PQE GROUP

GLOBAL **QUALITY** SOLUTIONS

TRAININGS CATALOGUE

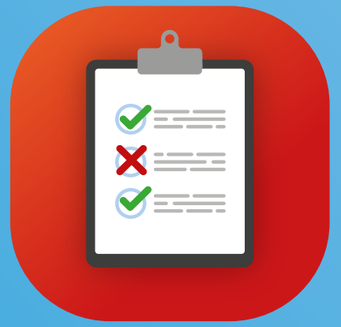
PQE GROUP

Areas

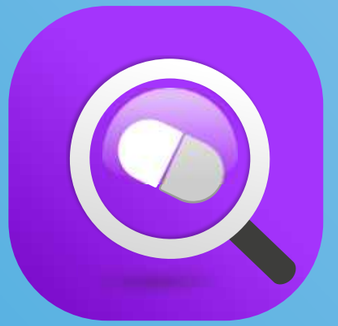
Data Integrity & Computer System Validation

Digital Governance

Qualification & Engineering



Compliance



PhV

Good Clinical Practice

Training

Data Integrity & Computer System Validation

Global leader in full product life cycle Computer System Validation, Data Integrity and IT Compliance.

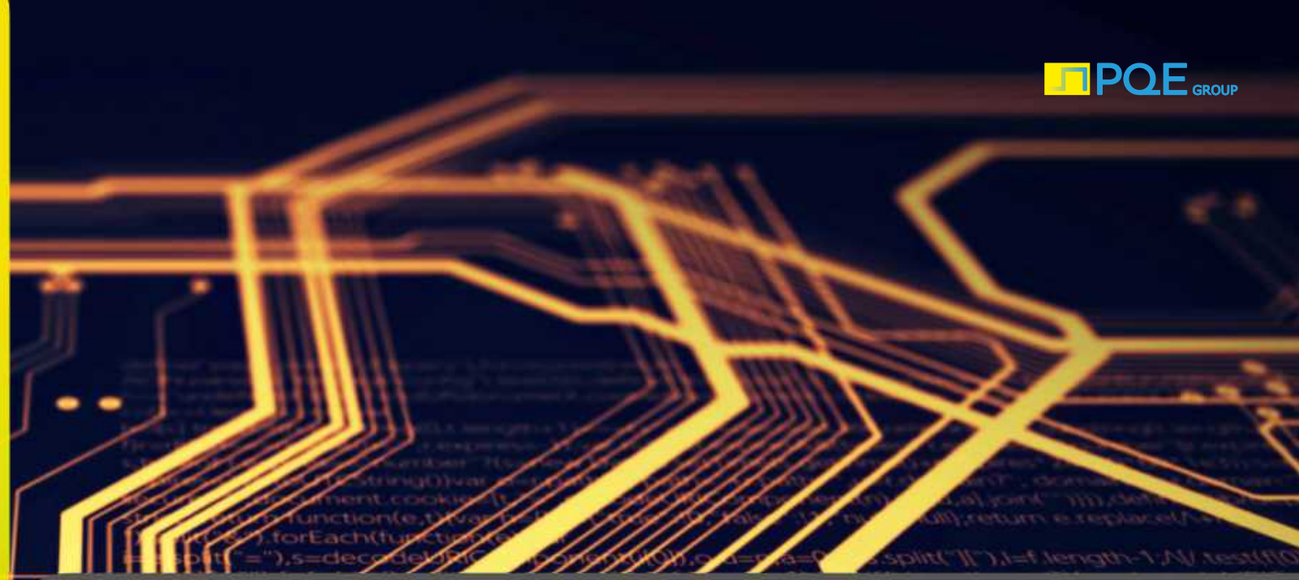
Pharma Capabilities | **Medical Devices** Capabilities

