Curriculum Vitae

Personal information

Stefanie Farrugia

Work experience

Malta Medicines Authority

Senior Head, Compliance Management, Inspectorate and Enforcement – April 2022 – to date

Responsibilities:
- Assisting in the overall running of the Inspectorate and Enforcement Directorate
- Coordination of specific projects such as the implementation of IT infrastructure within the Directorate
- Oversight and review of procedures
- Assisting in decisions related to inspections and enforcement cases
- Supporting market stakeholders to obtain and sustain GMP and GDP licences
- Supporting the team during internal audits

Key Accomplishments:

- Further theoretical knowledge on a more detailed level of local and EU regulations and guidelines and in turn the application to day-to-day issues with various stakeholders
- Supporting staff in various day to day issues
- Fulfilling the implementation of a new database to be used by Inspectorate employees to facilitate the generation of statistics.
- Delegating various tasks to fellow and students assigned to the Inspectorate Directorate
- Planning inspection schedules
- Reporting statistics to higher management

Head of Inspectorate and Enforcement – January 2021 – March 2022

Responsibilities:
- Assisting in the overall running of the Inspectorate and Enforcement Directorate
- Coordination of specific projects such as the implementation of IT infrastructure within the Directorate
- Oversight and review of procedures
- Assisting in decisions related to inspections and enforcement cases
- Supporting market stakeholders to obtain and sustain GMP and GDP licences

Key Accomplishments:
- Further theoretical knowledge on a more detailed level of local and EU regulations and guidelines and in turn the application to day-to-day issues with various stakeholders
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- Fulfilling the implementation of a new database to be used by Inspectorate employees to facilitate the generation of statistics.
- Delegating various tasks to fellow and students assigned to the Inspectorate Directorate

Malta Medicines Authority

Senior Pharmacist – October 2018 – December 2020

Responsibilities:
- Implementation of the new Regulation on Medical Devices (EU) 2017/745 and In Vitro Diagnostics (EU) 2017/746 in Malta as a National Competent Authority.
- Supporting the Quality Department to maintain conformity to ISO standard.
- Assisting in internal audits

DePuy Synthes – Cork, Ireland

Quality Engineer for Customer Quality Global for Power Tools – January 2017 – October 2018

Responsibilities:
- Sustaining the global complaints management system
- Ensuring that critical repair requests are escalated to complaints
- Training service centres and affiliates on Power Tools complaints through repair requests
- GDP and GMP basic re fresher training to different associates world wide
- Supporting service centres from Latin America and Asia Pacific with implementing the new system for service and repair
- Supporting TCS (subcontracting company in India) with entering of complaints and closing off any irregular cases
- Aligning process to regulatory requirements for on time reporting to the FDA
- Assist in implementing and closing off CAPAs and NCs leading to process improvements
- Reviewing late MDR reports and presenting monthly results with root cause analysis and corrective actions

Key Accomplishments:
- Managing staff to ensure the completion of projects and ensuring that they are well trained and understand what they need to do
- Project management

- Improved knowledge on statistical analysis and presentation of data to higher management
- Work load management and prioritization

DePuy Synthes – Oberdorf, Switzerland

Complaints Handling Manager/Consultant for Power Tools – March 2014 – December 2016

Responsibilities:
- Part of a group of consultants setting up a system to track and follow up service and repair complaints on medical devices namely Power Tools
- Training of staff and oversights of parts of a global project of complaint handling
- Supporting service centres from Latin America and Asia Pacific with implementing the new system for service and repair requests
- Supporting TCS (subcontracting company in India) with entering of complaints and closing off any irregular complaints
- Generation of MDR and ADI decision trees
- Creation and submission of Medwatches to the FDA

Key Accomplishments:
- Improved knowledge on medical devices.
- Working with a group Professionals from different countries around Europe enhanced my skills of working in a multi-cultural team.
- Creating a system and sustaining it for people with different backgrounds / languages and ideas was challenging.
- Making decisions and taking a risk based approach when faced with issues during the project.
- Managing staff to ensure the completion of projects and ensuring that they are well trained and understand what they need to do

Mylan Pharmaceuticals – Dublin

Process Engineer / Validation Scientist – September 2013 – March 2014

Responsibilities:
- Coordination of transfers in of new solid dose generic products through to validation and regulatory submission
- Generation of validation protocols and reports
- Review and approval of batch manufacturing records
- Supporting manufacturing in process related investigations
- Uploading and assessing documents on Trackwise
- Preparing documentation and supporting evidence for submission to respective Regulatory Authorities for Tech transfers

Key accomplishments:

- Enhanced knowledge about pharmaceutical processes, equipment and products
- Improved organisational and coordination skills
- Holistic involvement in product transfers between manufacturing sites

