QUALITY SYSTEMS Srl is expert in providing support in the preparation of FDA/AIFA inpection to Pharmaceutical, API and Medical Device manufacturers.
Our experience and approach guarantee a timely and cost effective successful inspections.

Services offered by QS:

- Compliance audits and mock FDA inspections
- Definition and implementation of quality assurance programs (e.g., change control, deviation and investigations, employee training, product annual review, complaints, stability, studies, etc.)
- Definition and implementation of validation studies
- Investigation and resolution of compliance and quality problems
- Compliance review of facilities and equipment design
- Development and presentation of employee training programs

QUALITY SYSTEMS Srl offers the best consulting services available, recommending compliance and quality solutions that comply with EU/US requirements without creating significant constraints on the efficiency and effectiveness of your operations.

QUALITY SYSTEMS Srl follows the company in all of the preparation steps to guarantee a successful inspection.

EU/US GMP

Inspection Preparation

- **Pharma** (R&D and market)
- **API**
- **Medical Device**

Specialisti in GMP

V20.1

EU/US GMP Inspection preparation

GMP compliance assessment

First approach to the inspection preparation is the “GMP compliance assessment” to identify gaps between the GMP compliance application in the Company and the “current GMP”interpretations and applications.
At the end of the GMP assessment a prioritised list of recommended actions is issued.
A GMP assessment is also performed, usually one month before the inspection, to check the implementation and compliance of the activities.
This final GMP assessment could be conducted by simulating an actual inspection (“Mock Inspection”) to develop also personnel attitude in approaching the inspectors.

Planning

QS provides GMP activities plan describing tasks, resources and timing to avoid inefficiency and maximise the benefits.

GMP documents

QS supports the company in the preparation of GMP documentation, SOPs, validation and qualification protocols reports and in documents’ review.

Supervision

We can can supervise the progress of the activities required for the inspection by checking their correct completion and monitoring their timing with feedback to the company management.

Inspection follow-up support

QS supports the company in answering to EU/US Authorities observations following to the inspection.

Personnel training

As part of the inspection preparation, QS offers training on specific , topics:

- EU GMP: interpretation and application (pharma manufacturing and R&D)
- US GMP 21CFR 210,211: interpretation and application (pharma)
- US GMP 21CFR 820: interpretation and application (medical device)
- How to prepare/conduct a GMP inspection

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