QUALITY SYSTEMS
Training & Consulting

EU/US GMP Inspection Preparation

Pharma (R&D and market)
API
Medical Device

GMP Specialist

EU/US GMP Inspection preparation

**Quality Systems Srl is expert in providing support in the preparation of FDA / AIFA inspections at pharmaceutical, API and medical devices manufacturers.
Our experience and approach guarantee a timely and cost effective successful inspections.**

*Quality Systems specializes in compliance consultation relating to current GMP regulations and EU/US requirements for drug products and active pharmaceutical ingredients (market and R&D) and Medical Devices. Services offered by QS include compliance audits and mock inspections, establishment and mplementation of quality assurance programs (e.g., change control, deviation and investigations, employee training, product annual review, complaints, stability, etc.), design of validation studies, investigation and resolution of compliance and quality problems, compliance review of facilities and equipment designs, and development and presentation of employee training programs. QS's consultation services and compliance programs are supported by Mr. John Y. Lee – ex FDA inspector. QS offers the best consultation available based on our intimate and current knowledge of EU/US regulations and policy, and industry practices.
Our experience is invaluable in recommending compliance and quality solutions that comply with EU/US requirements without creating significant constraints on the efficiency and effectiveness of your operations.*

GMP Compliance assessment

GMP Activities planning

Personnel training

Our approach to the inspection preparation

Quality Systems follows the company in all of the preparation steps to guarantee a successful inspection.

AIFA

FDA

GMP compliance assessment

Quality Systems 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 completion and compliance of the activities, this final GMP assessment could be conducted by simulating an actual inspection ("Mock Inspection") to develop personnel attitude in approaching the inspectors.

GMP activities planning

Quality Systems provides GMP plans of activities describing tasks, resources and timing.

Personnel training

As part of the inspection preparation, Quality Systems trains personnel in the following specifics topics.
Course material is developed and updated with the support of John Y Lee (former FDA inspector).

- EU/US GMP: interpretation and application (pharma manufacturing and R&D)
- US GMP 21CFR820: interpretation and application (medical device)
- How to prepare an GMP inspection
- How to conduct and FDA / AIFA inspection

GMP Documentation → **Supervision** → **Inspection follow up support**

GMP documents

Quality Systems support the company in the preparation of GMP documentation as SOP, validation and qualification reports and in the review of documents.

Supervision

Quality Systems 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

Quality Systems supports the company in answering to FDA/ AIFA following to the inspection.

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