



## Career Summary

**Date of Birth:**

1975

**Tommaso Amore**

**C&Q Manager**

**Nationality:**

*Italian*

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

**Education:**

Pisa University

He has spent 18 years in the pharmaceutical industry, having the opportunity to work in almost all typology of pharma manufacturing projects, ranging from medical device, bulk, biotechnology, blood fractionation, radio-pharmacy, Cell Stem, R&D up to fill/finishing facilities.

**Qualifications:**

Degree in Chemical Engineering (Master Level)

He has managed the engineering and construction (civil, piping, hvac and equipment installation) of new production facilities. His typical tasks range also from preparation of URS, Impact Assessment, Validation Master Plan and of qualification (DQ/IOQ/PQ) protocols to coordination of pre-validation and validation activities, including site Commissioning and Vendors and Contractors follow up, FAT and SAT activities.

**Language skills:**

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

He also had experience in preparing supporting documentation like SOP, Calibration and Maintenance Plan.

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

Tommaso is used to manage a working team since he has been a Project Manager of validation companies for more than 15 years.

## **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.).