- Warning Letters Triggered by Data Integrity Failures and 483s “Why do we care”
- Data Integrity Regulatory Trends and Applicable Requirements “What is required”
- Computer System Validation Principles
- Data Integrity Compliance Assessment
- Regulated Metadata and Data
- Computer Validation Life Cycle: Prospective Validation
- GAPs Solutions Portfolio “Quick Wins for Technical GAPs”
- How to Approach New Computer System “Avoid to Generate New GAPs”
- How to Maintain the Compliance Status “Avoid Rework and Waste of Efforts”
- Remediation Activities - Case Studies & Tools “How to Remediate and Validate”
- Data Integrity ALCOA+ Principles
- Audit Trail Review
- PLC- Based Systems Validation Approach
- Data Integrity Program Organization - Governance and Maintenance Activities
- Good and Bad Validation Practice
- Serialization Principles

Training

Digital Governance

The 4th Industrial Revolution brings new technologies with itself.



Pharma Capabilities

Medical Devices Capabilities

- GDPR Basic Concepts
- GDPR Daily Rules
- Company Accountability
- Key Roles
- GDPR Subject Rights
- Data Privacy by Design & by Default
- IT Infrastructure Qualification Strategy & Life Cycle
- New Technologies Requirements
- IT Infrastructure Control and Compliance - GPG Second Edition
- Cloud Service & Data Integrity
- Regulatory Drivers for IT Infrastructure Qualification
- Principles of Organization of an IT Department Operating in a Regulated Environment
- Drivers for IT Infrastructure Conceptual Design
- IT Infrastructure Qualification Maintenance
- Delivering IT Services to a Regulated Company
- Good Documentation Practice
- Basics of ISO-9001-2015
- Analysis of ISO-9001-2015
- Blockchain and DLT: Principles and Applications in the Regulated Industry
- Basics of AI and Predictive Analytics
- IIoT - Industrial Internet of things
- Overview of ITIL 4.0
- Fundamentals of Cybersecurity
- Cybersecurity Employee Awareness

Training

Qualification & Engineering

Our service excellence is achieved through an interdisciplinary teamwork among engineers and technicians, who have a unique integrated knowledge in process engineering, information technology and quality in regulated environments.

Pharma Capabilities

- General Concepts of Equipment Qualification & Instruments Calibration
- Qualification of Solid Dosage Forms Processes
- Qualification of Sterile Dosage Forms Processes
- Qualification of Biotech Processes
- HVAC & Clean Areas: Design, Regulatory Expectations and Qualification Practices
- Pharmaceutical Water Production, Storage and Distribution: Design, Regulatory Expectations and Qualification Practices
- Compressed Air Generation, Storage and Distribution: Design, Regulatory Expectations and Qualification Practices
- Nitrogen Storage and Distribution: Design, Regulatory Expectations & Qualification Practices
- Autoclave Qualification
- Moist Heat Sterilization
- Ethylene Oxide Sterilization
- Process Control Systems Validation
- Visual Inspection Machine
- Freeze Dryer Qualification
- VHP Sterilization
- Periodical Requalification
- Validation Master Plan
- HVAC Practical On-Site Testing
- Thermal Validation Practical On-Site Testing
- Transport, Warehouse and Controlled Temperature Units Validation
- Filling Lines Qualification

Medical Devices Capabilities

- Pharmaceutical Water Production, Storage and Distribution: Design, Regulatory Expectations and Qualification Practices
- Compressed Air Generation, Storage and Distribution: Design, Regulatory Expectations and Qualification Practices
- Nitrogen Storage and Distribution: Design, Regulatory Expectations & Qualification Practices
- Process Control Systems Validation
- Medical Devices Pathway for Compliance: Processes Development & Validation
- Medical Devices Process Validation: Case Studies
- Management Responsibility & Handling of FDA Inspections
- EtO Sterilization
- Validation Master Plan
- HVAC Practical On-Site Testing

Training
Compliance

We offer practical training courses based on latest pharma industry guidances, medical device regulations, real life experiences & all GxP related challenges your business may face.

