S.T.M.I

Quality Validation/Systems Manager

KEY SKILLS

- Validation, process development and transfer,
- Continuous process verification, SPC
- Team management
- Lean Manufacturing
- Troubleshooting/Problem solving
- Regulations: GMP (annex 15), 21CFR211 and 11, ICH
- Risk analysis (FMEA)
- Quality Risk Management
- Quality Systems (deviation, Change Control, CAPA)
- Audits and Inspections
- IT: Pack office, MS Project

PROFESSIONAL CAREER

March 2018-Present
Global Validation Manager-NORGINE. Rueil-Malmaison-France.

- Develop, implement and manage Global Validation Strategy
- Point of leadership for validation practitioners in the facilities, providing education, operational support, technical input and knowledge management to operational teams
- Lead and manage Community of Practice
- Ensure all equipment, facilities, utilities, computer systems, cleaning, processes and products are
- qualified/validated in accordant with cGMP
- Conduct external audits (suppliers, subcontractors)
- Develop policies, Global SOPs and tools to support validation
- Define Global KPI for validation and compliance objectives
- Identify potential compliance gaps, resource constraints, adverse trending

June 2016- February 2018:
Quality Systems Manager-SANOFI (Production of injectable forms) Maisons-Alfort-France.

- Maintain and enhance QMS to assure product quality and safety (Change control, deviations, CAPA, training, quality documentation …)
- Manage the quality systems team (40 employees)

- Lead the site in GxP compliance, ensuring compliance with regulatory requirements, Sanofi directives, standards and guidelines
- Coordinate the site qualification, validation and calibration annual planner
- Manage and perform audit of internal systems and external suppliers, subcontractors and service providers
- Lead the preparation of GMP inspections (FDA, ANSM, ANVISA,…), manage responses and CAPAs
- Coordinate quality training program, ensure that all employees undertake GxP training
- Responsible for Quality Risk Management Process
- Organization and animation of Management Quality Review

October 2012-May 2016
Validation Manager-SANOFI

- Manage Validation Engineers
- Manage the validation life cycle: initial, periodic validation and continuous process verification
- Develop global validation policies and SOPs
- Coordinate and planned validation of the manufacturing site in accordance with the Site Master Plan
- (SMP) including products transfer.
- Contribute to continuous improvement and compliance with regulatory requirements for topics related to validation (process, cleaning, extractables&leachables, etc..)
- Support big and key projects within the plant (new filling line in RABS, new isolators)
- Assure the ability to meet the Department goals in respect to Quality, developing validation KPIs
- Take part in internal/external audits (ANSM, FDA, ...)
- Evaluate change control during committee meetings to define validation and qualification needed

September 2005-September 2012
Quality Auditor and Inspection Manager-SANOFI

- Plan, coordinate and conduct quality audits at the manufacturing site
- Conduct suppliers, subcontractors and service providers audits
- Evaluate the compliance of the site with regulatory requirements, Sanofi directives and internal SOPs
- Identify non-conformance and contributed to the improvement of process by reviewing and approving corrective and preventive actions
- Follow-up CAPA issued from internal audits, group audits and Health Authorities inspections
- Responsible for preparing and managing inspections by Health Authorities (ANSM, FDA, ANVISA,
- Chinese and Uganda authorities, …)
- Train personnel for GMP, internal audits and HA inspection process

April 2005-September 2005
Quality Project Manager-SANOFI

- Coordination of transverse quality projects.

October 2004-December 2004:
Analytical development-SANOFI

- Validation of analytical methods
- Analytical transfers

February 2004-August 2004:
Quality Engineer (Training period of 6 months). A2A Ingénierie. Nanterre-France

- Led and coordinated the Management Quality Systems according to ISO 9001 v2000
- Managed quality documentation, performed internal audits, CAPA follow-up
- Prepare analytical Laboratory for COFRAC accreditation

EDUCATION

- **2003-2004 Master of Science in Control and Quality– Analytical Chemistry**-Cergy-Pontoise University (95-France)

- **2001-2003 Bachelor of Science in Chemical Engineering (Biochemistry option)**-Marne La Vallée University (77-France)

- **1999-2001 University Degree in Chemical Engineering**– Nancy II University (54-France

LANGUAGES

- French,
- English (C1),
- German (basic knowledge)

INTERESTS

- Travel, swimming, body combat