Call Us Today!

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Testimonial

"As a clinical research associate, I was looking to pivot into regulatory affairs but didn't know where to start. This course gave me everything—comprehensive modules, real-world case studies, and hands-on dossier training. The capstone project was especially helpful during interviews. I landed a regulatory associate position within two months of completing the program!"

– Priya S., Regulatory Affairs Associate, Bengaluru

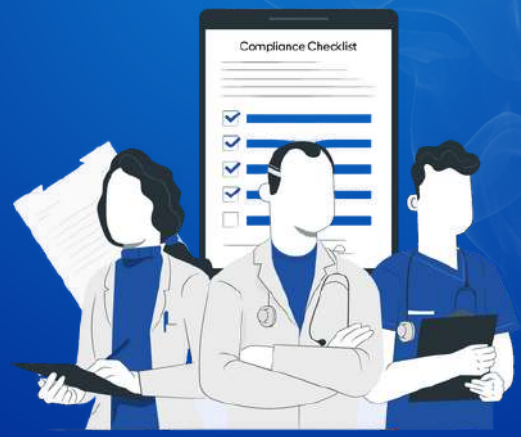
"With over 5 years in pharma manufacturing, I enrolled to deepen my understanding of global regulatory frameworks. The modules on GMP compliance and global submissions were eye-opening. The trainers are experienced and approachable, and the industry tools (like eCTD publishing) made the learning truly practical."

– Rohit Mehra, Senior QA Executive, Mumbai

RUVERA
Digital Learning

Technology Services Professional IT Services

Technology solutions for smarter and more efficient !!



ABOUT US

We believe every learner has the potential to shine in the IT industry. Our mission is to guide you step by step — from your first line of code to your first job offer. With caring mentors, real-time projects, and industry-relevant skills, we turn your dreams into a career you can be proud of.

REASONS WHY YOU SHOULD CHOOSE OUR SERVICES

Our advantages are:

- Learn from expert mentors, get one-on-one guidance, and master the latest technologies through hands-on projects and internships.
- Build real-world applications, prepare for interviews, and gain practical skills employers value.
- Benefit from strong placement support and a proven record of student success in top IT companies.

COMPANY VISION AND MISSION

Our Vision

To become a trusted technology partner that helps companies innovate and grow in the digital world.

Our Mission

- Providing relevant and effective technology solutions.
- Providing services with the best quality and competitive prices.

🎓 Regulatory Affairs Course Structure

📅 **Duration: 3 to 6 months (adjustable for fast-track or diploma formats)**

- **Pharmacy, life sciences, biotechnology, or medical graduates**
- **Working professionals in pharma/biotech**
- **Clinical research associates transitioning to regulatory roles**

📘 **Module 1: Introduction to Regulatory Affairs**

📌 **Definition and scope**
🌍 **Importance in healthcare product lifecycle**
🗺️ **Overview of global regulatory frameworks**
👩‍💼 **Regulatory affairs roles and career path**

🧪 **Module 2: Drug Development and Regulatory Process**

🧬 **Drug discovery and preclinical research**
🔬 **Clinical trial phases (I–IV)**
📈 **Product development lifecycle**
📅 **Regulatory checkpoints across the lifecycle**

🎓 Regulatory Affairs Course Structure

🌐 **Module 3: Global Regulatory Agencies & Guidelines**

- US: FDA (CDER, CBER), 21 CFR
- EU: EMA, EudraLex, CE marking
- India: CDSCO, DCGI
- 🌍 International: ICH, WHO, MHRA, TGA, PMDA
- 📖 ICH Guidelines: Q, S, E, M series (overview)

🗂️ **Module 4: Regulatory Submissions**

- 📄 Investigational New Drug (IND)
- 📝 New Drug Application (NDA)
- 📑 Abbreviated New Drug Application (ANDA)
- 🧾 Common Technical Document (CTD) & eCTD
- 📚 Dossier compilation: Modules 1–5
- ⏳ Regulatory strategy and timelines

🏭 **Module 5: Quality and GMP Compliance**

- 🔍 Introduction to Good Manufacturing Practices (GMP)
- 📜 GLP, GCP, GDP (overview)
- 🧰 Regulatory inspections and audits
- 🗃️ Documentation and SOPs

🎓 Regulatory Affairs Course Structure

🏷️ **Module 6: Labeling, Packaging & Advertising**

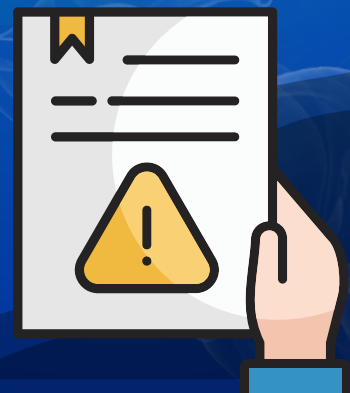
📦 Regulatory labeling requirements
🧾 Patient Information Leaflets (PILs), Summary of Product Characteristics (SmPC)
📢 Advertising compliance (FDA, EMA)
⚠️ Risk communication and black box warnings

🩺 **Module 7: Medical Devices and Combination Products**

🔧 Classification of medical devices (Class I–III)
🛠️ Regulatory pathways: 510(k), PMA (US); CE Marking (EU)
🔍 Unique Device Identification (UDI)
📊 Post-market surveillance

🧬 **Module 8: Biologics and Biosimilars**

🧫 Regulatory pathway for biologics (BLA)
🧫 Biosimilars vs. generics
🔬 Comparability studies and analytical similarity
📉 Emerging guidelines and challenges



🎓 Regulatory Affairs Course Structure

🌍 **Module 9: Regulatory Affairs in Emerging Markets**

India (CDSCO), China (NMPA), Brazil (ANVISA), etc.
📋 Country-specific registration requirements
🔄 Harmonization challenges

🛡️ **Module 10: Pharmacovigilance & Regulatory Reporting**

💊 Role of RA in drug safety
📢 Adverse Drug Reaction (ADR) reporting
🗓️ Periodic Safety Update Reports (PSURs), Risk Management Plans (RMPs)
🗒️ FDA MedWatch, EudraVigilance

💻 **Module 11: Digital & Electronic Regulatory Submissions**

🧮 eCTD software and publishing tools
📄 Document formatting and lifecycle management
🗄️ Overview of RIMS (Regulatory Information Management Systems)

🎓 Regulatory Affairs Course Structure

🧩 **Module 12: Capstone Project & Career Readiness**

📘 **Dossier compilation practice (mock IND or NDA)**
🗂️ **Case studies and simulated regulatory audits**
📄 **Resume and LinkedIn optimization**
💼 **Interview preparation and regulatory job roles**

🧰 **Tools & Guidelines Covered**

Submissions eCTD, CTD templates, publishing tools Guidelines ICH, FDA, EMA, CDSCO, TGA Software (optional) Veeva Vault, MasterControl, RIMS Docs 21 CFR, EudraLex Volumes, ICH guidelines

🧠 **Optional Add-on Specializations**

- 🧬 **Regulatory Affairs for Biologics & ATMPs**
- 🔁 **Post-Approval Changes (CMC changes)**
- 🕵️‍♀️ **Regulatory Intelligence & Strategy**
- 🏷️ **Global Labeling Operations**