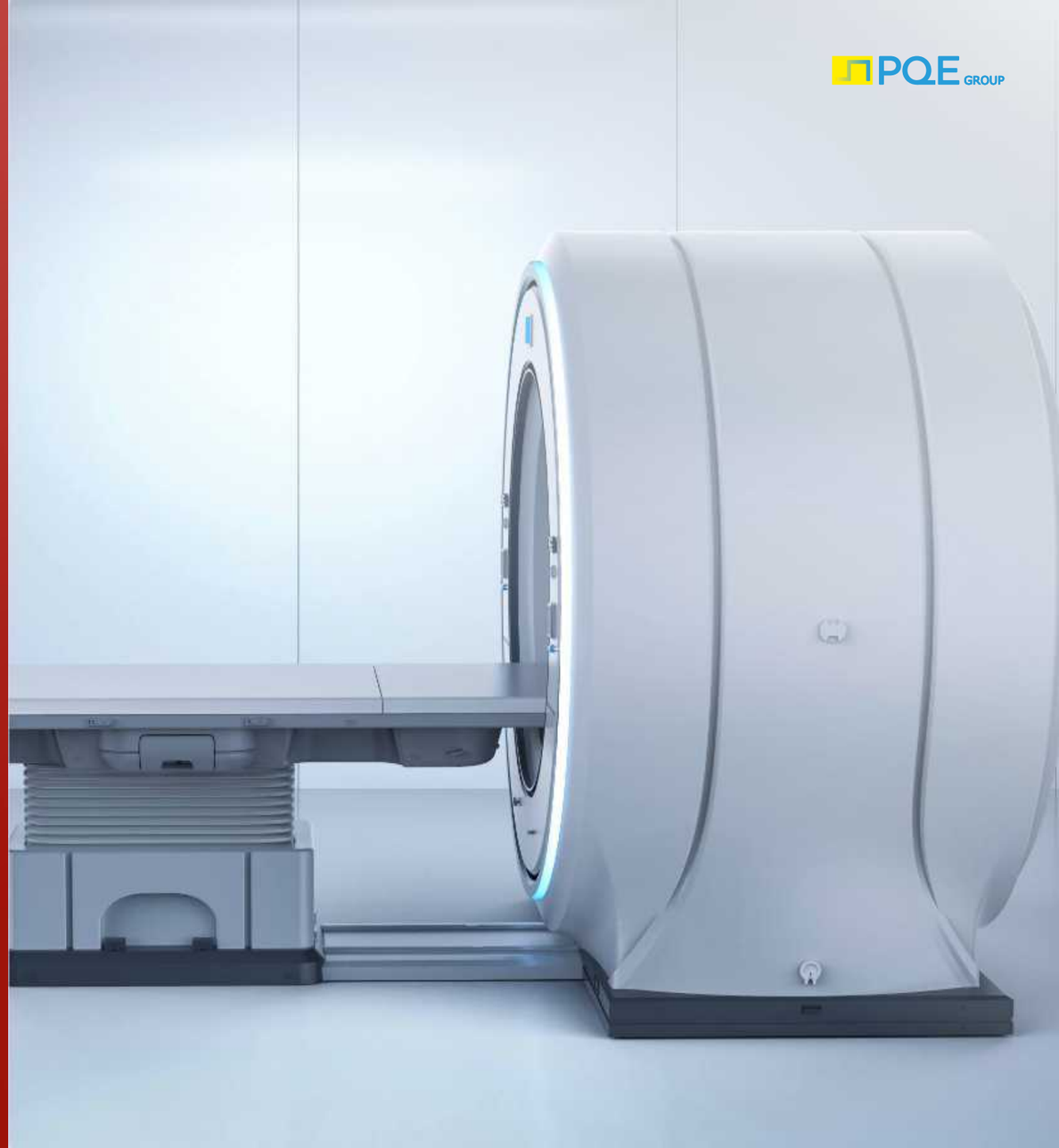
Pharma Capabilities

PQE GROUP

- Deviation Management and Investigation Techniques
- Cleaning Validation
- Data Integrity and ALCOA+
- Sterility Assurance and Annex 1
- Audit Management
- Good Manufacturing Practice
- Good Documentation Practice
- ICH Q7 - Good Manufacturing Practice Guide for API
- GMP for Medicinal Product
- Good Distribution Practice
- Change Control Management
- Cross-Contamination
- Housekeeping and Pest Control
- ICH Q9 - Quality Risk Management
- GDP - Quality Risk Management
- IPEC - Guidelines for Excipients
- Investigational Medicinal Products
- OOT, OOS and OOE Management
- GMP for QC Laboratory: Roles and Responsibilities
  5s Model
- Human Blood - Plasma production (Annex 14)
- Microbiological QC Lab Management
- Visual Management
- EU vs China GMP (FPF)
- PQR and AQR (Product-Annual Quality Review)
- Good Laboratory Practice
- Deviation Management
- Reagents and Standards Management
- Analysis and Sample Management
- Analysis Execution and Certification
- Analytical Methods Validation and Transfer
- Complaints and Recall
- GxP Compliance - General Training Concepts
- Self-Inspection
- Roles and Responsibilities in Manufacturing
- Materials Flow
- Manufacturing and Batch Approval
- Process Validation
- Process Transfer
- Sampling and Dispensing
- Storage and Shipping
- Quality Culture and Quality Metrics (Continuous Improvement)
- Analytical Procedures Lifecycle Approach
- Supplier Management
- Microbiological Environmental Monitoring
- How to Manage an FDA Inspection
- CAPA Management
- Training Management
- Facilities & Equipment/Utilities: Design, Qualification and Maintenance/Calibration
- Packaging & Labelling - GMP Requirements and Best Practices
- Stability Management

Medical Devices Capabilities

- Audit Management
- Good Distribution Practice
- Cross-Contamination
- Microbiological QC Lab Management
- Complaints and Recall
- Roles and Responsibilities in Manufacturing
- Materials Flow
- Process Transfer
- Storage and Shipping
- Quality Culture and Quality Metrics (Continuous Improvement)
