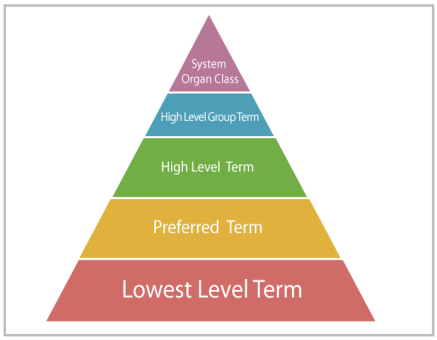
Level: Introductory/intermediate

Audience: Clinical research, drug safety and regulatory affairs staff, healthcare professionals

Category: Clinical trials, drug safety, regulatory affairs

Region: Europe, USA, other

CPD Points: 2



This course explains the regulatory requirements for the reporting of adverse events and suspected adverse reactions in clinical trials. It describes how investigators should report to sponsors, and how sponsors should report to regulatory authorities and other stakeholders in the safety of investigational products. It explains how events are characterized as serious or non-serious, expected or unexpected, and it distinguishes the requirements for each category. It describes controlled vocabularies used for coding of events in reports.

Who will benefit from this module?

This course provides essential information for clinical research, investigational product safety, and regulatory affairs staff of sponsors of clinical trials, as well as investigators and other healthcare professionals who undertake clinical trials.

Learning objectives

- Identify sources of legal requirements, regulatory guidance, and other requirements for the conduct of clinical trials
- Define reportable events and reactions in drug trials
- Discuss criteria for causality, expectedness, and seriousness of events
- Summarize investigators' responsibilities for reporting to sponsors and research ethics committees
- Specify requirements for expedited reporting by sponsors
- Outline the role of data monitoring committees
- Describe typical procedures for handling safety reports
- Outline follow-up procedures and the content of case narratives
- Describe trial monitoring activities related to safety reporting
- Discuss the handling of reports concerning marketed products
- Discuss the handling of reports of pregnancy and other special cases
- Outline the management of blinding
- Outline a typical timeframe for actions taken by a sponsor in response to reports of serious adverse events
- Identify requirements for periodic aggregate reporting
- Describe characteristics of the Medical Dictionary for Regulatory Activities
- Specify the levels of the MedDRA hierarchy
- Outline the use of MedDRA
- Outline the ISO standards for the identification of medicinal products

Module outline

Adverse events and safety reporting
In this session we explain the rationale for safety reporting in clinical trials, and we describe fundamental regulatory requirements. We discuss criteria for reporting, including causality, expectedness and seriousness. We set out the responsibilities of sponsors and investigators for individual-case expedited and aggregate reporting.

Safety reporting by drug sponsors
In this session we describe drug safety operations that will typically be carried out by a sponsor company or contract research organization engaged in clinical trials of medicinal products, and we outline some typical safety-reporting scenarios.

Controlled vocabularies
In this session we explain the requirement for the use of controlled vocabularies of medical terms in safety reporting. We describe the Medical Dictionary for Regulatory Activities (MedDRA) and identify the ISO standards for the identification of medicinal products (IDMP).

Assessment
Multiple-choice mastery assessment.

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CT14 Clinical Trial Safety Reporting Requirements in the EU and USA

Approximate study time: 2 hours

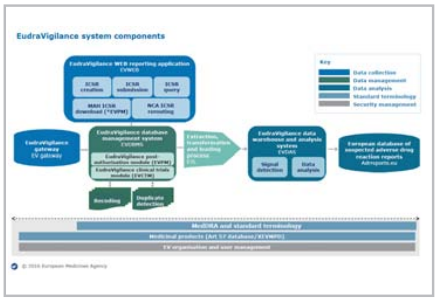
Level: Introductory/advanced

Audience: Clinical research, drug safety, and regulatory affairs staff, healthcare professionals

Category: Clinical trials, drug safety, regulatory affairs

Region: Europe, USA,

CPD Points: 2



This course sets out the legal and regulatory requirements for safety reporting in clinical trials of medicinal products under the jurisdictions of the European Union and the USA. It builds on the foundation laid by our companion course CT13, Safety Reporting in Clinical Trials, and provides greater detail of specific requirements in those jurisdictions.

Who will benefit from this module?

This course provides essential information for clinical research, drug safety, and regulatory affairs staff of sponsors of clinical trials, as well as investigators and other healthcare professionals who undertake clinical trials.

Learning objectives

- Identify relevant EU statutes and sources of regulatory guidance
- Identify online portals that are key to safety reporting in clinical trials in the EU
- Summarize investigators' and sponsors' responsibilities under the Clinical Trials Regulation
- Discuss the role of reference safety information in the EU
- Specify sponsors' responsibilities for reporting suspected unexpected serious adverse reactions in the EU
- Describe how to submit electronic reports to EudraVigilance
- Outline sponsors' responsibilities for reporting SUSARs to investigators under the Clinical Trials Regulation
- Identify submissions that sponsors must make to the EU Clinical Trials Information System
- Outline significant differences in requirements under the Clinical Trials Directive
- Identify relevant US statutes and sources of regulatory guidance
- Summarize clinical investigators' responsibilities for reporting to sponsors of trials conducted under an Investigational New Drug application (IND) to the US Food and Drug Administration (FDA)
- Discuss the assessment of causality of serious adverse events
- Summarize sponsors' responsibilities for review of safety information under an IND
- Specify sponsors' responsibilities for IND safety reporting to FDA and investigators
- Describe how to deal with anticipated events according to FDA guidance
- Specify timeframes for IND safety reporting

Learning objectives (continued)

- Specify requirements for analysis of similar events and submission of follow-up information
- Describe how to submit IND safety reports to the FDA
- Discuss requirements for electronic submission of IND safety reports
- Discuss requirements for investigators' reporting of unanticipated problems to investigational review boards
- Specify sponsors' responsibilities for submission of IND annual reports

Module outline

Legal and regulatory requirements in the EU
In this session, we set out the legal and regulatory requirements for safety reporting under the EU Clinical Trials Regulation. We specify the responsibilities of investigators and those of sponsors. We distinguish those reports that must be submitted by sponsors to the EudraVigilance portal and those that must be submitted to the Clinical Trials Information System. We specify the format and terminology that must now be used, and we identify the tools and pathways for electronic submission. Finally, we outline significant differences in requirements under the Clinical Trials Directive.

Legal and regulatory requirements in the USA
In this session, we set out the legal and regulatory requirements for safety reporting in clinical trials conducted (in the USA or elsewhere) under an Investigational New Drug application (IND) to the US Food and Drug Administration (FDA). We specify the responsibilities of investigators and those of sponsors. We describe the criteria for IND safety reports to the FDA, and the content, format and timing of their submission. We discuss investigators' obligation to report unanticipated problems to institutional review boards. Finally, we discuss IND annual reports and other safety reporting issues.

Pharmacokinetics and Pharmacodynamics

PKPD01 An Introduction to Pharmacokinetics and Pharmacodynamics in Drug Development and Registration

PKPD02 Conducting Pharmacokinetic and Pharmacodynamic Studies

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PKPD01 An Introduction to Pharmacokinetics and Pharmacodynamics in Drug Development and Registration

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

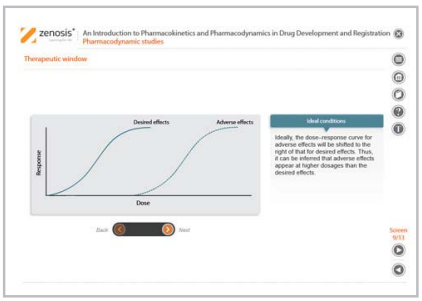
Audience: Research, Regulatory, Manager, Other

Category: Nonclinical, Clinical, Regulatory Submissions

Region: Europe, USA, Other

CPD Points: 1.5

Module outline
- Module overview
- Role of pharmacokinetics and pharmacodynamics
- PK and PD studies in drug development
- Drug administration routes
- Pharmacodynamic studies
- Assessment



Pharmacokinetic (PK) and pharmacodynamic (PD) studies provide a bridge between science and medicine in the development of a drug. In this module we describe the role of in-vivo PK and PD studies in a drug development programme, set out the uses to which the findings can be put, and discuss their implications for clinical development and application for marketing approval.

Who will benefit from this module?

Pharmacologists, nonclinical researchers, clinical researchers, regulatory affairs staff, and others who contribute to drug development and registration will benefit from this module.

Learning objectives

- Describe the role of pharmacokinetics and pharmacodynamics in drug development and registration
- Identify the main types of pharmacokinetic and pharmacodynamic studies conducted during drug development, their goals, and the uses of the data obtained
- Outline the pharmacokinetic characteristics of the various routes of drug administration
- Discuss how in-vivo pharmacodynamic studies provide a bridge between science and medicine in drug development and registration

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Role of pharmacokinetics and pharmacodynamics
Although pharmacokinetic (PK) and pharmacodynamic (PD) studies are routinely carried out in nonclinical and clinical stages of drug development, their role is perhaps less well understood than it ought to be by those who are not specialists in the field. In addition, greater emphasis is being placed by regulators on the value of PK and PD data. Evidence of good practice in the execution of PK and PD studies, and sound understanding of the implications of their findings, are becoming increasingly important in drug registration.

In this session we define PK and PD, outline the uses of PK and PD data in a drug development programme, and give examples of how good practice in obtaining and interpreting PK and PD data can contribute to the minimisation of risk for a drug.

PK and PD studies in drug development
In this session we discuss the various types of study carried out to acquire pharmacokinetic and pharmacodynamic data, grouping them into those conducted in animals only, in animals and humans, and in humans only. We identify their goals, rationale, and place in a drug development programme.

Drug administration routes
In this session, after introducing the principal pharmacokinetic parameters, we describe the PK and PK/PD characteristics of each drug administration route. We discuss the different medical-scientific questions to be addressed by PK/PD research for the different routes.

Pharmacodynamic studies
In this session we discuss the scope of pharmacodynamics, distinguish pharmacodynamic from clinical outcomes, and outline how the former may be used as surrogates for the latter. The core information from PD studies is a quantitative description of the dose–response relationship and the influence of various factors on this relationship. We emphasise the importance of interpreting the shape of the dose–response curve in making major decisions on a drug's development. Finally, we discuss factors that can influence the beneficial and adverse effects of a drug.

Assessment
Multiple-choice mastery assessment.

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PKPD02 Conducting Pharmacokinetic and Pharmacodynamic Studies

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

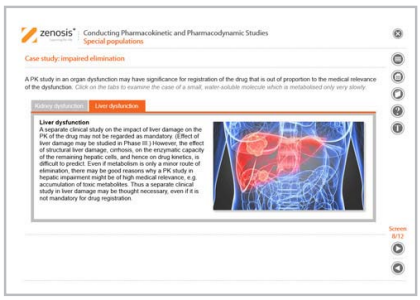
Audience: Research, Regulatory, Manager, Other

Category: Nonclinical, Clinical, Regulatory Submissions

Region: Europe, USA, Other

CPD Points: 1.5

Module outline
- Module overview
- Study design
- Sampling practice and outcomes
- Data analysis
- Special populations
- Generics and bioequivalence
- Assessment



This module extends the learner's understanding of pharmacokinetic and pharmacodynamic studies from the basics described in our companion module PKPD01, An Introduction to Pharmacokinetics and Pharmacodynamics in Drug Development and Registration. It provides detail on a variety of aspects of such studies: design, sampling, data analysis, research in special populations, and bioequivalence testing.

