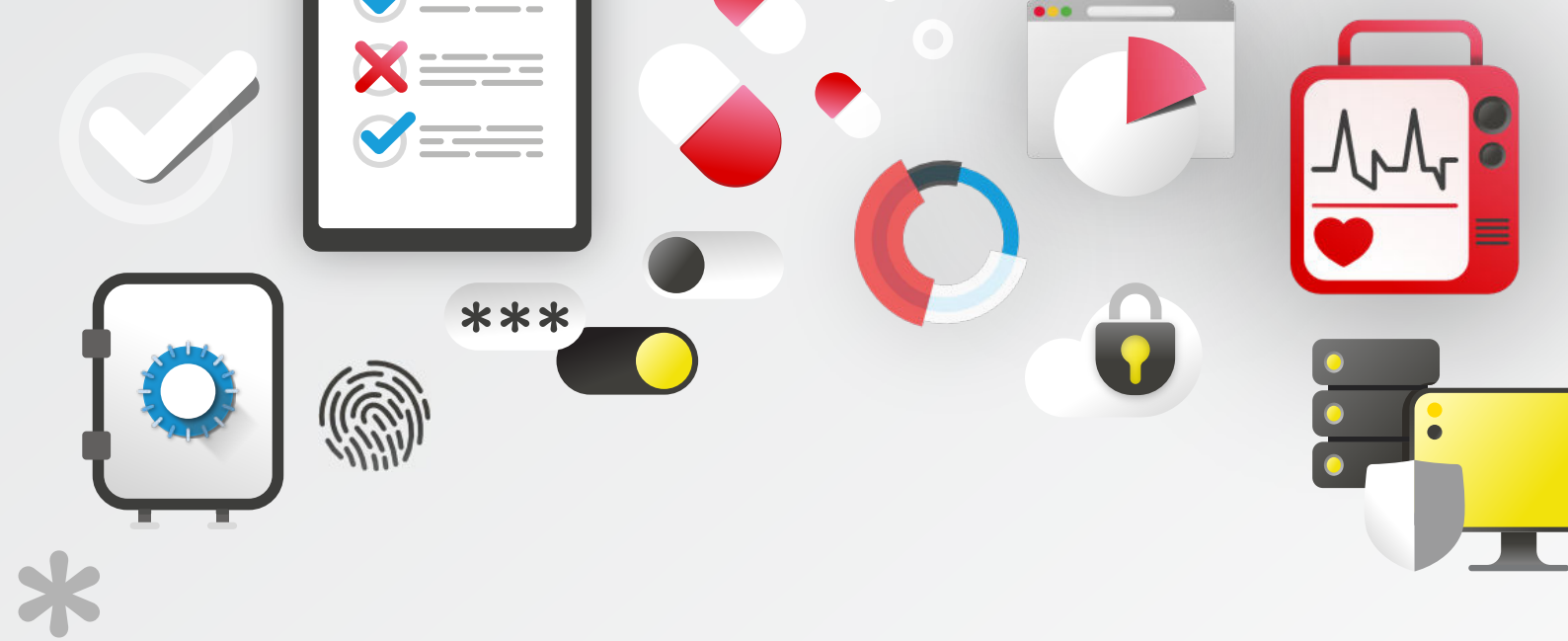


PQE GROUP

GLOBAL **QUALITY** SOLUTIONS

SERVICE CATALOGUE

DRIVING
LIFESCIENCES
INTO
SUSTAINABLE
FUTURE.

WHO IS **PQE**

We are a ISO 9001 certified technology solutions and compliance consulting services company with global capabilities deliverable throughout the entire product quality life cycle, allowing us to offer services at a very competitive price.

WHY **PQE**

Our broad service portfolio, extensive experience, effective project management, and exceptional cost effectiveness, have already proven to be a winning combination for global corporations, as well as small and medium sized companies.

PQE AT A GLANCE

- ISO 9001 certified Complete Quality Solution Provider since 1998
- GxP Broad Services Portfolio
- Worldwide offices from the U.S. to Japan
- Over a thousand of professional employees fluent in 25+ languages
- Full capabilities in solving 483, WL and Regulatory Emergencies
- Experience in managing large multi-site projects

DATA INTEGRITY ASSURANCE

Data is a fundamental part of any Life Science production cycle and has become a major concern for global regulatory authorities. Choose PQE and ensure patient safety and business continuity within the entire product life cycle.

Discover our solutions

Data Integrity Governance

The key action to design a compliant quality system to manage regulated Data.

VIEW THE **FULL PORTFOLIO**

Computer System Validation

The best practices for validating and monitoring your computerized systems.

VIEW THE **FULL PORTFOLIO**

Is your data **ALCOA+**?

A number of hidden potential violations may already be embedded in your current processes.

Don't risk losing quality and trust: choose the right training, guidance and support.

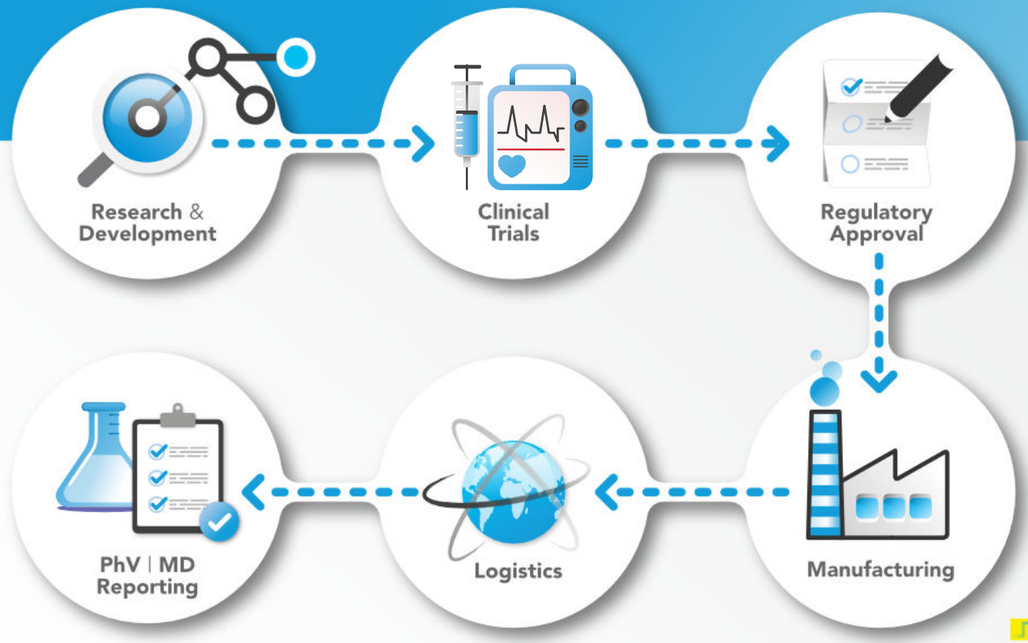
- Assess and evaluate risks
- Validate your system
- Avoid observations and enforcements actions
- Prevent impacts on business operations
- Ensure that all data is compliant to the newest regulations
- Achieve growth and success

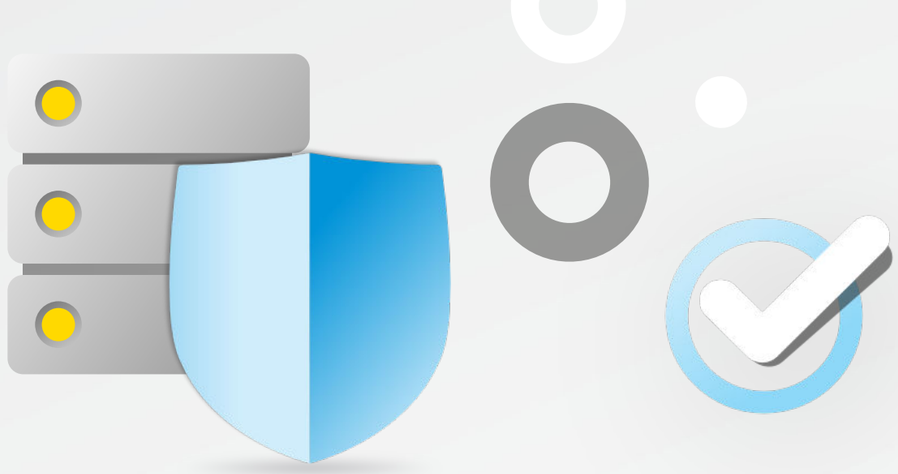
A	ATTRIBUTABLE
L	LEGIBLE
C	CONTEMPORANEOUS
O	ORIGINAL
A	ACCURATE
+	COMPLETE • CONSISTENT • ENDURING • AVAILABLE

Why PQE?

