QUALITY SYSTEMS
Training & Consulting

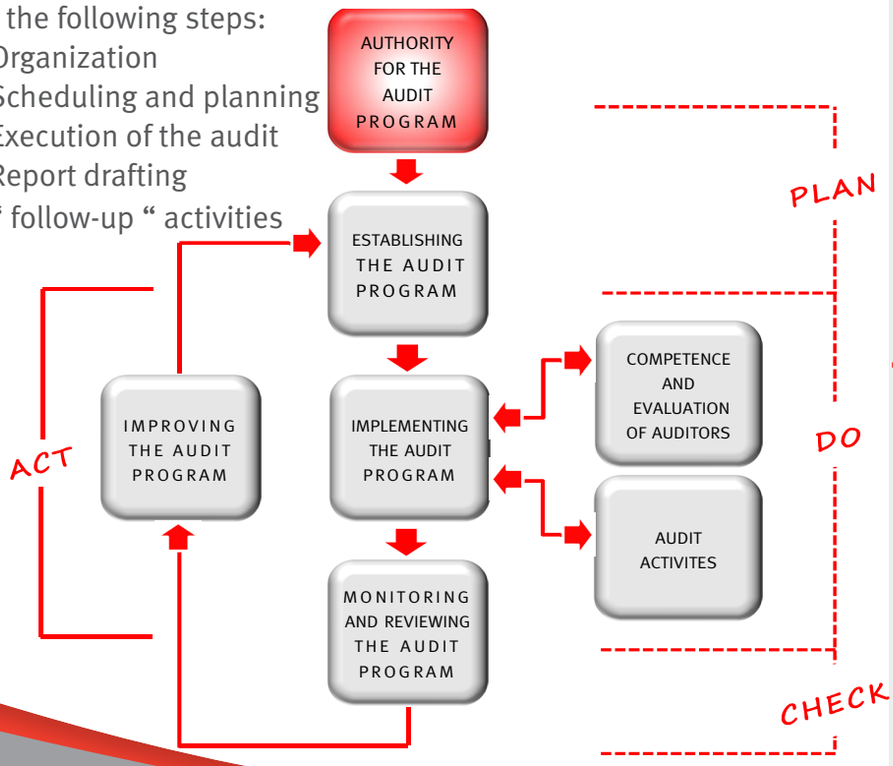
GMP Specialist

GMP Specialist

QUALITY SYSTEMS Srl provides a full AUDITING service of first and second part to Quality Systems of Life Science companies to meet the requirements of internal and supplier qualification as required by regulations and authorities.
We also perform due diligence in view of Merger & Acquisition or re organization.
We conduct audits to the companies' Quality Systems according to the relevant standards in the following areas:

- *Pharmaceutical*
- *Active ingredients*
- *Excipients*
- *Primary and secondary packaging material*
- *Distributors*
- *Biotechnology*
- *Medical Devices*
- *Cosmetics*
- *Supply Chain*

All audits are conducted in compliance with **ISO 19011** according to the following steps:
- Organization
- Scheduling and planning
- Execution of the audit
- Report drafting
- " follow-up " activities



COURSE
FOR
AUDITOR - LEAD AUDITOR OF QUALITY MANAGEMENT SYSTEMS ISO / GMP

(ISO 9001 : 2015 and EU GMP Part I and II)

APPROVED BY AICQ SICEV

Certification Body accredited by ACCREDIA -the Italian Accreditation Body- PRS n° 019C

Our strengths

Quality

Audits to Quality Systems that go beyond the standard criteria analysis and allow to correct and to improve company efficiency and efficacy.

Competence

We provide high quality services with **high added** value solutions. All our services are customized and designed according to the business requirements of each Company.

Confidential agreement and conflict of interest

We guarantee the highest confidentiality and independence in carrying out the assignments. We do not accept assignments in case of conflicts of interest.

Planning

The scheduling activity is carried out based on the needs of Customer to avoid inefficiency and maximize the benefits.
Depending on the purpose of the audit, we define together with the Customer the Audit plan including the agenda, the criteria, the scope of the audit and the items to be audited.
A Quality Agreement is stipulated with the Customer in order to define all the activities and responsibilities of both parties.

Experience

Since 1999 we performed more than 500 audits in EU, US, Japan and emerging countries (mainly in India and China) that consolidate our experience.

Audit Report

Audit Reports are written in English and include details about all the audited areas with classified observations and conclusions.
In particular, the Quality System, the production areas and processes and all the inspected areas are described in detail.
The classification of the observations allows companies to plan adequate follow-up.

Shared Audit

It's possible to conduct a shared audit putting together different companies to optimize audit and travelling costs.
We perform audit to a site considering the needs of each Customer of the shared audit and the audit report can be customized.
We guarantee the maximum confidentiality of the information.

Auditor

Our auditors are industry professionals with training and experience in conducting audits.
Most of the auditors are certified auditor ISO and GMP by AICQ - SICEV .

QUALITY SYSTEMS Srl
Via Vittorio Emanuele II, 3/B
20842 Besana (Milano) Italy

tel. +39 0362 801480
fax +39 0362 941150

www.qualitysystems.it
info@qualitysystems.it