Who will benefit from this module?

Pharmacologists, nonclinical researchers, clinical researchers, regulatory affairs staff, and others who contribute to drug development and registration will benefit from this module.

Learning objectives

- Summarise the advantages, and how to counteract the main weakness, of the core design of choice for many pharmacokinetic and pharmacodynamic studies
- Adopt good sampling practice
- Discuss non-compartmental and compartmental data analysis
- Describe the responsibilities of a clinical investigator.
- Describe the rationale and characteristics of studies in special populations
- Describe how to carry out bioequivalence testing

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Study design
In this session we discuss the core design of choice for many PK and PD studies: crossover. We outline its advantages and how to counteract an important weakness, which is the carry-over effect.

Sampling practice and outcomes
Arguably the most important aspect of the design of a PK or PD study is the sampling schedule. How many samples should be taken per subject and at which time points after dosing? Choice of these factors is crucial in minimising bias and maximising the precision of results. In this session we explain principles of good practice in sampling.

Data analysis
In this session, after introducing the principal pharmacokinetic parameters, we describe the PK and PK/PD characteristics of each drug administration route. We discuss the different medical-scientific questions to be addressed by PK/PD research for the different routes.

Special populations
Drug development entails research not only into the target population as a whole but into sub-populations with a common demographic or health characteristic that may produce treatment outcomes that differ significantly from the average. In this session we discuss such special populations and how they are studied.

Generics and bioequivalence
Licensing of generic drugs is an area in which pharmacokinetic studies constitute the prime determining factor. In the great majority of cases the test that determines the licensing of a generic drug is a comparison of its plasma concentration–time course with that of the product it copies – a bioequivalence test – to assess whether they are sufficiently similar. In this session we describe how to carry out bioequivalence testing.

Assessment
Multiple-choice mastery assessment.

Good Manufacturing Practice

GXP01: Good Practices (GxP) in Drug Development and Manufacturing

GMP01: An Introduction to Good Manufacturing Practice for Medicinal Products

GMP02: Good Documentation Practice

GMP03: Good Manufacturing Practice in Cleaning and Sanitation

GMP04: Good Manufacturing Practice for the Warehouse

GMP05: Good Manufacturing Practice in Processing Medicinal Products

GMP06: Good Manufacturing Practice in Packaging Medicinal products

GMP07: Corrective and Preventive Action (CAPA) in Medicinal Products Manufacture

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GXP01 Good Practices (GxP) in Drug Development and Manufacturing

Approximate study time: 30 minutes

Level: Introductory

Audience: All entry-level personnel in the pharmaceutical and biotechnology industries

Category: Good Manufacturing Practice, clinical trials, nonclinical studies, drug safety, regulatory affairs & compliance

Region: Europe, USA, Other

This short entry-level module introduces the learner to good practices (GxP) in drug development and manufacturing. It outlines how the industry operates and how it is regulated. It identifies regulatory authorities and other important sources of guidance on Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), and Good Laboratory Practice (GLP).

Who will benefit from this module?

All entry-level staff in the pharmaceutical and biotechnology industries will benefit from this module.

Learning objectives

- Outline the process of drug development and manufacture
- Outline the regulation of the industry
- Identify important sources of GxP laws and guidance

Module outline

Drug development and manufacturing
This session outlines the process of drug development and manufacture, from the discovery of new molecules, through nonclinical studies and clinical trials, to marketing approval application, manufacturing scale-up and quality management, and pharmacovigilance.

Regulation of the industry
This session outlines the regulation of the industry, introducing the learner to regulatory authorities and other sources of guidance on GMP, GCP and GLP.

Assessment
Multiple-choice mastery assessment.

GMP01 An Introduction to Good Manufacturing Practice for Medicinal Products

Approximate study time: 1.5 hours

Level: Foundation

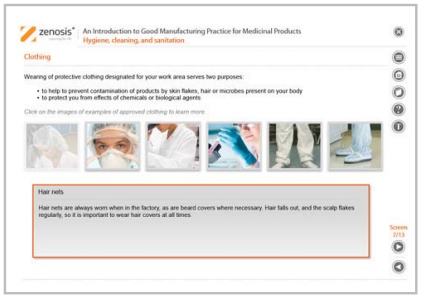
Audience: Manufacturing personnel

Category: GMP/QA/QC

Region: Europe, USA, Other

CPD Points: 1.5

Module outline
- Module overview
- GMP – what and why
- Principles of GMP
- Hygiene, cleaning, and sanitation
- Documentation and records
- Assessment



Good Manufacturing Practice (GMP) is a set of rules for medicines manufacturers to follow so that their products are safe, effective, and of good quality. The rules may be written into law or set out in guidance documents from regulatory authorities. Regulators will not allow medicinal products to be placed, or to remain, on the market in their country unless the products can be shown to be manufactured in compliance with GMP. To this end, they carry out inspections of manufacturing plants. Companies that persistently commit serious breaches of GMP requirements have suffered huge fines.

All manufacturing personnel must receive initial and ongoing training in the theory and practice of GMP. Everyone who works in a processing, quality control, packaging, or warehouse environment for a pharmaceutical or biotechnology company, or one of their contractors, must understand why GMP is important, how it applies to them, and how to comply with it. This module provides an ideal induction and refresher course in the basics of GMP. We begin by explaining what GMP is and why it is necessary. We then set out its main principles. Finally, we focus on two aspects of GMP that apply to everyone in the manufacturing environment: hygiene, cleaning, and sanitation; and documentation.

Who will benefit from this module?

Everyone who works in, or has occasion to enter into, a manufacturing environment in the pharma/biotech industry should have access to this module.

Learning objectives

- State what GMP is and describe why it is important
- Identify sources of GMP rules in regulations and internationally standardised guidance
- Identify major goals of GMP, outline what manufacturers must do to achieve them, and list some of the things that you need to do in order to contribute
- Comply with basic requirements regarding hygiene, cleaning, and sanitation
- Comply with basic requirements regarding documentation

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

GMP – what and why
This session explains what GMP is and why it is important, and it gives some lessons from history. It introduces the regulations and guidance documents which are the source of GMP rules. Finally it touches on regulatory inspections and the consequences that can arise from failure to comply with GMP requirements.

Principles of GMP
In this session we present an overview of the main principles of GMP, and we outline some things that manufacturing personnel need to do to comply with requirements. We identify the principal goals of GMP as: prevention of contamination; prevention of mix-ups; scrupulous documentation; validation and maintenance of processes and equipment; quality assurance by an independent unit; and training. We place GMP in the context of a company's quality management system.

Hygiene, cleaning, and sanitation
Prevention of contamination is one of the most important goals of GMP. Contamination of product is often difficult to detect, so GMP rules emphasise preventive measures, including: attention to personal health and hygiene, and the wearing of special clothing, by staff; and cleaning and sanitation of premises and equipment. In this session we set out the basics of GMP requirements in these vital areas.

Documentation and records
Comprehensive documentation of procedures, formulas, work instructions, and specifications, and thorough recording of batch data, are fundamental requirements of GMP. In this session, we explain why documentation is so important, identify different types of document required, and set out some simple rules for recording and correcting data.

Assessment
Multiple-choice mastery assessment.

GMP02 Good Documentation Practice

Approximate study time: 1 hour

Level: Introductory/Intermediate

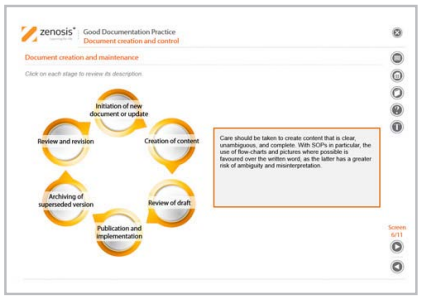
Audience: Manufacturing personnel

Category: GMP/QA/QC

Region: Europe, USA, Other

CPD Points: 1

Module outline
- Introduction
- Importance and principles of GDocP
- Types of documents
- Document creation and control
- Record keeping
- Assessment



Good Manufacturing Practice (GMP) for medicinal products relies on documentation. Good Documentation Practice (GDocP) is that part of GMP that applies to the creation, maintenance, use, and retention of documents to provide assurance of the quality of products.

In this module, we emphasise the crucial importance of GDocP and we identify five principles that underpin it. We explain the functions of the various types of documents that are used and discuss how they should be created and controlled. Finally, we set out requirements for record keeping – how data are to be entered into records, corrected if necessary, and how records must be retained.

Who will benefit from this module?

Everyone who works in a manufacturing environment in the pharma/biotech industry will benefit from this module. It will be of especial interest to quality assurance staff.

Learning objectives

- Explain why Good Documentation Practice is important, and identify principles that underpin it
- List the various types of documents used and explain their functions
- Discuss how documents should be created and controlled
- Specify requirements for record keeping, including those for entering and correcting data

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Importance and principles of GDocP
Good Documentation Practice underpins Good Manufacturing Practice. In this session we emphasise the crucial importance of compliance with, and we identify fundamental principles of GDocP.

Types of documents
In this session we describe the various types of documents found in a GMP-compliant environment – their functions, contents, and relationships.

Document creation and control
Careful control of GMP-relevant documentation is vitally important for quality management. In this session we identify principles of document control and characteristics of controlled documents, outline how documents should be created and maintained, and give advice on good practice in the creation of templates or masters for records.

Record keeping
Scrupulous and thorough recording of manufacturing activities is very important for a variety of reasons. In this session we set out these reasons, we provide rules for recording and correcting data in compliance with GMP requirements, and we specify requirements for the retention of records.

Assessment
Multiple-choice mastery assessment.

GMP03 Good Manufacturing Practice in Cleaning and Sanitation

Approximate study time: 1 hour

Level: Introductory/Intermediate

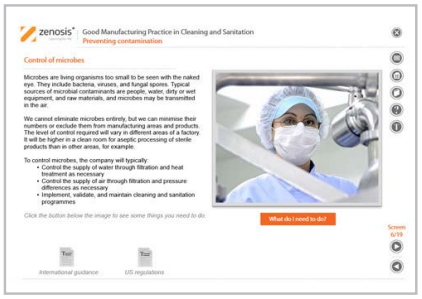
Audience: Manufacturing personnel

Category: GMP/QA/QC

Region: Europe, USA, Other

CPD Points: 1

Module outline
- Module overview
- Preventing contamination
- Cleaning and sanitation of premises
- Cleaning and sanitising of equipment
- Assessment



Cleaning and sanitation of premises and equipment are essential to efforts to prevent contamination of product, and they need to be done in compliance with Good Manufacturing Practice (GMP) regulatory requirements. This module shows why it is so important to do a good job, what to consider before and during each job, and how best to go about the work.

