GXP01 Good Practices (GxP) in Drug Development and Manufacturing

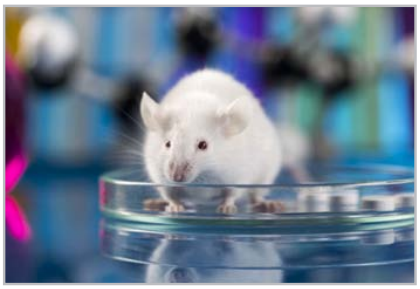
Approximate study time: 30 minutes

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.