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EU BIOTECH REGULATIONS AND CLINICAL COMPLIANCE

**Fully Accredited
By:**

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CPD
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PROGRAM OVERVIEW

EU's biotech regulations and clinical compliance landscape is among the most complex globally - **developing and approving biotech products in the EU demands simultaneous approvals from multiple regulatory frameworks**, including the Clinical Trials Regulation, Advanced Therapy Medicinal Products requirements, pharmacovigilance obligations, and the strict data protection standards imposed by GDPR. In practice, over **60% of biotech companies report delays or additional costs** driven by regulatory complexity, while a substantial proportion of applications face multiple rounds of review before meeting the EU's rigorous standards for safety, efficacy, and ethical compliance.

This certified program will sharpen your ability to **interpret the EU regulatory landscape, apply CTR and CTIS requirements, and manage sponsor responsibilities** with authority. You will strengthen your capacity to maintain ICH GCP-compliant practices, produce genuinely defensible documentation, and close compliance gaps decisively. These capabilities will help you eliminate avoidable risk and build regulatory strategies that hold up throughout clinical development.

You will develop practical expertise in **ATMP requirements, CMC compliance, and GMP quality systems**, alongside marketing authorization, dossier strategy, and pharmacovigilance. By aligning clinical evidence with quality expectations, you will be fully equipped to drive product development forward and answer regulatory scrutiny with confidence. This integrated command will **improve submission quality, protect product integrity, and accelerate more effective regulatory decision-making**.

ACCREDITATIONS



4.8



4.6



PROGRAM OVERVIEW

Through case-based learning and applied exercises, you will apply **ALCOA+ data integrity principles, assess digital compliance risks, conduct rigorous regulatory gap assessments, and develop effective CAPAs**. You will strengthen inspection readiness and learn to coordinate decisively across clinical, quality, and regulatory teams, building a cohesive compliance framework that holds across the entire biotechnology lifecycle.

Upon successful completion, you will earn the **Certification in EU Biotech Regulations and Clinical Compliance**, validating your expertise in EU biotechnology regulation, clinical trial compliance, and lifecycle regulatory management. This globally recognized credential demonstrates your capability to command compliance readiness, drive successful product approvals, and navigate evolving EU regulatory requirements with confidence.

ACCREDITATIONS



4.8



4.6



KEY SKILLS YOU WILL GAIN

From This Program



**EU BIOTECH REGULATIONS
CLINICAL TRIAL COMPLIANCE
CTR COMPLIANCE MANAGEMENT
CTIS SUBMISSION MANAGEMENT**

**ICH GCP COMPLIANCE
CLINICAL TRIAL OVERSIGHT
REGULATORY STRATEGY DEVELOPMENT
REGULATORY LIFECYCLE MANAGEMENT**

**ATMP REGULATORY COMPLIANCE
CLINICAL EVIDENCE STRATEGY
CMC COMPLIANCE MANAGEMENT
GMP COMPLIANCE**

**QUALITY SYSTEMS MANAGEMENT
MARKETING AUTHORIZATION STRATEGY
REGULATORY DOSSIER PREPARATION
PHARMACOVIGILANCE MANAGEMENT
SAFETY RISK MANAGEMENT**

**CLINICAL DATA INTEGRITY
ALCOA+ COMPLIANCE**

YOUR FACULTY DIRECTOR



Dr. Tatsiana Ripich

Distinguished EU Biotech Regulatory and Clinical Compliance Leader

Dr. Tatsiana Ripich is a highly accomplished regulatory, clinical, and quality affairs expert with extensive experience across **European regulatory affairs, clinical compliance, and product lifecycle management**. Holding a Ph.D. in Cell Biology and RAC Devices certification, she combines deep scientific expertise with hands-on regulatory experience spanning competent authorities, global industry, MedTech, and consulting.

Her career includes service at the **German Federal Institute for Drugs and Medical Devices (BfArM)**, giving her first-hand insight into how clinical trial and pharmacovigilance requirements are genuinely assessed and enforced. She currently holds senior leadership responsibilities across Regulatory, Clinical, and Quality Affairs, guiding strategy from development and clinical evidence through regulatory submissions and quality compliance.

Dr. Ripich has participated in regulatory inspections, including an **FDA inspection, and advises life-science organizations on EU regulatory strategy, clinical evidence, Quality Management Systems, and inspection readiness**. An experienced trainer and international speaker, she is widely recognized for translating the most complex regulatory requirements into clear, practical compliance strategies.