We begin by explaining how product may become contaminated and what can be done to prevent contamination through effective cleaning and sanitation procedures. We set out good practices to keep the factory clean and sanitary, and we describe how to prepare for and carry out cleaning and sanitation of premises. Finally we turn to the vitally important subject of cleaning and sanitising of production equipment.

Who will benefit from this module?

Everyone who works in a manufacturing environment in the pharma/biotech industry will benefit from this module.

Learning objectives

- Understand why cleaning and sanitation are so very important in preventing contamination of product
- Adopt good practices in preparing for, carrying out, and recording the cleaning and sanitising of premises and equipment

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Preventing contamination
Preventing contamination of product is one of the highest priorities in the factory, and effective cleaning and sanitation are essential to these efforts. In this session we describe sources of contamination and how to deal with them. We discuss the agents and equipment used, precautions to be observed, and the principles of the work required.

Cleaning and sanitation of premises
The whole factory must be kept clean and sanitary. In this session we discuss how to contribute to general cleanliness of the premises and how to go about cleaning surfaces in the buildings. We also outline pest control measures.

Cleaning and sanitising of equipment
Production equipment must be thoroughly cleaned, and sanitised as necessary, to prevent contamination of product. In this session we describe how to go about this vital task in compliance with GMP requirements. We discuss how the grade of work required may vary according to the use of equipment, and we emphasise that written and validated procedures must be followed exactly. We focus on equipment parts that require particular attention, and we explain the significance of hold and dwell times. We end with the completion of cleaning status tags and records, and we outline the use of automated clean-in-place systems.

Assessment
Multiple-choice mastery assessment.

GMP04 Good Manufacturing Practice for the Warehouse

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

Audience: Manufacturing personnel

Category: GMP/QA/QC

Region: Europe, USA, Other

CPD Points: 1.5

Module outline
- Module overview
- Working in the warehouse
- Receipt of inward goods
- Storage
- Dispatch, returns, and recalls
- Assessment

The warehouse plays a crucial role in a medicinal products factory. This module explains the requirements of Good Manufacturing Practice (GMP) for the warehouse, and how to comply with them.

We begin with an introduction to work in the warehouse of a medicinal products manufacturer, in which we describe the kinds of goods that come in and go out and how they may be stored in a typical layout. We identify methods of segregating stock, and we set out seven main goals of GMP for the warehouse. GMP for the warehouse overlaps with Good Distribution Practice (GDP), which applies to the whole distribution chain for products.

In the next session we discuss procedures for the receipt of inward goods and outline how the goods are checked, recorded and labelled, quarantined, sampled and tested, and released for use or rejected. In the third session, we describe good practice for storage, inventory control, and transfer of materials and products to and from production. Finally, we discuss dispatch of finished products, and procedures for dealing with returned or recalled products.

Who will benefit from this module?

This module provides essential training for all personnel who work in the warehouse of a medicinal products manufacturer. Other staff working in a manufacturing environment in the pharma/biotech industry will also benefit from this module.

Learning objectives

- Comply with the requirements of Good Manufacturing Practice for the warehouse
- Carry out the tasks and checks necessary when receiving goods
- Follow good practice for storage and inventory control
- Carry out the tasks and checks required for dispatch of finished products
- Deal appropriately with returned or recalled products

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Working in the warehouse
In this session we provide an introduction to work in the warehouse, in which we describe the kinds of goods that come in and go out and how they may be stored in a typical layout. We identify methods of segregating stock, and we set out seven main goals of Good Manufacturing Practice (GMP) for the warehouse. Finally, we mention a few types of document that are important to warehouse personnel.

Receipt of inward goods
The warehouse's control of stock begins with the receipt of inward goods. Materials offloaded at the reception bay need to be checked, identified, labelled, recorded, and quarantined by warehouse personnel; they then need to be sampled, tested, and released or rejected by the Quality unit. In this session we describe what is required of warehouse personnel in receiving inward goods.

Storage
Goods released for use by the Quality unit need to be stored in such a way that they will not suffer contamination, degradation, or damage, will not be incorrectly picked, and can be located and used well before their expiry date. In this session we discuss good storage practices, including control of inventory, good housekeeping, issue of materials to production, and control of printed materials.

Dispatch, returns, and recalls
In this session we describe release and dispatch of finished products from the warehouse. We also outline procedures for dealing with returned products and for recall of products.

Assessment
Multiple-choice mastery assessment.

GMP05 Good Manufacturing Practice in Processing Medicinal Products

Approximate study time: 1 hour

Level: Introductory/Intermediate

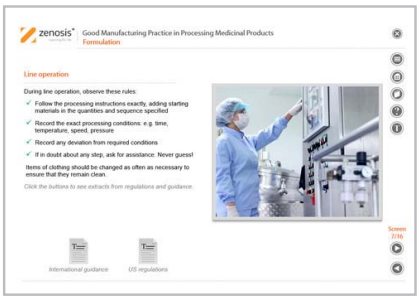
Audience: Manufacturing personnel

Category: GMP/QA/QC

Region: Europe, USA, Other

CPD Points: 1

Module outline
- Module overview
- Dispensing
- Formulation
- Yield and reconciliation
- Assessment



Operations in the dispensary and on processing lines are at the heart of medicinal product manufacturing. This module describes how to carry out such operations in compliance with the requirements of Good Manufacturing Practice.

We discuss how to: dispense starting materials; set up, control, and record formulation processes; evaluate product yield and calculate materials reconciliation. We set out the Good Manufacturing Practice (GMP) requirements that must be met in carrying out these tasks.

Who will benefit from this module?

This module provides essential training for all personnel who work on the processing of medicinal products. Other staff working in a manufacturing environment in the pharma/biotech industry will also benefit from this module.

Learning objectives

- Dispense starting materials in compliance with GMP requirements
- Set up, control, and record formulation processes in compliance with GMP requirements
- Evaluate product yield and check materials reconciliation in compliance with GMP requirements

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Dispensing
The dispensary is the place where raw materials entering the processing area are controlled. It is where starting materials coming from the warehouse are weighed and transferred into containers ready to be taken for formulation operations. Dispensing is a critical step in production and must be done with great care. Any error can have a substantial impact on product quality. In this session we discuss good practice in dispensing starting materials.

Formulation
Formulation processes are the prime engines of pharmaceutical manufacturing. Control of these processes is central to the assurance of product quality. In this session we set out the main tasks involved in processing a batch after starting materials or intermediate product have been dispensed, and we describe relevant GMP requirements.

Yield and reconciliation
Product yield evaluation and material reconciliation are two ways of checking the balance between the amount of material input to a process and the amount output from it. If the balance does not lie within acceptable limits, this may indicate a problem with the process. In this short session we discuss the importance of yield and reconciliation, how to check them, and what must be done to comply with GMP requirements with regard to them.

Assessment
Multiple-choice mastery assessment.

GMP06 Good Manufacturing Practice in Packaging Medicinal Products

Approximate study time: 1 hour

Level: Introductory/Intermediate

Audience: Manufacturing personnel

Category: GMP/QA/QC

Region: Europe, USA, Other

CPD Points: 1

Module outline
- Module overview
- Packaging quality
- Control of printed materials
- The packaging run
- Reconciliation of materials
- Assessment

Packaging operations constitute the last manufacturing step before release of a product to the market. They convert bulk product to the final product.

Packaging for medicinal products is subject to Good Manufacturing Practice rules similar to those for the products themselves. In this module we describe the functions that packaging must fulfil and the quality controls that are applied to packaging materials and operations. We set out the requirements for control of printed materials. We describe preparation, in-process control, and completion of a packaging run. Finally, we explain how to carry out reconciliation of packaging materials.

Who will benefit from this module?

This module provides essential training for all personnel who work on the packaging of medicinal products. Other staff working in a manufacturing environment in the pharma/biotech industry will also benefit from this module.

Learning objectives

- Describe the functions of packaging and give examples of controls applied to packaging materials and operations to provide assurance of quality
- Specify requirements for control of printed materials
- Adopt good practice in the preparation, in-process control, and completion of a packaging run
- Explain how to carry out reconciliation of packaging materials

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Packaging quality
Packaging, or container-closure, systems must contain and protect the product from spoilage, preserve its stability, and provide evidence of tampering as required. Labelling must provide the correct information about the product, its storage requirements, and its use. Information that allows the distribution of batches to be traced should be included, and measures to defeat counterfeiters are increasingly required.

Packaging quality affects product quality, so packaging materials, systems, and operations are subject to quality assurance requirements that are similar to those for starting materials and products. Controls must be in place to provide assurance that packaging fulfils its various functions. In this session we set out those functions and sketch examples of the kinds of controls that are necessary.

Control of printed materials
Control of printed materials is an especially important part of packaging operations. All information on packaging materials and inserts must correctly apply to the product and batch. Mislabelling/misbranding of a drug is a very serious error.

In this session we describe controls applied to printed materials at the printer, on receipt of inward goods, and in storage, issue, and return to store. We outline how variable data such as batch numbers and expiry dates can be coded on packaging materials. Finally, we emphasise the importance of reconciliation of printed materials.

The packaging run
A packaging run is subject to controls similar to those for the processing of product. Checks must be carried out beforehand, in-process and other quality controls need to be applied during the run, all operations must be recorded, and cleaning needs to be done afterwards.

In this session we identify documents that need to be followed for the run, we describe line clearance and set-up tasks, and we discuss in-process controls and statistical quality control.

Reconciliation of materials
Reconciliation of materials is an important control for packaging operations. In this session we describe the reconciliation of quantities of product and of printed matter.

Assessment
Multiple-choice mastery assessment.

GMP07 Corrective and Preventive Action (CAPA) in Medicinal Products Manufacture

Approximate study time: 1 hour

Level: Introductory/Intermediate

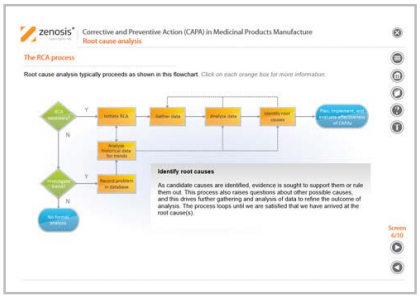
Audience: Manufacturing personnel

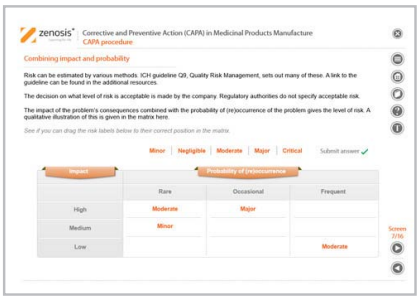
Category: GMP/QA/QC

Region: Europe, USA, Other

CPD Points: 1

Module outline
- Module overview
- CAPA principles
- CAPA procedure
- Root cause analysis
- Tracking, escalation, and trending
- Assessment





A company's Corrective and Preventive Action (CAPA) system establishes how personnel should deal with manufacturing problems that have occurred or that may occur if not prevented. This module explains the principles of corrective and preventive action and describes typical CAPA procedure. It goes on to introduce root cause analysis and outline the role of progress tracking, escalating, and trending of CAPA procedures.

Who will benefit from this module?

This module provides essential training for all personnel who work in a manufacturing environment in the pharma/biotech industry.