PQE Group, with multidisciplinary teams with 20+ years of extensive experience and scalable delivery model based on a robust risk analysis, has an unmatched record of supporting clients in turnkey validation projects with **FDA**, **EMA**, **WHO**, **COFEPRIS**, **GILS**, **TGA**, **SSA**, **SFDA**, **ANVISA**, **INVIMA** and other regulatory authorities.

We can support you in every phase of the product lifecycle, assuring Data Integrity throughout all steps of the process, from Clinical Trials to Pharmacovigilance and MD Post Market Surveillance.





Data Integrity Governance

- Data Integrity Policy
- Data Integrity Historical Verification
- ALCOA Assessment
- Data Integrity Remediation Plans
- Continuous Monitoring Procedures for Data Integrity
- Audit Trail Review Methodologies

Computer System Validation

- Computer System Validation Strategy
- Best Practices for Cost Saving & Quality of 21 CFR Part 11 Compliance Strategy
- Validation Templates and System Specific Packages
- Ongoing Adaptation of Risk Based Computer Validation Approach to Current Regulatory Expectations
- Computer Validation of Global and Local IT Systems (e.g. ERP, MES)
- Laboratory & Process Control Systems Validation
- CSV Best Practices
- User Requirements and Process Mapping
- Data Migration Verification Strategy and Execution
- System Testing (Unit & Integration Tests, UAT)
- Validation Test Planning, Execution & Documentation
- Best Practices Procedures to Maintain the Validated Status
- Change Management & Periodic Review
- 21 CFR Part 11 & EU GMP Annex 11 Assessments
- Risk-prioritized & Turnkey Remediation Projects
- 21 CFR Part 11 Inspection Readiness Projects

DIGITAL GOVERNANCE

With new advanced technologies and new standards for Compliance and Cybersecurity, developing an intelligent network and infrastructure is a top level priority for Life Science businesses. Choose PQE Group's all-in-one integrated solutions to coordinate your Corporate Digital Development.

Discover our solutions

IT Operations
Get cross-cutting support by our qualified tech experts.

Quality by Design
Layout a bullet-proof strategy for managing systems.

IT Projects
Develop, migrate, fix and upgrade your infrastructures.

Remote Delivery
Work in total safety with smart technologies for management.

Cybersecurity
Assess vulnerabilities and plan to protect your network.

VIEW THE **FULL PORTFOLIO**

VALUE PROPOSITION

ALL IN ONE LIFE SCIENCE IT SERVICES

Here is why you should choose PQE Group as your compliance and quality service provider.

- Teams of qualified IT experts
- Proven knowledge in new technologies
- Familiarity with suppliers and manufacturing best practices
- Supporting Pharmaceutical and Medical Device firms
- Fully customizable IT service models
- Cost-effective solutions

IT STRATEGY

COMPUTER SYSTEM VALIDATION

IT TECHNICAL PROJECTS & OPERATIONS

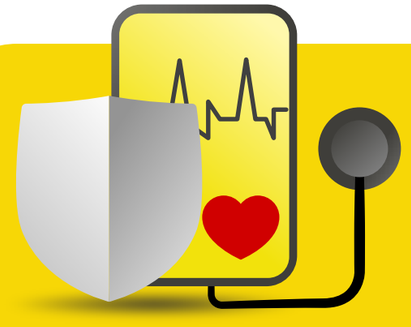
IT INFRASTRUCTURE QUALIFICATION

CYBER SECURITY

a challenge for **Life Science** companies

PQE allows to embed Cybersecurity barriers within the System Life Cycle to secure data and to ensure the business operations.

PQE services are oriented to support the Life Science industry to adapt to the change and to enter the gates of the Technological Revolution through a proved streamlined methodology, aimed at transforming challenges into tangible results with structure, processes and mind-sets in place. Combine the deep knowledge in the Regulatory expectations, configuration management and change control, we help company to secure the IT/OT environments.



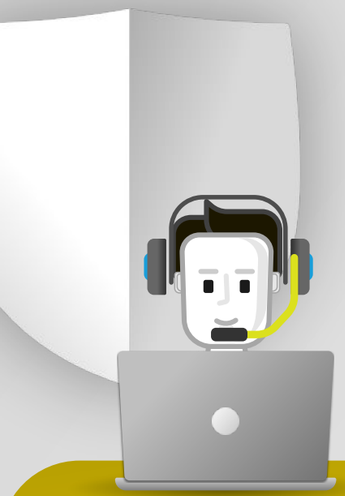
FOCUS ON:

Cybersecurity for **connected MD**

Protect your product's functionality and patients' safety.

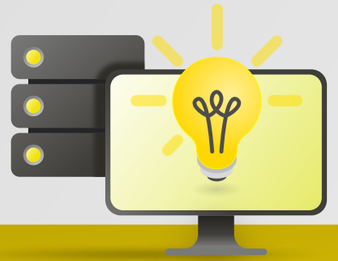
DOWNLOAD **CYBERSECURITY FOR CONNECTED MD** FOCUS

DOWNLOAD **CYBERSECURITY** FOCUS



IT Operations

- IT Management as a Service
- IT Temporary Management
- IT Service Desk (I & II Level - Office, Lab & Production)
- GDPR as a Service



IT Projects

- IT Infrastructure Implementation
- Computerized System Upgrades (e.g. Win 7/10)
- Company to Company IT Migration
- IT Technical Gap Fixing for Data Integrity

Cybersecurity

- Maturity Assessment
- Vulnerability & Penetration Test
- Risk Analysis
- Remediation Plan
- Employee Awareness
- OT Security

Quality by Design

- ERP Doctor, SW Selection
- Cloud Adoption Strategy
- Blockchain
- Robot Process Automation
- Artificial Intelligence

Remote Delivery Technologies

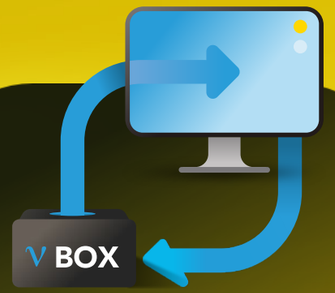
- ALM (Application Lifecycle Management)
- Smart Glasses
- V-Box
- E-Learning Platform

REMOTE SERVICE DELIVERY TECHNOLOGIES

Service Delivery is rapidly evolving to cope
the challenges triggered by new markets
and by new onboarded local resources

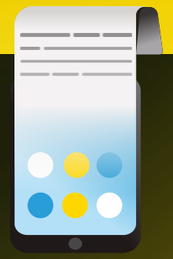
Resulting Needs for

- Remote execution of Services
- Capability to support less experienced onshore resources
- Execution of remote support: IT, vendor, quality, maintenance etc.



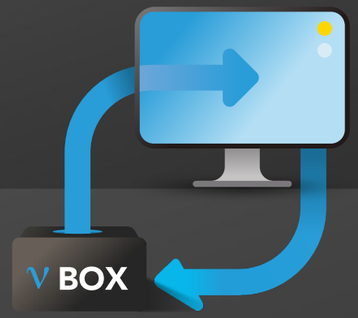
Remotizer νBox

PQE Smart Glasses



Application Lifecycle Management System

PQE ALM



Remotizer
νBox

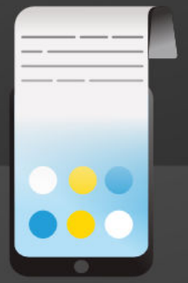
- νBOX: Hardware to allow full and secured remote control of customer standalone workstation fully plug and play
- Designed to bypass all the network constraints and to allow connect with standalone workstations
- Assembled in multiple variants to allow connection to every system (all operative systems - i.e. Windows 95)

- IT Service Deck / Operator
  - Remote support/maintenance troubleshooting on standalone PC by IT/Vendor specialists
  - Remote User Administration
  - Technical tasks to be performed in restricted areas (e.g. Biological Safety Level 2-3-4 Labs)
- Supervisor
  - Remote Audit Trail review
  - Remote Data review
- Quality Operator
  - Validation/Qualification tasks
- No tool/drivers installation required
- No client configuration needed

PQE
Smart Glasses

- Smart Glasses are wearable computer glasses that add information alongside or to what the wearer see*
- In the initial configuration, the PQE AR Smartglasses will be configured to
  - share the video captured by the operator with remote operator
  - establish an audio channel between the operators
  - share focus areas and documents
- Different variants are planned, based upon the intended use (e.g. virtual audits, computer assessments, assistance, maintenance, training)

