Karlsruher Institut für Technologie

FTU Fortbildungszentrum für Technik und Umwelt

# Quality Management in Regulated Research (GxP) (Online-Training)

QP200e

GxP commonly refers to the standard quality management systems in pharmaceutical, chemical, biotechnology, food, and medical device industries. This three-day training offers a comprehensive overview of internationally required quality assurance systems in regulated research and development (R&D) focusing on Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and Good Manufacturing Practice (GMP). Participants will learn about study processes, data management, regulatory requirements, documentation and data integrity practices, as well as audits and inspections. Practical examples provide valuable insights into research, development and production.

The course is particularly suitable for graduates, doctoral students and postdocs from the fields of medicine, biology, chemistry and life sciences, as well as for anyone seeking insight into quality assurance in pharmaceutical and biotech companies.

By attending this seminar, you will receive proof of a GxP-compliant training.

The following topics will be covered:

- Quality Management in Regulated Research, Development and Production
- Regulatory Basics of GLP: Scope, Objectives, and Principles
- Structure and Organizational setup of GLP Testing Facilities
- GLP Study Process, Study Plans, Documentation and Data Management, Archiving, Audits and Regulatory Inspections
- Fundamentals of GCP, Regulatory an Ethical Basics, Objectives and Responsibilities
- Phases of GCP-Testing, Special Case: Medical Devices and Combination Products
- Introduction to GMP: Drug Approval and Regulatory Basics
- Roles in a GMP Environment; Quality Management and Documentation
- General Requirements, Requirements in R&D, in Quality Control and in Production
- GMP Audits and Inspections
- Good Distributional Practice (GDP): Introduction and Practical Examples
- Requirements for Data Integrity and Validation of Computerized Systems under GxP

Duration: 3 days

## TERMINE, PREISE UND BUCHUNGSMÖGLICHKEIT

↗ Informationen und Buchungsmöglichkeiten

Geplante Termine:
07.05.–09.05.2025
Kurspreis(1): 990 EUR
Preis Graduierte(1): 690 EUR

(1) Änderungen vorbehalten

## KONTAKT UND BERATUNG

Administration/Beratung: **Paula Seipenbusch**, ↗ Kontakt
Fachliche Fragen: **Dr. Cornelia Kautt**, ↗ Kontakt

INFORMATIONEN
↗ techlab@ftu.kit.edu
↗ Übersicht Themenbereich

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