ICTQual AB

Qualification Specification

ICTQual AB Level 7 Postgraduate Diploma in Pharmaceutical Regulatory Affairs (PgD Regulatory Affairs)

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ICTQual AB's

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About ICTQual AB's

ICTQual AB is a distinguished awarding body based in the United Kingdom, dedicated to fostering excellence in education, training, and skills development. Committed to global standards, ICTQual AB's provides internationally recognized qualifications that empower individuals and organizations to thrive in an increasingly competitive world. Their offerings span diverse industries, including technical fields, health and safety, management, and more, ensuring relevance and adaptability to modern workforce needs.

ICTQual AB's delivers high-quality educational solutions through a network of Approved Training Centres worldwide. Their robust standards and innovative teaching methodologies equip learners with practical knowledge and skills for personal and professional growth. With a mission to inspire lifelong learning and drive positive change, ICTQual AB's continuously evolves its programs to stay ahead of industry trends and technological advancements.

Course Overview

The ICTQual AB Level 7 Postgraduate Diploma in Pharmaceutical Regulatory Affairs (PgD Regulatory Affairs) is a specialised postgraduate qualification designed to develop advanced regulatory knowledge, critical understanding, and professional competence within the pharmaceutical and healthcare sectors. This programme provides learners with the expertise required to navigate complex regulatory frameworks and to support the safe, effective, and compliant development, approval, and lifecycle management of medicinal products and healthcare technologies.

The pharmaceutical industry operates within highly regulated national and international environments that are continually evolving in response to scientific innovation, global harmonisation, and increased regulatory scrutiny. Regulatory affairs professionals play a vital role in ensuring that organisations comply with legal, ethical, and quality requirements while facilitating timely market access for medicines. As a result, there is an

increasing demand for skilled professionals who can interpret legislation, manage regulatory submissions, and advise organisations on regulatory strategy and compliance.

This Level 7 qualification equips learners with in-depth knowledge of global regulatory systems, quality management frameworks, clinical trial governance, and risk-based regulatory approaches. The programme emphasises critical analysis, evaluation of complex regulatory information, and the practical application of advanced regulatory strategies in real-world contexts. Through this advanced learning approach, learners are prepared to operate effectively in senior regulatory roles and to contribute meaningfully to patient safety, healthcare quality, and organisational regulatory excellence.

Aims of the Qualification

The ICTQual AB Level 7 Postgraduate Diploma in Pharmaceutical Regulatory Affairs (PgD Regulatory Affairs) aims to:

- Develop advanced professional competence in pharmaceutical regulatory affairs aligned with international regulatory standards
- Enable learners to critically evaluate regulatory frameworks, policies, and compliance requirements across global markets
- Prepare professionals to contribute effectively to regulatory strategy, governance, and decision-making within pharmaceutical and healthcare organisations
- Support Continuing Professional Development (CPD) and career progression into senior regulatory and leadership roles

Objectives

On successful completion of this qualification, learners will be able to:

- Critically analyse and interpret complex pharmaceutical legislation, guidelines, and regulatory policies
- Apply advanced regulatory strategies to support product development, registration, and post-marketing activities
- Evaluate quality management systems, clinical trial governance, and risk management practices within regulated environments
- Demonstrate ethical, professional, and compliant decision-making in regulatory affairs contexts

- Integrate current developments and emerging trends in pharmaceutical regulation into professional practice
- Apply advanced knowledge to real-world regulatory challenges across international markets

Targeted Audience

This qualification is designed for professionals who are currently working in, or aspiring to work in, regulatory and compliance-focused roles within the pharmaceutical and healthcare sectors, including:

- Regulatory Affairs professionals seeking career advancement
- Pharmaceutical, biotechnology, and medical device professionals
- Quality assurance, quality control, and compliance managers
- Clinical research and clinical trial professionals
- Healthcare professionals transitioning into regulatory roles
- Graduates with relevant backgrounds seeking postgraduate-level regulatory expertise
- Professionals aiming to enhance CPD and prepare for senior or strategic positions

