Caterina De Carlo

Contact: caterina.decarlo@qes-consulting.com

Qualification

Master Degree:	**Chemical Engineer**, University of Naples Federico II (105/110, year 2010)
Post Graduate:	University Master "Technologies of Pharmaceutical Industry", University of Siena (10/10, year 2013)
Technical Training:	Lean Six Sigma (2015)

Resume

I have been working for several pharmaceutical companies, marketing authorization holder (Novartis, Kedrion), contract manufacturing (Catalent, Patheon) and consulting (S4BT consultant at DMS, Novartis and COC), reaching a strong knowhow in quality assurance and technical operation mostly for drugs but also for medical devices and cosmetics (Catalent, COC), experience in statistical analysis applied to the manufacturing process (oral solid, soft-gel, sterile liquid and lyophilized) using Lean and statistical tools such as Lean Six Sigma and Minitab®. Team and Project Management experience has been gained during previous and the current roles. English professional proficiency has been achieved by periodic corporate, client and regulatory audit, mostly in the contract manufacturing industries. Recently, I have begun the experience of Trainer as freelance and at education centers about characterization and statistical analysis of manufacturing process (Quality by Design, Risk Analysis according to ICH, Process Validation, CPV, Minitab). Available for permanent role (Lombardy, Switzerland).

Work Experiences

Since June 2015 I am in force at **Patheon SpA** as **QA Head – Validation, CPV, Change Control and Master Batch Record**, as Responsible for the QA Process and Cleaning Validation team (8 employees), CPV team (3 employees), Change Control Team (5 employees), MBR Team (2 employees).

CORE ACTIVITIES

- Aseptic operations for Media Fill Approach definition of the initial validation, routine re-validation and aseptic process changes;
- Process and Cleaning Validation for new products (around 20/year) and legacy product changes (at least 5/year), deviation and complaint handling during the new product introductions. Both for the manufacturing and packaging phase;
- Continued Process Verification (on going process verification) for statistical analysis of the processes in order to assure the state of control during the product life cycle.
- Quality Risk Management;
- Change Control for GMP action plan approval and implementation monitoring;
- Mater Batch Record for manufacturing document management;
- Audit from Corporate, Client and Regulatory Agency (i.e. AIFA, FDA).

DEPUTY QA MANAGER

- Site Quality System improvement participating to the Corporate projects, for issuing the corporate standards;
- Unique Quality Assurance representative in the project for starting-up or revamping of sterile areas.

- Approval of the equipment qualification documents (VMP, URS, IQ/OQ/PQ), and technical assessment;
- Approval of plans and masters for the periodic Calibration and Maintenance activities.

PREVIOUS

- **Validation Engineer at Catalent SpA** (Latina, 2014-2015). My core activities were the approach definition and document writing for equipment qualification, process validation, cleaning validation, periodic instrument calibration, management of junior employees and consultants. Other activities were the technical support for audit, change controls, deviation and CAPA handling.
- **Quality Operation Consultant at S4BT srl** (Latina, 2013-2014) I was project leader and manager for junior consultants. The main projects had been at Novartis for the revamping of packaging department with 5 new lines (equipment qualification and packaging process validation with deviation handling) and the commissioning of 3 tableting machines; at DSM for a new product introduction (process and cleaning validation); at COC for managing the AIFA deviations.
- **Validation Specialist at Haupt Pharma** (Latina, 2013) for Process & Cleaning validation, media fill applied to beta and non-beta lactam antibiotics, sterile powder.
- **QA Assistant for Starting up of New GMP Plant at Kedrion Spa** (Siena, 2011-2012) I was the unique QA representative on Site for the start-up of the new GMP plant and product transfer of the plasma derived orphan drugs as spinoff of the Headquarter.
- **QA Aseptic Operation Specialist at Novartis** (Siena, 2010-2011) as quality on the floor for the process compliance check and the support to the production, audit and the deviation management for the aseptic filling and automatic visual inspection.

Technical Skills

Quality: Validation Activities, GMP documentation (SOP, Agreement, Assessment, Master document, training, protocol, Report), Risk Management and tools, Audit, deviation and compliant handling, Quality by Design, Lean Six Sigma with process characterization and statistical data analysis through statistical software (Minitab).
Regulatory (pharmaceutical, cosmetic and Medical Device): EU GMP Vol. 4, US GMP CFR 21, ICH, PIC, PDA, Global Harmonization Task Force on Medical Devices (GHTF), ISO 9001, ISO14644, ISO 22716, ISO 13485, ISO 14971.
Software: Minitab, Microsoft Word, Power point, Excel, Outlook, Project, Trackwise, Sentry, Atlas, SAP, Desigo, LIMS, Mathlab, C++, Mathcad, Sigma Plot, Fluent (CFD), Aspen tech.

Soft Skills

I am able to work cross-functionally, under pressure and goal oriented. I take in care the relationship with my team, through daily technical support and with one to one meeting oriented to provide feedback in order to highlight their strong and weak points than developing the best way for their professional growth. I am able to job with autonomy providing timely and clear feedbacks with a strong leadership attitude.