Global Regulatory Affairs Hands-on Training Program with Project Work

- Course Duration: 30 Days
- Get Recording + LIVE Class Access
- Timings: 9:00 PM – 10:00 PM IST
- Venue: Online
- 100% Placement Assistance by the Biotecnika Placement Team
- Project Work: Options available – 15 days, 1 month, or 3 months

Instructor Profiles

Bhanu Melvin

Scientist & Trainer – Clinical Data Management, Pharmacovigilance & Regulatory Affairs @ Biotecnika
Former Regulatory Affairs Officer – Trucare Group of Companies, United Arab Emirates

With a robust academic background in pharmacy and over a decade of diverse experience spanning academia, healthcare, regulatory affairs, and corporate training, Bhanu Melvin brings a comprehensive and practical approach to professional skill development.

She has successfully trained 1,500+ learners — from academic aspirants to industry professionals — in critical domains including:

- Clinical Research
- Pharmacovigilance
- Clinical Data Management
- Regulatory Affairs
- Clinical SAS Programming

Bhanu holds prestigious global certifications in:

- Pharmacovigilance
- Lean Six Sigma Black Belt
- Clinical Research

- Clinical SAS Programming
- ISO 9001:2015 Lead Auditing

Her multidisciplinary expertise enables her to seamlessly connect scientific knowledge with regulatory frameworks, ensuring students gain both theoretical insight and industry-ready skills. Passionate about empowering professionals, she specializes in designing skill-oriented curricula, enhancing compliance processes, and streamlining clinical workflows — preparing learners for success in the fast-evolving life sciences sector.

Dr. Ganeshan, Ph.D.

Scientific Expert – QA/QC & Global Regulatory Affairs @ Biotecnika
Former Clinical Director – Medical Electronic Systems India Pvt. Ltd.

Dr. Ganeshan holds a Ph.D. in Microbiology and brings extensive expertise across biosimilars, quality assurance, medical diagnostic laboratories, and medical devices. As the former Clinical Director at Medical Electronic Systems India Pvt. Ltd., he led research and development efforts that resulted in the creation of an advanced diagnostic kit for semen analysis.

With strong proficiency in clinical trials, data analysis, and regulatory affairs, Dr. Ganeshan has a proven track record of bridging research innovation with compliance excellence. His passion for teaching and continuous learning enables him to present complex scientific and regulatory concepts in an engaging, relatable manner, preparing learners for real-world challenges in the life sciences and regulatory domains.

Course Curriculum

Induction Session

Week 1–2: Introduction & Global Regulatory Frameworks

- Fundamentals of Regulatory Affairs
- Overview of global regulatory agencies (FDA, EMA, MHRA, TGA, CDSCO, PMDA)
- Clinical trial approval process (Global perspective)
- ICH GCP
- Drug development lifecycle (Preclinical, Clinical, Post-market)
- Roles and responsibilities of regulatory professionals
- Assessment/Assignment for Week 1 & 2

Week 3: Regulatory Submissions & Documentation

- IND (Investigational New Drug) & NDA (New Drug Application) (FDA)
- MAA (Marketing Authorization Application) (EMA)
- ANDA (Abbreviated New Drug Application) for generics
- CMC (Chemistry, Manufacturing, and Controls) documentation
- Hands-on CTD/eCTD dossier preparation
- Assessment/Assignment for Week 3

Week 4: Clinical Trial Regulations & Compliance

- Clinical trial approval process (Global perspective)
- GCP (Good Clinical Practice) and GMP (Good Manufacturing Practice)
- Ethical considerations and IRB/IEC submission
- Adverse event reporting & pharmacovigilance
- Hands-on: Preparing a clinical trial protocol
- Assessment/Assignment for Week 4

Week 5: Regulatory Strategy & Post-Market Requirements

- Labeling, advertising, and promotional regulations
- Post-marketing surveillance & pharmacovigilance
- Medical devices & combination product regulations
- Hands-on Assignment: Labeling, Brochure, and IFU Preparation
- Assessment/Assignment for Week 5