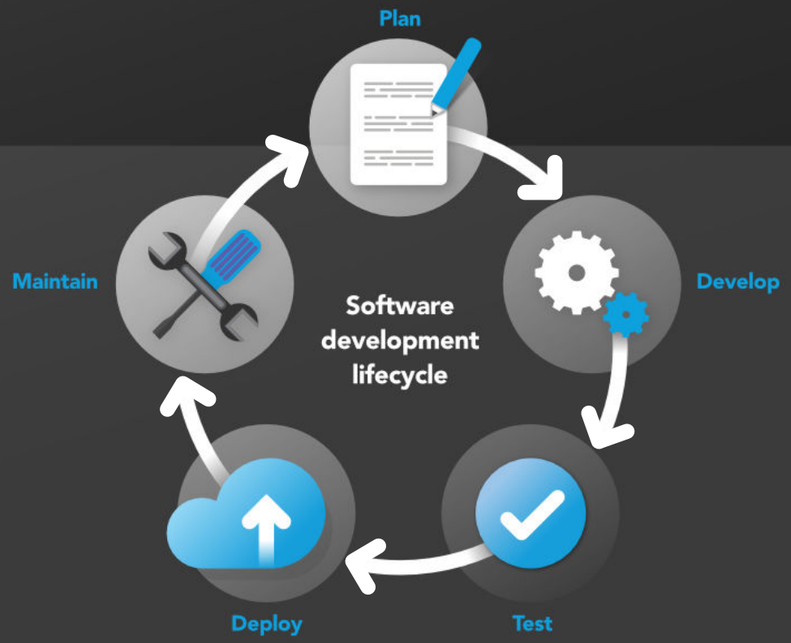
- Video call environment sharing, real-time visual feedback
- Maintenance Support from vendor specialists
- Training on the job



Application Lifecycle Management System

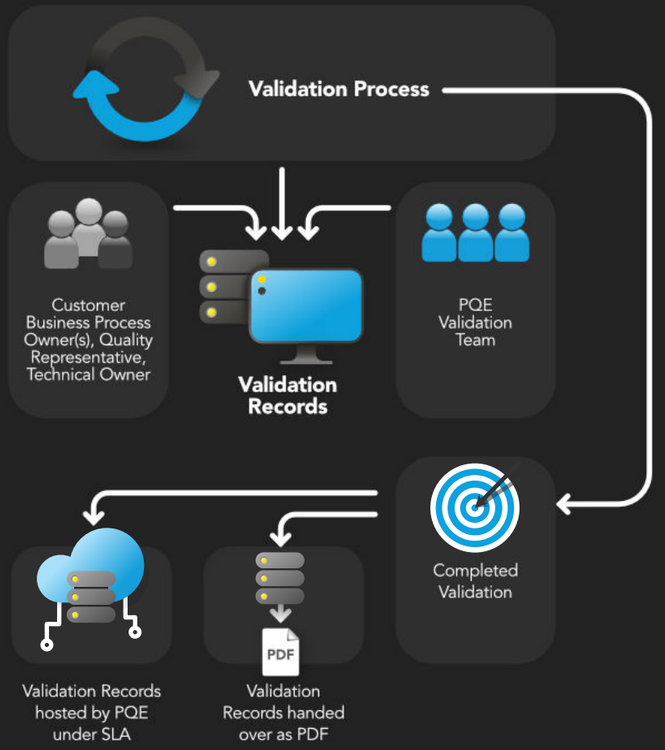
PQE ALM

- ALM is a SW platform which allows to manage electronically the validation records
  - Requirements
  - Specifications
  - Testing Scripts & Runs
  - Defects
  - Validation Documents
- ALM allows to manage all the validation tasks paperless (waterfall & agile), providing same functionalities allowed by HP/Microfocus ALM



- Solution hosted in the PQE IT Infrastructure with an encrypted access to the customers
- Managed by the PQE Competence Center and pre-validated
- Once accepted the Validation Package from the Customer, Records are maintained according to pre-established procedures to ensure.
  - The integrity of Validation data
  - The segregation of customer specific data

Validation records maintenance



QUALIFICATION & ENGINEERING

The act of Validation involves all product, process and facility matters.
Choose PQE's solutions to ensure that your plant site meets your business objectives while being fully compliant with the latest regulations and standards.

Discover our solutions

Process Qualification

Make sure all equipment, facilities and systems are always fit for their intended use and avoid the risk of non-conforming products.

VIEW THE **FULL PORTFOLIO**

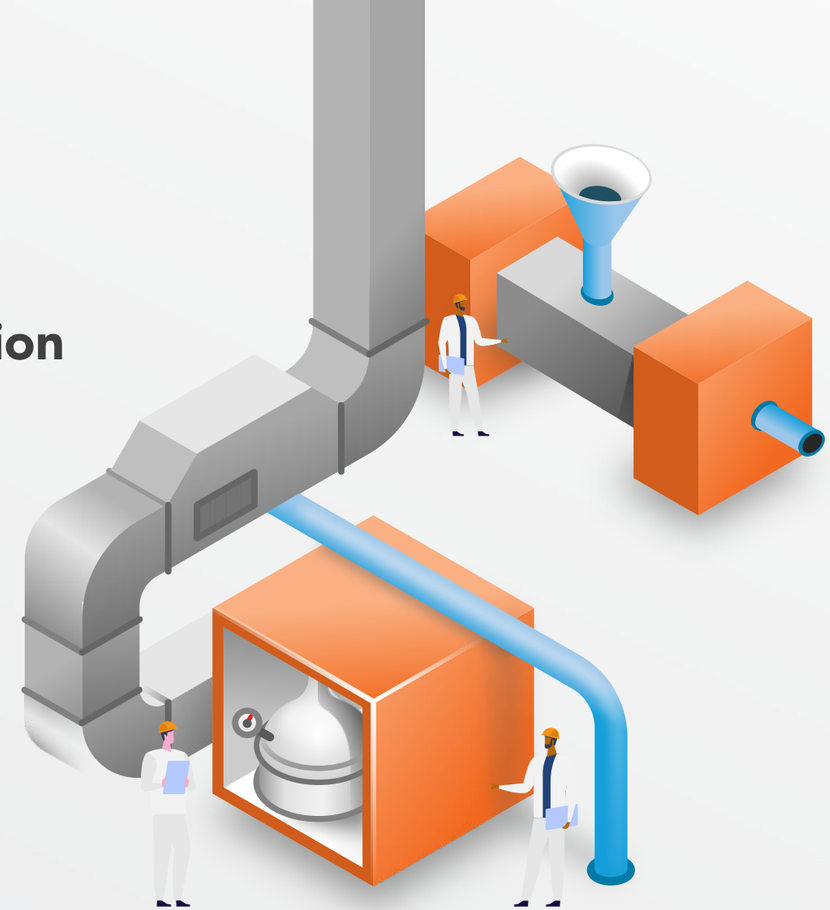
Facility Validation

Assess the feasibility of the facility design to ensure that your plant project meets all the business objectives and the regulatory requirements.

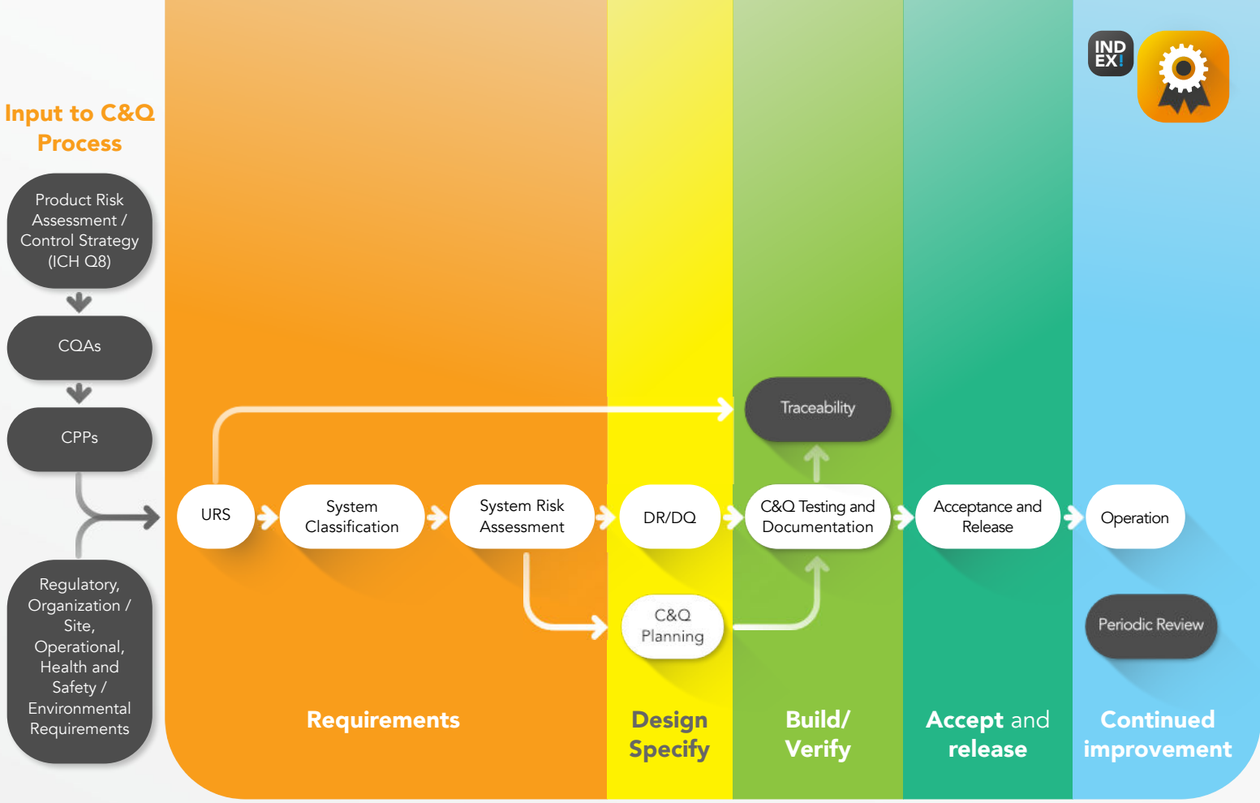
VIEW THE **FULL PORTFOLIO**

Modern and **Integrated Approach** to and **Qualification**

An interdisciplinary teamwork consisting of engineers and technicians with focused expertise in process engineering, qualification, information technology, quality and used to operate in regulated environments, will provide you a full service, including the use of our in house measurement instruments park.
Our qualification solutions are based on the latest regulatory requirements and guidelines maintaining the focus on minimizing cost and compliance related risks.



