one step institute

S.T.J.I

QA/QC Consultant and Trainer

PROFESSIONAL EXPERIENCE

June 2018 to present
QA/QC Consultant and trainer

Providing Quality Management Expertise & Customized Training :

- Internal process and quality system audits/assessments
- GMP customized trainings, including new/updated Quality regulations, specific regulations and related Quality management topics
- Audit readiness and support
- GxP Document control
- Standard Operating Procedure (SOP) development and implementation including training (QA & QC)
- Supplier quality and purchasing controls and Qualifications
- Complaints, Deviations, Corrective Action/Preventive Action (CAPA), processes and systems implementation/improvement
- Provide a consultation & build up a new microbiology sections in Pharma and Food, o QC Laboratory equipments installation and qualification including related documentation (Protocols, reports, SOPs…)
- Build up the documents system for microbiology lab for aseptic and not aseptic processing (SOP,Methods ,Logbooks and reports)
- Applying a Quality control for microbiology methods and confirmation testing for results o Handling OOS & applying A CAPA.
- Make inspections for Microbiology lab for assisting and gap solutions
- Assisting a Laboratories for cGMP requirements and for 21 CFR parts 210 and 211 in case of aseptic processing,
- Validation of microbiology methods

Educational Manager at Wanylab , training center

- Adapt a training system management according to pedagogical, social, economic and technical developments
- Define training topics in accordance of the market needs and regulatory and normative up-to-date requirements
- Organize the schedule of activities
- Coach and orientate trainees in their missions

April 2016 to April 2018
Quality Site Head at Algeria SANDOZ SPA/Novartis Technical Operations and CEC team member-Algeria

Quality Control/Quality Assurance/Site Remediation Project Responsible /Novartis Country Executive Committee team member /Quality Support to Sandoz Distribution Center

- Ensure total quality management for the company in accordance with the requirements of the local Health Authorities and Company GMP and Quality standards.
- Novartis Country Executive Committee team member - Quality Country Representative.
- Implement programs to promote quality awareness among the employees at the Algiers site through for example quality training, quality committees, quality audits and GMP inspection.
- Monitor and supervise, via Quality Control Head and supervisors, the activities of quality control, and IPC laboratories where laboratory analysts perform physical, chemical testing of raw materials, packaging materials, intermediates and finished products plus activities of microbiological lab for raw materials, packaging materials and finished products as well as microbiological compliance issues for example environmental, utilities etc.
- Monitor and supervise quality activities via QA Head, Quality Operations, Quality Systems and GMP Compliance and Auditing Supervisors including QA Suppliers managerand e-Compliance&Data Integrity Officer. This includes all compliance activities according to established SOPs and the Company Quality Manual related to validation and qualification of products, facilities, utilities and environment.
- Support QA Manager Commercial Operations including the Distribution Center. This includes all compliance activities according to established SOPs and the Company Manual related to distribution of products, Complaints management, recall and Pharmaco-vigilance QA oversight.
- Support the Qualified person in handling products Release to the market, recall and counterfeit incidences according to Novartis Quality Manual and the MCC requirements.
- Escalation of all incidents that may adversely affect the quality, safety, identity, strength, purity, availability or efficacy of a commercial product and/or may compromise the company Quality System and reputation.
- Coordinate the Recall Committee in Algiers.
- QA Oversight on local compliance concerning the implementation of applicable local Health Authority and internal pharmacovigilence Procedure
- Provide Quality support to Marketing, Legal, and Manufacturing , Sciences and Technologies (MS&T) and Regulatory Affairs
- Put in place and Perform periodic reviews and monitoring of thekey quality performance indicators (KPI) for the Site and propose solutions for improvement. Report in a monthly basis to the SLT and to the Global.
- Responsible for the timely implementation of HSE requirements within the Quality department.
- Support the implementation of Operational Excellence program and deploy PSQDC, DMAIC and LEAN Six Sigma principals and tools.
- Implement and participate to PSQDC TIER1, 2, 3 at department and site level with an effective follow up of the CAPA to reach excellence.
- Sponsor Green Belt project in QA department and ensure GB projects implementation (follow up and tracking)
- Proactively managing people resources &development, talent management and retention, successor's identification and development.
- Budget and expense management in consultation with the Finance function.
- To enforce the Code of Conduct and monitor employees' activities within the spirit of the company's policy.
- Site Advisor for Deviations, Complaints , Out Of Specification Investigation certification

February 2013 to April 2016
HEAD OF QUALITY ASSURANCE & eCompliance at SANDOZSPA- ALGIERS.

