S.E.A.H

Qualification & Validation Manager

MAIN COMPETENCIES

- **Life cycle validation**
- **Project management**
- **Continuous improvement project management**
- **cGMP**
- **Risk assessment**

EXPÉRIENCE

VYGON

Qualification & Validation Manager janvier 2020 - Present (9 mois) Belgique

Q/V Projects management Planning

Reporting, KP'I

Deviation, CAPA and CC

ERAS Engineering Belgium

Specialist Qualification & Validation For ERAS Engineering Belgium

septembre 2016 - janvier 2020 (3 ans 5 mois) Mont St Guibert Belgium

Qualification project management:

Revamping & green field qualification projects

- Clean utilities
- Process equipments

BOIRON Belgium

Qualification & Validation Sr Specialist (For Real Staffing Group)

février 2016 - juin 2016 (5 mois) Harzé, Liège Belgique

Ensure that all qualifications and validations are performed according to the regulatory and customer requirements

Coordinate qualification activities

Ensure that all activities are properly documented, in collaboration with users and QA

Write qualification and validation protocols and reports and other documentation related to the activities

Write Validation master plan (VMP), Risk assessment and Gap Analysis Investigate deviations and execute CAPAs

Define and execute improvement projects and initiatives Participate in customer and authority audits

GSK Saint-Amand les Eaux, France

QA Validation for RA Department (for Pauwels Consulting)

décembre 2015 - février 2016 (3 mois) Saint-Amand les eaux, France

In order to prepare FDA submission of filling unit SA03: o Review of: SAT, FAT, IQ, OQ and PQ Files

- Review of notifications files (deviations, CAPA…)
- Report to management default points with corrective and improvement plans

GSK

GQCDI: Global Quality Control Deviation and Improvement Management (By Pauwels Consulting)

février 2015 - septembre 2015 (8 mois) Wavre, Belguim

- Act as a doer and support operations teams in the deviation management: write deviations with the right level of quality, perform root cause analysis using appropriate tools (6M, 5 Why's, problem statement, IS/IS NOT…), define suitable CAPA with internal customers (Production, Technical Services, QA).
- Act as a doer and Implement CAPA; check their effectiveness by performing shopfloor / Gemba / Audit.
- Implement continuous improvement projects linked with root causes of deviation: define solutions with operators, technicians and supervisors, ensure a sustainable and comprehensive implementation of the action plan.
- Carry out trend analysis on recurring problems (linked with deviations), propose a strategy of improvement to fix them.

GlaxoSmithKline

Validation Coordinator C & Q for new Technologies (by Pauwels Consulting)

septembre 2013 - juillet 2014 (11 mois) Wavre

C&Q Validation Coordination

- In the context of investments projects (new or upgrades) in production, ensure proper execution of the C&Q methodology and application of cGMP (Validation Master Plan, Design Qualification, Commissioning, Installation & Operational Qualification and Validation Reports)
- Advice the various actors in case of issues or deviations
- Ensure that all GMP aspects are respected during the project
- Manage the project respecting the established commissioning / qualification timelines and coordinate all actors (Contractors, Engineering, Users) to align them with the project planning
- Chemical Compatibility Expertise
- Manage Chemical compatibility projects, respecting timelines and coordinate actors (users, contractors)
- Provide Scientific Global support to users and GSK SME: review of Chemical compatibility assessment,
- Improvement and/or creation of chemical compatibility documents: SOP,
- Global guideline, Library, Data base
- Writing assessment, Gap analysis and Scientific rational to support chemical compatibility applications

Amaris consulting

Consultant

janvier 2013 - juillet 2013 (7 mois) Bruxelles

- Internal projects
- training: stess management
- training: Project management
- communication tools and applications

Baxter Healthcare

QC Continous improvement coordinator (AMARIS Consulting Belgium)

janvier 2012 - décembre 2012 (1 an) Baxter Biosciences Lessines

Writing SOP

Writing protocls and reports for analytical transfer managing validation QC tests

managing QC tranfert tests Analytical method developpment FMEA, Risk Assessement

NextPharma

QC Stability & Development supervisor (Amaris Consulting Belgium)

août 2011 - novembre 2011 (4 mois) Braine l'alleud, Belgium

Managing all QC activities for Developpement center (PDC)

Stability studies (writing protocols, reports and correction of testing Raw data) Wrinting protocols and reports for analytical validation

Review SOP

managing deviation, OOS reports Managing CAPA

Baxter BDCE (Baxter Distribution Center Europe)

Validation coordinator (Amaris Consulting Belgium) janvier 2011 - juillet 2011 (7 mois) Lessines

Managing validation activities Writing protocols and reports managing validation tests problem solving

GlaxoSmithKline

Support validation at filling department (by Pragmagora consultance)

mai 2008 - mai 2010 (2 ans 1 mois) GSK Bio Rixensart

Support validation:

coordination of project validation (cleaning, equipments, new products, process, autoclaves)

writing of protocols and reports validation coordination of validation testing deviation and CAPA management Problem solving

Institut préparatoire Tunis

Assistante à l'institut préparatoire aux études des ingénieurs de Tunis

octobre 2003 - juin 2006 (2 ans 9 mois)

donner des cours théoriques et pratiques aux étudiants ingénieurs

Galvanoplasty laboratory

responsable laboratoire galvanoplastie janvier 2001 - janvier 2003 (2 ans 1 mois)

Cote d'Or, Tunis, Tunisia

Organize production areas, trouble shoot and resolve issues on the production lines

Assure the right chemical composition of different galvanoplasty continents Personal management (2 teams of 25 persons each)

Medacta Manufacturing

Production Manager

janvier 1999 - novembre 2000 (1 an 11 mois) Tunis , Tunisia

Write and review of standard operating procedure (SOPs) Managing deviations, reviewing and approving batch records Organize production areas from a quality perspective Troubleshoot and resolve issues, on the production lines.

Implement Standard Work on the packaging line Site trainer including induction training

Personal management (20 persons)

FORMATION

- Polytech' Lorraine (ENSIC) & Faculté des Sciences de Tunis

PhD en Chimie organique, Chimie (Equivalence en Belgique: PhD en Science d'ULg) Cefochim- Nivelles. Belgique

(2014 - 2014)

- PNL On line

(2014 - 2014)

- Forem Formation Nivelles

Quality management, Quality assurance · (2007 - 2008)

- Ecole polythechnique de Lorraine+ Faculté des Sciences de Tunis

Doctorat, Chimie · (2001 - 2007)

COMPETENCIES

SAP

GMP

Ms Office

LANGUAGES

Arabe (Native or Bilingual)

French (Bilingual)

Anglais (Full Professional)

Allemand (Elementary)