

 **PQE** GROUP  
GLOBAL QUALITY SOLUTIONS

COMPANY PROFILE

## 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
- 28 worldwide offices ranging from the U.S. to Japan
- Thousands of professional employees fluent in 25+ languages
- Proven record of successful remediation of Regulatory Emergencies  
along with FDA 483's and Warning Letters



### VISION

Think Business:  
Invest in Knowledge,  
People & Ethics



### MISSION

Become market leader  
as solution provider for  
sustainable compliance.



### CORE VALUES

- Quality oriented
- Innovative
- Flexible & Dynamic
- Ambitious
- Ethical
- On Time



### KEY ASSETS

- Rapid Problem Solving
- Transparency
- Efficiency
- Know How
- Value for Money
- Multiculturalism & Global Footprint

# Message from the C.E.O. & Founder

Since the foundation of PQE Group, I have strongly believed that our core values, know-how, people and ethics, can make PQE Group the market leader for sustainable compliance solutions in Europe and beyond.

As a matter of fact, we are growing year by year thanks to a full time workforce of dedicated employees, which allows us to enhance our robust and standardized commitment to excellence.

Our passion for the growth and development of life science companies enables PQE to consistently exceed our customer's expectations.

This is the reason why we have successfully completed thousands of projects around the world, working in more than 20 different languages.

Come discover what our customers have experienced.



**Forbes**

Business  
Council

2021  
OFFICIAL MEMBER

**43 NATIONALITIES**



**1500+**  
EMPLOYEES WORLDWIDE

A collage of icons related to pharmaceutical and medical device quality, including a test tube, a pill, a heart rate monitor, a smartphone with a gear icon, a magnifying glass, a gear, a checkmark, and a ribbon award.

**GxP**  
0384628101

**1400+**  
CLIENTS BOTH IN PHARMACEUTICAL  
AND MEDICAL DEVICE

**28 OFFICES**

**19 LEGAL ENTITIES**

A central globe with a grid of office locations, connected by dashed lines to smaller icons of office buildings around it.

**12K+**  
PROJECTS  
PERFORMED  
SINCE 1998

A stack of four colorful binders (yellow, red, blue, green) with white pages.

PQE Group is a leading quality solution provider for the Life Sciences industry that offers both high-level and hands on consulting services around the world. With 28 offices and a global presence, the PQE Group supports small, medium and large sized organizations in their development and compliance-related challenges with specific capabilities in:



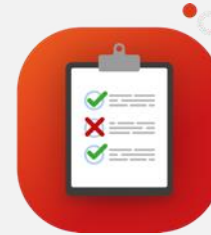
Data Integrity Assurance



Technical Qualification



Quality Engineering



Quality Compliance



Training



Digital Governance



Laboratory Excellence

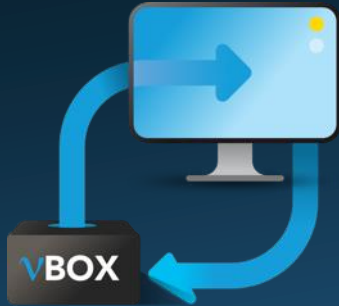


Regulatory Affairs



Audits

# Advanced Remote Service Technologies



Remotizer  
vBOX

Designed to allow full and secured remote control of customer standalone workstations (fully plug and play).



PQE  
Smart Glasses

AR wearable glasses aimed to share video, files and establish audio channels with remote operators, ideal for remote audits and assessments.



**PQE** ALM  
Application Lifecycle  
Management

ALM is a SW platform that manages all the validation tasks paperless (waterfall & agile), providing same functionalities allowed by HP/Microfocus ALM.

# Support to regulated agencies



EUROPEAN MEDICINES AGENCY  
SCIENTIA MEDICINAE MORBIA

## EMA

- Qualified as Computer System Auditor
- Comments to GMP Annex 1 (in PDA)



Comisión Federal para la Protección  
contra Riesgos Sanitarios

## COFEPRIS Mexico

- GMP rule update
- Computer Validation & Data Integrity Training to Inspectors



ГМАС  
и ИИ

## GILS Russia

- Data Integrity Guidance
- Computer Validation & Data Integrity Training to Inspectors



AGENZIA ITALIANA DEL FARMACO

## AIFA Italy (part of EMA)

- Computer Validation Training to Inspectors



agencia española de  
medicamentos y  
productos sanitarios

## AEMPS Spain (part of EMA)

- Computer Validation Training to Inspectors



## DIGEMID Peru

- Computer Validation & Data Integrity Training to Inspectors



Instituto de  
Salud Pública  
Antonia Brindley  
Gobierno de Chile

## ISP Chile

- Computer Validation & Data Integrity Training to Inspectors



## ANVISA Brazil

- Laboratory Computer Validation Training to Inspectors & Regulatory reviewers



## Ecuador

- Computer Validation & Data Integrity Training to Inspectors



## SP Dominican Republic

- Computer Validation & Data Integrity Training to Inspectors

# A Globally awarded company



## Champion Enterprise Award

(2018 – 2019 – 2020 – 2021)

by ITALY POST and L'Economia (weekly financial magazine by Corriere della Sera), placing 9th place among 500 fastest growing companies in Italy.