Week 6: Regulatory Document Preparation & Review

- Audit trail report, critical subcontractor quality agreement, and ISO certification
- Risk management files and biological evaluation files
- Post-marketing surveillance files, PSUR, and PMCF files
- Hands-on document review
- Assessment/Assignment for Week 6

Week 7: Case Study, Industry Collaboration & Career Path

- Real-life case studies and working with manufacturers
- Real-life case studies and working with manufacturers
- Document review with practical industry insights
- Career Opportunities in GRA: Stakeholders, Roles, Salary Trends & Pathways
- Professional Resume Strategy Session
- Live Q&A & Feedback
- Final Assessment

Regulatory Affairs Project List

1-Month Project List

1. Role of ICH Guidelines in Global Drug Regulation – Impact of ICH guidelines (Q, S, E, M series) on regulatory submissions. Deliverable: Report mapping major ICH guidelines to drug development stages.
2. Lifecycle Management of a Drug Product: Regulatory Perspective – Variations, renewals, and post-approval changes across markets. Deliverable: Post-approval change classification flowchart.
3. Regulatory Strategy for Filing a Generic Drug (ANDA Process) – Bioequivalence, patent certification, labeling requirements. Deliverable: Step-by-step ANDA strategy.
4. Labelling and Packaging Regulations in Major Markets – US, EU, India requirements, serialization, barcoding. Deliverable: Label review checklist.

5. Impact of Brexit on Drug Regulatory Submissions – Changes in submissions, licensing, pharmacovigilance post-Brexit. Deliverable: UK MHRA strategy guide.
6. Benefit–Risk Assessment for a Legacy Medical Device – Framework compliant with EU MDR/IMDRF. Deliverable: Scoring framework, labeling, evaluation, surveillance, and risk plan.
7. Requirements Comparison: India Schedule Y vs ICH CMC – Align biologics requirements. Deliverable: Comparison grid, checklist, and recommendation memo.
8. Benefit–Risk Framework for a Simple Biologic – Scoring sheet per ICH & ISO 14971. Deliverable: Scoring matrix, mock evaluation, presentation.
9. Labelling Comparison for Biologics – FDA vs EMA. Deliverable: Label analysis, regional differences, short report.
10. Risk Assessment for a Hypothetical Insulin Pump – ISO 14971 application. Deliverable: Hazard list, FMEA, mitigation strategy, SOP.
11. Labelling Compliance Case Study: Contact Lens in UAE Market – Regional labeling adaptation. Deliverable: Regulatory review, packaging proposal, mock label design.

3-Month Project List

12. Detailed Process for Registering Drugs, Cosmetics, and Medical Devices in EMA – EMA framework, CE marking, Australian and cosmetic registration. Deliverable: Detailed process documentation and presentation.
13. Comparative Study of Regulatory Approval Processes: US FDA vs EMA – Pathways, timelines, documentation. Deliverable: Flowcharts and comparison guide.
14. Drug Master File (DMF): Structure, Submission & Global Requirements – US, EU, India strategies. Deliverable: DMF template/checklist.
15. Documentation for Clinical Trials: IND vs CTA – US and EU clinical trial submissions. Deliverable: Submission checklist.
16. Dossier Preparation: CTD vs eCTD – Structure, modules, technical requirements. Deliverable: Sample Module 1 & 2 outlines.
17. Regulatory Requirements for Herbal or Traditional Medicines – India, EU, US regulations. Deliverable: Overview table.
18. ISO 13485 Surveillance Audit vs FDA QSR Inspection – Mock audits. Deliverable: Two audit reports, comparison matrix, harmonization discussion.
19. CE-Marking Technical File for a Legacy Medical Device – EU MDR compliance. Deliverable: Classification, dossier, labeling, gap analysis, presentation.
20. Checklist for Global IND/NDA/BLA Submissions – US, EU, India. Deliverable: Submission checklist, annotated notes, presentation.
21. Post-Market Surveillance Strategy for a Wearable Device – EU MDR compliance. Deliverable: Plan, SOP template, corrective action flow diagram.