Learning objectives

- Explain what a CAPA system is and describe how it operates in a company's Quality Management System
- Describe how a typical CAPA procedure is carried out
- Outline the purpose and practice of root cause analysis
- Discuss the role of progress tracking, escalating, and trending of CAPA procedures

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

CAPA principles
In this session we explain what a CAPA system is and why it is important. We explain the differences among correction, containment, corrective action, and preventive action. We specify sources of information about manufacturing problems, and we emphasise the importance of documentation of a CAPA system.

CAPA procedure
Problems that may give rise to CAPAs are best tackled by systematically progressing through a number of stages of procedure. In this session we set out the typical stages of a CAPA procedure, along with the questions to be addressed and the actions taken at each stage.

Root cause analysis
Root cause analysis is a rigorous approach to finding the deepest causes of problems. In this session we emphasise the value of applying CAPA to root causes rather than their symptoms. We set out the stages of a typical analysis, and we list examples of tools for finding causes and studying trends.

Tracking, escalation, and trending
One of the most common findings of regulatory inspectors is the lack of effective and timely closure of CAPA reports. In this short session we emphasise the importance of tracking the progress of CAPA procedures, escalating issues, and reviewing trends in the CAPA system.

Assessment
Multiple-choice mastery assessment.

Drug Safety

PV03: An Introduction to Drug Safety and Pharmacovigilance

PV04: Signal Detection and Management in Pharmacovigilance

PV05: Risk Management Planning for Medicinal Products

PV06: Urgent Safety Restrictions

PV07: Good Pharmacoepidemiology Practice

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PV03 An Introduction to Drug Safety and Pharmacovigilance

Approximate module time: 2 hours

Level: Foundation

Audience: Drug Safety, Regulatory, Compliance, Manager, Other

Category: Drug Safety, Clinical

Region: USA, Europe, Other

CPD Points: 2

Module outline
- Module overview
- Regulation and company organisation
- Before a product is marketed
- After a product is marketed
- Quality system, inspections and audits
- Review and further information
- Assessment

Drug safety monitoring and risk management are vitally important for medicinal product developers, licence holders and clinical investigators. In addition to their duty to protect public health, increasingly tight regulation and potentially massive payments to litigants provide strong incentives for pharmaceutical and biotechnology companies to ensure that they maintain efficient systems for drug safety / pharmacovigilance and that all staff are aware of the basic requirements. This course will provide them with an overview of the most important aspects of this discipline, both before and after marketing of products, especially as they apply in Europe and the USA.

Who will benefit from this module?

Entry-level staff, and those seeking a refresher, in drug safety / pharmacovigilance and clinical departments will find the course invaluable, as will clinical investigators and other healthcare professionals. Staff in other departments of pharmaceutical and biotechnology companies will benefit from taking the course to gain an appreciation of the basics of the subject.

Learning objectives

- Explain, with examples, why drug safety monitoring / pharmacovigilance is necessary
- Describe ways in which drug safety / pharmacovigilance is regulated nationally and internationally, and identify international policy-making bodies.
- Outline how drug safety / pharmacovigilance responsibilities are organised within pharmaceutical and biotechnology companies.
- Sketch how a product safety database is compiled, how a product's safety profile is assessed, and how safety information is included in documentation for regulatory authorities, healthcare professionals, and consumers.
- Apply appropriate terms to describe different types of adverse effect.
- Specify requirements to report adverse reactions to regulators.
- Outline requirements for safety data and for risk management plans in applications for marketing approval.
- List tasks involved in monitoring adverse reactions to marketed products, and sketch how safety signals are detected and tested.
- Identify factors that influence the evaluation of a product's benefit/risk balance, and list actions that may be taken in response to changes in the balance.
- Identify ways in which the quality of a pharmacovigilance system may be assured, and outline preparations for a regulatory inspection or audit.

Module outline

Module overview
Describes what the course is about, sets out learning objectives, defines key terms and provides a brief overview of course content.

Regulation and company organisation
Explains the rationale for modern drug safety / pharmacovigilance (PV) regulation and practice, describes international policy-making bodies and sources of regulatory guidance, and outlines company drug safety / PV organisation, product safety databases and core safety information.

Before a product is marketed
Sets out the fundamentals of pre-marketing drug safety / PV: safety information for investigators, describing adverse effects, clinical trial reporting requirements, safety data in marketing applications, risk management planning, and product information.

After a product is marketed
Sets out the fundamentals of post-marketing PV: monitoring adverse drug reactions, licence holders' reporting requirements, detecting and testing safety signals, assessing benefit/risk balance, risk minimisation, communicating new safety information, product withdrawal.

Quality system, inspections and audits
Describes measures, increasingly emphasised by regulators, to ensure adequate performance of a PV system: the organisation's PV quality system, regulatory inspections, and audits.

Review and further information
Summarises key points and provides links to important guidance documents and other reference sources.

Assessment
Multiple-choice mastery assessment.

PV04 Signal Detection and Management in Pharmacovigilance

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

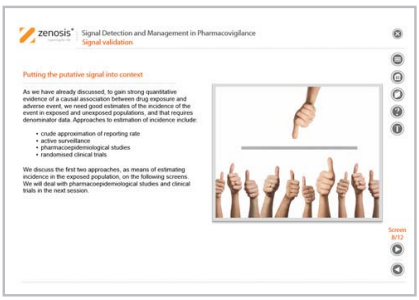
Audience: Drug Safety, Regulatory, Compliance, Manager

Category: Drug Safety

Region: USA, Europe, Other

CPD Points: 1.5

Module outline
- Module overview
- Signal detection
- Signal validation
- Signal analysis and prioritisation
- Risk assessment and minimisation
- Assessment



The fundamental aim of drug safety assessment is to establish what adverse reactions may be caused by a medicinal product. Factors such as seriousness, severity, and frequency of reactions are then taken into account, along with the medical benefit of the drug, in establishing the benefit/risk profile of the product.

Product licence holders and regulatory authorities monitor the safety of licensed drugs to detect adverse reactions that are unexpected qualitatively or quantitatively and that alter benefit/risk balance, and they take risk minimisation action as necessary. Such pharmacovigilance principally involves the identification and evaluation of safety signals in information obtained from a wide range of data sources.

The methods used range from traditional medical assessment of individual spontaneous reports of adverse events, through 'data mining' of large databases, observational studies of 'real world' prescription and use, to interventional clinical trials.

This module provides a guide to signal detection and management for approved products. The subject is presented as a process comprising four stages: signal detection, signal validation, signal analysis and prioritisation, and risk assessment and minimisation.

Who will benefit from this module?

All staff working in medical, drug safety, or pharmacovigilance departments of pharmaceutical or biotechnology companies or contract research organisations should have access to this module. It will also be of value to healthcare professionals and regulatory authority personnel.

Learning objectives

- Identify methods of signal detection and discuss their limitations
- Describe how to accumulate evidence on a causal association between a drug and an event
- Specify factors that increase the priority assigned to a signal, and describe methods of further investigation
- Discuss reassessment of benefit/risk balance in the light of a previously unexpected reaction to a product, and specify actions to minimise risk

Module outline

Module overview
An outline of the module's scope and objectives, notes on terminology, description of the role of signal detection and management, definition of safety signal, and an explanation of the approach adopted in the module.

Signal detection
The question we address in this session is: 'Are there data that may indicate a safety signal?'. The various sources of safety signal-relevant data are set out. 'Traditional' signal detection by qualitative review of individual case reports is described, followed by a discussion of quantitative analysis of aggregate data on drug–event associations to detect signals of disproportionate reporting, a process known as 'data mining'.

Signal validation
The question we address in this session is: 'Is there a safety signal?'. Steps taken to determine our degree of confidence in the existence of a signal are described. The development of a case series is outlined, and qualitative clues to causality are listed. Approaches to estimation of the incidence of the adverse event(s) in the exposed population are described: including crude approximation of reporting rate, and active surveillance through cohort/prescription-event monitoring and observational study in registries.

Signal analysis and prioritisation
The question we address in this session is: 'How important is the signal, and do we know enough about it?'. Factors that increase the priority assigned to a signal are listed. The consequences of assignment of a category of risk are outlined. Further investigation of a signal through controlled research, in the form of pharmacoepidemiological studies or clinical trials, is described, and factors influencing a decision to undertake such an investigation are set out.

Risk assessment and minimisation
The question we address in this session is: 'How does the signal affect benefit/risk balance, and what do we need to do about it?'. Factors affecting re-assessment of the benefit/risk profile of a product in the light of verification of a previously unexpected reaction are set out. Possible risk minimisation actions are listed. Requirements for reporting to regulatory authorities are described, and advice is given on communicating safety information to healthcare professionals and consumers.

Assessment
Multiple-choice mastery assessment.

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PV05 Risk Management Planning for Medicinal Products

Approximate study time: 1¼ hours

Level: Introductory/Intermediate

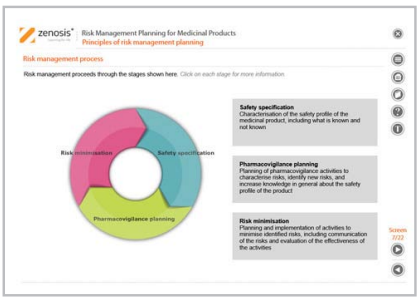
Audience: Drug Safety, Regulatory, Compliance, Manager

Category: Drug Safety

Region: USA, Europe, Other

CPD Points: 1

Module outline
- Module overview
- Principles of risk management planning
- Regulatory requirements for risk management plans
- Assessment



Proactive risk management is a major component of good pharmacovigilance practice. This module sets out the principles of risk management planning and outlines regulatory requirements for risk management plans in regions that are major markets for medicinal products.

Who will benefit from this module?

All staff working in medical, drug safety, or pharmacovigilance departments of pharmaceutical or biotechnology companies or contract research organisations should have access to this module. It will also be of value to healthcare professionals and regulatory authority personnel.

Learning objectives

- Explain important principles of risk management planning
- Give examples of risk minimisation activities
- Describe the selection of risk minimisation activities that are proportional to a product's benefit/risk balance and do not impose undue burden on stakeholders
- Outline regulatory requirements for risk management plans in regions that are major markets for medicinal products

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Principles of risk management planning
In this session we set out principles of risk management planning as a major component of good pharmacovigilance practice. We discuss the modern emphasis on proactive risk management in addition to routine pharmacovigilance measures. We describe risk assessment factors important in safety specification, pharmacovigilance planning, and risk minimisation for a drug. We then focus on the selection, implementation, and evaluation of non-routine risk minimisation activities.

Regulatory requirements for risk management plans
In this session we outline regulatory requirements for risk management plans in regions that are major markets for medicinal products: Europe, the USA, and (in a brief sketch) Japan. We describe the structure, main components, and submission requirements for EU Risk Management Plans and US Risk Evaluation and Mitigation Strategies, and we sketch notable aspects of risk management requirements in Japan.

Assessment
Multiple-choice mastery assessment.