- Supplier Management
- Training Management
- ISO 13485:2016 - Medical Devices Quality Management Systems Requirements for Regulatory Purposes
- ISO 13485:2016 vs ISO 13485:2003 Important Changes
- 21 CFR Part 820
- How to Manage an FDA Inspection 21 CFR PART 803 - 806
- Medical Device Reporting Reports of Corrections and Removals
- MDSAP - Medical Device Single Audit Program for the Manufacturers of
- Medical Devices
- Design Control & Design Changes EN ISO 14971:2012 Medical Devices Application of Risk Management to Medical Devices
- Medical Device Directive (MDD) 93/42 EEC
- New MDR "New European Regulations for Medical Devices"ISO CEI/IEC 62304:2006
- Medical Device Software - Software Life Cycle ProcessesUsability
- Process Validation for MD
- MD Compliance - General Training Concepts



Training
Pharmacovigilance

In 2010, Regulatory Authorities raised the bar of compliance of the Pharmacovigilance System and an increasing number of countries are now performing routine regulatory inspections targeting Pharmacovigilance.

Pharma Capabilities

- European PV processes (case processing, risk management plan, periodic aggregate report, signal detection, risk managament system)
- PV requirements across the World
- EU Pharmacovigilance System Mater File (PSMF)
- GVP Module I on Quality Management System in Pharmacovigilance
- Quality across EU GVP modules
- Audit Management: GVP Module IV and ISO 19011:2018
- Medication Error Management
- GDPR in Pharmacovigilance
- Post-authorisation safety study: PASS and PAES
- Electronic Archiving and Paperless System Management
- Archiving Requirements in Pharmacovigilance and Outsourcing models

Training

Good Clinical Practice

The development of a GCP Quality Management System (plan and resources) is the basis to promote and support compliance, while minimizing regulatory risk.
PQE proposes the implementation of a GCP quality strategy, tailored to the Client's requirements, and supports an effective and compliant conduction of clinical trials, based on the practice of the most innovative Quality by Design and Quality Risk Management approaches.