PQE Group received the **“Special Mention” and a nominee in the “100 Italian Excellences” 2018 Manual**, recognizing the companies who, through their work, allow Italy to be considered a synonym of excellence in the world (under the patronage of the Presidency of the Council of Ministers of Italy).



Named for two years in a row (2018 & 2019) among the

## Excellent Companies

in Italy according to the research conducted by the Osservatorio PMI carried out at Global Strategy.



Financial Times: Among

## FT 1000 Fastest Growing Companies in Europe



London Stock Exchange Group's: Among

## #1000 Companies to inspire Europe

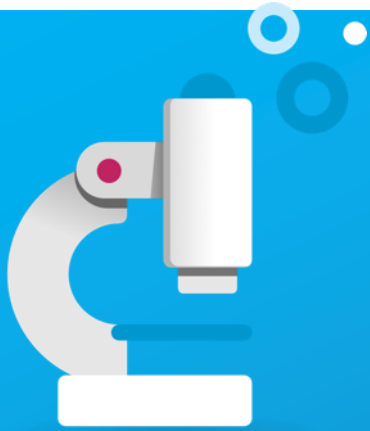


**2nd** Europe's most active pharmaceuticals professionals on social



winner of the 4<sup>th</sup> edition of the **“Best Managed Companies Award”** an initiative promoted by Deloitte Private to support and reward Italian business excellence





Future comes from innovation, and innovation strives with information, research and knowledge. As a quality solutions provider, we undertake specialty Research & Development Projects aside our core services to sustain initiatives with a high value for the Life Science industry and overall the global community we live in.



Presented at the CHIST-ERA Projects Seminar and co-funded by the European Union, the SPuMoNI project brings together the expertise of leaders in the pharmaceutical production system, Istituto de Angeli (Fareva), with University partners from Ireland, Greece and Spain. PQE Group coordinated the consortium, allowing the team to reach the project's objective: assess data produced by computerized systems using Blockchain, Big Data Mining and intelligent software technologies in order to design a compliant quality model, identify behavior patterns that may violate ALCOA+ premises and, finally, develop a prototype system that can improve the pharmaceutical manufacturing industry.



With the recent global health crisis, our community has been flooded with unverified news. Having the privilege of working with scientific graduates and PhD as our consultants, PQE Group has taken on the social responsibility of conducting an in-depth research work to evaluate and verify facts and myths about the current pandemic, engaging in the scientific divulgation process with easy publications for the general public to understand.

# Corporate Social Responsibility

Everyday at PQE Group, employees and managers work together at all levels to foster a positive change in community, environment, and in the Life Science industry as well.

To do so, we promote Corporate Responsibility, ethical behavior, business practice and a culture based on respect of people and environment.



# Our educational programs



Knowledge and constant learning is a key element, our aim is to help our employees to reach success expressing their full potential and talents.

