Certificate Course in

Biopharmaceutics in Drug Development

A practical course on biopharmaceutics for new and generic drug development, blending science with regulation. Focus on dissolution testing and modeling/simulation to connect lab research with regulatory practice.

Learning Roadmap *

** All phases will be conducted online/virtual.*

Phase 01

Structured Learning

- Self-Paced
- Access to lectures & materials
- Assignments & exercises

Phase 02

Project-Based Learning

- In-depth training
- Capstone project
- Case studies

Phase 03

Submission & Certification

- Project submission
- Final assessment
- Certification (Completion/attendance)

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HIGHLIGHTS

- FUNDAMENTALS OF BIOPHARMACEUTICS
- PHARMACOKINETICS, BIOAVAILABILITY, BIOEQUIVALENCE
- BIOPREDICTIVE DISSOLUTION METHOD DEVELOPMENT
- BIOWAIVER, IVIVC, BASICS OF PBPK/PBBM

INSTRUCTORS

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Head, Biopharmaceutics,
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Dr. Reddy's Laboratories Ltd

WHO IS THIS COURSE FOR?

This certificate program is designed for individuals who are keen to build practical skills in biopharmaceutics concepts and modeling and contribute meaningfully to drug development. It is ideally suited for:

Early-career professionals
in the pharmaceutical, biotechnology, and contract research industries who want to strengthen their understanding of how formulation variables and physiological factors impact drug absorption and performance.

Researchers and scientists
involved in formulation science, drug delivery, pharmacokinetics, and clinical pharmacology who seek to apply mechanistic modeling to optimize dosage forms.

Graduate and postgraduate students
(PharmD, MPharm, PhD, MSc, etc.) in pharmacy, pharmaceutical sciences, industrial pharmacy, or clinical research who want to gain hands-on experience with modern software tools and biopharmaceutical study designs.

Regulatory affairs professionals
who wish to deepen their insight into biopharmaceutics specifications, Biopharmaceutics Classification System (BCS) biowaivers, and global regulatory submissions.

WHO IS THIS COURSE FOR?

Formulation and clinical trial managers

looking to enhance their ability to bridge the gap between in vitro performance and in vivo outcomes within development programs.

Educators and academic researchers

interested in updating their knowledge base and integrating practical biopharmaceutics and absorption modeling concepts into teaching or research programs.

Anyone aiming to transition into

or specialize in biopharmaceutics analysis within the broader field of drug development, including professionals in allied domains such as medical writing, data management, or quality assurance.

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WHY THIS COURSE?

- Engage with industry experts and peers to exchange knowledge and practical insights throughout the programme.
- Develop a solid foundation in bioequivalence (BE) study design and regulatory principles.
- Learn to establish meaningful In Vitro-In Vivo Correlations (IVIVC) to predict clinical performance.
- Apply biopharmaceutical classification systems (BCS/MCS) and statistical methods to evaluate formulation robustness.
- Understand the latest FDA and global regulatory guidelines for biopharmaceutics, dissolution specifications, and biowaivers.
- Explore advanced concepts like physiologically-based pharmacokinetic (PBPK) modeling and mechanistic absorption simulations.
- Strengthen your ability to accelerate formulation development and make informed, data-driven decisions in drug development.

COURSE MODULES

Module 1: Physicochemical and Biopharmaceutic Fundamentals

Covers the foundational concepts of biopharmaceutics and pharmacokinetics, including physicochemical properties, anatomy and physiology, and formulation development. It also introduces in vitro method development and regulatory expectations for dissolution and biowaivers.

Module 2: Integration and Application – I

Focuses on applying fundamentals to develop bio-indicative dissolution methods for solid and complex dosage forms. It also addresses biowaivers, SUPAC changes, and regulatory aspects of dissolution specifications and similarity. Plan to cover in depth about dissolution evaluation from biopharmaceutics and biopredictivity perspectives.

Module 3: Pharmacokinetics, Bioavailability & Bioequivalence Fundamentals

Provides core understanding of pharmacokinetics, including ADME processes, modeling approaches, and enzyme/transporter effects. It also introduces bioequivalence concepts and global regulatory requirements. Along with USFDA, EMA, harmonized ICH guidance and other specific agency requirements may also be covered.

COURSE MODULES

Module 4: Integration and Application – II

Emphasizes advanced applications such as BE data analysis, IVIVC development, and PBPK modeling. It also covers virtual bioequivalence, food effects, and critical bioavailability considerations. Few aspects on 505b(2) may also be covered.

Module 5: Case Studies and Projects

Involves practical learning through case study discussions integrating earlier modules. Concludes with capstone project presentations to apply and demonstrate overall understanding.

COURSE LOGISTICS

Duration
July - December 2026

Optional In-person Workshop *
At PSG IMSR, Coimbatore

** Participants are responsible for their own travel and accommodation.*

REGISTRATION DETAILS

Category	Registration Fee (INR)
Students/Trainees	20,000
Academicians	25,000
Industry Professionals	40,000

SCAN TO REGISTER