- Validate procedures, materials, equipments and systems
- Establish a consistent product delivery
- Prove with documented evidence the reliability of the processes
- Avoid reject, reworks and down time
- Ensure compliance with regulatory authorities' standards
- Achieve growth and success



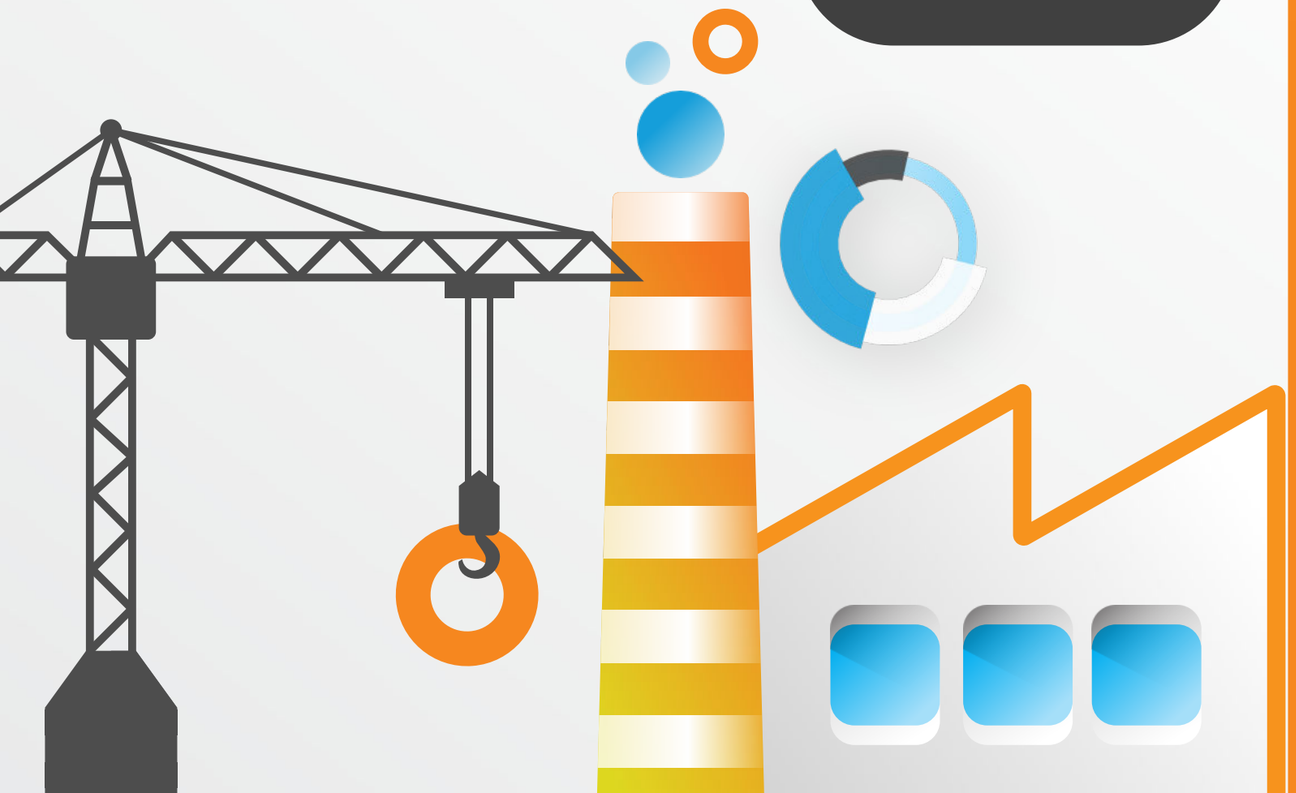
FOCUS ON:
ANNEX 1

With the release of the Second Issue of 2020 GMP Annex I, the standard for all sterile manufacturers has been widely extended and revised.
PQE Group has collected all the information you need to comply in an exhaustive guide.
Don't wait: request the download now for free and get all the insights on sterile assurance.

DOWNLOAD **ANNEX 1** FOCUS

DESIGN METHODOLOGY

There are many steps in the design of a pharmaceutical and medical device facilities. In PQE's approach and solutions, we emphasize delivery based on our three key project principles:



MEETING STAGE	DESIGN PHASE	DELIVERABLE
First Meeting	Design Input Definition	Design Input Checklist
	Design Drivers	Regulatory and Business Requirements
	Space Allocation	Block Layout
Second Meeting	Preliminary Design	Plant Layout Draft
Third Meeting	**Final Design**	Plant Layout Final

Process Qualification

- Qualification Protocols Writing and Execution
- Installation, Operational and Performance Qualification
- Validation Master Plan
- Calibration services
- Witnessing of Supplier Testing Activities (FAT/SAT support)
- Inventory of Process Equipment and Utilities
- Process Risk Management
- User Requirement Specifications
- Technology Transfer
- Process Analytical Technology (PAT) Support
- Clean Room Qualification
- Temperature Mapping Services
- Transport Validation

Facility Validation

- Concept Development for Manufacturing Facilities and Laboratories
- Support for Basic & Detail Design Support
- Technology Transfer Support
- Regulatory | GMP Review
- Design Qualification
- Construction Supervision
- Project Management
- Visual Factory Programs
- Risk-Based Process Equipment & Utilities Maintenance Plans
- Value Stream Mapping
- Overall Equipment Efficiency (OEE)
- De-Bottlenecking and No Added Value time reduction programs
- Cost-Effectiveness optimization with Operational Excellence Programs
- Lean-Production programs
- Procurement Support

LABORATORY EXCELLENCE

From regulatory compliance to training, and from instrumentation to automations, we support your laboratories in reaching the highest potential. Meet your operational and business objectives with the technical and professional assistance of our consultants.

Discover our solutions

Laboratory **Instrument** Management

Get full support to the principal QC and Microbiological Lab instruments (including custom instruments)

Laboratory **Personnel**

Integrate our licensed and expert professionals in your lab personnel.

Laboratory **System**

Benefit from a bulletproof Project Management strategy.

LAB 4.0

Establish the best process roadmap for developing smart solutions for your lab.

Full support for **Labs**

We provide the expertise and counseling you need to secure the best lab performances and avoid non-conforming products and products' recalls. Don't risk losing quality and trust: choose the right training, guidance and support.

- Optimize your analytical method
- Deploy complex laboratory systems
- Fully integrate your digital system with smart solutions
- Manage your instruments suppliers
- Rely on competent and expert personnel

Laboratory **Instrument** Management

- Preventive Maintenance
- Periodic Qualification
- Supplier Management

Laboratory **Personnel**

- Chromatography (HPLC, UHPLC, GC)
- Spectrophotometry (IR, UV)
- Spectroscopy (AAS)
- Sterility Test
- LAL Test
- Bioburden and Environmental Monitoring

We also support your business with specific capabilities in development and process optimization through:

- Analytical Method Optimization
- Method transfer
- Method validation

Project Management for the **deployment** of **complex systems**

- CDAS (Chromatographic Data Acquisition System)
- LIMS (Laboratory Information Management System)
- ELN (Electronic Laboratory Notebook)
- SDMD (Scientific Data Management System)

LAB 4.0

- Smart Lab
- Paperless Automation
- Saas and Cloud solutions

Quality Compliance

For Life Science businesses in highly regulated environments, compliance is not an option. Prepare to successfully pass audits and inspections for your product with PQE Group's tailored and cost-effective programs for Quality Management.

Discover our solutions

Pharma
Compliance

Align to GxP standards and learn how to efficiently conduct pharmacovigilance and clinical trials.

VIEW THE **PHARMA SOLUTIONS**

MD
Compliance

Develop and maintain your QMS to ensure compliance with applicable regulatory requirements and standards.