PV06 Urgent Safety Restrictions

Approximate study time: 45 minutes

Level: Introductory/Intermediate

Audience: Drug Safety, Regulatory, Compliance, Manager

Category: Drug Safety

Region: Europe

CPD Points: 0.75

Module outline
- Module overview
- Principles
- Procedure
- Assessment

An Urgent Safety Restriction (USR) is a regulatory action taken, in response to a safety signal, to make an interim change to the terms of the marketing authorisation for a medicinal product in Europe. This module describes the principles and procedures for USRs.

Who will benefit from this module?

All staff working in medical, drug safety, or pharmacovigilance departments of pharmaceutical or biotechnology companies with products authorised in Europe should have access to this module. It will also be of value to healthcare professionals and regulatory authority personnel.

Learning objectives

- Explain the purpose of Urgent Safety Restrictions in Europe
- Describe how an USR may be triggered
- Describe the general regulatory requirements for preparation and initiation of an USR
- Outline the 24-hour procedure for execution of an USR
- Specify the requirements for a variation application following an USR

Module outline

Module overview
An outline of the module's objectives, and notes on terminology.

Principles
In this session we define Urgent Safety Restriction and explain its purpose in the European Union and other countries of the European Economic Area. We describe how an USR may be triggered. Finally, we give some examples of safety signals that may, and some that may not, give rise to an USR.

Procedure
In this session we describe how to prepare for and initiate an Urgent Safety Restriction (USR) for a centrally authorised product and for a product authorised through the Mutual Recognition or Decentralised Procedure. We outline the 24-hour procedure for execution of an USR, and the follow-up actions required, in each case. Finally, we specify the requirements for a variation application following an USR.

Assessment
Multiple-choice mastery assessment.

PV07 Good Pharmacoepidemiology Practice

Approximate study time: 1 hour

Level: Intermediate

Audience: Drug Safety, Research

Category: Drug Safety

Region: Europe, USA, Other

CPD Points: 1

Module outline
- Module overview
- Study planning and data collection
- Analysis, interpretation, and communication
- Assessment

Pharmacoepidemiology is the study of the use and effects of drugs in large numbers of people. It provides a bridge between clinical pharmacology and epidemiology. The increasing demand for real-world evidence of the safety, efficacy and utility of medicinal products has focused greater attention on pharmacoepidemiological research. This module will help those who plan and conduct such research, and analyse and report the findings, to follow good practice.

Who will benefit from this module?

Staff working in drug safety and pharmacovigilance or clinical research departments of pharmaceutical and biotechnology companies will benefit from this module. It will also be of value to healthcare professionals.

Learning objectives

On completion of this module, you should be able to follow good practice in:

- Planning pharmacoepidemiological research
- Collecting data in such research
- Analysing data from pharmacoepidemiological studies
- Interpreting and communicating the results of such studies

Module outline

Module overview
An outline of the module's scope and objectives, and a glossary of terms.

Study planning and data collection
In this session, we:

- Outline the role and formulation of a research question and study protocol
- Discuss the choice of study design and research methods
- Identify types of data source and means of data collection
- Summarise obligations for protection of subjects
- Discuss operational definition and validation of drug exposure, outcomes, and covariates
- Give examples of good practice in data collection, management, and verification

Analysis, interpretation, and communication
In this session, we:

- Discuss data analysis and the interpretation of results
- Outline the role and formulation of a statistical analysis plan
- Describe obligations for provision of a study report and communication of findings

Assessment
Multiple-choice mastery assessment.

ICT

ICT01: Compliance with Regulation 21 CFR Part 11 on Electronic Records and Electronic Signatures

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ICT01 Compliance with Regulation 21 CFR Part 11 on Electronic Records and Electronic Signatures

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

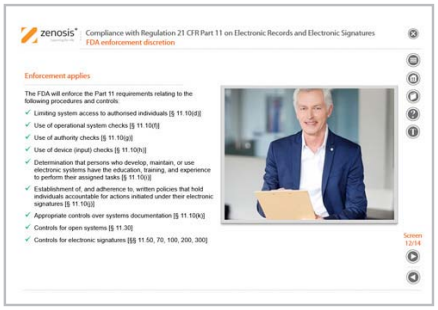
Audience: Research, Regulatory, Manager, Other

Category: Information and Communication Technology

Region: USA

CPD Points: 1.5

Module outline
- Module overview
- 21CFR11 and its scope
- Procedures and controls
- Electronic signatures
- FDA enforcement discretion
- Assessment



Part 11 of Title 21 of the US Code of Federal Regulations (21CFR11) sets out requirements that computer systems must meet to satisfy the Food and Drug Administration (FDA) that electronic records and electronic signatures provided by those systems are trustworthy and reliable to the same extent as paper counterparts. The regulation sets out controls and procedures which need to be established and followed for relevant computer systems in FDA-regulated environments. An FDA-regulated environment is a 'GxP' environment operated by an organisation involved in activities leading to the marketing of drugs or medical devices in the USA; examples are drug manufacturing sites, medical device manufacturing sites, analytical laboratories, clinical investigational sites, and nonclinical study laboratories.

21CFR11 applies to records that are required to be submitted to the FDA, or that are subject to FDA inspection, and that are in electronic form – that is, as computer files. It applies to all computer systems used to create, modify, maintain, archive, retrieve, or transmit such records – from a humble spreadsheet program to a complex information management system.

Companies that market or intend to apply for approval to market drugs or medical devices in the USA must comply with 21CFR11, whether or not they are based in the USA. Suppliers to such companies of materials, equipment, or data that are subject to FDA regulation must also comply.

Who will benefit from this module?

This module provides essential training for all personnel who use computer systems in GxP environments.

Learning objectives

- Define regulation 21CFR11 and explain its context and purpose
- Specify criteria to determine which environments, computer systems, electronic records, and electronic signatures must comply with the regulation
- Describe procedures and controls required by the regulation for electronic records and electronic signatures
- Describe the consequences of the FDA's discretion in enforcing compliance with some of the provisions of the regulation

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

21CFR11 and its scope
We define regulation 21CFR11 ('Part 11'), explain its purpose, and set out criteria for identifying the environments, computer systems, electronic records, and electronic signatures to which it applies. We describe how underlying legal requirements are specified by predicate rules. We point out that it is not the type of computer system that determines whether Part 11 applies, but the use to which the system is put. Finally, we introduce the regulation's distinction between closed and open systems.

Procedures and controls
We describe the procedures and controls that need to be established and followed to comply with Part 11. We identify those for which the FDA exercises enforcement discretion. We give examples of open systems and outline additional procedures and controls required for them.

Electronic signatures
We set out Part 11's requirements for electronic signatures. We specify the information to be provided and we outline constraints on the way signatures are linked to records. We emphasise the importance of uniqueness of signatures and verification of the identity of signatories. We mention the need for one-off certification with the FDA. We outline components of non-biometric and biometric signatures. Finally, we set out procedures and controls required for user names and passwords.

FDA enforcement discretion
We describe the FDA's narrow interpretation of Part 11, and its effect on the need to comply with some of the regulation's provisions. We discuss the latest relevant FDA guidance for industry and the effect of the agency's interpretation on its enforcement of compliance with requirements for validation, audit trails, record retention, and record copying. We also specify the exemption for legacy computer systems.

Assessment
Multiple-choice mastery assessment.

Medical Devices

MD01: An Introduction to the Regulation of Medical Devices

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MD01 An Introduction to the Regulation of Medical Devices

Approximate study time: 1 hour

Level: Introductory

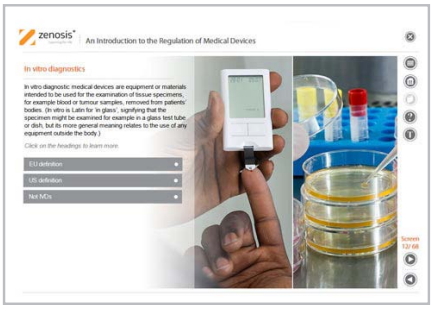
Audience: Research, Regulatory, Manager, Other

Category: Medical devices

Region: Europe, USA

CPD Points: 1

Module outline
- Module overview
- Medical devices and their regulation
- Regulation of medical devices in the USA
- Regulation of medical devices in Europe



This module provides an introduction to the basics of medical device regulation, especially the requirements that manufacturers must meet in order to market devices in Europe and the USA.

We explain what medical devices are and give examples of the various types. We outline the principles of their regulation and the criteria for placing them on the market. We identify major players in regulation worldwide.

We then outline prominent characteristics of the regulation of medical devices in the USA and in Europe. The module is up to date with the current upheaval in European Union legislation on medical devices.

Who will benefit from this module?

This module provides essential training for all personnel concerned with the development, regulatory compliance, or marketing of medical devices. It is especially suitable for induction training of entry-level staff.

Learning objectives

- Define and give examples of the various categories of medical device
- Outline the principles of medical device regulation and the criteria for placing devices on the market
- Identify major players in the regulation of medical devices worldwide
- Identify legal statutes and sources of regulatory guidance on medical devices in the European Union and the USA
- Outline prominent characteristics of the regulation of medical devices in the USA
- Outline prominent characteristics of the regulation of medical devices in the European Economic Area

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Medical devices and their regulation
In this session we explain what medical devices are and how they differ from medicinal products. We define various special categories of such devices. We identify basic principles of their regulation, including risk classification. We outline requirements for technical documentation, clinical data, and post-market surveillance and vigilance. Finally, we identify the major players in regulation.

Regulation of medical devices in the USA
In this session we outline prominent characteristics of the regulation of medical devices in the USA.

Regulation of medical devices in Europe
In this session we outline prominent characteristics of the regulation of medical devices in the European Economic Area.

Assessment
Multiple-choice mastery assessment.

Validation

VAL01: Introduction to Validation

VAL02: Validation Plans and Documentation

VAL03: Commissioning and Installation Qualification

VAL04: Operational and Performance Qualification

VAL05: Equipment Cleaning Validation

VAL06: Computer Systems Validation, Part 1: Planning

VAL07: Computer Systems Validation, Part 2: Implementation

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VAL01 Introduction to Validation

Approximate study time: 1.5 hours

Level: Introductory

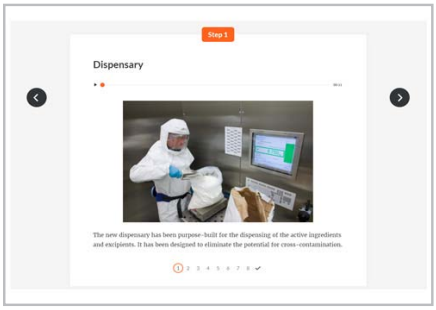
Audience: Manufacturing personnel

Category: Validation, GMP

Region: North America, Europe, other

CPD Points: 1.5

Module outline
- Regulations, guidance and definitions
- Development of risk-based approach to validation
- What to validate?
- Stages of validation
- Documentation and change control
- Assessment



Validation of equipment, services, systems and processes is vitally important in the medicines and healthcare products industries. Regulatory authorities require documented evidence that manufacturing processes will consistently result in products meeting predetermined quality standards. This module provides an introduction to validation and to the regulations and guidance that apply to it. It describes the activities of a typical validation team as they carry out a project for a pharmaceutical company.

Who will benefit from this module?

