

A large, curved banner image showing a sunset or sunrise over a landscape. The sun is bright and low on the horizon, creating a lens flare effect. A vibrant rainbow arches across the sky. The foreground shows a dark, silhouetted landscape with some trees. The banner is bordered by a yellow arc at the top and a grey arc at the bottom.

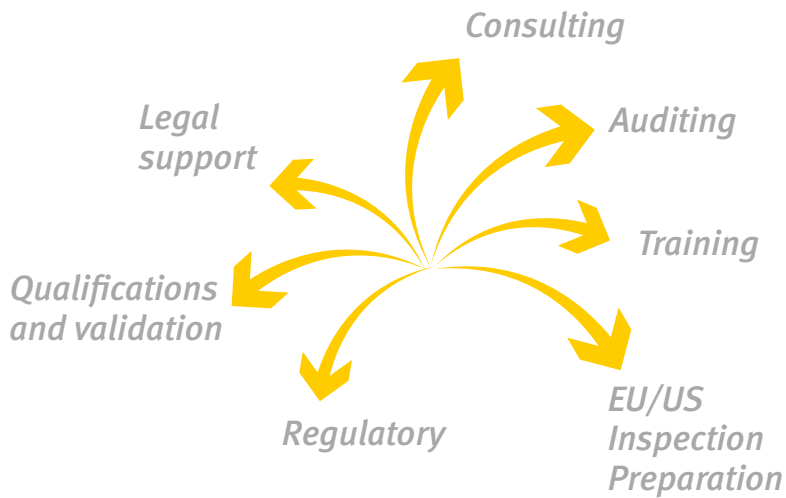
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*Compliance in life sciences*

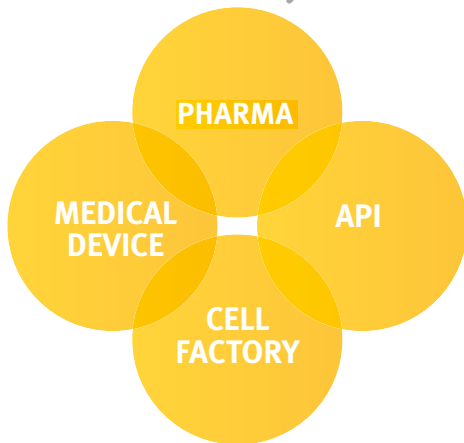
# GMP Specialist

QUALITY SYSTEMS SRL IS A LEADING COMPANY PROVIDING EXPERT EXPERIENCE AND ADVICE IN GXP COMPLIANCE TO PHARMACEUTICAL, CHEMICAL, MEDICAL DEVICE AND COSMETIC COMPANIES.

RELIABLE GXP SUPPORT SINCE 2001.

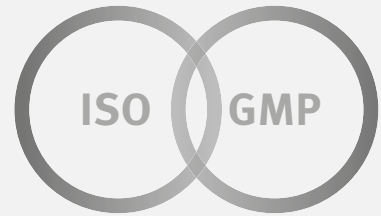


## Areas of expertise



Quality Systems Srl supports Companies with a various and wide training programs and with effective consulting activities.

Depending on your needs QS will be able to find the perfect solutions at the best price.



# Our services

## Consulting

- GMP risk assessment
- Reorganization of QA process
- Writing and review: SOP, VMP, PQR, SMF
- Due diligence

## Training and Seminars

- In house training
- GMP Seminars & Workshops
- GxP courses and soft skills
- GMP Games
- GMP/ISO Auditor Certification

## Regulatory

- Writing CTD for API
- Writing Technical Dossier for MD

## EU/FDA inspection

- Inspection preparation FDA/EU
- Mock Inspection

## Legal support

- International consulting and legal advice from leading law firm offices specialised in pharmaceutical areas

## Auditing

- Third party audit GLP, GCP e GMP Audit
- Internal and supply chain GMP audit

## Validation

- Equipment qualification
- Computer validation and impact assessment
- Cleaning validation
- Monitoring of validation activities and document review



INSPECTION PREPARATION  
AUDITING  
CONSULTING  
TRAINING  
LEGAL SUPPORT

*Our cooperation with international experts (ex-FDA inspectors) guarantees a continuous update of our training materials and our professionals.*

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