one step institute

W.E.A.B
Technical Service Manager

PROFESSIONAL EXPERIENCE

Aug 2014 – Present **STERIS CORPORATION – Life Sciences Formulated Chemistries**

Global Technical Service Manager

- Responsible for providing technical support, to (bio)pharmaceutical industries, related to cleaning, disinfectants, sterility assurance and process validation
- Provide interpretation and consultation to the (bio)pharmaceutical industries on regulations, guidelines and standards
- Responsible for audit and audit for cause to support the Customers in their root cause investigations.
- Provide on-site support and customer webinars and seminars
- Provide industrial presentation, workshop, and training at different industrial organizations such ISPE, A3P, PDA, ECA, etc.
- Responsible for supporting new/current product development/support projects and other product and customer related efforts
- Responsible for the collection of market intelligence information including competitive product information and market trends to support STERIS new and current product/market growth
- Lead workshop to improve inspection readiness to regulatory audits, manufacturing process control in non-sterile and sterile manufacturing, contamination control program

Jul 2013 – Aug 2014 **Catalent Phama Solution - Sterile Manufacturing Plant, Belgium**

QA Release / Regulatory Manager & Qualified Person (GMP/GDP)

- Manage a multidisciplinary team of QA Validation, QA shop floors and QA release officers / manager and Regulatory manager for different field operational trouble shooting, release, process / equipment validation, new product introduction (NPI), regulation submission, external / internal audit ...
- Assure responsibility of the pharmaceutical products manufactured on site under EU directive 2001/83/EC (for human), Directive 2001/82/EC (for veterinary) and Directive 2001/20/EC (medicinal product investigation) – Acting as a QP commercial/R&D and QRP.
- Certify and decide on quality and release of all products (human, veterinary, investigational medicinal product, stability and clinical batches) in accordance with the applicable specifications and regulatory requirements
- Challenge, Review and approve critical and major Deviations, change control and market compliants
- Review and approve quality and technical agreement with suppliers, QPs clients
- External audit of suppliers, API manufacturers...
- Lead and propose continuous improvement project as batch record trackers and release process, inter-departmental communication and deviation root cause analysis ...

Jan 2013 - Jul 2013 **GSK Biologicals Vaccine manufacturing plans Rixensart. Belgium**

Change agent Leader - Total Quality Control

- Leader and co -leader on change organization (Total Quality Control) to Improve Performance and processes and reduce cost with a project scope: reduce the lead time of one vaccine production
- Leader and co - leader on several improvement levers as performance, processes and people levers.
- Work in an ADP change framework developed with McKinsey.

Jan 2012 – Dec 2012 **GSK Biologicals - Coupling & formulation business unit, Belgium**

Inspection Readiness Leader

- FDA and EMEA quality standard knowledge Assure to inspection readiness of the production people and building

- Lead several and define the strategy of quality improvement projects (Ex.: Aseptic manipulation, Media & buffer hold time, Cold chain, computer system, autoclave, facility design…)
- SPOC (single point of contact) for the preparation and falling on inspection audit (AFPMS, EMEA, FDA …) for the coupling formulation and business unit
- Train and coach people to be inspection ready
- Review and analyze cGMP gaps to identify / develop response / action plan strategies
- Develop inspection responses to regulatory observations

Jan 2011 - Jul 2013 **GSK Biologicals - Coupling & formulation business unit, Belgium**

Project Manager Leader

- Responsible of project portfolio over than 2MEuro aligned to production, Authorities and Shareholders Demand
- Manage team of project managers responsible of different building and projects
- Develop (70/20/10) and coach my teams in project management, communication, quality management and being accountable to deliver on commitments by putting in place / in use tools Gate
- Manage (MBTI and Emotional intelligence well developed) my own team (leadership empowerment, coaching). Plus, leading several teams Simultaneously by using objective / participative management
- Manage budget- endeavoring to proactively Improve profit ability and reduce cost by Developing and controlling the project finances
- Manage issues and complex situations with clear decision -making Throughout the project lifecycle and put in place action / remedial strategy to reach the target
- Organize and monitor the performance efficiency progress of the project lifecycle management process
- Foster motivation and development of the staff through adequate communication, workout and coaching
- In charge of several Lean and continuous improvement projects (reduction of deviation, Visual Board, Training Package for PMO) with total of profit and avoidance cost more than 400KEuro and 128 FTE days

Aug 2009 - Dec 2010 **GSK Biologicals - support coupling / formulation, Belgium**

Project Manager

- Responsible of project portfolio over than 1MEuro aligned to production, Authorities and Shareholders Demand
- Managing & Developing People within my team and leading several teams simultaneous
- Managing critical interdepartmental communication (teamwork) in between validation, regulatory, quality assurance (local and global), engineering and different suppliers
- Manage project lean manufacturing (shop floor, visual dashboard), continuous improvement (5S, PUCC, …)
- Identify the needs in budget (CAPEX / OPEX) and resources for all projects to be Implemented
- Submit an investment plan and capital requirement needs for new project
- Redact / follow / manage: change controls and validation cycles
- Investigate / solve process / technical anomalies and Deviations
- Train production and support personnel for new Project Implementations (transversal)

Jan 2009 – Jul 2009 **SERVIER industries, Orleans - France**

Transversal Production supervisor & Clean Process

- Manage and Coordinate the optimization and validation of production equipment and clean processes.
- Define validation strategy and budget needs for each project
- Investigate on equipment and process anomalies deviations with QA / maintenance / production team
- Redact change controls and protocols / reports for IQ / OQ and PQ
- Review and approve batch records