Manufacturing personnel in the pharma/bio-tech, dietary supplement, and medical devices industries need to understand the principles and practice of validation, as set out in this module. In particular, the module provides essential learning for engineering, production, and quality management personnel in the pharmaceutical industry.

Learning objectives

- Define terms relating to validation
- Access sources of regulations and guidance on validation in the medicines and healthcare products industries
- Specify the phases of equipment qualification and process validation and describe the goals of each phase
- Use risk assessment to determine the scope of a validation project
- Describe the relationships between specifications and protocols in the V model of validation
- Discuss criteria for User Requirements Specification, Factory Acceptance Testing, and Site Acceptance Testing
- Identify important documents created and used during a validation project, and specify their relationships
- Describe procedures for change control of validation documentation

Module outline

Regulations, guidance and definitions
This session emphasises the need to comply with regulatory requirements and guidance on validation, identifying important regulatory authorities and international collaborations. It identifies the phases of equipment qualification, describes the purpose of process validation in relation to process control, and defines important terms relevant to validation.

Development of risk-based approach to validation
This session explains why, in the absence of process validation, testing of samples is inadequate to provide assurance of product quality, safety and effectiveness. It outlines the historical development of validation requirements and identifies some current trends. It emphasises the importance of a risk-based approach to validation and describes factors for assessing risk.

What to validate?
This session explains how to develop the scope of a validation plan, distinguishing critical and non-critical equipment, services and utilities. It specifies criteria for validation of computerised systems and for selection of process steps for validation. Finally, it discusses the importance of validation of cleaning and laboratory test methods.

Stages of validation
This session describes the 'V model' approach to equipment qualification. It outlines the contents of a User Requirements Specification document, and explains the role of Factory Acceptance Testing and Site Acceptance Testing. It distinguishes commissioning and qualification, and describes the phases of qualification and validation. Finally, it identifies standard operating procedures that are created during qualification and validation.

Documentation and change control
This session identifies important documents created during a validation project, and outlines relationships among protocols and reports. It describes how to record deviations and failures, and their resolution. Finally, it discusses requirements for change control of validation documentation.

Assessment
The assessment tests the learner's assimilation of the module's content.

VAL02 Validation Plans and Documentation

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

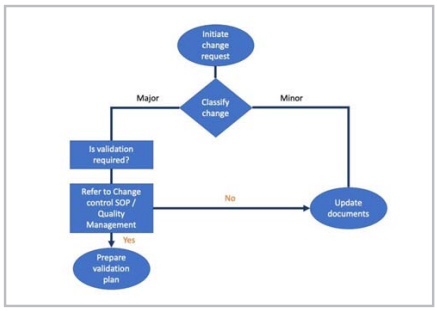
Audience: Manufacturing personnel

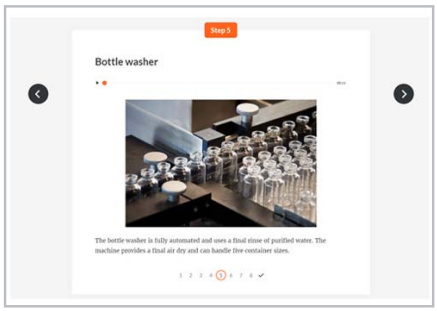
Category: Validation, GMP

Region: North America, Europe, other

CPD Points: 1.5

Module outline
- Validation master plan
- Project validation plan
- Validation documentation
- Scheduling, resource planning, and change control
- Assessment





Essential to validation is the provision of documented evidence verifying that manufacturing processes will consistently result in products meeting predetermined quality standards. This module describes the purpose, content and use of validation master plans, project validation plans, and other documentation for validation projects in the medicines and healthcare products industries. It describes the activities of a typical validation team as they carry out a project for a pharmaceutical company.

Who will benefit from this module?

Manufacturing personnel in the pharma/bio-tech, dietary supplement, and medical devices industries need to understand the principles and practice of validation, as set out in this module. In particular, the module provides essential learning for engineering, production, and quality management personnel in the pharmaceutical industry.

Learning objectives

- Describe the purpose and scope of validation master plans, outline their typical structure and contents, and explain their importance to management
- Contribute to the creation of project validation plans and protocols
- Identify important validation documents, specify their interrelationships, and describe how they are created and maintained
- Prepare and use validation schedules and resource plans, explain the basics of change control, and outline regulatory requirements for reporting and validating manufacturing changes

Module outline

Validation master plan
This session describes the purpose and scope of validation master plans. It outlines the structure and contents of a typical validation master plan.

Project validation plan
This session describes how to use risk assessment to establish the scope of a project validation plan. It distinguishes prospective validation, continuous process verification, and concurrent validation. It identifies equipment and services that typically require qualification.

Validation documentation
This session identifies important validation documents and specifies their interrelationships. It outlines responsibilities and systems for control and approval of documentation in a validation project. It explains how to contribute to the development of validation protocols. It outlines how deviations and failures are dealt with, and the handling of raw data and reports. Finally, it describes procedures for tracking, cataloguing and archiving validation documents.

Scheduling, resource planning and change control
This session describes the purpose and use of validation schedules and validation resource plans. It discusses revalidation requirements in change management, and outlines requirements for reporting manufacturing changes to regulators.

Assessment
The assessment tests the learner's assimilation of the module's content.

VAL03 Commissioning and Installation Qualification

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

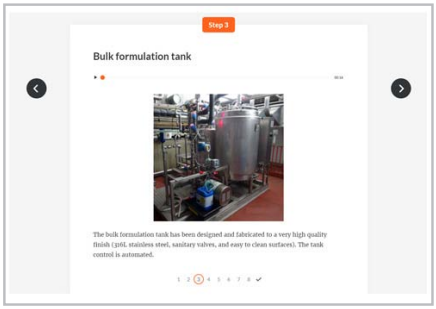
Audience: Manufacturing personnel

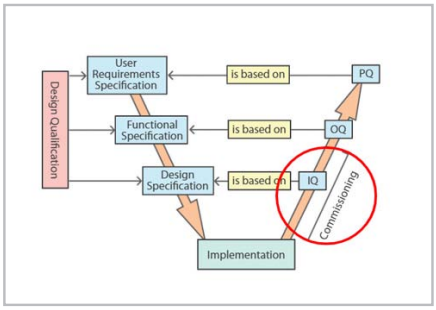
Category: Validation, GMP

Region: North America, Europe, other

CPD Points: 1.5

Module outline
- Introduction
- Basics of commissioning and Installation Qualification
- Impact assessment
- Installation Qualification
- IQ documentation
- Assessment





Before equipment can be used routinely in production, it must first be commissioned and, if necessary, undergo Installation Qualification (IQ). This module describes commissioning and IQ requirements and procedures in the medicines and healthcare products industries. It follows the activities of a typical validation team as they carry out a project for a pharmaceutical company.

Who will benefit from this module?

Manufacturing personnel in the pharma/bio-tech, dietary supplement, and medical devices industries need to understand the principles and practice of validation, as set out in this module. In particular, the module provides essential learning for engineering, production, and quality management personnel in the pharmaceutical industry.

Learning objectives

- Define commissioning and Installation Qualification activities and scope
- Explain the purposes of, and differences between, commissioning and qualification
- Determine qualification requirements based on an impact assessment
- Prepare and execute IQ protocols
- Describe requirements for the content and approval of IQ reports

Module outline

Introduction
A brief introduction to the validation project that provides a case study for Zenosis modules on validation.

Basics of commissioning and Installation Qualification
This session defines commissioning and Installation Qualification (IQ), summarises their purposes, and identifies differences between them. It outlines the progression of commissioning and IQ in a validation project, along with the roles of Factory Acceptance Testing and Site Acceptance Testing. It describes how responsibilities for commissioning and IQ are assigned in a typical company. It identifies vendor equipment documentation that may be included in specifications, as well as the contents of commissioning reports.

Impact assessment
This session explains the roles of impact assessment and criticality assessment. It discusses how to draw system boundaries and use impact assessment to determine the scope of qualification work required.

Installation Qualification
This session describes how to decide which components of each system require qualification and which need only be commissioned. It identifies systems/services that support the production line, and gives examples of tests applied to them as part of qualification. It identifies important parts of IQ protocols, and gives examples of qualification criteria specified in protocol test sheets. Finally, it outlines requirements for calibration of devices, instruments and systems.

IQ documentation
This session specifies important characteristics of IQ protocols, and outlines how to execute the protocols. It identifies documents that typically need to be completed during qualification. It specifies contents of an IQ report, and identifies requirements for the sign-off of protocols and reports.

Assessment
The assessment tests the learner's assimilation of the module's content.

VAL04 Operational and Performance Qualification

Approximate study time: 1 hour

Level: Introductory/Intermediate

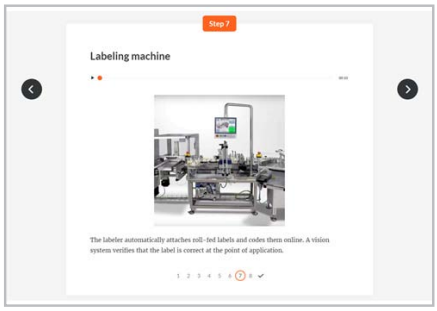
Audience: Manufacturing personnel

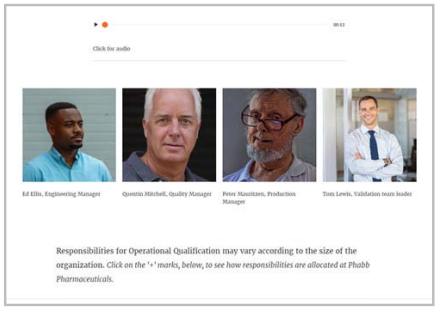
Category: Validation, GMP

Region: North America, Europe, other

CPD Points: 1

Module outline
- Introduction
- Operational Qualification
- Performance Qualification
- Assessment





Having undergone Installation Qualification, before equipment can be used routinely in production, it needs to undergo Operational Qualification (OQ) and Performance Qualification (PQ). This module describes OQ and PQ requirements and procedures in the medicines and healthcare products industries. It follows the activities of a typical validation team as they carry out a project for a pharmaceutical company.

Who will benefit from this module?

Manufacturing personnel in the pharma/biotech, dietary supplement, and medical devices industries need to understand the principles and practice of validation, as set out in this module. In particular, the module provides essential learning for engineering, production, and quality management personnel in the pharmaceutical industry.

Learning objectives

- Define OQ and PQ
- Explain the scope of OQ and PQ
- Identify typical responsibilities of company staff for OQ and PQ
- Specify the steps of OQ and PQ and describe activities to be carried out
- Prepare, approve and execute OQ and PQ protocols
- Write OQ and PQ reports

Module outline

Introduction
A brief introduction to the validation project that provides a case study for Zenosis modules on validation.

Operational Qualification
This session explains how to identify equipment, systems and services to which Operational Qualification (OQ) applies. It identifies typical responsibilities of company staff and vendors for OQ. It specifies prerequisites for OQ and describes steps in the OQ process. It identifies tests required of equipment, systems and services during OQ. The learner is shown how to develop, review and execute protocols that specify the tests required, and to write OQ reports.