Certification Framework

Qualification title	ICTQual AB Level 7 Postgraduate Diploma in Pharmaceutical Regulatory Affairs (PgD Regulatory Affairs)
Course ID	PHR0101
Total Qualification Time	1200 Hours
Guided Learning Hours	600 Hours
Grading Type	Pass / Fail
Competency Evaluation	Coursework / Assignments / Verifiable Experience
Assessment	The assessment and verification process for ICTQual AB's qualifications involves two key stages: **Internal Assessment and Verification:** ✓ Conducted by the staff at the Approved Training Centre (ATC) to ensure learners meet the required standards through continuous assessments. ✓ Internal Quality Assurance (IQA) is carried out by the centre's IQA staff to validate the assessment process. **External Quality Assurance:** ✓ Managed by ICTQual AB's verifiers, who periodically review the centre's assessment and IQA processes. Verifies that assessments are conducted to the required standards and ensures consistency across centres

Entry Requirements

To enrol in ICTQual AB Level 7 Postgraduate Diploma in Pharmaceutical Regulatory Affairs (PgD Regulatory Affairs), learner must meet the following entry requirements:

- ✓ **Age Requirement:** Learners must be at least 21 years old at the time of registration.
- ✓ **Educational Background:** A high school diploma or equivalent is required. Prior knowledge in pharmacy, pharmaceutical sciences, life sciences, healthcare management, or related disciplines is recommended but not mandatory.
- ✓ **Professional Experience:** Although not compulsory, learners with experience in pharmaceutical companies, regulatory agencies, clinical research, or healthcare organisations may find the programme particularly valuable.
- ✓ **English Proficiency:** Proficiency in English is essential for successful completion of the programme. Non-native speakers are advised to hold an IELTS score of 5.5 or an equivalent qualification.
- ✓ **Additional Requirement:** Learners should have access to a personal computer or laptop with reliable internet connectivity and a suitable study environment. A genuine interest in pharmaceutical compliance, global regulations, and healthcare governance is strongly encouraged.
- ✓ **Centre Requirements:** Centres delivering this qualification must employ suitably qualified teaching staff, provide access to pharmaceutical regulatory resources, and maintain strong academic quality assurance systems to support learners effectively.

Qualification Structure

This qualification comprises 6 mandatory units, totalling 120 Credits. Candidates must successfully complete all mandatory units to achieve the qualification.

Mandatory Units	
Unit Ref#	**Unit Title**
PHR0101-01	Global Pharmaceutical Regulatory Frameworks and Compliance
PHR0101-02	Regulatory Strategy in Drug Development and Approval
PHR0101-03	Quality Management Systems and Good Manufacturing Practices (GMP)
PHR0101-04	Clinical Trials, Ethics, and Regulatory Oversight
PHR0101-05	Risk Management and Pharmacovigilance in Regulatory Affairs
PHR0101-06	Research Methods and Innovation in Regulatory Sciences

Centre Requirements

To ensure quality training delivery, centres must adhere to the following standards:

1. Centre Approval

- ✓ Centres must be formally approved by ICTQual AB's before delivering this qualification.
- ✓ Approval involves a review of facilities, policies, and staff qualifications.

2. Qualified Staff

- ✓ **Tutors:** Delivering the ICTQual AB Level 7 Postgraduate Diploma in Pharmaceutical Regulatory Affairs (PgD Regulatory Affairs) should hold a Level 7 or higher qualification in Pharmaceutical Sciences, Regulatory Affairs, Pharmacy, Life Sciences, or a related discipline. They should have relevant professional experience within pharmaceutical or healthcare regulatory environments and possess a sound understanding of international regulatory frameworks, compliance requirements, and current industry practices.
- ✓ **Assessors:** Must hold a recognized assessor qualification (e.g., CAVA, AVRA) or equivalent)
- ✓ **Internal Quality Assurers (IQAs):** Must hold a recognized IQA qualification (e.g. Level 4 Award in the IQA and Level 4 Certificate in Leading the IQA) and experience to oversee assessment standards.

3. Learning Facilities

Centre must offer:

- ✓ Private study areas and internet-enabled workspaces (for blended or physical delivery)
- ✓ Academic and pastoral support for learners
- ✓ Administrative support must be available to manage enrolment, tracking, and learner queries efficiently

4. Health and Safety Compliance

- ✓ All training facilities must comply with health and safety regulations.

- ✓ Centres must conduct regular risk assessments for practical activities.

5. Learning Resources

- ✓ **Course Materials:** Approved textbooks, study guides, and digital content must align with the qualification standards.
- ✓ **Assessment Tools:** Templates and guidelines must be provided to ensure standardized evaluation processes.
- ✓ **E-Learning Support:** Centres offering online or blended learning must implement an effective Learning Management System (LMS).

