Career Summary

Antonio Santillo

C&Q Manager

Date of Birth:

1965

Nationality:

Italian

Education:

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Qualifications:

Chemical Industrial technical high school

Biomedical and Biological analyst

Language skills:

- Italian: mother tongue
- English: Good written and spoken

Antonio is a consultant with many years of experience (over 30 years) in the chemical-pharmaceutical sector. Technical and managerial skills acquired during the professional career in leading multinational companies in the pharmaceutical industry.

Experienced with laboratories and pharmaceutical plants (APIs and Final Drugs), with good knowledge of critical and non-critical systems linked to the specific areas from a GMP point of view, this allows to follow the main Qualifications activities in the following areas:

- **Laboratory (Chemical and Microbiological) instruments and its Installation/Qualification (i.e HPLC, GC, UV/VIS and FTR Spectrophotometers, Analytical balance, Systems for microorganism testing Biosafety Cabinets, Isolator, Autoclaves etc.)**
- **Analytical Method Validation according USP/ICH guidelines**
- **Laboratory network qualification for data storage and Audit trial.**
- **Computer Systems Validation process in pharmaceutical manufacturing systems developed following the Good Automated Manufacturing Practice GAMP5 and FDA 21CFR11 or European Guidelines (Annex 11)**
- **Commissioning & Qualification activities**
- **Optimization of production processes**
- **Evaluation and feasibility studies of technical-plant engineering solutions in full compliance with the relevant regulations**
- **Supervision of installation, installation and startup of plants and equipment.**
- **Process & Cleaning activities**
- **cGMP / Regulatory Compliance**

Responsibilities and professional assignments

- Develop the project C&Q master plans, identify task lists and project timelines in line with the objectives and goals of the projects, and propose sub-plans to facilitate the C&Q process, and eliminate road blocks.
- Lead the C&Q cost and schedule planning and control process.
- Interface with the project teams to develop the overall C&Q phase project plan and schedule which includes risk assessment, design review/DQ, test matrix, FAT, SAT/commissioning, installation, operational and performance qualification for all systems.
- Work closely with the Construction Management team to align the C&Q program with the construction program.
- Work closely with the R&D and tech transfer team to align the C&Q program with tech transfer and process validation activities.
- Responsible for the C&Q staff plan, hiring, management, mentoring and development.
- Lead the C&Q team (technical writers, commissioning engineers, interfaces to calibration and system owners) and manage day-to-day C&Q activities.
- Work closely with Automation/IT, Quality, and Technology Leads to ensure readiness for facility, process and clean utilities commissioning and qualification.
- Ensuring C&Q program alignment along with engineering best practices. Provide oversight to project contractors to ensure C&Q program are followed per procedures.
- Responsible for project C&Q documentation development and management and quality of the turnover documentation library.
- Managing commissioning and qualification phase improvement (lessons learned, deviation management and resolution, etc.).