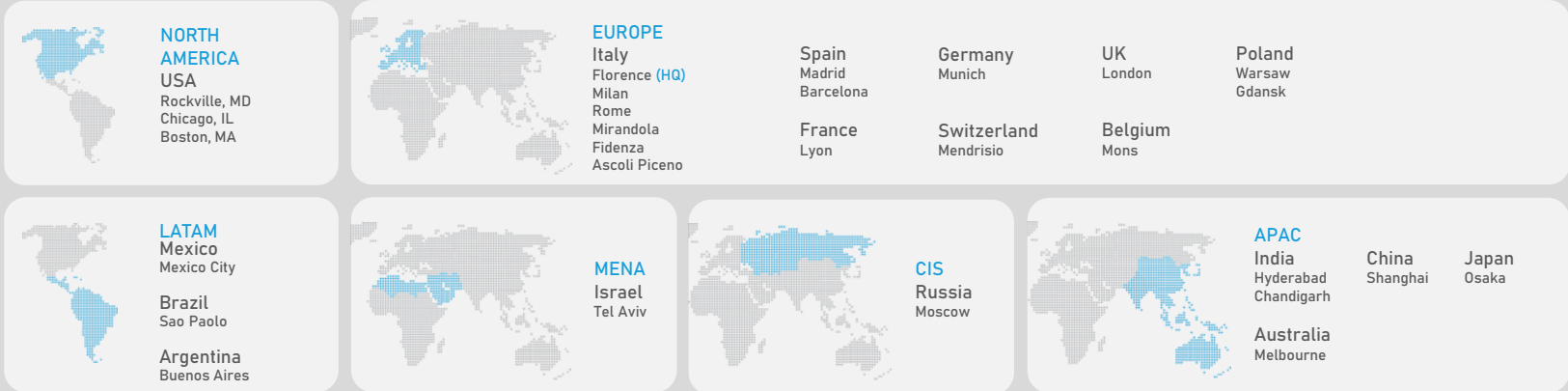
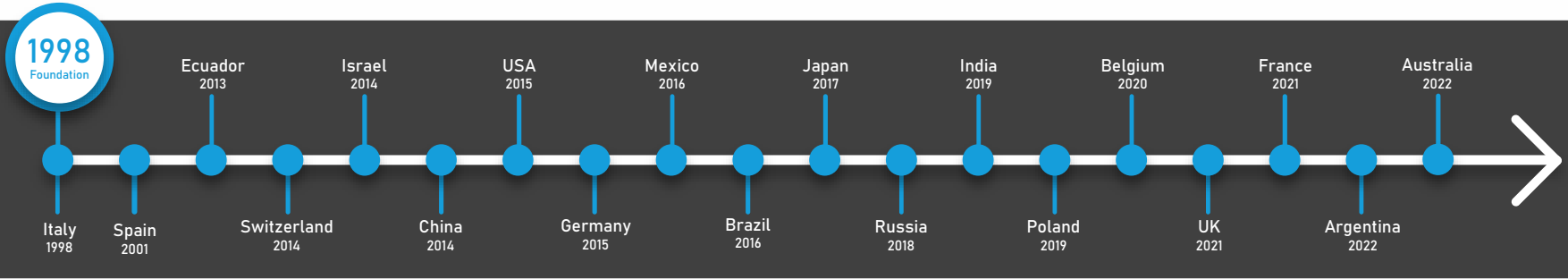
A photograph of a modern interior space, likely a meeting room or lounge. The room features a concrete wall and ceiling. In the foreground, several white, modern-style chairs with green legs are arranged. The wall behind the chairs has three horizontal bars of different colors (black, blue, black) with white text on them.

