J.B.E.Y

Pharmacist
Master of Quality Management and Pharmaceutical Marketing
QA and Vigilances System expertise

- **10 years experience in the medical device industry** with a solid expertise in device vigilance system (class II/III) applied in the EU, US and CA markets.
- **Solid experience of the QMS processes**: complaint handling unit, non conformities and deviations, CAPA and audits (internals and externals), review and update of procedures.
- **Supporting two FDA projects** (Switzerland and France), and Notified Body certification audits.
- **2 years experiences in digital therapeutics** (SaMD) in building a complaint handling unit and supporting MDR transition.
- Previous training certification of **ISO 9001 auditor obtained from AFNOR organization** on 2013.

REGULATORY ENVIRONMENT

- ISO 13485
- 21 CFR PART 820 / 803 / 806 / 810
- MDR 2017 / 745
- MEDDEV Guidelines (Vigilance System)
- Canadian Medical Device Regulation
- MDSAP requirements

PROFESSIONAL EXPERIENCE

2018 – Today
Contractor (Established Limited Company) : Quality Assurance services for medical devices and pharmaceuticals companies

2017 – 2019
Complaint Handling Manager and Vigilance Leader
Voluntis (France)

- Build up and drive a Complaint Handling and Vigilance Unit
- Improve a complaint handling and vigilance process in view of first launch on the market of Insulia (software as medical device class IIb) in the US
- Act as Vigilance Contact Person for National Competent Authorities in charge of vigilance reporting

- Act as complaint and vigilance SME for internal processes and projects
- Lead reconciliation meeting with medical affairs and support team department
- Manage complaint related to pre-market clinical investigation
- Participate in elaboration of Safety Data Exchange Agreements with Voluntis partners (big pharma)
- Perform trending of the complaint handling and vigilance activity
- Coordinate complaint investigation with the support team
- Review Post Marketing Surveillance SOP to comply with new Medical Device Regulation
- Manage product Recall in the US, Canada, and EU regions

2016 – 2017
Quality Assurance Consultant
Zimmer Biomet (France) – FDA Remediation project

- Part of the complaint handling team work stream in the framework of remediation project with a view of a successful FDA inspection (0 finding)
- Handle medical device (class IIb – class III) complaint files within EtQ database
- Submission of vigilance report to National Competent Authorities in Europe
- Coordinate complaint investigations with dedicated SME
- Conduct Health Hazard Evaluation
- Collaboration in CAPA investigation (root cause analysis (5Y's, Ishikawa Diagram) – preventive and correction action identification)

2013 – 2016
Complaint Handling Specialist
Depuy Synthes (Johnson & Johnson) (Basel) – FDA Remediation project

- Contact and coordination point for market reports (complaints / incidents).
- Legacy review and remediation action of complaint files according to defined protocols.
- Maintaining and Optimizing Fine procedures for receiving, tracking, editing, enclosure and evaluation of messages
- Coordinate all complaint processes received from service centers
- Manage documentation and complaint process using EtQ and SAP software
- Ensure the documentation and their traceability
- Organize and Share information through SharePoint
- Lead of local analysis / statistics and reports demonstrating the resulting improvement potential related to complaint handling process
- Information point for all inquiries regarding complaints reports through Cognos and Webi
- Support for the implementation of Field Actions
- Perform the Device History Review as part of the complaint investigation process as per complaint handling procedure through SAP.
- Point of Reference for France and Russia service centers, supporting the implementation and coordination of Service packs according to the new process
- Put in place KPI related to the Service and Repair Requests handling process, in order to monitor service centers compliance to the procedure and investigators performance.

2013
Quality Assurance Specialist
Allergan France (Paris) – maternity leave replacement

- Handling of local complaints (pharmaceutical and medical devices) though Trackwise and Argus

- Documents system management through Coral
- Review and update of local standard operating procedures
- Training system handling
- Handling of deviation and CAPAs implementation and monitoring through Trackwise
- Performing internal and/or external audits
- Perform training on QA procedure for all new employees

2008
Quality Assurance Specialist Post Marketing Coordinator
Baxter France (Paris) – 4 years

- Local Complaints handling (pharmaceutical and medical devices) trough Pilgrim system
- Answer the safety queries from the healthcare professionals and health authorities
- Manage communication with French MOH through periodic vigilance reports
- Monitor local Product Surveillance related regulations and update as needed local procedure
- Revise and write new procedures
- Participate to internal audits QA aspects, supervise the performance of corrective actions
- Participate to annual internal audit program
- Perform training on relevant procedures to sales forces, customer facing employees, and technician on a yearly basis and every new persons joining Baxter company
- Perform training on complaint handling process to third parties and customers

2008
Quality Coordination of Third Parties through a global database
Sanofi – Aventis (Paris) – 7 months internship

- Within the department of IQC: Industrial Quality and Compliance, as a member of QMTP team: Quality Management of Third Parties
- To make a global update of the situation related to active suppliers of excipient and primary packaging
- To update the third parties audits program
- To update the third parties global database in relationship with Sanofi - Aventis manufacture sites
- To answer the queries from SA manufacture sites

2007
Implementation of a Quality Management System certified ISO 13485:2003
Accuray Europe (Paris – California) – 5 months internship

- To understand and transpose the Quality Management System from the head quarter (Accuray Inc.) based in the USA to Accuray Europe
- To review the different procedures of QMS with the process owner and assess their transposition within Accuray Europe
- To adapt global procedures at a local level in compliance with the European and French regulatory requirements.
- To provide training on validated procedures to Accuray Europe Managers
- To organize internal audit plan preparing the ISO 13485 : 2003 certification

EDUCATION

- **2013 – 2014 _** Thesis for the diploma of Docteur d'Etat en Pharmacie (**Pharm.D**)

- **2011 – 2012 _** Faculté de Pharmacie de Chatenay Malabry – Paris XI (Chatenay-Malabry – 92) _ **M2 Master Pharmaceutical Marketing**

- **2007 – 2008 _** Faculté de Pharmacie de Chatenay Malabry – Paris XI (Chatenay-Malabry – 92) **M2 Quality Management System of healthcare products**, sponsored by Pr. Tchoreloff

- **2006 – 2007 _** Faculté de Pharmacie de Chatenay Malabry – Paris XI (Chatenay-Malabry – 92) _ **Master M1 Medicines and other healthcare products**

- **2002 – 2008 _** Faculté de Pharmacie de Chatenay Malabry – Paris XI (Chatenay-Malabry – 92)

- **2000 – 2002 _** Faculté de Médecine Paris Ouest – Université René Descartes Paris V (Paris – 75)

COMPUTER

- Microsoft Office Pack, Outlook, Visio, Lotus Note, SharePoint
- TrackWise, Pilgrim – PMDA, ARGUS, Catsweb, EtQ, MasterControl,
- SAP, Webi, Cognos

LANGUAGES

- Native: French
- Fluent: English, Arabic (literary)
- Basics: Spanish, German

ACTIVITIES AND HOBBIES

- Member of the Theater association of the Faculté de Pharmacie de Chatenay Malabry de 2005 à 2006
- **Hobbies:** Sport (running, gym, soccer, diving), Cinema, theater, tourism