- Implement the Company Quality Manual within the assigned Operating Unit including performing the gap analysis for applicable Quality Modules, implementing Standard Operating Procedures and quality processes,
- Establish a Quality Remediation Plan /Workstream, a part of Algiers Remediation Project to provide the framework for the site to meet global and local Quality standards and requirements including follow-up and monthly report to the Global Quality.
- Perform and lead the management of risk assessment programs at site and provide recommendations and solutions to close gaps and ensure sustained compliance with the Corporate Quality Manual requirements.
- Quality organization improvement and optimization to ensure appropriate QA management is in place to cover site activities comply with GMP requirements (Investigations, recall,Training, Supply, Manufacturing, QC activities…), recruit talents and high skilled associates.
- Coordinate and supervise release activities for the Site to ensure products are released and distributed on the local markets in compliance with the local requirements and regulations.
- Release finished goods to the market
- Ensure all complaints/deviation investigations are recorded, investigated and closed in a timely manner.
- Participate to the Recall Committee in Algiers, communicate with site Quality Head on significant quality issues,risks, exceptions, etc…
- Lead training initiatives, support training and team development, and participate in high performing teams in QA Department to support business growth.
- Ensure the implementation of the HSE Guidance in QA department
- Implementation of several Quality software like deviations/Complaints/OOS/Change Control electronic management system "TrackWise" ,"SAP" ERP , Elearning System"SELS", Thirdparty management "PAP3rd Part", …
- Quality data maintainer and Batch info user in SAP (Systems, Applications and Products for data processing)

August 2012 to February 2013
QUALITY ASSURANCE MANAGER AT BIOPHARM INDUSTRIES

November2008 to August 2012
QUALITY OPERATION LEADER AT PFIZER/SAIDALMANUFACTURING-ALGIERS_Quality Control and Quality Assurance

- Batch Release(review batch records and final decision to release)
- Management of the Quality systems (Deviation/Change Management/Complaints/Analytical investigation, GMP Documentation Archive, Procedures, Documentation, Qualification, Process validation...),
- Submission and follow-up of the authorizations and statements to the authorities (The Ministry of Public Health and The National Control Laboratory of Pharmaceutical Products) for New Products, renewal of market authorization and for Lab Reagents/Raw Materials/Packaging Materials annual importation program,
- Internal audit
- Budget management of The Quality department (Budgeting/Variances/Product Cost/Investments/savings/ bi annual budget review& quarterly forecast revenue and expenses)
- GxP Training Management (on-site,web training),
- Self-Inspection and Audit of suppliers, third part and contractors,
- Performancefollow-upofQOemployees-AnnualObjectivessettingandfollow-up,mid year and End year evaluation,
- PointofcontactwiththecorporateandMonthlyMetricsreporttotheQualitycenter,
- Support to QA Pfizer Algiers Distribution Center.

January 2005 to October2008
QUALITY CONTROL SUPERVISOR AT THE QUALITY CONTROL LABORATORY OF PFIZER-ALGIERS

- Planning and management of physico-chemical and microbiological analysis of raw material, packaging components, intermediate product sand finished products inaccordance with the manufacturing program,
- Checking of the generated results and management of the analytical investigations,
- Setting and ordering of reagents, consumables and equipment,
- Laboratory staff management,
- Writing and reviewing the laboratory documentation: Procedures, methods, COA, specifications...
- Training of the laboratory staff on procedures, analytical methods, Good Manufacturing Practices(GMP), Good Laboratory Practices(GLP),Good Documentation Practices(GDP) and Quality-Assurance systems related to the laboratory OOS, Deviation, Validation)

April 2003 to December 2004- MICROBIOLOGIST AT THE QUALITY CONTROL LABORATORY OF PSM (PFIZER-ALGIERS)

- Assay of antibiotics by turbidimetry and diffusion
- Search of dry form microbial contamination (compressed tablet-capsule)
- Physico-chemical and pharmacotechnical analysis: HPLC and UV-VIS spectrophotometric assay, IR, Dissolution.
- Packaging components control (Boxes, inserts, labels, PVC, aluminum foil…etc.)
- HandlinganalyticalandmicrobiologicaltestingofEquipmentcleaningvalidation

October1997toJanuary2003-MICROBIOLOGICALLABORATORYSUPERVISOROF L.P.A, BOUDOUAOU (Algerian Pharmaceutical Laboratory)

- Release/reject of tested incoming materials and/or manufactured products
- Microbial products Stability management (FUST and Lifecycle support of product)
- Ensure adequate planning of routine Microlab testing, stability testing and other Micro-lab related activities (e.g. OOS investigations, analytical transfers)
- Hire and train lab personnel to assure adequate staffing
- Organize good working process with respect to compliance, performance, timing and costs by adequate management of resources (personnel, equipment and costs)
- Ensure all personnel follow HSE requirements

April1995toSeptember1997: MICROBIOLOGIST AT THE QUALITY CONTROL LABORATORY OF L.P.A, BOUDOUAOU (Algerian Pharmaceutical Laboratory)

- Media fill and enumeration testing of imported and manufactured products
- Purchase ,installation and check of equipment
- Purchase and management of reagents and culture media including preparation and growth promotion selectivity tests
- Writing procedures related to Microbiological methods and Equipment instructions.
- Control of raw material, packaging components, bulk and finished products
- Routine Water testing – periodic monitoring (Potable water, purified water) and testing under Performance qualification
- Environment Monitoring (Qualification and routine basis)