VIEW THE **MD SOLUTIONS**

Are you **100% compliant?**

Lack of inspection readiness or failed attempts at post-inspection remediations may lead to huge operating and legal costs like warning letters, product recalls, withdrawals and sanctions. Don't risk losing quality and trust: choose the right training, guidance and support.

- Prepare for FDA and other authorities' inspections
- Review documentation and records
- Identify gaps and take remedial actions
- Execute mock inspections and CAPA
- Achieve total control over production and processes
- Benefit from outsourced Quality Management System support
- Enhance resources' competences and behavior

IND EX!

GLP
Good **Laboratory** Practice
DOWNLOAD **GLP** FOCUS

GCP
Good **Clinical** Practice
VIEW **GCP** SOLUTIONS

GxP

GMP
Good **Manufacturing** Practice
DOWNLOAD **GMP** FOCUS

GDP
Good **Distribution** Practice
DOWNLOAD **GDP** FOCUS

GVP
Good **Pharmacovigilance** Practice
VIEW **GVP** SOLUTIONS

PQE GROUP

FOCUS ON:

Medical Cannabis Solutions

Learn how to update your processes and assure the quality of your product.

DISCOVER **MORE**

FOCUS ON:

Statistics in Pharmaceutical Manufacturing

Practical tools for knowing, monitoring and improving production processes.

PROCESS KNOWLEDGE is the common tract to most of the current reference documents (e.g., ICH Q8 - Q9 - Q10 - Q11 - Q12 - Eudralex Annex 15, etc.), guidelines (FDA Guidances on Process Validation, Quality Metrics, etc.) and initiatives that regulate the today pharmaceutical world.

DOWNLOAD **STATISTICS** FOCUS

FOCUS ON:

Prevent Viral Contamination

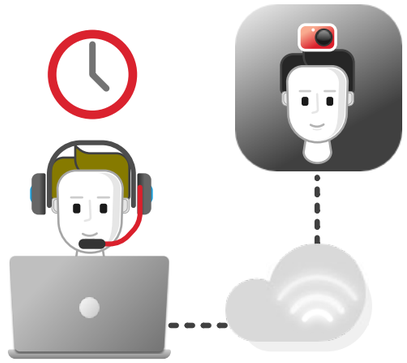
Recent Coronavirus outbreaks have suddenly highlighted the need for an overall estimation of the efficacy of the contamination control policies.
Choose PQE to perform your Viral Contamination Assessment

DOWNLOAD **PREVENT VIRAL CONTAMINATION** FOCUS

FOCUS ON:

Business Continuity PLAN & Crisis Plan

DOWNLOAD **BUSINESS CONTINUITY PLAN & CRISIS PLAN** FOCUS



FOCUS ON:

Front-end back-end service model

Thanks to its global and multicultural asset, PQE Group can easily and steadily deliver its turn-key solutions and services from remote, with our front-end plus back-end strategy.
When on-site audits and mockup inspections are not practical or hindered by geopolitical or health circumstances, choose PQE Group's flexible delivery models.
Read more about this topic in our case studies:

CASE STUDY FOR **GXP PROJECTS**

CASE STUDY FOR **MDR PROJECTS**

FOCUS ON:

ANNEX 1

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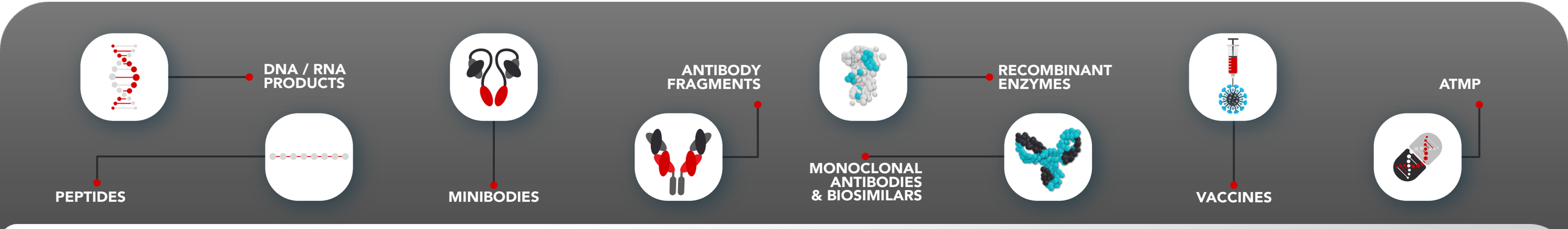
DOWNLOAD **ANNEX 1** FOCUS

Biotech Service Portfolio

From molecular biology products to huge proteins PQE Group can support your Biotech Product across the whole process.



BIOTECHNOLOGICAL PROCESSES SUPPORT

Cell-Line Engineering

- Cell line engineering and characterization according to ICH/ GMP guidelines
- MCB and WCB production and characterization (including viral characterization)

Process Development

- Upstream development
- Downstream development
- Final formulation development
- Analytical methods development
- Up-scale from lab to pilot scale
- Production process and analytical methods definition

Technology Transfer

- Production process (upstream, downstream, formulation & filling) transfer up to industrial scale
- Analytical methods transfer and suitability
- Viral clearance studies, scale down models
- Related validation activities (E&L, sterility assurance etc.) and documental activities (SOPs, BRs, RA etc.) support

Process Validation

- Validation batches, cell banks, EoPC, bulk and purified product characterization (including viral characterization support)
- Analytical methods validation
- Review and definition of relevant documentation
- SMF/DMF/IND/IMPD and regulatory documentation support

Production

- Support to Clinical studies and commercial batches production
- Related documentation revamping/optimization
- Process and methods optimization support, periodic qualification, support to changes and comparability exercises

PQE GROUP

Nitrosamine Risk
Evaluation & control support

Choose PQE group for immediate support to manage the entire process.

BACKGROUND NITROSAMINE ISSUE
JULY 2018

NDMA
in valsartan

NDEA
in other sartans

NDMA, NDEA, NDIPA, NMBA
in other sartans

NDMA
in pioglitazone hydrochloride

SEPTEMBER 2019

NDMA
in Ranitidine HCl

31 MARCH 2021
for chemical medicines

1 JULY 2021
for biological medicines

ASAP

26 SEPTEMBER 2022
for chemical medicines

1 JULY 2023
for biological medicines

URGENT

STEP 1

RISK EVALUATION:

MAHs - together with API and finished product manufacturers - to perform risk evaluation of medicinal products containing chemically synthesized API

STEP 2

CONFIRMATORY TESTING:

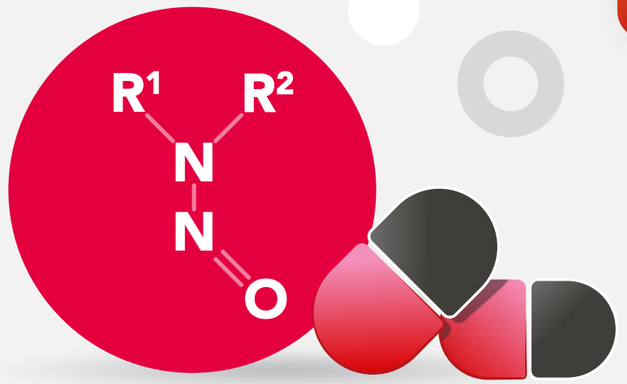
Confirmatory testing of all medicinal products identified to be at risk of presence of nitrosamines

STEP 3

CHANGES TO THE MARKETING AUTHORISATION:

MAHs to apply for a variation to introduce any required changes, such as amendment of the manufacturing process or changes to product specifications

PQE Methodology & **full compliance** support



PRIORITIZING THE RISK EVALUATION 1
Knowledge of factors impacting the risk

QUALITY RISK MANAGEMENT 2
Failure Mode Effects Analysis (FMEA) tool

CONFIRMATORY TESTING 3
Determine which nitrosamines could potentially be present

REGULATORY SUPPORT 4
Change management
Classification of changes
Variation Application

CHEMICAL AND MANUFACTURING
Root causes of nitrosamine formation and contamination

ANALYTICAL REQUIREMENTS
Define the expected regulatory standard

CONTROL LIMITS AND CONTROL STRATEGY TOXICOLOGY ASSESSMENT
Assessment & Control of mutagenic impurities (based on ICH M7 guideline)

Pharma Compliance Portfolio

Align to GxP standards and learn how to efficiently conduct pharmacovigilance and clinical trials.