Performance Qualification
This session specifies the purpose of Performance Qualification (PQ), and identifies typical responsibilities of company staff for PQ. It specifies the steps of PQ and describes the activities to be carried out, including environmental microbial monitoring where necessary. The learner is shown how to prepare, review and execute PQ protocols and write PQ reports.

Assessment
The assessment tests the learner's assimilation of the module's content.

VAL05 Equipment Cleaning Validation

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

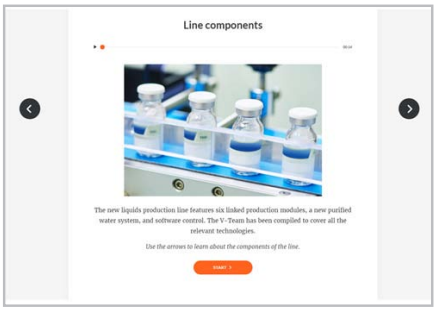
Audience: Manufacturing personnel

Category: Validation, GMP

Region: North America, Europe, other

CPD Points: 1.5

Module outline
- Introduction
- Scope of cleaning validation
- Validation of test methods
- Acceptance criteria
- Writing and executing protocols and writing reports
- Assessment



Manufacturers of medicines and healthcare products must establish, validate and maintain an equipment cleaning programme. This is a regulatory requirement because validated cleaning procedures contribute to the assurance of product purity and safety. This module provides a comprehensive account of equipment cleaning validation requirements and procedures. It follows the work of a pharmaceutical company's validation team as they establish and validate the cleaning program for a new production line.

Who will benefit from this module?

Manufacturing personnel in the pharma/bio-tech, dietary supplement, and medical devices industries need to understand the principles and practice of cleaning validation, as set out in this module. In particular, the module provides essential learning for engineering, production, and quality management personnel in the pharmaceutical industry.

Learning objectives

- Define cleaning validation terminology, and explain regulatory requirements
- Determine the scope of cleaning validation
- Carry out and validate tests of cleanliness
- Determine acceptance criteria
- Develop and execute a cleaning validation protocol
- Analyse and report cleaning validation results, and outline an ongoing cleaning and monitoring programme

Module outline

Introduction
An introduction to the validation project that provides a case study for Zenosis modules on validation, plus definitions and a glossary.

Scope of cleaning validation
This session compares and contrasts different approaches to equipment cleaning validation: equipment-train vs individual item; common vs dedicated equipment; batch-to-batch vs product-to-product cleaning; automated vs manual. It identifies requirements that cleaning SOPs need to meet. It explains the bracketing of products for cleaning validation. It outlines the qualification of clean-in-place systems, and the use of previous cleaning validation data. Finally, it describes techniques for testing surface residues.

Validation of test methods
This session identifies analytical techniques that are appropriate for cleaning validation studies. It defines limit of detection (LOD) and limit of quantitation (LOQ). Finally, it explains how to carry out swab recovery studies.

Acceptance criteria
This session identifies factors to be considered when determining acceptance limits for product carryover. It explains how to use toxicity and solubility data in determining acceptance criteria. It describes the selection of worst-case, follow-on, and representative products for cleaning validation studies. It explains how to calculate Maximum Allowable Carryover (MAC), and Surface Area Limit (SAL) for swab testing.

Writing and executing protocols and writing reports
This session identifies essential elements of a cleaning validation protocol. It describes how to specify worst-case conditions for cleaning validation, and sampling at the most difficult-to-clean locations. It explains why a cleaning validation protocol is usually applied to actual batch manufacture. It provides checklists for preparedness to execute a cleaning validation protocol, and for the documentation of results. It summarises the content of a cleaning validation report. Finally, it outlines ongoing cleaning requirements after validation.

Assessment
The assessment tests the learner's assimilation of the module's content.

VAL06 Computer Systems Validation, Part 1: Planning

Approximate module time: 1 hour

Level: Introductory/Intermediate

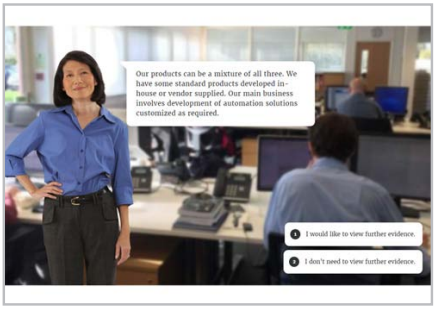
Audience: Manufacturing and ICT personnel

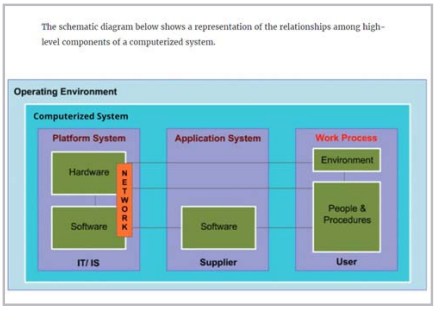
Category: Validation, GMP, ICT

Region: North America, Europe, other

CPD Points: 1

Module outline
- Introduction
- The planning phase
- Validation strategy and plan
- Assessment





In the medicines and healthcare products industries, computerised systems used in automated manufacturing or laboratory processes to which Good Manufacturing Practice requirements apply need to be validated. This module describes the planning of such validation. It follows the work of a pharmaceutical company's team as they validate the dispensary control system for a new production line.

Who will benefit from this module?

Manufacturing personnel in the pharma/bio-tech, dietary supplement, and medical devices industries need to understand the principles and practice of computerised system validation, as set out in this module. In particular, the module provides essential learning for engineering, information and communication technology, production, and quality management personnel in the pharmaceutical industry.

Learning objectives

- Define computer systems validation
- Outline criteria for selecting systems to be validated and for initial estimation of the degree of validation required
- Access important guidance documents by industry bodies and regulatory authorities
- Identify the phases of the computer systems lifecycle and describe the activities that are performed in each phase
- Describe considerations influencing validation strategy
- Assess software suppliers and their products
- Outline the contents of a validation plan

Module outline

Introduction
This session defines computer system validation and specifies its benefits. It identifies, in general terms, which systems need to be validated. It identifies sources of guidance from industry bodies and regulatory authorities, and it discusses the importance of protection of data integrity.

The planning phase
This session identifies the phases of the computer systems lifecycle, and outlines the activities that are performed in the planning phase. It specifies the purposes of a User Requirements Specification and a traceability matrix.

Validation strategy and plan
This session specifies criteria for regulatory assessment. It outlines FDA requirements on electronic records and electronic signatures. It describes in detail how to assess software suppliers and their products. It sets out principles of risk management. Finally, it outlines the contents of a validation plan, including change management.

Assessment
The assessment tests the learner's assimilation of the module's content.

VAL07 Computer Systems Validation, Part 2: Implementation

Approximate study time: 1 hour

Level: Introductory/Intermediate

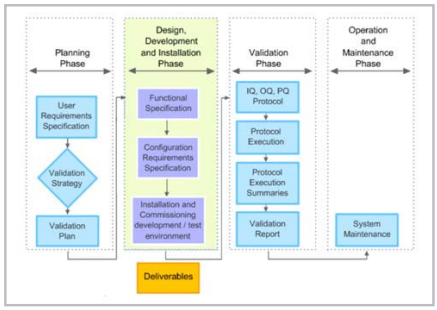
Audience: Manufacturing and ICT personnel

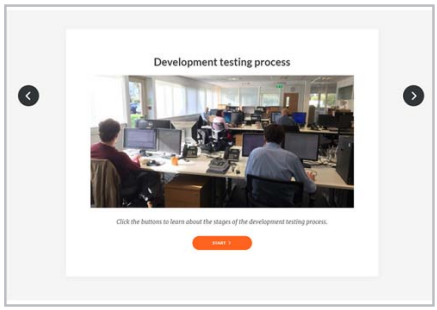
Category: Validation, GMP, ICT

Region: North America, Europe, other

CPD Points: 1

Module outline
- Design, development and installation phase
- Validation phase
- Operation and maintenance phase
- Assessment





This module describes the design, development and installation phase, the validation phase, and the operation and maintenance phase of the validation of computerised systems in medicines and healthcare products manufacturing environments. It continues to follow the progress of a pharmaceutical company's project to validate a new dispensary control system.

Who will benefit from this module?

Manufacturing personnel in the pharma/bio-tech, dietary supplement, and medical devices industries need to understand the principles and practice of computer systems validation, as set out in this module. In particular, the module provides essential learning for engineering, information and communication technology, production, and quality management personnel in the pharmaceutical industry.

Learning objectives

- Describe the design, development and installation phase of projects to validate computerised systems
- Describe the validation phase of such projects
- Describe the operation and maintenance phase
- Determine which systems to validate
- Determine the amount of validation required, and the strategy to use

Module outline

Design, development and installation phase
This session specifies the roles of functional and design specifications. It outlines the development testing process, and describes the formulation and use of test plans, cases and scripts. It identifies characteristics of good testing practices, and emphasises the importance of development change management.

Validation phase
This session specifies the activities to be performed in the validation phase, and outlines their timing. It states the purposes of platform qualification, application installation qualification, operational qualification, and performance qualification. It specifies tests typically carried out in operational qualification and performance qualification. Finally, it describes the roles of validation change management and the validation report.

Operation and maintenance phase
This session describes the measures that need to be in place during the operation and maintenance phase. It outlines the management of the decommissioning of a system. It identifies changes that need to be controlled in the operation and maintenance phase.

Assessment
The assessment tests the learner's assimilation of the module's content.

Sales & Marketing

SAM01: Legal and Regulatory Framework for Advertising and Promotion of Prescription Drugs in the USA

SAM02: Regulatory Requirements and Guidance on Advertising and Promotion of Prescription Drugs in the USA

SAM03: Consumer-directed Advertising and Online Promotion of Prescription Drugs in the USA

SAM04: Marketing of Prescription Drugs in the USA — Interactions with Healthcare Professionals

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SAM01 Legal and Regulatory Framework for Advertising and Promotion of Prescription Drugs in the USA

Approximate study time: 1 hour

Level: Introductory

Audience: Sales and marketing, regulatory affairs, and legal personnel

Category: Sales and marketing

Region: USA

CPD Points: 1

Module outline

- Regulation of advertising and promotion of drugs
- Classifying promotional communications
- Advertisements and promotional labeling
- Statutory and regulatory requirements
- Types of advertisement
- Misbranding and distribution of an unapproved drug
- FDA offices
- FDA advisory and enforcement actions
- Civil litigation by competitor
- Submission of communication materials to FDA
- FDA's Bad Ad Program
- Compliance programs and OIG enforcement
- Provision of samples
- Assessment

Advertisements and promotional labeling of prescription drugs in the USA must comply with statutory and regulatory requirements. Advertising and promotion are also subject to guidance from the Food and Drug Administration (FDA) and from industry and professional codes of practice. By identifying the requirements and summarizing the extensive guidance that applies, this course and its companions will help you to advertise and promote your products without incurring legal or regulatory sanctions.