6. Assessment and Quality Assurance

- ✓ Centres must ensure assessments meet ICTQual AB's competency standards.
- ✓ Internal quality assurance (IQA) must be conducted to maintain consistency.
- ✓ External verifiers from ICTQual AB's will review assessment and training practices.

7. Learning Support

- ✓ **Qualification Guidance:** Support for coursework and assignments.
- ✓ **Career Pathway Assistance:** Information on progression opportunities in pharmaceutical and healthcare sectors.
- ✓ **Accessibility Support:** Accommodations for learners with disabilities or language barriers.

8. Policies and Compliance

Centres must uphold the following policies in accordance with ICTQual AB's standards:

- ✓ Equality, Diversity, and Inclusion Policy.
- ✓ Health and Safety Policy.
- ✓ Safeguarding and Learner Protection Policy.
- ✓ Complaints and Appeals Procedure.
- ✓ Data Protection and Confidentiality Policy.

9. Reporting Requirements

- Centres must provide ICTQual AB's with regular reports on learner registrations, progress, and certification outcomes.
- Assessment records must be maintained for external auditing and quality assurance purposes.

Support for Candidates

Centres should ensure that materials developed to support candidates:

- ✓ Facilitate tracking of achievements as candidate's progress through the learning outcomes and assessment criteria.
- ✓ Include information on how and where ICTQual AB's policies and procedures can be accessed.
- ✓ Provide mechanisms for Internal and External Quality Assurance staff to verify and authenticate evidence effectively.

This approach ensures transparency, supports candidates' learning journeys, and upholds quality assurance standards.

Assessment

This qualification is competence-based, requiring candidates to demonstrate proficiency as defined in the qualification units. The assessment evaluates the candidate's skills, knowledge, and understanding against the set standards. Key details include:

1. **Assessment Process:**

   - ✓ Must be conducted by an experienced and qualified assessor.
   - ✓ Candidates compile a portfolio of evidence that satisfies all learning outcomes and assessment criteria for each unit.

2. **Types of Evidence:**

   - ✓ Observation reports by the assessor.
   - ✓ Assignments, projects, or reports.
   - ✓ Professional discussions.
   - ✓ Witness testimonies.
   - ✓ Candidate-produced work.
   - ✓ Worksheets.
   - ✓ Records of oral and written questioning.
   - ✓ Recognition of Prior Learning (RPL).

3. **Learning Outcomes and Assessment Criteria:**

   - ✓ **Learning Outcomes:** Define what candidates should know, understand, or accomplish upon completing the unit.
   - ✓ **Assessment Criteria:** Detail the standards candidates must meet to demonstrate that the learning outcomes have been achieved.

This framework ensures rigorous and consistent evaluation of candidates' competence in line with the qualification's objectives.

Unit Descriptors

PHR0101-01- Global Pharmaceutical Regulatory Frameworks and Compliance

This unit provides learners with an advanced understanding of global pharmaceutical regulatory systems and compliance requirements. It examines the roles of major regulatory authorities, international harmonisation initiatives, and legal frameworks governing medicinal products. Learners critically evaluate regulatory expectations across jurisdictions and apply compliance principles to complex, real-world pharmaceutical and healthcare contexts.

Learning Outcome:	Assessment Criteria:
1. Understand the structure and function of international regulatory bodies such as FDA, EMA, and ICH.	1.1 Critically evaluate the legislative powers of the FDA, EMA, and MHRA in their respective regions. 1.2 Analyze the influence of the ICH on global drug development standards and data requirements. 1.3 Assess the role of national agencies in emerging markets in adopting international benchmarks. 1.4 Critique the organizational challenges within regulatory bodies during the review of complex therapies. 1.5 Appraise the collaboration mechanisms between the WHO and regional authorities for global health security. 1.6 Compare the administrative procedures for "Scientific Advice" across different global jurisdictions.
2. Analyse the role of global harmonisation in ensuring consistent pharmaceutical standards.	2.1 Analyze the impact of the Common Technical Document (CTD) on cross-border registration efficiency. 2.2 Evaluate the success of the PIC/S in harmonizing Good Manufacturing Practice (GMP) inspections. 2.3 Critique the technical barriers that prevent full global harmonisation of pharmaceutical laws. 2.4 Assess the role of Mutual Recognition Agreements (MRAs) in reducing the regulatory burden on manufacturers. 2.5 Analyze how global harmonisation affects the availability of essential medicines in developing nations. 2.6 Synthesize the benefits of using international pharmacopoeial standards for raw material testing.
3. Evaluate compliance requirements for pharmaceuticals, biologics, and medical devices across jurisdictions.	3.1 Critically compare the regulatory compliance pathways for small molecule drugs versus biologics. 3.2 Evaluate the unique quality and safety requirements for Advanced Therapy Medicinal Products (ATMPs).

