

GxP Basics

Product lifecycle

Discovery → Development → Tech transfer → Commercialization → Product discontinuation

Regulatory milestones: IND, NDA

Standards: GLP, GCP, GMP, HIPAA, CLIA

Most common issues – FDA findings (FY13)

Clinical Investigator	IRB
<ul style="list-style-type: none"> Failure to follow the investigational plan and/or regulations Protocol deviations Inadequate recordkeeping Inadequate accountability for the investigational product Inadequate communication with the IRB Inadequate subject protection – failure to report AEs and informed consent issues 	<ul style="list-style-type: none"> Inadequate initial and/or continuing review Inadequate SOPs Inadequate membership rosters Inadequate meeting minutes Quorum issues Subpart D Issues (Records and Reports) Inadequate communication with C/IRB

Changes in quality thinking and philosophy

The evolution of pharma quality thinking

Discovery → Product Development → Technology Transfer → Commercial Manufacturing → Product Discontinuation

Quality by Design & Testing

Quality by Manufacture and Control

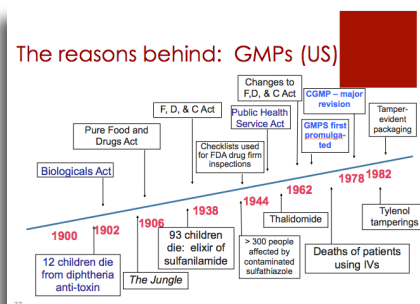
Quality by Design through Process Understanding

Variation is normal

ICH Q8 – Pharmaceutical Development | ICH Q9 – Quality Risk Management | ICH Q10 – Pharmaceutical Quality Systems | ICH Q11 – Dev. & Mfg. of Drug Substances

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.

Contact Jim Vesper at +1 585.442.0170 or email jvesper@learningplus.com.

Prosecutions of those involved

NEWS

United States Department of Justice
1125 Attorney General of New Jersey
970 Broad Street, Seventh Floor
Newark, New Jersey 07102

Christopher J. Christie, U.S. Attorney

August 13, 2007
FOR IMMEDIATE RELEASE

South Essex Superior & Circuit Drug Manufacturers Able Labs
Frank Gully, Adams Drug Administration Company

Filed in the sixth Able managers to plead guilty in the case.

The government charged a broad-based fraud scheme involving numerous drug products, and counterfeiters who manipulated the approved manufacturing process for drug products and improperly changing test parameters to obtain satisfactory test results. Each of the defendants who pleaded guilty previously outlined their supervisory roles and participation with other chemists which resulted in falsifying, altering and manipulating testing and reporting requirements which were required to be submitted to the FDA.

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.