In this course we set out the legal framework for the regulation of advertising and promotion of prescription drugs in the USA. We identify the regulatory authorities and sources of guidance. We summarize basic requirements that advertisements and promotional labeling must meet, and we identify consequences that may follow failure to comply.

In companion courses, we deal with regulatory compliance in general, with considerations that are particular to consumer-directed advertising and online promotion, and with certain interactions with healthcare professionals.

Who will benefit from this module?

Sales and marketing personnel need to understand the legal and regulatory requirements that must be met when advertising and promoting prescription drugs in the USA. In addition, this module will be of particular benefit to regulatory affairs and legal personnel involved with aspects of marketing.

Learning objectives

- Identify the federal laws and regulatory authorities that govern advertising and promotion of prescription drugs in the USA
- Identify sources of guidance on such advertising and promotion
- Distinguish various types of promotional communication
- Discuss the distinction between advertisement and promotional labeling
- Specify statutory and regulatory requirements that must be met by promotional communications that make product claims
- Distinguish various types of advertisement
- Outline the activities of the offices of the Food and Drug Administration (FDA) that oversee compliance with requirements on advertising and promotion
- Identify advisory and enforcement actions by the FDA, and other consequences of violations of federal law
- Specify requirements for submission of promotional materials to the FDA
- Outline the role of the Office of Inspector General and its compliance program guidance

SAM02 Regulatory Requirements and Guidance on Advertising and Promotion of Prescription Drugs in the USA

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

Audience: Sales and marketing, regulatory affairs, and legal personnel

Category: Sales and marketing

Region: USA

CPD Points: 1.5

Module outline

- Common drug advertising and promotion issues
- Relate brand and established names
- Frequency of presentation of established name
- Be consistent with the prescribing information (PI)
- Information possibly consistent with the PI
- Information not consistent with the PI
- Include only substantiated information
- Be truthful and not misleading, reveal material facts, and provide fair balance
- Include information on risks
- Balance risks and effectiveness
- Reveal other material information
- Avoid selective presentation of favorable information
- Endorsements and testimonials
- Avoid broadening or inadequate representation of indications
- Use up-to-date information
- Use statistics carefully
- Avoid misleading juxtaposition of information
- Avoid misbranding of an investigational drug
- Brief summary and adequate information for use in print media
- Major statement in broadcast ads
- Make adequate provision for access to product labeling
- Treat comparative claims with care
- Comparisons of price, dosing, and indications
- FDA examples of violative and non-violative ads
- Assessment

Advertisements and promotional labeling of prescription drugs in the USA must comply with statutory and regulatory requirements. Advertising and promotion are also subject to guidance from the Food and Drug Administration (FDA) and from industry and professional codes of practice. By identifying the requirements and summarizing the extensive guidance that applies, this course and its companions will help you to advertise and promote your products without incurring legal or regulatory sanctions.

In this course we explain how to advertise and promote prescription drugs in various media, whether to healthcare professionals or consumers, in compliance with legal requirements and guidance from the FDA.

In companion courses, we set out the legal framework for regulation, and we deal with considerations that are particular to consumer-directed advertising and online promotion and to interactions with healthcare professionals.

Who will benefit from this module?

Sales and marketing personnel need to understand the legal and regulatory requirements that must be met when advertising and promoting prescription drugs in the USA. In addition, this module will be of benefit to regulatory affairs and legal personnel involved with aspects of marketing.

Learning objectives

- Identify common issues with drug advertising and promotion
- Specify regulatory requirements for the presentation of brand and non-proprietary names of drugs
- Emphasize the importance of consistency with prescribing information, and give examples of types of information that are, and types that are not, consistent
- Describe how to support claims for products in promotional communications
- Be truthful and not misleading, reveal material facts, and provide fair balance between effectiveness and risks in promotional communications
- Avoid the pitfalls of: selective presentation of favorable information, broadening or inadequate representation of indications, use of out-of-date information, misuse of statistics, misleading juxtaposition of information, and misbranding of an investigational drug
- Deal appropriately with endorsements and testimonials
- Outline the role of the brief summary and adequate information for use in print advertisements and promotional labeling
- Outline the role of the major statement, and make adequate provision for access to product labeling, in broadcast advertisements
- Treat comparative claims with care
- Make comparative promotional claims regarding price, dosing, and indications

SAM03 Consumer-directed Advertising and Online Promotion of Prescription Drugs in the USA

Approximate study time: 1 hour

Level: Introductory/Intermediate

Audience: Sales and marketing, regulatory affairs, and legal personnel

Category: Sales and marketing

Region: USA

CPD Points: 1

Module outline

Direct-to-consumer (DTC) advertising
- The big picture
- Information generally expected in DTC ads
- Modified requirements for communications in print media
- Omit some prescription information
- Use consumer-friendly language
- Presenting quantitative efficacy and risk information
- Broadcast advertisements
- Major statement
- Adequate provision
- Pre-dissemination review of television advertisements
- PhRMA Guiding Principles

Online promotion
- Static versus interactive communications
- Responsibility for interactive promotional media
- Requirements for submission of interactive promotional media
- Responding to unsolicited requests for off-label information
- Media with character space limitations
- Correcting independent third-party misinformation
- Assessment

Advertisements and promotional labeling of prescription drugs in the USA must comply with statutory and regulatory requirements. Advertising and promotion are also subject to guidance from the Food and Drug Administration (FDA) and from industry and professional codes of practice. By identifying the requirements and summarizing the extensive guidance that applies, this course and its companions will help you to advertise and promote your products without incurring legal or regulatory sanctions.

Unlike the great majority of other countries, the advertising of prescription drugs directly to consumers is permitted in the USA. Spending by drug companies on direct-to-consumer (DTC) advertising of prescription drugs has increased more than four-fold over two decades, with a dramatic increase in the number of TV ads. In addition, the Internet and social media platforms have increasingly enabled companies to engage more actively with the public.

In addition to those that apply to all advertising and promotion of prescription drugs, specific regulatory requirements and industry and regulatory guidances apply to DTC advertising and promotion, including online promotion, and we discuss these in this course.

Who will benefit from this module?

Sales and marketing personnel need to understand the legal and regulatory requirements that must be met when advertising and promoting prescription drugs in the USA. In addition, this module will be of benefit to regulatory affairs and legal personnel involved with aspects of marketing.

Learning objectives

- List types of information generally expected to be included in consumer-directed communications
- Specify modified regulatory requirements for DTC communications in print media
- Access FDA guidance on presenting quantitative efficacy and risk information in DTC communications
- Summarize statutory requirements and FDA guidance on presentation of the major statement in broadcast advertisements, and outline the response of an industry advocacy group
- Specify ways of making adequate provision, in broadcast ads, for access to product labeling
- Comply with statutory requirements and FDA recommendations on pre-dissemination submission of broadcast ads to the agency for review, and outline FDA enforcement actions for non-compliance
- Access guiding principles, from the Pharmaceutical Research and Manufacturers of America, on DTC advertising
- Identify sponsors' responsibilities for interactive promotional media
- Submit interactive promotional media to the FDA in compliance with the agency's draft guidance
- Respond, in compliance with FDA draft guidance, to unsolicited requests for off-label information
- Comply with FDA draft guidance on how sponsors should deal with promotional communications in online media that impose limits on the number of text characters that can be used
- Correct online misinformation by independent third parties, in compliance with FDA draft guidance

SAM04 Marketing of Prescription Drugs in the USA — Interactions with Healthcare Professionals

Approximate study time: 1 hour

Level: Introductory/Intermediate

Audience: Sales and marketing, regulatory affairs, and legal personnel

Category: Sales and marketing

Region: USA

CPD Points: 1

Module outline

- Statutes and regulations
- Regulatory and industry guidance
- Anti-Kickback Statute
- False Claims Act
- Major settlements under FCA/AKS
- Physician Payments Sunshine Act
- Drug samples
- Distribution of reprints and other publications
- Detailing by sales representatives
- Speaker programs
- Third-party scientific and educational events
- Medical advisory boards
- Responding to unsolicited requests for off-label information
- Gifts of educational or non-educational items
- Assessment

The heaviest legal penalties imposed on drug companies concern interactions with healthcare professionals in the context of prescription drug marketing, notably for violations of the Anti-Kickback Statute and the False Claims Act. Monetary penalties have amounted to billions of dollars in some cases.

Payments or other transfers of value made to certain healthcare professionals or teaching hospitals must be reported to the government. In addition, company-sponsored speaking programs and detailing by sales representatives must comply with provisions of the Federal Food, Drug, and Cosmetic Act on advertising and promotion. Industry guidance urges drug companies to follow the highest ethical standards as well as all legal requirements. In this course we identify the laws and guidance that apply, and we provide information that will help companies to market their products without incurring penalties.

In companion courses on marketing of prescription drugs in the USA, we deal with the legal and regulatory framework for advertising and promotion of drugs, with general regulatory compliance in that context, and with considerations that are particular to consumer-directed advertising and online promotion.

Who will benefit from this module?

Sales representatives and marketing personnel need to understand the legal and regulatory requirements that must be met, and the industry guidance that applies, when interacting with healthcare professionals in the context of marketing of prescription drugs in the USA. In addition, this module will be of benefit to regulatory affairs and legal personnel involved with aspects of marketing.

Learning objectives

- Identify the principal US legal statutes and regulations on interactions between drug companies and healthcare professionals (HCPs)
- Identify Important sources of guidance from the Office of Inspector General (OIG) of the Department of Health and Human Services, the Pharmaceutical Research and Manufacturers of America (PhRMA), and the Food and Drug Administration (FDA)
- Outline the provisions of the Anti-Kickback Statute, and access regulations on its 'safe harbors' provisions
- Outline the provisions of the False Claims Act, including the use of qui tam 'whistleblower' lawsuits, and understand the risk of heavy penalties for violations
- Comply with reporting requirements under the Physician Payments Sunshine Act
- Comply with the requirements of the Prescription Drug Marketing Act and the Affordable Care Act as regards the provision of drug samples to HCPs
- Follow guidance from the FDA on distribution of reprints and other publications to HCPs
- Comply with limitations on detailing by sales representatives
- Comply with legal requirements, and OIG, PhRMA and FDA guidance, on company speaker programs and third-party scientific and educational events
- Outline the role of medical advisory boards and comply with PhRMA guidance on bona fide consulting services
- Respond appropriately to unsolicited requests for off-label information
- Comply with PhRMA guidance on gifts of educational or non-educational items to HCPs

How can Zenosis benefit me?

Benefits of Zenosis e-Learning to an organisation and end user:

24/7 learning – Users can access modules when they want. For example at work, at home or when travelling.

Always up to date – New information allows the end user to always be in touch with changing regulations and legislations.

No geographical barriers – Bringing users together from various locations on a specific date is eradicated.

User overheads are lower - No travel, accommodation, or food costs to account for.

Flexibility – The end-user is able to skip through information they may already know, and a beginner has up to a year to access the information if they need it or simply for reference.

Self-paced learning – This allows the user to learn at their own speed; to stop and start as they choose.

Custom design – We can amend or change a module to meet specific company needs.

Greener – The company's carbon foot print is reduced with no travel.

CPD points – Users earn Continuing Professional Development (CPD) points awarded by the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom.

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