



Career Summary

Date of Birth:

1969

Alessandro Gianola

C&Q and Construction Manager

Nationality:

Italian

Alessandro is a Senior C&Q Manager, with a significant background in biotech projects and in design and commissioning of automation systems.

Education:

Politecnico di Milano

He has spent more than 20 years in the pharmaceutical business, having the opportunity to work in almost all typology of pharma manufacturing projects, ranging from bulk, biotechnology, blood fractionation, R&D up to finishing facilities. His typical tasks range from preparation of Validation Master Plan and of qualification (DQ/IOQ) protocols to coordination of pre-validation and validation activities, including site Commissioning and Vendors and Contractors follow up, FAT and SAT activities. Lately he has managed the construction (civil, piping, hvac and equipment installation) of a new Biotech production department.

Qualifications:

Degree in Industrial Technology (Master Level)

Having a specific experience with process and logistic automation field, Alessandro matured a deep knowledge of requirements for qualification of computerised systems and in particular of GAMP and 21CFR Part 11.

Language skills:

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

He also has deep experience in PLC programming (Siemens, Allen-Bradley), LAN architectures and SCADA system engineering.

In the past he has set up a complete Quality System in accordance to ISO9001.

Alessandro is used to manage a working team since he has been a partner of a validation company for more than 15 years.

Alessandro is the owner of Pharmatec srl.



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.).
- Ensure Planning and Construction operations are supportive of the instructional goals of the district.
- Evaluate construction contract documents for compliance with district design guidelines and educational specifications for facilities.
- Assumes leadership and responsibilities for the management of construction projects, project budgetary controls, initiation of change requests on behalf of the district, and review costs and make recommendations for the approval or denial of project change requests