

**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

Antibody structure and function

Antibodies, also known as immunoglobulins, are large glycoproteins with a Y-shaped structure. The molecule has two 'arms', each formed by a pair of polypeptides – the long 'heavy chain' and the short 'light chain' (see the diagram) – linked together by disulfide chemical bonds (not shown in diagram). Each chain has a 'constant' part and a 'variable' part. It is the variable part that binds to an antigen.

Click on the button step to learn more

Legend:
 - constant heavy
 - variable heavy
 - constant light
 - variable light

Slide 01/12

Validation of purification

Column loading capacity
 Validation of the purification process should also take into account the effects of column loading capacity, column regeneration and validation and establish limits for the lifespan of column materials.

Slide 10/17

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.