GXP

GMP/GDP

- Inspection Readiness Program (FDA, EU, ANVISA, CFDA, PMDA, MFDS, TGA, COFEPRIS and other regulatory bodies)
- Post-Inspection support (US FDA form 483, Warning Letters, Imports Alerts, Non-compliance reports)
- Complex CAPA/Remediation plan management & execution
- Quality Management System implementation or optimization
- Continuous Improvement and KPI/Quality Metrics Implementation
- Sterility Assurance
- Technology Transfer support
- Validation support (Analytical, Cleaning, Process)
- Auditing & Due Diligence (Products or Site acquisitions)
- Support in critical event management (Complaints, Deviations, OOS, Recalls, Stability)
- Managed Service (APQR, Batch Record Review and Product Release)
- Risk Management Implementation
- Historical data review of laboratory and production data
- Supplier Management and Monitoring Strategies
- Training (System Implementation / Mentoring / Coaching / Upskilling)
- CAPA System Implementation
- Change Control System Implementation
- Capacity and Skills Assessments
- Improving Quality and reducing defects – Six-Sigma

GCP (Clinical Trials)

- Auditing service
  (e.g. Initial, Follow-up, For Cause, i.e. CROs qualification, Investigational Sites, Centralized Laboratories)
- SOPs/Policies Development, Issuing and Review
- GCP review of Study Protocol, Informed Consent form, CRF, Investigator Brochure and Clinical Study Report
- TMF and ISF review and quality check
- GAP analysis of the quality System vs new EU-CT regulation and ICH E6 R2
- Data Integrity and Compliance Assessments
- Clinical Process mapping
- Training (From basic GCP to advanced specific trainings)
- E-Learning content development
- Training on the job (i.e. Audit with Junior Auditors and CRA)
- Computer System Validation (i.e. eCRF, eSD, eTMF, Patient Database, IV/WRS, CTMS),
  Data Migration plan and Data Quality Control
- Inspection Readiness and Support (Sponsor, CRO, Investigational Site, Back & War Room)
- CAPA definition and implementation
- Archiving Requirements for Study Documents
- Due Diligence process
- Clinical Study Setup
- QA Services & Training
- Compliance Verification with minimal technical requirements for clinical sites involved in Bioequivalence studies
  (Determina AIFA n.809-2015)
- Risk analysis for clinical audit planning
- Risk Analysis model definition for clinical trials
- Vendors – CRO Selection

GLP

- Facility Assessment and Audit
- GLP Remediation Plan & Execution
- Documentation Redaction Support
- GLP Study Monitor
- Study Audit
- GLP QA Support
- GLP Training
- First Certification Support

GVP (Pharmacovigilance)

- Auditing service
  (qualification of vendors/service providers, audit to affiliates, commercial partners, internal audits to the whole PV system or to specific processes, mock-inspection, assessments)
- Inspection readiness support
  (training, documents preparation, war room, mock inspections, CAPA plan preparation support)
- PV Quality Assurance Outsourcing and EU-QPPV Outsourcing
- Policies/Manuals/SOPs/WIs: development, issuing and review
- Risk analysis for strategic and tactical audit planning
- E-Learning Content development and training execution
- PV documents preparation and review (PSMF, PSUR/PBRER, DSUR, RMP, Signal detection reports, SDEA, etc)
- Pharmacovigilance Processes Mapping
- Gap Analysis of the Quality System vs EU GVP
- Data Integrity and Compliance Assessments
- Computer System Validation (i.e. LifeSphere Safety, Argus Safety, ARISg, SafetyDrug)
- Data Migration support and validation
- Remote Data Entry/QC support into the Safety Database

Medical Device Compliance Portfolio

Develop and maintain your QMS to ensure compliance with applicable regulatory requirements and standards.

FOCUS ON:

MDSAP Support

MDSAP operational phase started in January 2017

Medical Device Single Audit Program (MDSAP) is an international program that will allow Auditing Organization to conduct a single regulatory audit of a medical device manufacturer's QMS that will satisfy the requirements of multiple regulatory jurisdictions.

Health Canada only accept MDSAP certificates as of **1st January 2019** Manufacturers who intend to market in Canada must consider to get MDSAP certificate

Life Science Quality

- 21 CFR 820 compliance
- ISO 13485 compliance
- MDSAP Compliance & Validation Support
- Notified Bodies Audits & FDA Inspections Support
- Mock Inspections
- R&D support
- DHF, DMR, DHR creation and review
- Quality Policies & Manual, Standard Operating Procedures
- Documentation Management
- CAPA and Complaints management system implementation
- Vigilance and MDR system implementation
- Risk Management, Usability Support
- MD Software Life Cycle validation
- MDR and IVDR requirements
- PMS, PMCF and Clinical Evaluation
- Auditing service
  (qualification of suppliers and specific audit to data and/or documents – Follow-up, For Cause, i.e. CROs, Investigational Sites, Centralized Laboratories)
- SOPs/Policies Development, Issuing and Review
- Process Mapping
- Trainings
- Data management
- Quality management
- Clinical evaluation management
- ISO 14155 compliance
- CEP/CER preparation

REGULATORY AFFAIRS

Our service begins with the development of the regulatory strategy and concludes with the editing, amendment and submission of the necessary documents of the dossier. Due to the expertise of our consultants, fully electronic submissions for the EU | USA | Canada | Switzerland, along with paper submissions are handled in the fastest and most professional manner, while ensuring that dossiers are compliant to the strictest regulations.

Discover our solutions

Pharmaceuticals

Support product registrations in EU/CH/USA/LATAM, monitor and track progress, interface with Regulatory Agencies on Client's behalf.

VIEW THE **FULL PORTFOLIO**

Medical Devices

Prepare registration dossier | technical file for your MD and IVD products.

VIEW THE **FULL PORTFOLIO**

Leverage **regulatory** strategy

To successfully comply with regulatory requirements and avoid penalties, rejects and delays, Life Science businesses need to be aware of the challenges posed by different laws operating in different market regions. Don't risk losing quality and trust: choose the right training, guidance and support.

- Manage products' approval and registration
- Speed up products' launch
- Reach different countries and assure global coverage
- Keep products on the market consistently
- Coach R&D to collect the right data from the first stages
- Improve and standardize regulatory processes

Regulatory **intelligence**

PQE capabilities PQE can provide regular updates to make you aware of regulatory requirements applicable to Clients' portfolio. All updates to Guidance/ Regulations under discussion will be monitored to provide insight into the direction that Regulatory Agencies expectation will take. New Guidance and Regulations can be translated if required.

Service model:

- Monitored sources and frequency of updates are agreed in advance.
- The format can be tailored on Customer needs
  (e.g. newsletter, update in-house database, etc.)

Relevant projects:

- PQE is a CMC Regulatory Intelligence Provider of Clarivate Analytics supporting development and update of the CMC Cortellis Data Base.
- PQE is providing customized RA intelligence services to Drug Product and Drug Substance Manufacturers.

Full regulatory support for API developers and manufacturers

CMC Writing Service

Preparation of ASMF | DMF | JMF | Chinese MF | …

Dossiers for CEP

Lifecycle support (amendments, and CEP renewals)

Drug Substance Scientific and Regulatory Intelligence

Rationale for Starting Material (ICH Q11)

Regulatory advice & CMC Intelligence Services (ICH and Local Guidance)

eCTD for APIs

Excipients / Packaging

Type IV | Type III DMF for US

Type II | Type III DMF for Canada

Excipient DMF for China

eCTD Publishing service for excipients and Container Closure Systems

Regulatory Site Compliance Assessment

DMF Gap analysis vs ICH guidelines and local regulatory requirement (e.g. Japan, China, Russia, etc.)

Compliance Verification of DMF vs GMP documentation

Drug Substances Application Support

EU Submission | Notified Contact at EDQM

US Agent service | Japan ICC Service

Chinese Responsible Agent

FOCUS ON:

In-country Caretaker Service

To export products in Japan and handle Japanese regulatory procedures smoothly, foreign Life Sciences businesses are required to appoint an ICC (in-country caretaker) that will perform tasks concerning registration, review, GMP, translation and so on. Thanks to our local experts and the broad presence of PQE locations across relevant market regions such as Japan, we can support you globally thinking locally.

DOWNLOAD **ICC** FOCUS

FOCUS ON:

Chinese responsible agent role

To register products in China and handle Chinese regulatory procedures smoothly, foreign Life Sciences businesses are required to appoint a CRA (Chinese Responsible Agent) that will perform tasks concerning registration, review, sample import, translation and so on. Thanks to our local experts and the broad presence of PQE locations across relevant market regions such as China, we can support you globally thinking locally.

