



School of Pharmaceutical Sciences & Technology

Curriculum for
Fellowship Program in

PHARMACEUTICAL REGULATORY AFFAIRS



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(Deemed to be University)

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Course Title: PHARMACEUTICAL REGULATORY AFFAIRS

Course Type: FELLOWSHIP

Duration: 360 Hours (can be structured as 24 Credits)

Mode: Lectures, Practicals/Hands-on, Project

Overview

The Fellowship in Pharmaceutical Regulatory Affairs is an intensive, short-term postgraduate program designed to develop practical regulatory competencies required for global pharmaceutical product approval and compliance. The program emphasizes understanding of global regulatory frameworks, dossier preparation (CTD/eCTD), GMP/GCP/GLP systems, and hands-on documentation exercises aligned with real-world industry regulatory expectations.

Objectives:

After successful completion of the course fellow students can able to

- Understand global and national pharmaceutical regulatory frameworks and compliance systems.
- Prepare and review regulatory dossiers for drug products across major submission pathways.
- Apply GMP, GCP and GLP principles for regulatory documentation and audits.
- Develop competency in CTD/eCTD module preparation, labeling compliance, and lifecycle management.
- Execute practical regulatory documentation tasks using regulatory publishing tools and templates.

Course Outcome:

CO No.	Course Outcome
C01	Explain global and Indian pharmaceutical regulatory frameworks, authority roles, and compliance systems.
C02	Prepare regulatory submissions including CTD/eCTD, drug product applications, and labeling documents.
C03	Apply GMP, GCP, GLP, and QMS principles to regulatory documentation, audits, and inspections.
C04	Analyze regulatory pathways for biologics, devices, nutraceuticals, and emerging therapies.

Teaching & Learning Methods:

The program emphasizes hands-on, case-based learning combining lectures, regulatory document drafting, industry seminars, software-based dossier preparation, and supervised capstone project work.



Syllabus

Theory - 10 Credits (150 Lecture Hours)

Module 1: Global & Indian Regulatory Frameworks (45 hours)

- Introduction to Regulatory Affairs, global authority structures (US FDA, EMA, MHRA, PMDA, TGA, WHO).
- Indian regulatory bodies (CDSCO, DCGI, State FDA) and NDCT Rules (2019).
- Legal basis for regulation, Acts, Rules, Schedules, GRP principles.

Module 2: Dossier Preparation & Submission Pathways (45 hours)

- CTD/eCTD structures, NDA, ANDA, BLA, MAA submissions.
- Administrative, quality (CMC), non-clinical and clinical modules.
- Labeling, SmPC, PIL, artwork, lifecycle management and variations.

Module 3: GxP & Quality Systems (30 hours)

- GMP, GCP, GLP, ICH Q-series, E-series, S-series.
- Data Integrity (ALCOA+), QMS, inspections, audits, Part 11 compliance.

Module 4: Emerging Product Regulation & Trends (30 hours)

- Biologics, biosimilars, ATMPs, devices, nutraceuticals and herbal regulations.
- Accelerated pathways, orphan drugs, digital health and regulatory convergence.

Practical/Hands-on Component: 8 Credits (120 Lab/Attachment Hours)

1. Regulatory Documentation Lab

- CTD/eCTD mock module compilation.
- Administrative forms, labeling & packaging compliance files.

2. Regulatory Software & Tools

- Regulatory publishing tools and intelligence databases.
- Document formatting, validation and checklist preparation.

3. GxP Documentation & QA

- SOP writing, deviation/CAPA, change control, batch record review.

4. Industry/Clinical Attachment

- Regulatory/QA division exposure at pharma, CRO or consultancy (subject to availability).

Project: 6 Credits (90 Self Study/Research Hours)

In project the fellow must work on the preparation of a regulatory documentation dossier or strategic analysis. Deliverables include a written report, compiled regulatory file and presentation.

References:

1. Rao KV, Surendiran A. Pharmaceutical Regulatory Affairs: Practical Guide. Hyderabad: PharmaMed Press (B.S. Publications); 2018.
2. Kumar R. Pharmaceutical Regulatory Affairs – International Perspectives. Hyderabad: PharmaMed Press; 2014.



3. United States Food and Drug Administration. Guidance for Industry: Regulatory Information. Silver Spring (MD): U.S. Department of Health & Human Services; [Internet]. Available from: FDA Guidance Documents.
4. European Medicines Agency. Scientific Guidelines for Medicinal Products. Amsterdam: EMA; [Internet]. Available from: EMA Scientific Guidelines.
5. World Health Organization. Prequalification of Medicines Programme: Technical Guidance. Geneva: WHO Press; 2020.
6. International Council for Harmonisation (ICH). ICH Harmonised Guidelines (Q, E, S, M4 CTD). Geneva: ICH Secretariat; [Internet]. Available from: ICH Official Publications.
7. Nawaz S. Global Regulatory Systems – A Comparative Perspective. Boca Raton (FL): CRC Press; 2019.
8. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. New Delhi: Government of India; 2019.
9. Aulton ME, Taylor K, editors. Aulton's Pharmaceuticals: The Design and Manufacture of Medicines. 6th ed. London: Elsevier; 2021.
10. Eichler HG, Oye K, Baird LG, Abadie E, Brown K, Drum CL, et al. Adaptive pathways: planning for the future of medicine development. Clin Pharmacol Ther. 2015.
11. Rathore AS, Sofer G. Process Validation in Manufacturing of Biopharmaceuticals. Boca Raton (FL): CRC Press; 2012.
12. Kessler DA, Pines A. Medical Device Regulation: The FDA and Beyond. New York: Springer; 2015.
13. Rowlands M. Pharmaceutical Compliance and Enforcement Answer Book. New York: Practising Law Institute; 2017.
14. Sahoo, U. Regulatory Affairs in Pharmaceuticals: A Global Perspective. New Delhi: PharmaMed Press; 2020.
15. Sharma R, editor. Fundamentals of Pharmacovigilance. 2nd ed. New Delhi: Elsevier; 2019.
16. International Medical Device Regulators Forum (IMDRF). Essential Principles of Safety and Performance of Medical Devices. Ottawa: IMDRF Secretariat; 2018.
17. International Council for Harmonisation (ICH). Pharmaceutical Quality System Q10. Geneva: ICH Secretariat; 2008.
18. International Conference on Harmonisation. Validation of Analytical Procedures Q2(R1). Geneva: ICH Secretariat; 2005.
19. International Society for Pharmaceutical Engineering (ISPE). GAMP 5: Guide for Validation of Automated Systems. Tampa (FL): ISPE; 2008.