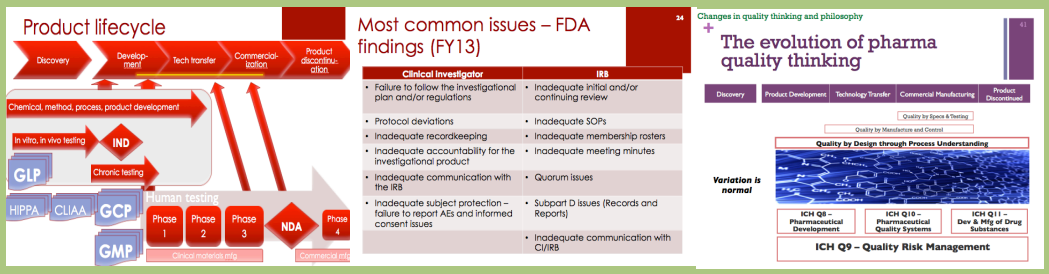
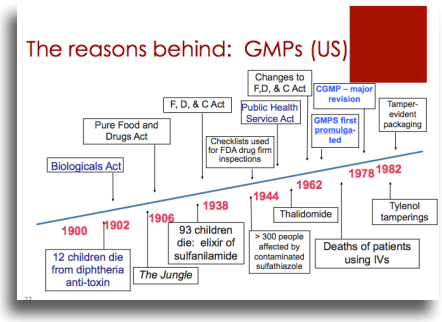
GxP Basics



An in-house course from *LearningPlus*

An overview of regulations that apply to nonclinical testing (GLPs), clinical testing (GCPs), and drug manufacturing (GMPs)



Description

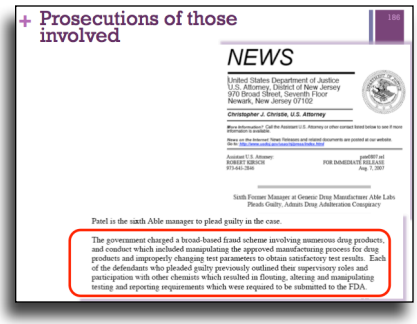
This course provides an overview of the regulations and requirements that apply to the "product life cycle" and how pharma products are discovered, tested, reviewed, and (hopefully) approved by the drug regulatory authority.

The background and historical context of good laboratory practice (GLP), good clinical practice (GCP), and good manufacturing practice (GMP) in the U.S. are presented along with summaries of each regulation's expectations. The term "GxP" is often used to encompass all three sets of requirements.

Examples of recent FDA Warning Letters provide examples of firms failing to meet the requirements.

Audience

Those new to the pharma/biopharma industry, including operations/laboratory, quality, and management groups.



Course goal

Examine the reasons for GxPs (GLP, GCP, and GMP) and how these regulations shape and impact the the pharmaceutical industry today.

Objectives

- Define key terms related to the regulation of drug development, testing, and manufacturing.
- Describe the differences between regulations and expectations.
- Describe the key situations/tragedies that were the catalyst behind GLPs, GCPs, and GMPs.
- Identify the essentials of GLP, GCPs, and GMPs.
- Identify when GLPs, GCPs, and GMPs apply in the course of the drug life cycle.
- Describe what can happen in the event of noncompliance with the regulations.

Length

Three hours.

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