

Pharmaceutical Quality and Regulatory Affairs

Duration: 5 Days

Language: en

Course Code: PO3 - 112

Objective

Upon completion of this course, participants will be able to:

- Understand the principles of pharmaceutical quality management.

- Develop skills to ensure compliance with regulatory requirements.
- Learn about the latest standards and guidelines in pharmaceutical quality.
- Explore strategies for effective regulatory affairs management.
- Enhance their ability to implement quality systems in pharmaceutical production.

Audience

This course is intended for:

- Pharmaceutical quality assurance professionals
- Regulatory affairs specialists
- Pharmaceutical production managers
- Compliance officers
- Healthcare professionals involved in drug development
- Graduate students in pharmaceutical sciences and related fields

Training Methodology

The course employs a blend of instructional methods, including:

- Interactive lectures
- Hands-on quality management and regulatory sessions
- Group discussions and case studies
- Expert-led Q&A sessions
- Comprehensive course materials and resources

Summary

This advanced course provides a comprehensive understanding of pharmaceutical quality assurance and regulatory affairs. Participants will explore quality management principles, regulatory requirements, and the latest practices in ensuring pharmaceutical products' safety, efficacy, and quality. The course combines theoretical knowledge with practical

applications, preparing professionals to navigate the complex landscape of pharmaceutical regulation and quality assurance.

Course Content & Outline

Section 1: Introduction to Pharmaceutical Quality Management

- Overview of pharmaceutical quality management systems
- Key concepts and principles of quality assurance
- The role of quality management in the pharmaceutical industry

Section 2: Regulatory Frameworks and Requirements

- Overview of global regulatory bodies and their requirements
- Key regulatory guidelines: FDA, EMA, ICH
- Navigating the regulatory submission process

Section 3: Quality Control and Assurance Practices

- Good Manufacturing Practices (GMP)
- Quality control methods and tools
- Ensuring product safety and efficacy through quality assurance

Section 4: Risk Management and Compliance

- Identifying and managing risks in pharmaceutical production
- Strategies for maintaining compliance with regulatory standards
- Case studies of compliance challenges and solutions

Section 5: Practical Applications and Future Trends

- Implementing quality systems in pharmaceutical production
- Emerging trends in pharmaceutical quality and regulation
- Collaborative problem-solving and case studies
- Course review and expert Q&A

Certificate Description

Upon successful completion of this training course, delegates will be awarded a Holistique Training Certificate of Completion. For those who attend and complete the online training course, a Holistique Training e-Certificate will be provided.

Holistique Training Certificates are accredited by the British Assessment Council (BAC) and The CPD Certification Service (CPD), and are certified under ISO 9001, ISO 21001, and ISO 29993 standards.

CPD credits for this course are granted by our Certificates and will be reflected on the Holistique Training Certificate of Completion. In accordance with the standards of The CPD Certification Service, one CPD credit is awarded per hour of course attendance. A maximum of 50 CPD credits can be claimed for any single course we currently offer.

Categories

Health, Safety & Environment HSE, Healthcare & Pharmaceutical, Quality & Productivity

Tags

Quality control QC, Healthcare, Regulatory Affairs, Pharmaceutical Quality

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