Jan 2008 - Jul 2008 **Université de la Méditerranée (Aix -Marseille, France) - Organic Chemistry Pharmaceutical Laboratory - UMR CNRS 6517**

Research Pharmacist

- Research Student, Analytic and organic chemistry, University of Liège - Faculty of pharmacy
- Lead and coach 100 students in practice laboratory work per year

INDUSTRIAL ASSOCIATIONS & ACTIVE MEMBERS

Jan 2014 – Present: **Secretary and Board member of the UPIP VAPI – Benelux**

UPIP-VAPI was a union of industrial pharmacists and Qualified Persons, but in the meantime has adjusted its statutes to become a platform for all pharmacists active in the pharmaceutical industry and for those interested in its activities. The organization has over 300 members from all branches of the pharmaceutical industry. UPIP-VAPI have a clear and progressive view on the pharmacist's goal to guarantee the quality of all products manufactured by a pharmaceutical company. As such, UPIP-VAPI organize different GMP trainings and workshop event with regulators and pharmaceutical industry... For more info, visit our website: http://www.vapi-upip.be/

Jan 2016 – Present **Active participation in different pharmaceutical associations**

GIC A3P (2016): EMA Guidance on sterilization and aseptic manufacturing
UPIP VAPI (2016): lead the workshop for the revision of the EU GMP Annex 1 on Manufacture of Sterile Medicinal Products
PDA (2017): Planning committee member of the 12th USA Microbiology Conference Parenteral Drug Administration (PDA)
EIPG (2017): Co-author of the QP code of conduct
ECA (2017): Member of the Taskforce for the revision of the EU GMP Annex 1 on Manufacture of Sterile Medicinal Products
ISPE (2017): Reviewer of the ISPE guideline on process validation
PMTC (2017): co-author, white paper on manufacturing technology and biopharmaceutical future trends
PDA (2018): Member of the PDA Letter Editor Committee
PDA (2018): Planning committee member of the 13th Microbiology Conference Parenteral Drug Administration (PDA)
ISPE (2018): Observer Member of the ISPE Belgium affiliate
PDA (2019): Planning committee member of the Biomanufacturing Conference Parenteral Drug Administration (PDA)

VOLONTARY WORK

Apr 2018 – Present **QA/QP Coach and trainer**

- Coach and train junior QA/QP to develop robust QA/QP skills and regulatory knowledge
- Understand the QP responsibility and span of control
- Prepare QA/QP to leads regulatory audits
- Support QA/QP on batch assessment and certification
- Coach the trainee to improve investigation and audit skills
- Train and coach the trainee to develop critical thinking, emotional intelligence and soft skills using MBTI approach

TRAINING & EDUCATION

Jan 2012 – Jun 2012	Certified as Project Manager - MS project: Green Belt certified for the project "reduce by 36% the number of deviation falling on project management with profit more than 317KEuro and a reduction of 128 FTE days"
Sep 2008 - Dec 2008	Interuniversity Master degree in pharmaceutical industries - University of Liège Production process knowledge / quality / regulatory / galenic / marketing / pharmaceutical management.
Sep 2003 - Jun 2008	Degree in pharmaceutical science - ULg (Mention: Very good, second ranked in year)

UNIVERSITY LINK

Sept 2018 – Present	Assistant teacher for the complementary master's degree in pharmaceutical industries "CMC and eCTD" - University of Brussel/Liège/Louvain
Sept 2016 – Present	External teacher for the master degree in pharmaceutical industries "pharmaceutical and project management" - University of Liège
Sept 2015 – Present	External teacher for the master degree in Radio pharmaceutical «quality Assurance and pharmaceutical management » - University of Liège

PUBLICATIONS

1. El Azab W., 2016, Investigation of Microbiological Contamination in Water Systems: a Case Study. In: Madsen R. and Moldenhauer J., Contamination Control in HealthCare Product Manufacturing, PDA and DHI, Vol. 4, p. 197
2. El Azab W., Impact of the changes to the European Good Manufacturing Practice on Cleaning Validation: Part I, GMP Journal, edition April/May, (2016).
3. El Azab W., Impact of the changes to the European Good Manufacturing Practice on Cleaning Validation: Part II – Frequently Asked Questions, GMP Journal, edition Oct/Nov, (2016).
4. El Azab W., Water Types and Microbial contamination/biofilm generation, PDA letter, edition February 2017
5. El Azab W., Les nouvelles exigences des bonnes pratiques de fabrication européennes concernant la validation du nettoyage, A3P La Vague, Edition September 2017
6. El Azab W., The New European Good Manufacturing Practice requirements regarding Cleaning Validation, PDA chapter Midwest, Edition April 2017
7. El Azab W., What a Qualified Person Must Know About the Recent Cleaning Validation Update?, EQPA Newsletter, edition June 2017
8. Tidswell E. and El Azab Walid, Recurring microbial contamination is still a challenge for the pharmaceutical industry, PDA journal, edition September 2017
9. El Azab W., Cleaning and disinfection program part of the lifecycle approach: a risk-based rather arbitrarily imposed approach, GMP Journal, edition Jan/Feb 2018
10. El Azab W., What Annex 1 Means for Sterilization and Moist Steam, PDA letter, Edition September 2018

INFORMATICS SKILLS

- Pack office, Access, SAP,
- Track Wise, JDE Edwards,
- Documentum, MS project,
- leadership impact, MBTI Training

LANGUAGES

- **French** - Fluent
- **Arabic** - Fluent
- **English** - Fluent
- **German** - School Level