CERTIFICATION ESAME *Pharmaceutical Business School*

MICROCREDENTIAL – Professional Specialization in

"Professional Specialization in GCP and GCLP Auditing"

ORGANIZED BY & LOCATIONS:

- Technology-based organization fostering educational initiatives for the Pharmaceutical Industry, Biotech, Medtech y Healthcare: **ESAME Biomedical S.L. (ABRAfarma)**
- International Institution Specialized in GCP & GCLP: **The QARP Academy**
- Professional & Educational Institution: **ESAME Pharmaceutical Business School**

País Vasco: Avda. Zugatzarte 8 Planta 1 5; 48930 Getxo Bizkaia

Madrid: c/ Velazquez 57 1º dcha; 28001 Madrid

Barcelona: Avda. Diagonal 463 bis 3º 3ªy4ª; 08036 Barcelona

CLASS MODALITY:

This edition will be conducted in live sessions by videoconference

LANGUAGE:

Sessions will be delivered in English

DATES & SCHEDULE:

April 7 to June 11: 20026

Sessions: Monday to Thrusday 18:00-21:00(CET)

Opening Session: April 7 at 17:00 (CET)

PRICE: 3.630 € (VAT included)

[1] This certification is a non-regulated qualification, awarded by ESAME Escuela del Medicamento, S.L.U.

What is the CERTIFICATION ESAME Pharmaceutical Business School in Professional Specialization in GCP and GCLP Auditing?

Professional Specialization Course in GCP and GCLP Auditing is developed by *ESAME* and *The QARP Academy*, designed for professionals who seek to:

1. Acquire the intensive training required to perform their functions as a **GCP and GCLP Auditor.**

2. Upon completion of the course, candidates may take the ESAME Certification Examination for Specialization as an Auditor of Good Clinical Practice and Good Clinical Laboratory Practice (GCP & GCLP) – **'Professional Specialization in GCP and GCLP Auditing'.**

Who is the Course Designed For?

The course is aimed at **Clinical Research Associate, Quality Specialists, Project Managers, Data Managers, Clinical Leads, Clinical Trial Managers, and GxP personnel** with at least 1 year of professional experience.

Other candidates may be admitted based on a personal interview if they seek to specialize as a **GCP and GCLP Auditor** or need to develop their knowledge in this field.

What is the Structure of the Course?

The course program encompasses all essential theoretical knowledge and practical competencies required for a professional GCP/GCLP Auditor. It is organized into 15 modules and delivered through combined theoretical and practical sessions, each lasting 3 hours, four days per week (12 hours per week).

What are the Admission Requirements?

- Candidates are required to be over 25 years of age.
    - Clinical Research, Clinical Trial Monitors, CRAs, Study Managers, Study Coordinators; or
    - Quality Specialists, Project Managers, Data Managers, Clinical Leads,

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Clinical Trial Managers, GxP personnel.

- Applicants must have an academic qualification in Medicine, Pharmacy, or Life Sciences, and/or the skills and competencies necessary to perform effectively as a GCP/GCLP Auditor, or to further develop their knowledge in this field.

Course Summary and Objectives

- **Sectoral Training Requirements**

  The training needs of **Auditors** in the **Good Clinical Practice (GCP)** and **Good Clinical Laboratory Practice (GCLP)** areas are closely linked to compliance with international regulations, quality assurance, and **safeguarding participants' and patients' rights in clinical research**. The main areas in which these professionals require training are detailed below:

  ### 🩹 1. Regulatory and Compliance Knowledge

  - International regulations: ICH-GCP (International Council for Harmonisation – Good Clinical Practice), ISO 15189, ISO/IEC 17025, GLP (Good Laboratory Practice), among others.
  - National legislation in clinical research and public health.
  - Regulations from health authorities such as EMA, FDA, INVIMA, ANMAT, COFEPRIS, etc.

  ### 🔍 2. Auditing Skills

  - Plan, execute and conducting internal and external audits.
  - Prepare comprehensive audit plans and checklists.
  - Apply effective interviewing and communication techniques with audited personnel.
  - Document findings, non-conformities, and corrective actions in formal reports.
  - Conduct post-audit follow-up and evaluate the effectiveness of corrective and preventive actions (CAPAs)."

  ### 🩹 3. Technical Knowledge of the Audited Area

  a) For BPC Auditors:

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- Design and execution of clinical trials.
- Informed consent and research ethics.
- Clinical data management and patient safety.
- Good pharmacovigilance practices.
- Management of deviations, amendments and protocol violations.

b) For BPL Auditors (Clinical Laboratory):

- Validation and verification of analytical methods.
- Internal and external quality control.
- Traceability and management of biological samples.
- Documentación de procedimientos estándar (SOPs). Standard operating procedures documentation (SOPs).
- Management of laboratory equipment and instrumentation.

💻 4. Quality Management Systems

- Implementation and auditing of Quality Management Systems (QMS) in line with ISO standards.
- Risk assessment and root cause investigation
- Performing audits following continuous improvement philosophies (PDCA, Six Sigma, Lean, etc.)

🧠 5. Soft Skills and Cross-Functional Competencies

- Critical and analytical thinking.
- Management of time and priorities.
- Multidisciplinary teamwork.
- Professional ethics and confidentiality.

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- Clear and effective verbal and written communication.

🔄 6. Continuous Professional Development

- Engagement in courses, seminars, workshops, and professional conferences.
- Subscription to regulatory bulletins and scientific literature.
- Staying updated on new technologies applied to clinical trials and laboratory operations (eCRF, LIMS, AI, etc.)

- **Objetives:**
    - Obtain the intensive training required to perform functions as a GCP and GCLP Auditor.
    - Successfully sit the **ESAME EUROPEAN CERTIFICATION Exam in "Professional Specialization in GCP and GCLP Auditing'** at the end of the course.

- **Course Summary:**
    - Microcredential – Professional Specialization: 120 horas - 12 ECTS
    - Expected participants: Average of 25 students
    - Target organizations: Companies involved in clinical trials or providing consultancy in clinical trial and laboratory quality assurance.

- **Learning Outcomes and Achievement Type**

- At the end of the course, participants will be able to plan, execute and document audits in the context of clinical trials, in line with GCP (Good Clinical Practice), GCLP (Good Clinical Laboratory Practice), ICH, ISO 19011, and other relevant international quality standards.
- This achivement is professional and specialized, guiding participants to function as internal or external auditors in regulated clinical environments, and positioning them as experts in regulatory compliance and quality assurance.

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Principal Occupacional Group:

- ✓ Clinical Trials Quality Auditor

Key Competencies (ESCO):

- ✓ Plan and perform audits
- ✓ Ensure regulatory compliance
- ✓ Apply good clinical practice (GCP)
- ✓ Analyse risk factors in regulated environments
- ✓ Perform root cause analysis (RCA)
- ✓ Manage quality documentation
- ✓ Implement data integrity principles (ALCOA+)
- ✓ Apply relevant ISO standards (9001, 19011)
- ✓ Document and report audit findings
- ✓ Collaborate efficiently in multidisciplinary teams

Academic & Teaching Staff:

- Academic Direction (*ESAME*):
  - **Gonzalo Hernández Herrero**

- Scientific Direction (*The QARP Academy*):
  - **Elena Efimova, MEd**
  - **Maxim Bunimovich, MD, MRQA, MSQA**
  - **Stanislav Praslov, MD, RQAP-GCP, MRQA**

- Teaching Faculty: recognized specialist professionals in Auditing sector.

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FOR MORE INFORMATION AND REGISTRATION:

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