Your  
**Future**  
awaits

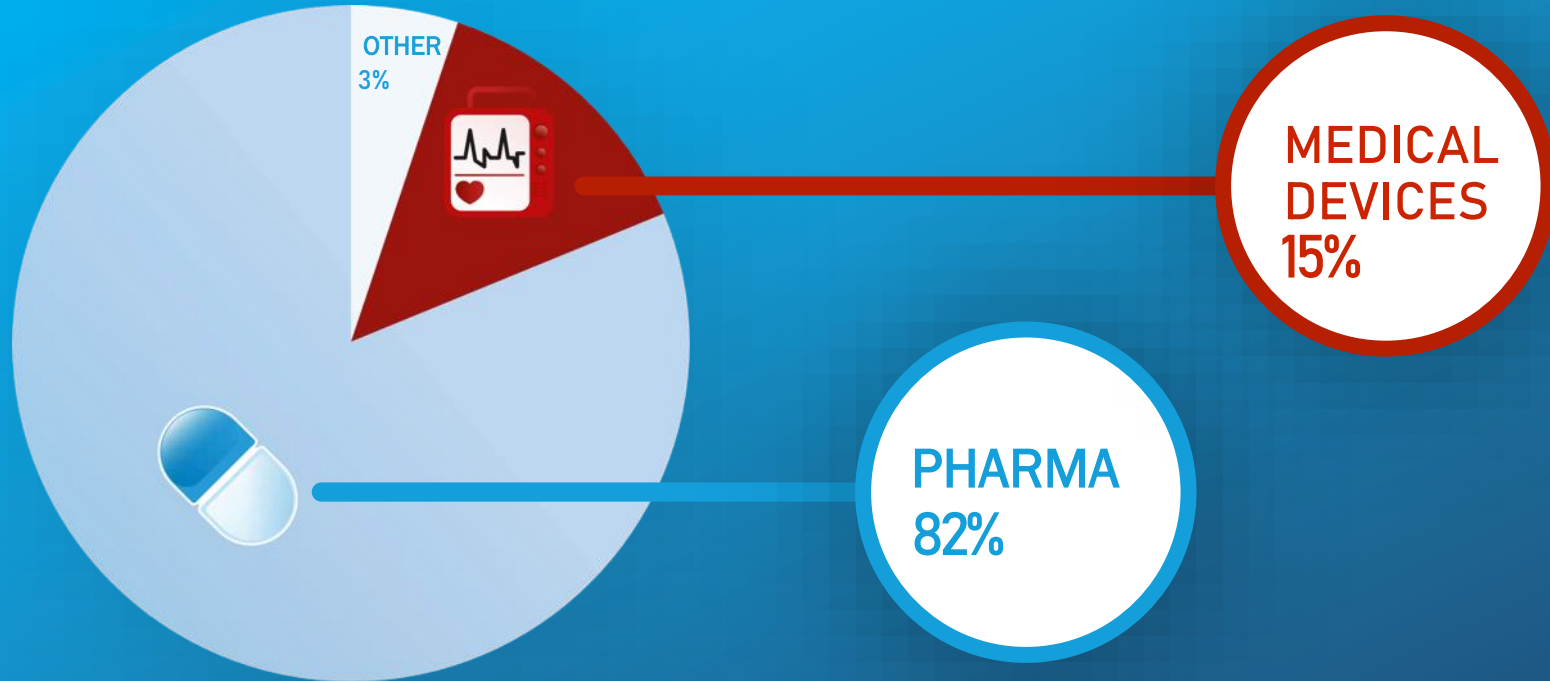
# Our story

CELEBRATING EXCELLENCE SINCE 1998

20+ YEARS OF CONSTANT GROWTH, WITH NEW OPENINGS ALL OVER THE WORLD.



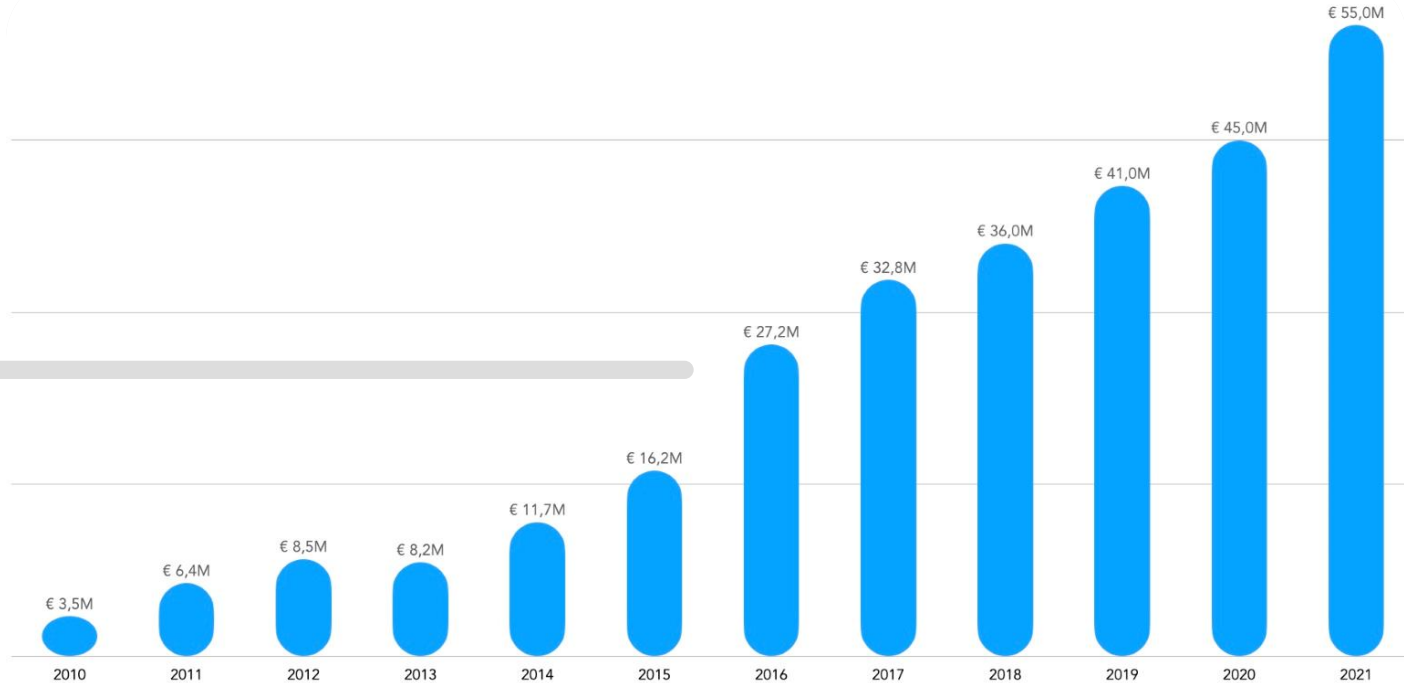
# Our business scope



# Constantly growing revenues

10X CORPORATE REVENUES IN A DECADE.

SELLING IN  
MORE THAN  
40 COUNTRIES





**HEADQUARTERS**

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