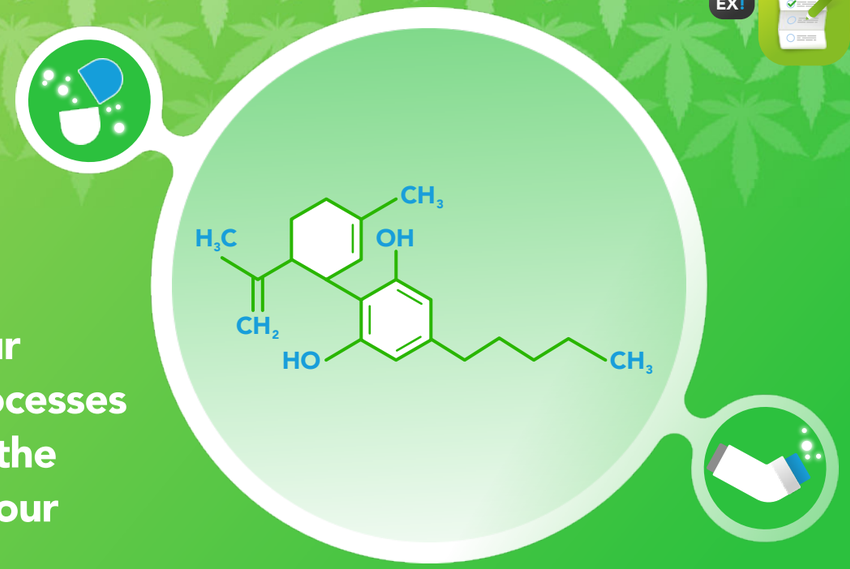
PQE GROUP

Cannabis related **regulatory** standards

Keep your investment under control with the help and guidance of our team of experts, specialized in Regulatory and Compliance solutions.

Why choose PQE Group?

- Global and local Regulatory Intelligence
- Focus on innovation and competitiveness
- Strong knowledge of legal requirements
- Scientific Data-analysis method to comply to the regulatory expectations
- Technical and strategic support during regulatory procedures
- Ability to negotiate with the Regulatory Authorities and Drug Development Networking
- 20+ years of experience in the Life Science industry at a global level
- 1000+ consultants distributed all over the world to support your business locally



Update your primary processes and assure the quality of your product.

While most medical organization have stated support of allowing access to medical cannabis, in countries like the United States of America the medical use of cannabis is legal, with a doctor's recommendation, in 36 states. Twelve other states have laws that limit THC content, for the purpose of allowing access to products that are rich in cannabidiol (CBD), a non-psychoactive component of cannabis. Although cannabis remains a Schedule I drug, the Rohrabacher–Farr amendment prohibits federal prosecution of individuals complying with state medical cannabis laws.

Those firms who wish to invest in this field must know their market and always be compliant to the newest quality standards. With PQE Group's tailored program, specifically intended for the Medical Cannabis industry, you can guarantee safety and effectiveness while protecting your business from costly observations.

Pharmaceuticals
Portfolio

Regulatory & Development Strategic Services

- Regulatory Strategic Master Plan and Feasibility Studies: Worldwide regulatory support for new chemical entities, biological products and generics/biosimilar from strategic advice on regulatory filings to evaluation and resolution of complex scientific and regulatory issues. Bioequivalence Study Designs review
- Full development Plan: assistance in designing plans for NMEs or new indications/new formulations to support US 505(b)(1) and 505(b)(2) type submissions, and EU full applications (Art. 8.3 EU Directive 2001/83)
- IND/IMPD compiling: our Experts will support you drafting the dossier from scratch with the level of detail required delivering an adequate and complete document according to your project milestones
- Scientific Advice, Protocol Assistance and Parallel Advice requests
- Merge & Acquisition services: due diligences for the quality, pre-clinical and clinical components of dossiers
- Drug Development Trainings

Regulatory Services for Market Authorization

- Full support for medicinal product registration:
  - MAA submission according to all existing legal basis, including preparation of regulatory strategy plan,
  - Gap analysis of dossiers already submitted to any countries (versus GMP documentation and/or current Regulations),support during pre-submission phase and dossier drafting
- Drug life-cycle management: Variation/Change Application Dossier, EU renewals, EU line extension
- Promotion activities: Regulatory review and support for Approval of Advertising, Educational Material to HCP/HCO, Scientific Service Quality System
- Dossier reformatting & Electronic submission
- Merge & Acquisition services: due diligences for the quality, pre-clinical and clinical components of dossiers
- Regulatory Compliance Assessment on Regulatory Affairs Department to verify the compliance of activities management with current regulatory guidelines/requirement

Why PQE

To easily navigate the increasingly complex regulatory market and help our clients comply and sell their products in **EU**, **US** and **Canada**, **LATAM**, **MENA**, **CIS**, **Africa** and **APAC**, PQE Group relies on highly flexible and close multicultural teams of consultants expert in the laws and regulations operating in various countries.

FOCUS ON:
New products Strategy Development

DOWNLOAD
NEW PRODUCTS STRATEGY DEVELOPMENT
FOCUS

Medical Device Portfolio

Medical Device Regulatory Services

- US Agent
- 510K
- Device Listing
- Establishment registration
- Regulatory intelligence
- Regulatory strategic plan
- Regulatory Dossier | Technical File preparation
- Technical documentation assessment

EU **MDR**

Medical Devices in Europe

With its 123 articles, 10 chapters and 17 annexes, EU MDR 2017/745 is a fundamental revision of the European regulatory framework that aims at ensuring the quality and safety of Medical Devices being produced or supplied into Europe. The new set of requirements includes a reinforcement of the existing rules and criteria, a wider definition of a Medical Device, and the introduction of Economic Operators as a target of the new regulation.

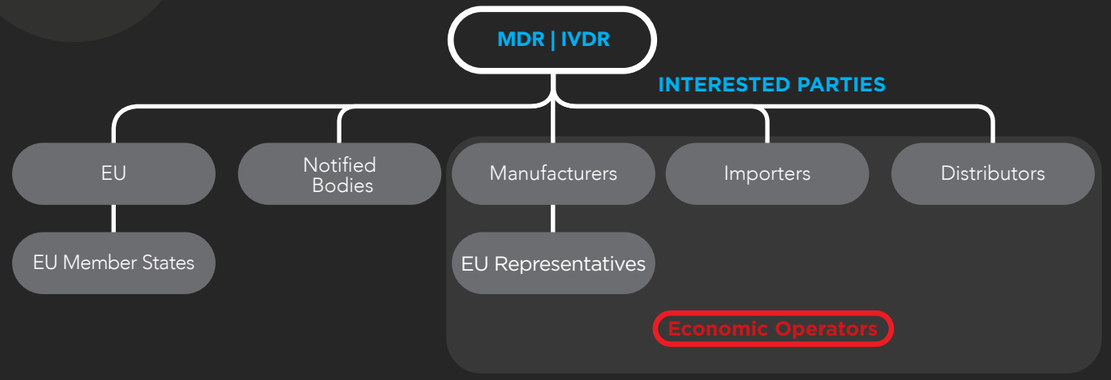
The changes from the current Medical Device Directive may be seen as a mere revision, but are to be considered as a whole new legislation entering into force on May 2021 will be relevant to any company that wishes to produce or supply MD in Europe, from start-up business that intend to reduce time-to-market, to already established organizations that want to secure business continuity and effectively manage the transition timeline.

EU **IVDR**

In Vitro Medical Devices in Europe

Within its 113 Articles, 10 Chapters and 15 Annexes, EU IVDR 2017/746 is a fundamental revision of the European regulatory framework that aims at ensuring the quality and safety of In Vitro Diagnostic Medical Devices being produced or supplied into Europe. The new set of requirements includes a reinforcement of the existing rules and criteria, a wider definition of an In Vitro Medical Device, and the introduction of Economic Operators as a target of the new regulation.

The changes from the current In Vitro Medical Device Directive may be seen as a mere revision, but are to be considered as a whole new legislation that entering into force on May 2022 and will be relevant to any company that wishes to produce or supply IVD MD in Europe, from start-up business that intend to reduce time-to-market, to already established organizations that want to secure business continuity and effectively manage the transition timeline.



MDR support services

- Person Responsible for Regulatory Compliance
- Clinical Evaluation Plan/Report Preparation
- Post Market Clinical Follow up
- Post Market Surveillance
- Manufacturer and Device Registration
- Recording and Reporting Incidents
- Implementation of Unique Device Identification
- Classification Assessment of Devices According to New Rules
- Devices without a medical intent

DOWNLOAD **MDR** FOCUS

IVDR support services

- Person Responsible for Regulatory Compliance
- Clinical Performance Report Preparation
- Post Market Performance Follow Up
- Post Market Surveillance
- Manufacturer and Device Registration
- Recording and Reporting Incidents
- Implementation of Unique Device Identification
- Classification Assessment of Devices According to New Rules
- Performance Evaluation Plan and Scientific Validity, Analytical Performance and Clinical Performance Report Preparation

PQE GROUP

AUDITS

Due to recent regulatory developments concerning raw materials, suppliers, manufacturing and distribution, auditing has become a task of critical importance for Life Science businesses.
PQE Group supports Pharma and MD companies in performing many types of certified audits, from routine monitoring to due diligence purposes.

Discover our delivery model

On Site

Profit by our geographical coverage to execute on-site Audits.

Remote

Choose remote auditing when on-site visits are not convenient.

Virtual

Enhance remote audit sessions with virtual facility walkthrough.

