MERCURY

Technical Evaluation of Medications

28 June – 2 July 2027
Nairobi (Kenya)



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Technical Evaluation of Medications

Ref: 16139_1068802 **Date:** 28 June – 2 July 2027 **Location:** Nairobi (Kenya) **Fees:** 5300 Euro

Introduction:

The Technical Evaluation of Medications training course provides healthcare professionals, pharmacists, and regulatory specialists with in-depth knowledge and practical skills to assess the quality, safety, and efficacy of pharmaceutical products.

This Technical Evaluation of Medications course covers the essential scientific and regulatory frameworks involved in medication evaluation, with a focus on technical documentation, analytical methods, and compliance with international standards. Participants will gain insights into critical aspects, including drug formulation analysis, stability testing, and bioequivalence studies.

The Technical Evaluation of Medications program highlights the importance of risk assessment and quality control in the pharmaceutical supply chain. It emphasizes understanding technical dossiers, inspection protocols, and decision-making criteria for the approval of medications. Learners will conduct thorough technical evaluations that support regulatory submissions and ensure patient safety.

Targeted Groups:

This Technical Evaluation of Medications training targets professionals seeking specialized knowledge and skills:

- Pharmacists play a crucial role in the drug approval process.
- Quality control analysts in pharmaceutical manufacturing.
- Regulatory affairs specialists handle medication dossiers.
- Clinical researchers are engaged in drug development.
- Healthcare professionals oversee medication safety.
- Pharmacovigilance officers monitor adverse effects.
- Medical product inspectors and auditors.
- Pharmaceutical project managers.
- Students aiming for careers in pharmaceutical sciences.
- Professionals preparing for certification in drug evaluation.

Targeted Competencies:

Participants will gain the following competencies during the Technical Evaluation of Medications program:

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- Ability to conduct comprehensive technical reviews of pharmaceutical products.
- Proficiency in analyzing laboratory reports and clinical trial data.
- Competence in applying international regulatory standards.
- Skills to identify potential quality and safety issues.
- Expertise in managing technical documentation for regulatory purposes.
- Capacity to assess medication risks and ensure compliance.
- Capability to support drug approval with evidence-based evaluation.
- Effective communication of technical assessment outcomes.
- Improved critical thinking and problem-solving in medication evaluation.

Course Objectives:

Participants will achieve the following objectives by completing the Technical Evaluation of Medications course:

- Understand principles of pharmaceutical formulation and manufacturing.
- Analyze technical documentation related to drug registration.
- Evaluate medication quality through analytical and stability tests.
- Interpret regulatory guidelines and compliance requirements.
- Apply risk management practices in drug evaluation.
- Develop skills to assess bioequivalence and clinical data.
- Critically appraise technical dossiers for medication approval.
- Enhance decision-making capabilities for regulatory submissions.
- Communicate technical findings effectively to stakeholders.
- Integrate quality assurance strategies in pharmaceutical processes.

Course Content:

Unit 1: Fundamentals of Medication Evaluation:

- Overview of pharmaceutical sciences and drug development.
- Key concepts in medication formulation and pharmacokinetics.
- Understanding drug manufacturing processes and quality control.
- Introduction to technical dossiers and regulatory submissions.
- Roles of international regulatory agencies and standards.
- Drug safety and efficacy assessment principles.
- Terminology and documentation in technical evaluation.

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Unit 2: Analytical Methods for Medication Quality:

- Techniques for chemical and physical analysis of drugs.
- Methods for stability testing and shelf-life determination.
- Interpretation of assay and impurity profiles.
- Bioanalytical methods for pharmacokinetic studies.
- Quality Control Sampling and Laboratory Best Practices.
- Use of chromatography, spectroscopy, and dissolution testing.
- Documentation and reporting of analytical results.

Unit 3: Regulatory Frameworks and Compliance:

- Overview of global pharmaceutical regulations FDA, EMA, WHO.
- Regulatory pathways for drug approval and registration.
- Good Manufacturing Practices GMP and compliance audits.
- Preparation and evaluation of Common Technical Document CTD.
- Risk assessment and mitigation strategies.
- Labeling, packaging, and pharmacovigilance requirements.
- Case studies on regulatory challenges and solutions.

Unit 4: Bioequivalence and Clinical Data Assessment:

- Concepts of bioavailability and bioequivalence.
- Design and evaluation of clinical pharmacokinetic studies.
- Statistical approaches to data interpretation.
- Review of clinical trial protocols and ethical considerations.
- The Impact of Patient Variability on Medication Efficacy.
- Integration of clinical and laboratory data for evaluation and assessment.
- Regulatory criteria for bioequivalence approval.

Unit 5: Practical Aspects and Decision Making:

- Steps in conducting a technical evaluation of medications.
- Tools for document review and checklist development.
- Communication skills for presenting evaluation findings.
- Problem-solving in medication quality issues.
- Collaboration with regulatory and clinical teams.
- Preparation for audits and inspections.
- Final project: Complete technical dossier assessment.

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Final Insights & Key Takeaways:

The Technical Evaluation of Medications course equips professionals to conduct thorough assessments, ensuring the safety and efficacy of medications. Mastery of analytical methods and regulatory knowledge enhances the drug approval process. Participants develop the critical competencies necessary to navigate complex pharmaceutical evaluations with confidence. This training supports improved healthcare outcomes through rigorous medication quality assurance.