September 1994 to March 1995– COLLEGE TEACHER IN NATURAL SCIENCES (Bach-Djerrah College)

TRAINING

- **From September 1992 to June 1993:** end-of-course internship at the National Institute of Public Health (INSP) on food products' control.
- **June 1993: University degree of applied studies in Biology** [Diplôme d'études universitaires appliqués(DEUA)], option: Microbiological and biochemical analysis at the University of Sciences and Technology Houari Boumediene (U.S.T.H.B.)
- **May 1995: Training at "ADWIYA" Tunis, SANOFI AVENTIS partner** on the **microbiological control of non- sterile pharmaceutical products.**
- **June 1995: Computer training at the Algerian Pharmaceutical Company** [Laboratoire Pharmaceutique Algérien (LPA)], on **windows and its applications.**
- **From May to July 2002: Training& certification at the Algerian Pharmaceutical Company** [Laboratoire Pharmaceutique Algérien (LPA)] **on Good Manufacturing Practice (GMP).**
- **October 2003: Training at Pfizer-Morocco on cleaning validation methodology and approach including Analytical part.**
- **November 2003: Training on Good Manufacturing Practice (GMP) and Good Documentation Practice (GDP).**
- **January 2004: Training on chemical methods** (HPLC assay, UV-VIS Spectrophotometric assay, IR identification, TLC (Thin-layer Chromatography), pharmaco-technical tests, and dissolution).
- **October 2003-2004: English learning,"** Global English" lessons;
- **January 2006**: **Training on« Six Sigma, Right First Time» Method** One by Rath & Strong
- **May 2006: Training on «Leadership Situational II »** by Ken Blanchard Companies
- **May 2008: Training on «Human Error Reduction» and «Human Error Investigation & Diagnostics»** by TALSICO
- **May and September 2008: Training on «ISO 14001 Environmental Management System**» by WISAFE
- **March 2009: Training on «Leading Edge II»** by Pfizer Global HR June2009: Training on «Finance for non-finance Managers» by Pfizer Global Finance
- **April 2010: Training on «Lean Laboratory Concept»** by Pfizer Global Operational Excellence OPEX.
- **May 2010: Training on «Change Management»** by Pfizer Global HR
- **May-June 2010: Training on « Right First Time» and «Method Two, Greenbelt »** by Pfizer Global OPEX
- **October 2010: Training on « Development of a training evaluation system»** by Cesi-Algeria.
- **December 2010: Site Auditor training and certification by Manufacturing and Supply Quality Audit MSQA**, Pfizer.
- **May 2011: Training on «Communication & Leadership»** Dale Carnegie Training. PFIZER
- **April 2012: Cornerstones of Management training** «Effectiveness of Leadershi Styles M1" by Hay Group. PFIZER

- **March 2013: Training on "TRACKWISE"** Quality Management System Software: Deviation/ OOS-OOT/ Quality Event/ CAPA/ Technical Complaints/ Audit management - by Global IT SANDOZ.
- **April 2013: Workshop for Site Change Champion**–Quality Culture Change Program-NOVARTIS.
- **May 2013: Training on "TrackWise"** IT Tool to manage Deviation/ complaint/ OOS/ CAPA/ Change Control/ Audit as Super User and System Owner - SANDOZ.
- **February 2014: Training on Learning system "SELS"** as Business Unit Responsible and System Owner-SANDOZ
- **May 2014: Train the Trainer session on Batch Record review and release.** SANDOZ KALWI-India
- **Oct 2013 to April 2014: SAP implementation**–Quality/ e Compliance part - SANDOZ
- **Jan 2015:M1 Leading at the frontline (Leadership management)**-NOVARTIS Global RH
- **Sept 2016: Quality Master Program Module 1** (Company development training modules Drug development, Active Pharmaceutical Ingredient, Drug Product/Finished Product, People)–NOVARTIS Global Training & Learning
- **November 2016: Site certified investigator and advisor for deviations, events, complaints and OOS** by Global QA Sandoz.

PROFESSIONNAL AFFILIATION

- **A3P**Algeria Member
- **Quality Assurance, GMP and ICH Guidelines** group member
- **IFMSA volunteer:** "Talks for Brains" activity, Medical Education Systems program

LANGUAGES

- **French:** Near native / fluent
- **English:** Very good command
- **Arabic:** Native / fluent

COMPUTER

- **Proficient in Microsoft Word, Excel, PowerPoint …**
- **ERP Software** (MAPS, ADONIX & SAP)
- **Quality Systems management software:** Trackwise , eLearning platforms (Plateau , SELS, Up4Growth , LMS)

INTERESTS

- Theatre and cinema
- Hiking in mountain
- Spent time reading books
- Be a volunteer in a charity and not for profit activities