SUB12 Registration of Medicinal Products Based on Monoclonal Antibodies

Approximate study time: 1.5 hours

Level: Intermediate

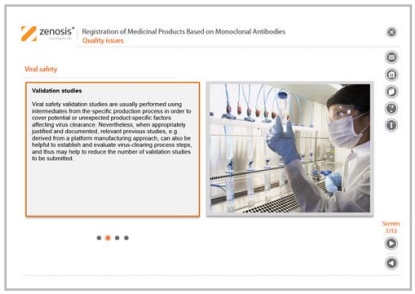
Audience: Regulatory, other

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.