	3.3 Assess the classification logic for medical devices and its impact on the depth of clinical evidence required. 3.4 Analyze the compliance risks associated with "Combination Products" (e.g., drug-eluting stents). 3.5 Critique the regulatory oversight of "Companion Diagnostics" used in personalized medicine. 3.6 Appraise the impact of "post-Brexit" UKCA marking versus CE marking for medical device compliance.
4. Apply regulatory knowledge to interpret legislation and implement compliance strategies.	4.1 Interpret complex pharmaceutical statutes to identify potential compliance gaps in a company's operations. 4.2 Design a multi-national compliance roadmap for a product with diverse regional requirements. 4.3 Develop a strategy to mitigate legal risks when moving a product from "investigational" to "marketed" status. 4.4 Justify the use of regulatory intelligence data in making strategic investment decisions for new products. 4.5 Evaluate the effectiveness of internal "Standard Operating Procedures" (SOPs) in meeting legislative demands. 4.6 Propose a change management plan to adapt to major legislative shifts (e.g., New EU Medical Device Regulation).

PHR0101-02- Regulatory Strategy in Drug Development and Approval

This unit develops advanced knowledge of regulatory strategy across the drug development lifecycle. Learners explore strategic planning for regulatory submissions, scientific advice, and approval pathways. Emphasis is placed on integrating regulatory requirements with clinical, quality, and commercial considerations to support timely market access and effective decision-making in complex and evolving regulatory environments.

Learning Outcome:	Assessment Criteria:
1. Examine the stages of drug development and the role of regulatory affairs in each phase.	1.1 Critically analyze the regulatory milestones from the "Discovery" phase to "Phase I" clinical trials. 1.2 Evaluate the role of "Pre-IND" or "Scientific Advice" meetings in reducing development risks. 1.3 Assess how regulatory input shapes the "Target Product Profile" (TPP) during mid-stage development. 1.4 Analyze the impact of "Good Laboratory Practice" (GLP) data on the success of an IND application. 1.5 Critique the interaction between regulatory affairs and clinical teams during the design of Phase III trials. 1.6 Appraise the regulatory requirements for "Scale-up" during the transition to commercial manufacturing.
2. Develop regulatory strategies to support product registration, labelling, and post-approval changes.	2.1 Formulate a registration strategy that utilizes "Accelerated Approval" or "Priority Review" pathways. 2.2 Develop a global labeling strategy that balances commercial needs with regional safety requirements. 2.3 Design a post-approval variation strategy to manage manufacturing site changes or dosage updates. 2.4 Evaluate the impact of "Labeling Claims" on the market positioning and reimbursement of a drug. 2.5 Propose a "Lifecycle Management" plan to extend market exclusivity through regulatory mechanisms. 2.6 Justify the choice of a specific submission route (e.g., Centralized vs. Decentralized) for a new drug launch.

3. Understand dossier preparation and submission requirements for global regulatory authorities.	3.1 Critically evaluate the technical requirements of Module 3 (Quality) of the eCTD for global submissions. 3.2 Analyze the importance of the "Clinical Overview" (Module 2.5) in persuading regulators of a drug's efficacy. 3.3 Determine the specific regional administrative requirements (Module 1) for the US, EU, and Asian markets. 3.4 Critique the role of "Quality Overall Summary" (QOS) in facilitating a smooth technical review. 3.5 Evaluate the impact of "eCTD Validation Errors" on the overall submission timeline. 3.6 Appraise the strategies for managing "Questions from Regulators" during the dossier review period.
4. Assess the impact of regulatory timelines on drug development and market access.	4.1 Critically analyze how "Regulatory Review Cycles" affect the financial "Net Present Value" (NPV) of a drug. 4.2 Evaluate the relationship between regulatory approval and Health Technology Assessment (HTA) timelines. 4.3 Assess the benefits of "Orphan Drug Designation" on the time-to-market and exclusivity periods. 4.4 Analyze the impact of "Clock Stops" and "Extended Reviews" on the competitive advantage of a firm. 4.5 Critique the role of "Pediatric Investigation Plans" (PIPs) in delaying or speeding up adult drug launches. 4.6 Propose a strategy to synchronize global submissions to minimize the "Market Access Gap" between regions.