Pharma Capabilities

- Deviation Management in Clinical Studies
- Randomization in Clinical Trials
- Validation of IRT Systems
- GCP Principles & Addendum Overview
- Regulatory Framework for Study Conduction (European, Italian and FDA Regulations)
- IMP Management in Clinical Trials
- Safety Management in Clinical Trials
- Management of the Clinical Trial Master File
- Data Integrity Requirements for Clinical Trial Management
- Clinical IT Supplier Management: Criticalities and Main Aspects
- Risk Management in Clinical Trial

DELIVERY MODEL

Classroom

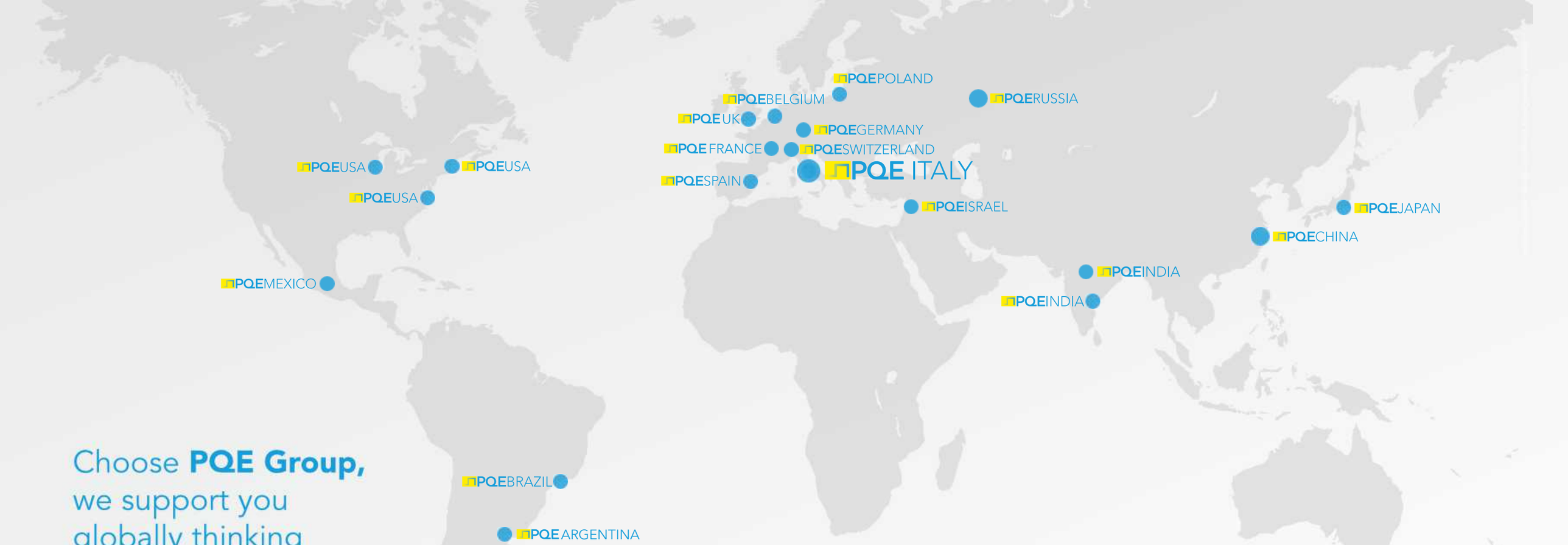
F2F Coaching

E-Learning

Webinar

Tailor made

AVAILABLE IN:



Choose **PQE Group,**
we support you
globally thinking
locally.

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