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PROGRAM AGENDA

MODULE 1: OVERVIEW OF THE EU BIOTECH REGULATORY LANDSCAPE

- Key EU legal framework and agencies (EMA, NCAs, ethics committees) and how responsibilities split
- Product-type scoping: medicinal product vs ATMP vs borderline/combination considerations
- How guidance, Q&As, and scientific advice fit into strategy
- Where MedTech/IVD differs (high-level evidence + lifecycle mindset)

MODULE 2: EU CLINICAL TRIALS REGULATION (CTR) AND CTIS: SUBMISSION TO CLOSE-OUT

- CTR lifecycle and CTIS workflow: What goes where (Part I/Part II thinking)
- Timelines, RFIs, substantial modifications, and version control discipline
- Sponsor oversight and inspection-relevant documentation through the trial

MODULE 3: ICH-GCP AND ETHICAL COMPLIANCE (PRACTICAL IMPLEMENTATION)

- GCP principles applied to real trial execution (Risk-based quality management)

- Essential documents/eTMF expectations and inspection-ready writing
- Deviation management and CAPA fundamentals

MODULE 4: ATMPs AND INNOVATIVE THERAPIES: REGULATORY CONSIDERATIONS

- ATMP overview and what changes vs “traditional” biotech products
- Key development and evidence challenges (Manufacturing variability, comparability mindset)
- Cross-functional alignment: RA–Clinical–Quality–CMC for advanced therapies

MODULE 5: BIOTECH PRODUCT DEVELOPMENT & REGULATORY STRATEGY (LIFECYCLE VIEW)

- Defining regulatory strategy: Target indication, claims, and evidence plan
- Interactions with authorities (Scientific advice: When/why/how)
- Building a decision trail that supports lifecycle changes



PROGRAM AGENDA

MODULE 6: CMC COMPLIANCE: WHAT REGULATORS EXPECT AND HOW TO PREPARE

- Control strategy fundamentals: CQAs, critical steps, and specs
- Analytical strategy and stability expectations (Pragmatic, risk-based)
- Change control and comparability through scale-up/tech transfer

MODULE 7: GMP FOR BIOTECH PRODUCTS & QUALITY SYSTEMS

- GMP expectations across development vs commercial reality
- QMS essentials (Training, deviations, investigations, OOS/OOT basics)
- Inspection readiness patterns: What evidence inspectors typically test

MODULE 8: EU MARKETING AUTHORISATION PROCEDURES AND DOSSIER STRATEGY

- Centralised pathway basics and what “good” looks like in the dossier narrative
- Common gaps that derail assessment (Consistency, traceability, rationale)
- Lifecycle management: Variations and post-authorisation commitments (Overview)

MODULE 9: PHARMACOVIGILANCE (PV) AND RISK MANAGEMENT

- PV system basics and key obligations across the lifecycle (High-level)
- Signal and risk management concepts; How PV impacts development decisions
- Interfaces: PV–RA–Clinical–Quality and documentation expectations

MODULE 10: DATA INTEGRITY, DIGITAL COMPLIANCE, INSPECTIONS & EMERGING TRENDS

- Data integrity (ALCOA+) and computerized system expectations; Audit trails
- GDPR considerations and decentralized/digital trial elements (Risk-based adoption)
- Audit/inspection readiness and upcoming regulatory trends (AI, personalized medicine)

YOUR CHARTER DESIGNATION



Chartered Institute of Professional Certifications' programs are unique as they provide you with professional charter designations and marks that can be used across your lifetime once you have completed our programs.

Upon successfully completing this program, you will be awarded the **Certification in EU Biotech Regulations and Clinical Compliance**, ready to be added to your resume, CV, and professional credentials. This certification is industry-recognized and carries lifelong validity.

This certification is powerful and lasting proof of your **expertise in EU biotechnology regulation, clinical trial compliance, and lifecycle regulatory management**. It validates your capability to navigate the most complex regulatory requirements, strengthen clinical compliance, and drive successful product development and approval. It also demonstrates your readiness to command inspection requirements and evolving compliance expectations across the biotechnology lifecycle. This program is developed by the **Chartered Institute of Professional Certifications**, and its content has been certified by **CPD Certification Service** as adhering to the highest standards of continuing professional principles.

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of Our Programs

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