PHR0101-03- Quality Management Systems and Good Manufacturing Practices (GMP)

This unit focuses on the design, implementation, and evaluation of pharmaceutical quality management systems and Good Manufacturing Practices. Learners critically examine regulatory standards, inspection processes, and compliance strategies. The unit develops the ability to assess quality risks, manage deviations, and ensure product quality, safety, and efficacy across complex manufacturing and supply chain operations.

Learning Outcome:	Assessment Criteria:
1. Gain knowledge of GMP principles and their application to pharmaceutical manufacturing.	1.1 Critically evaluate the implementation of "Quality Risk Management" (ICH Q9) in a GMP facility. 1.2 Analyze the specific GMP challenges associated with the production of sterile injectable medicines. 1.3 Assess the role of "Process Validation" in ensuring consistent quality across commercial batches. 1.4 Critique the strategies for "Cleaning Validation" in facilities using multi-product equipment. 1.5 Evaluate the impact of "Continuous Manufacturing" technologies on traditional "Batch-based" GMP rules. 1.6 Appraise the legal and ethical duties of the "Qualified Person" (QP) in the final release of a product.
2. Evaluate the role of quality management systems in ensuring product safety and efficacy.	2.1 Analyze how a "Pharmaceutical Quality System" (ICH Q10) aligns with business objectives and safety. 2.2 Evaluate the effectiveness of "Change Control" systems in preventing unintended quality issues. 2.3 Assess the role of "Management Review" in driving continuous improvement within a QMS. 2.4 Critique the integration of "Deviation Management" with "Root Cause Analysis" (RCA) techniques. 2.5 Evaluate the importance of "Supplier Quality Management" in securing a global supply chain. 2.6 Appraise the impact of "Quality Culture" on the long-term sustainability of manufacturing compliance.

3. Apply regulatory frameworks to audit, inspection, and compliance activities.	3.1 Design a comprehensive "Inspection Readiness" plan for a facility facing a regulatory audit. 3.2 Apply regulatory guidance to justify the categorization of audit findings (e.g., Major vs. Critical). 3.3 Analyze the tactical steps for responding to an FDA "Form 483" or an EMA non-compliance report. 3.4 Evaluate the use of "Remote/Virtual Inspections" in the current regulatory environment. 3.5 Critique the role of "Self-Inspections" in identifying systemic quality failures. 3.6 Propose a strategy for managing "Third-party Audits" of contract manufacturing organizations (CMOs).
4. Understand documentation requirements and quality risk management in pharmaceutical production.	4.1 Critically evaluate the application of "FMEA" (Failure Mode and Effects Analysis) in manufacturing risk. 4.2 Analyze the importance of "ALCOA+" principles in maintaining the integrity of electronic batch records. 4.3 Assess the documentation requirements for "Equipment Qualification" (IQ/OQ/PQ) in a regulated environment. 4.4 Critique the strategies for "Knowledge Management" as part of the quality lifecycle (ICH Q10). 4.5 Evaluate the legal requirements for "Product Quality Reviews" (PQR) in detecting quality trends. 4.6 Justify the documentation hierarchy required to support a "Global Master File" (GMF).

PHR0101-04- Clinical Trials, Ethics, and Regulatory Oversight

This unit provides an in-depth understanding of the regulatory and ethical frameworks governing clinical research. Learners examine clinical trial design, regulatory submissions, ethical review processes, and oversight mechanisms. The unit emphasises critical evaluation of patient safety, data integrity, and regulatory compliance in the planning and conduct of complex clinical trials.