An ISO certified quality system

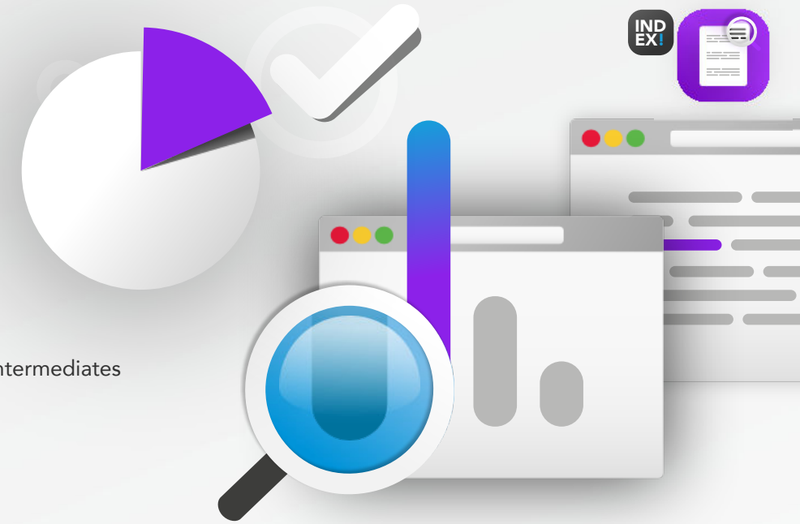
A lack of expertise when planning and executing auditing activities may lead to delays in validation and severe impacts on inspection readiness. Don't risk losing quality and trust: choose the right training, guidance and support.

- Achieve a corporate standard common methodology
- Scrutiny your suppliers
- Conduct internal, clinical and PhV audits
- Lower costs, time and effort
- Provide accepted compliance solutions to cover gaps
- Facilitate inspection gap closure
- Rely on a high number of lead auditors per region

Why PQE

With plenty of subsidiaries and offices located worldwide, PQE Group can break language barriers and minimize travel costs for clients, deploying locally our teams of experienced auditors with more than 15 years of exposure to the auditing process.

And when on-site visits are not practical, our flexible delivery model allows us to guarantee business continuity and the lowest possible impact on all auditing operations: during the recent global health crisis, PQE successfully completed all planned audits remotely, via documentation reviews and SME discussions.



Pharma & API

- Manufacturers of API, Excipients and Intermediates
- Software Suppliers
- Clinical & Pre-Clinic Audits
- Investigational Site Audit
- Sterilisation Facilities
- Suppliers of Equipment & Utilities
- Pharmacovigilance & Safety Issues
- Due diligence Audit for GxP Compliance IT Systems and Business Plan Challenging
- CMO for FDF Biosimilars Manufacturers Distributors & Logistic Operator Contract Laboratories/GMP/GLP/CROs

Medical Device & IVD

- Internal auditing
- Molds Supplier
- Process Equipment & Utilities Suppliers
- Raw Material Manufacturers
- Components and Semi-finished Parts Manufacturers
- OEM Manufacturers
- Contract Manufacturing Organizations
- Contract Testing Laboratories

PQE solutions

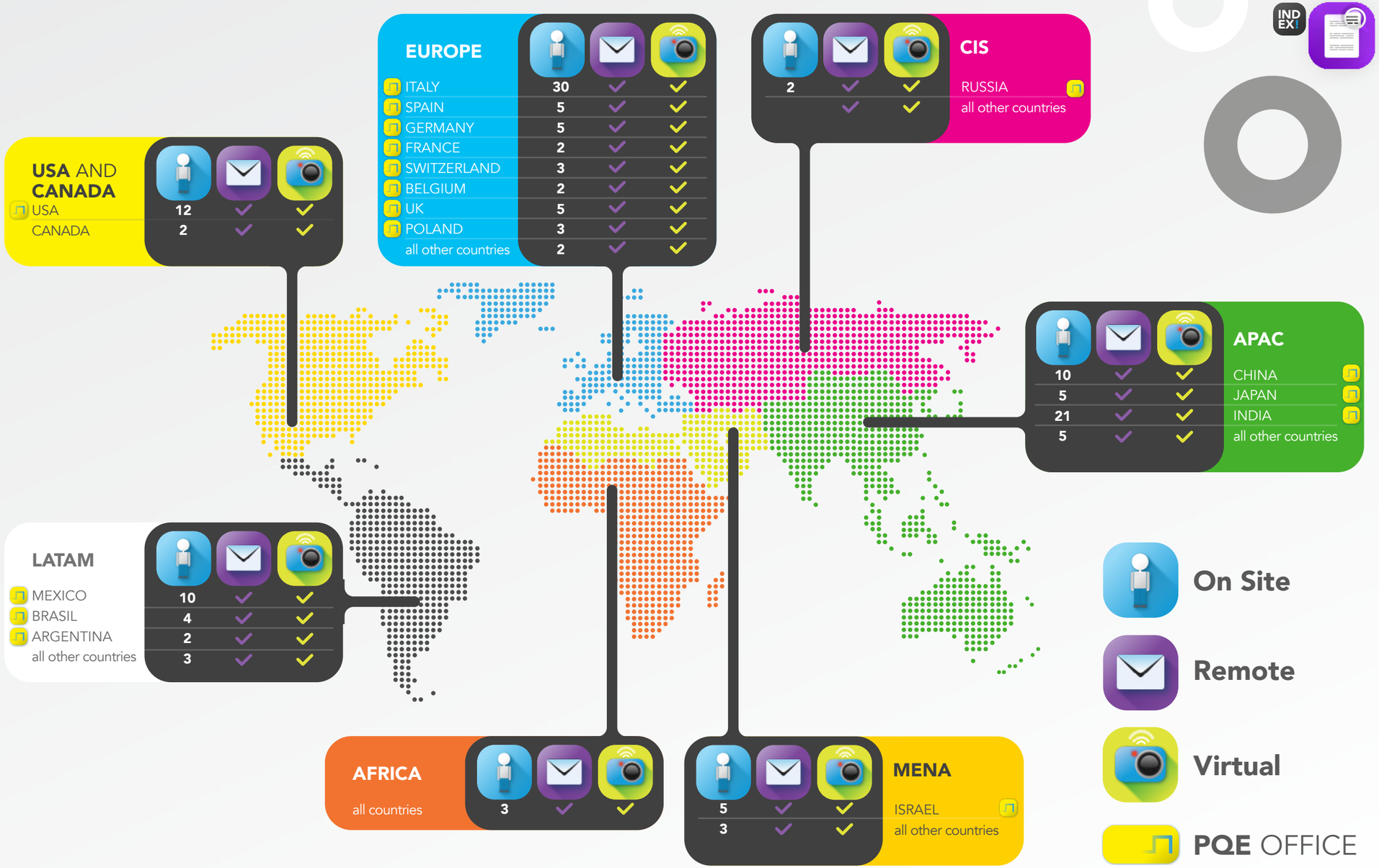
Can help in overcoming disruptions or delays, thanks to:

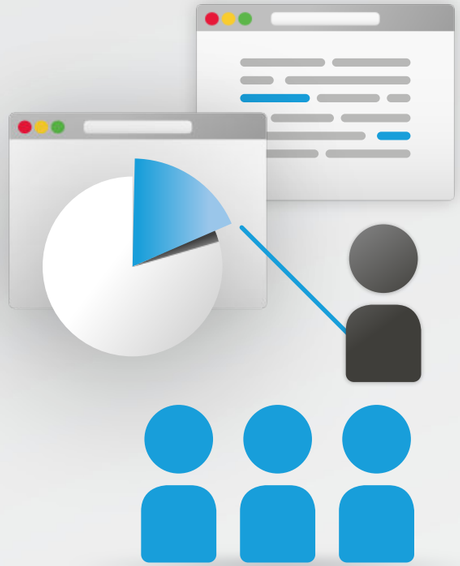
1. **A Global network of local auditors**
   - we can execute audits worldwide with our local auditors located in PQE subsidiaries and offices

2. **Remote** (desktop) and **Virtual audits**
   - In case on-site audits are not allowed due to restrictions applied also to local personnel movement, we can execute remote (desktop) audits, enhanced with Virtual facility walk-throughs where possible

Thanks to PQE Group methodology we guarantee a low impact to Auditing activities, which can be done remotely when necessary:

- **Documentation Review**
- **SME Interview & Discussion**
- **Virtual Facility Tour**





PQE GROUP

TRAININGS

Provide the correct training on policies, procedures, documentations and behavior to your resources.

DOWNLOAD **TRAININGS** CATALOGUE

DELIVERY MODEL

- Classroom
- F2F Coaching
- E-Learning
- Webinar
- Tailor made

AVAILABLE IN:

- Data Integrity & Computer System Validation
- Digital Governance
- Qualification & Engineering
- Compliance
- PhV
- Good Clinical Practice

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