Entrepreneurship Development Institute of India
Ahmedabad

EXECUTIVE MANAGEMENT PROGRAMME

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One-Day | 4 Hours

Objective

Align business strategy with the development of safe, effective, and economical pharmaceutical drug products, while navigating regulatory expectations and global market opportunities.

Decision Making for Regulatory Compliance Risk Management using the most complex US FDA Compliance of CGMP Regulation 21 CFR Part 211, while reducing the effort and cost of compliance.

Provide details on the EDII's Pharma Compliance Skill Development Certificate Programme (EDII's Pharma Hand Holding) Empowering Pharmaceutical Entrepreneurs.

Who Should Attend?

Small and Mid-Sized Pharmaceutical Entrepreneurs (Decision Makers):

→ Chairman → CEO → CFO → Head of Quality → Head of Operations

Why Attend?

- Already in, or planning to enter, the US pharmaceutical market
- Learn how to manufacture world-class medicines (safe, effective, economical)
- Build decision-making expertise that impacts compliance, cost, and global access
- Reduce the effort and cost of compliance with CGMP regulations

Schedule:

- Session Duration: 4 Hours
- Date & Time:
- Format: Virtual

Programme Fees:

Programme Highlights

- Role of Decision Makers
  - o Perception vs. reality in quality
- Leadership compliance choices and their impact on the cost
  - o Cost of Compliance
  - o Reducing Effort and Cost of Compliance by 40-60%
    - Provide a List of ineffective programmes
  - o Difference between Global Regulators
  - o Difference Between Industry Auditors and the US FDA Federal Inspector
    - Pharmaceutical Quality System Suggestions

- Understanding the US Market
  - Drug shortages market opportunity
  - Faster approval pathways for small businesses
  - FDA Drug Shortage Resource

- Quick Overview of Compliance
  - Difference Between Regulation, Guidelines, and Standards

- Building CGMP Expertise using the most complex US FDA CGMP Regulation
  - Reduce the Reliance on expensive and ineffective Western Consultants
  - Avoiding failed Over-Kill Western compliance programmes transferred to India

- Support for small companies with limited funding

- Reducing Compliance Costs
  - Seems Large investments long-term small Investment
  - Cost comparisons and smarter compliance choices
  - Using the right technology

- Use of Artificial Intelligence (AI) in CGMP Regulations:
  - Convenience vs. Compliance

EDII's Pharma Compliance One-Year Skill Development Certificate Programme (Hand Holding)

- Expert-Led Guided Support Compliance Programme
  - Pharmaceutical Quality Culture Development
  - US FDA Issue Resolutions
  - CGMP Programme Development
    - Quality System
    - Change Management
    - Deviation Management
    - Investigations
    - Computer System Validation
    - Process Validation

- Step-by-Step CGMP Compliance Mentorship Programme
  - Review of the Pharmaceutical Quality System

- Interactive Learning Programme
  - Interactive Virtual CGMP Training
  - Develop Company Expert Trainers

- Personalized Advisory Programme
  - One-on-One with Executive Compliance Advisory
  - Regulatory Navigation Programme
  - Design Pharmaceutical Quality System
    - Simplify the most complex US FDA Pharmaceutical Quality System Program Implementation

- Mentored Compliance Programme (0nce a Month)
  - Following Completion of Yearly Interactive Programme

Speaker : Purna Thakker

Purna Thakker is a globally recognized regulatory strategist, inventor, and quality systems expert with over 35 years of experience across the pharmaceutical, biotechnology, and cell & gene therapy (CGT) industries. As the Founder & CEO of ADPT Solution, he leads the development of the OC11 Single Validation Platform, a revolutionary GxP-compliant SaaS that eliminates the need for redundant computer system validation (CSV) across systems like eQMS, LIMS, CMMS, eBatch Records, and Training.

He is a CPHI Mentor (2024) and has served in senior leadership roles at Novartis, Pfizer, Warner-Lambert / Parke-Davis, and Hitachi Chemical (Minaris). Purna is known for his practical approach to compliance, having led over 200+ global audits and developed regulatory frameworks used across five continents. He has a track record of successfully remediating FDA 483s, implementing data integrity programmes, and supporting the commercialization of the first FDA-approved CAR-T therapy, Kymriah®.

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- *India-Uzbekistan Entrepreneurship Development Centre (IUEDC), Tashkent*
- *Cambodia-India Entrepreneurship Development Centre (CIEDC), Phnom Penh*
- *Vietnam-India Entrepreneurship Development Centre (VIEDC), Hanoi*
- *Rwanda-India Entrepreneurship Development Centre (RIEDC), Kigali*