Learning Outcome:	Assessment Criteria:
1. Analyse the regulatory processes governing clinical trials at national and international levels.	1.1 Critically compare the EU Clinical Trials Regulation (CTR) with the FDA 21 CFR Part 312 requirements. 1.2 Analyze the role of the "Clinical Trials Information System" (CTIS) in cross-border trial coordination. 1.3 Evaluate the regulatory hurdles for starting "Phase I" trials in sensitive or vulnerable populations. 1.4 Assess the requirements for "Safety Reporting" (DSURs) throughout the duration of a clinical trial. 1.5 Critique the management of "Substantial Amendments" and their impact on trial timelines. 1.6 Appraise the role of "Voluntary Harmonisation Processes" in multi-country trial approvals.
2. Understand ethical considerations in human subject research, including informed consent and data protection.	2.1 Critically evaluate the application of the "Declaration of Helsinki" in modern drug research ethics. 2.2 Analyze the ethical complexities of "Informed Consent" in emergency or pediatric clinical research. 2.3 Assess the impact of "GDPR" and "HIPAA" on the management of patient-level clinical trial data. 2.4 Critique the ethical balance between "Placebo-controlled" trials and "Standard-of-care" comparisons. 2.5 Evaluate the transparency requirements for registering trials on public databases (e.g., ClinicalTrials.gov). 2.6 Appraise the ethical responsibilities of sponsors towards participants after a trial has ended.

3. Apply regulatory requirements to trial design, monitoring, and reporting.	3.1 Apply "Good Clinical Practice" (GCP) standards to the design of a "Risk-Based Monitoring" plan. 3.2 Evaluate the regulatory criteria for reporting "SUSARs" (Suspected Unexpected Serious Adverse Reactions). 3.3 Design a strategy for handling "GCP Non-Compliance" at a specific clinical trial site. 3.4 Analyze the requirements for a "Clinical Study Report" (CSR) following ICH E3 guidelines. 3.5 Critique the use of "Adaptive Trial Designs" and their acceptance by regulatory authorities. 3.6 Appraise the role of the "Trial Master File" (TMF) in proving the integrity of trial results.
4. Critically evaluate the role of ethics committees and institutional review boards.	4.1 Critically evaluate the structure and independence of "Institutional Review Boards" (IRBs) in the US. 4.2 Analyze the decision-making process of "Ethics Committees" (ECs) regarding participant risk-benefit. 4.3 Assess the impact of "Centralized Ethical Review" on the startup speed of multi-center trials. 4.4 Critique the conflict-of-interest policies for members of national and local ethics boards. 4.5 Evaluate the role of "Lay Members" in ethics committees in ensuring public trust in research. 4.6 Appraise the authority of ethics committees to halt a clinical trial based on safety concerns.

PHR0101-05- Risk Management and Pharmacovigilance in Regulatory Affairs

This unit explores advanced principles of risk management and pharmacovigilance within regulatory affairs. Learners analyse systems for detecting, assessing, and mitigating risks associated with medicinal products across their lifecycle. The unit develops the ability to design and evaluate risk management plans and regulatory responses that protect public health in dynamic and uncertain environments.

Learning Outcome:	Assessment Criteria:
1. Understand the principles of pharmacovigilance and drug safety monitoring.	1.1 Critically evaluate the process of "Signal Detection" using quantitative data mining techniques. 1.2 Analyze the legal accountability of the "QPPV" (Qualified Person for Pharmacovigilance) in the EU. 1.3 Assess the role of the "Pharmacovigilance System Master File" (PSMF) in regulatory oversight. 1.4 Evaluate the requirements for "Expedited Reporting" of serious adverse events from global markets. 1.5 Critique the transition from "Safety Monitoring" in trials to "Post-Marketing" surveillance. 1.6 Appraise the influence of the "MedDRA" coding system on the accuracy of safety data analysis.
2. Evaluate risk management strategies to minimise adverse events and ensure patient safety.	2.1 Critically evaluate the effectiveness of "Risk Management Plans" (RMPs) in minimizing drug-related harm. 2.2 Analyze the use of "Direct Healthcare Professional Communications" (DHPC) as a safety tool. 2.3 Assess the criteria for implementing "Pregnancy Prevention Programs" for high-risk medications. 2.4 Critique the impact of "Black Triangle" (EU) or "Boxed Warnings" (US) on prescribing behavior. 2.5 Evaluate the regulatory logic for "Post-Authorisation Safety Studies" (PASS) to address safety gaps. 2.6 Propose a framework for monitoring "Medication Errors" as part of a pharmacovigilance system.