Watson Pharmaceuticals - Malta

Product Transfer / Process Support Scientist– October 2011 – September 2013

Responsibilities:
- Coordination of transferring new solid dose generic products to the Malta plant from the initial stages through to validation and aiding in regulatory submission.
- Preparation of risk assessment for new products using FMEA
- Creation of a manufacturing gap analysis comparing transfer site to the site in Malta
- Generation of batch manufacturing records and protocols for optimization and validation batches
- Supervision during optimization and validation batch execution
- Compilation of reports for optimization and validation batches
- Performing investigations following events whenever a particular product is causing repetitive problems for which the root cause is unknown.
- Liaising with all departments for a smooth transfer of a new product on site and launch onto the market in a timely manner.
- Generating and closing off of Events, CAPAs and Change Controls

Key accomplishment:
- Developed organization, management and coordination skills though managing various projects in parallel which also required coordination between various departments
- Improved level of knowledge about machinery and formulation
- Successful transfer of eight new molecules on site
- Successful optimization of two products that by getting to the root cause through thorough detailed investigations.
- Constant support to the Quality and Production Departments when faced with investigations regarding problems encountered during manufacturing
- Developed a better eye for detail and an out of the box way of thinking
- Developed a very systematic way of working to allow for proper management of each project.
- Incorporate quality in every step of a particular project by anticipating potential issues. Taking preventative measures in order to avoid numerous corrections
- Designing the manufacturing process on transfer of a product in a way that keeps in mind product containment, both for health and safety purposes and to reduce losses and contamination.

Pro-Health Ltd. - Malta
Local importer and distributor of medicinal products and cosmetics

Medical Representative – August 2010 – September 2011

Responsibilities
- Visiting medical professionals on a regular bases presenting them with knowledge and updates on a portfolio of medical products
- Organizing events and conferences for medical professionals to discuss specific products
- Preparing presentations and brochures for medical professionals

Key Accomplishments

- Event coordination for Medical Professionals
- Presentation skills
- Developing strong, professional relationships
- Sales and Marketing techniques

Watson Pharmaceuticals - Malta

QC Analyst – June 2010 – August 2010

Responsibilities
- Testing of finished products according to the product method. Depending on the product an array of tests had to be performed and each analyst was given certain tests according to a schedule

Key Accomplishments
- Following lab methods to perform a required test
- Importance of accuracy and precision in all testing which I mastered
- Proper documentation of all steps

October 2009 – June 2010 – Final Year of B.Pharm(Hons.) Degree that required a full scholastic year working full time at a pharmacy to obtain the license of a Pharmacist, followed by final end of course exams and submission of a thesis. My thesis was entitled – Training and Development for Pharmaceutical Industry Personnel.

Arrow Pharm (Malta) Ltd. (later bought by Watson Pharmaceuticals) - Malta

QA Assistant – June 2009 – September 2009

Responsibilities
- Compilation of Annual Product Reviews
- Checking internal audit points and closing them off with the various departments
- Preparation for an FDA audit
- Preparation of stability protocols and checking of stability data while the stability officer was on marriage leave
- Supporting the QA department in preparation of any documentation as necessary

Key Accomplishments
- Experience of several audits including an FDA audit which the company passed through successfully with minor recommendations
- More knowledge about stability systems

Arrow Pharm (Malta) Ltd. (later bought by Watson Pharmaceuticals) - Malta

Production Operator – October 2008 – January 2009

Responsibilities
- Training on all processes from dispensing, granulation, milling, blending, compression, encapsulation and coating so that I could operate the machinery to execute all processes according to the batch manufacturing record.

Key Accomplishments
- Very good understanding of the manufacturing process of solid dosages (tablets and capsules)
- Respect from all production operators for taking personal interest in their work and experiencing it first hand

Arrow Pharm (Malta) Ltd. (Watson Pharmaceuticals) - Malta

QA Assistant – June 2007 – September 2008

Responsibilities
- Coordination of the training system and transferring the paper based training documentation system to a validated online system. During the time I was taking care of training the company doubled in size hence training demands for new employees was high.
- Compilation of Annual Product Reviews
- Supporting the Quality department in various tasks such as preparation of SOPs, Mastering and Cancelling of documents, archiving of documents and retain samples, checking of retain samples and trending of data from batch manufacturing records and product specifications.

Key Accomplishments
- Successful migration of the training system to an online system where better control and traceability of the whole system could be kept by QA.
- Organization of Annual GMP re-training event for the whole company.
- This position gave me a good overview of the whole quality system including a good familiarization with the documentation system and GMP requirements.

Education and training

2022 – ongoing	Pharm D degree with the University of Malta
2012 – 2014	MSc Industrial Pharmaceutical Science Royal College of Surgeons Dublin and Institute of Technology Sligo
2004 – 2010	B.Pharm (Hons.) University of Malta

Additional information

Publications	N/A
Projects	N/A
Memberships	N/A
Other Relevant Information	N/A