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GXP AND REGULATORY SERIES

The *GxP and Regulatory Series* provides a comprehensive view of good clinical practice and regulatory guidelines within the pharmaceutical and biotech industry. Courses in this series provide insight on electronic signatures and records, clinical research and applied statistics, and adverse event reporting. In addition, this series provides detailed information on good clinical, laboratory, and manufacturing practices.

About Pharmaceutical Institute

Pharmaceutical Institute combines advanced instructional design and cutting-edge technology with unmatched subject matter expertise to provide high-impact training solutions to its pharmaceutical and biotech clients. A subsidiary of Campbell Alliance, the leading pharma-dedicated management consulting firm, Pharmaceutical Institute delivers strategic, immersive training programs that improve the effectiveness of professionals in key industry functions, including managed markets, sales, marketing, regulatory, and clinical.

Topics covered include:

- 21 CFR Part 11
- Biostatistics
- Drug Safety: Adverse Event Reporting
- GCP1: Good Clinical Practice Level 1
- GCP2: Good Clinical Practice Level 2
- GLP: Good Laboratory Practice Overview
- GMP: Good Manufacturing Practice Overview
- GxP Industry Overview

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21 CFR Part 11

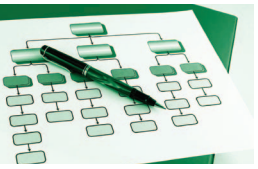
In August 1997, the FDA gave the industry a set of rules for electronic signatures and electronic records. It became 21 CFR Part 11: Electronic Signatures, Electronic Records. This course discusses why Title 21 of the Code of Federal Regulations Part 11, or "21 CFR Part 11," was developed, explains the role that Part 11 plays in the adherence to other sections of 21 CFR, and explores the general concepts of security in a Part 11 compliant system.

Biostatistics

Using real examples from medical literature, this course introduces clinical research and applied statistics. It also prepares learners to critically read and understand medical literature.

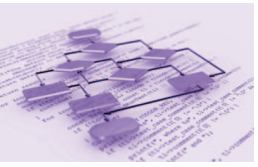
Drug Safety: Adverse Event Reporting

This course introduces the reasons for tracking adverse events and serious adverse events in clinical studies, the importance of reporting adverse events and serious adverse events, and the steps that should be taken when reporting an adverse event.



GCP1: Good Clinical Practice Level 1

Good Clinical Practice (GCP) refers to a set of international ethical and scientific quality standards for designing, conducting, recording, and reporting on trials that involve human subjects. GCP compliance ensures the protection of the rights, safety, and well-being of trial subjects and the credibility and integrity of clinical trial data. This course reviews clinical trials, GCP guidelines, and informed consent.

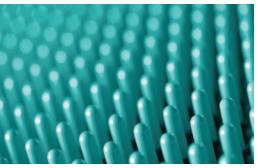


GCP2: Good Clinical Practice Level 2

The second course in the Good Clinical Practice (GCP) series reviews the standards used in clinical studies from start-up to post-study audits.

GLP: Good Laboratory Practice Overview

This course introduces the concepts and requirements necessary for compliance with Good Laboratory Practice (GLP). The course will help prepare learners to establish and document a system of GLP controls required to test medical products where data are intended for inclusion in a regulatory filing in the United States, the European Union, Japan, and many other parts of the world.



GMP: Good Manufacturing Practice Overview

This course introduces the concepts and requirements necessary for compliance with Good Manufacturing Practice (GMP) for pharmaceuticals and biopharmaceuticals. The course prepares learners to establish and document a system of GMP controls required to manufacture drug products in the United States, the European Union, Japan, and many other parts of the world.

GxP Industry Overview

This course provides an introduction to the drug development pipeline; the regulatory authorities that oversee the drug development process; and the standards that have been developed to ensure the safety, efficacy, and security of drugs, biological products, and medical devices. It also describes the process of identifying, developing, and testing new drugs and the regulatory authorities that oversee the process. In addition, it discusses the standards maintained by regulatory authorities to guide laboratory testing, clinical trials, and drug manufacturing.