3. Apply international guidelines for signal detection, reporting, and benefit-risk assessment.	3.1 Apply statistical algorithms (e.g., PRR or ROR) to identify new safety signals in a safety database. 3.2 Evaluate the content and quality of "Periodic Benefit-Risk Evaluation Reports" (PBRERs). 3.3 Conduct a comprehensive "Benefit-Risk Assessment" following the discovery of a major new toxicity. 3.4 Critique the global reporting requirements for "Individual Case Safety Reports" (ICSRs) under E2B standards. 3.5 Analyze the role of "Signal Management" committees in validating emerging safety threats. 3.6 Appraise the regulatory consequences (e.g., license suspension) of a negative benefit-risk balance.
4. Develop frameworks for regulatory compliance in post-marketing surveillance.	4.1 Design a compliance framework for identifying adverse events reported via social media and websites. 4.2 Evaluate the readiness of a company for a "Pharmacovigilance Inspection" by national authorities. 4.3 Analyze the compliance risks of "Safety Data Exchange Agreements" (SDEAs) with commercial partners. 4.4 Critique the role of "Literature Monitoring" in identifying safety information for generic drugs. 4.5 Evaluate the use of "Real-World Data" (e.g., electronic health records) in long-term safety surveillance. 4.6 Propose a strategy for managing "Urgent Safety Restrictions" (USRs) across multiple international regions.

PHR0101-06- Research Methods and Innovation in Regulatory Sciences

This unit equips learners with advanced research skills relevant to regulatory sciences. It examines qualitative and quantitative research methodologies, data analysis, and ethical considerations. Learners design and undertake research or innovation-focused projects, critically evaluating evidence to inform regulatory decision-making, policy development, and strategic change within complex pharmaceutical and healthcare settings.

Learning Outcome:	Assessment Criteria:
1. Gain advanced knowledge of research methodologies relevant to regulatory affairs.	1.1 Critically compare the validity of "Systematic Reviews" versus "Meta-Analyses" in regulatory science. 1.2 Evaluate the role of "Observational Studies" in providing real-world evidence for drug efficacy. 1.3 Analyze the use of "Health Economics and Outcomes Research" (HEOR) in supporting regulatory filings. 1.4 Critique the methodologies used for "Regulatory Impact Assessments" of new public health policies. 1.5 Assess the value of "Comparative Effectiveness Research" in defining the clinical value of a drug. 1.6 Evaluate the role of "Patient-Reported Outcomes" (PROs) as primary endpoints in research studies.
2. Apply quantitative and qualitative research methods to regulatory science challenges.	2.1 Apply quantitative methods to model the "Success Probability" of a drug through different regulatory stages. 2.2 Design a qualitative study to understand the barriers to "Regulatory Compliance" in small biotech firms. 2.3 Evaluate the application of "Bayesian Statistics" in the review of drugs for rare diseases. 2.4 Synthesize data from various research sources to propose a new regulatory pathway for a specific technology. 2.5 Critique the use of "Artificial Intelligence" in predicting the toxicological profiles of new molecules. 2.6 Justify the selection of "Mixed-Methods Research" to address complex policy questions in pharmacy.

3. Understand how innovation impacts pharmaceutical regulation, including emerging therapies and digital health.	3.1 Critically evaluate the regulatory challenges for "Cell and Gene Therapies" (ATMPs) in terms of quality. 3.2 Analyze the "Software as a Medical Device" (SaMD) framework for AI-driven diagnostic tools. 3.3 Assess the regulatory implications of "3D Printing" of personalized dosages at the point of care. 3.4 Critique the oversight of "Wearable Devices" that collect clinical trial data remotely. 3.5 Evaluate the concept of "Agile Regulation" for rapidly evolving digital health technologies. 3.6 Appraise the impact of "Decentralized Clinical Trials" (DCTs) on data integrity and regulatory review.
4. Critically analyse regulatory research to propose evidence-based improvements in compliance and policy.	4.1 Critically analyze academic research to identify "Inefficiencies" in the current drug approval process. 4.2 Propose an evidence-based modification to "Orphan Drug Legislation" to prevent market monopolies. 4.3 Evaluate the short- and long-term implications of allowing "Real-World Evidence" for initial drug approvals. 4.4 Design a "Policy Brief" based on research to influence a change in national medicine pricing laws. 4.5 Critique the "Ethics of Innovation" when regulating life-saving but high-cost therapies. 4.6 Appraise the role of "Stakeholder Consultation" in the development of new regulatory guidelines.

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