



Curriculum Vitae

Personal information **Roberta Agius**

Work experience

1. Employer: Department of Pharmacy, University of Malta
 - Start date: 102017
 - End date:
 - Position: Lecturer
 - Activities:
 - Country: Malta
2. Employer: Malta Medicines Authority
 - Start date: 052018
 - End date:
 - Position: Pharmacokinetics Assessor
 - Activities:
 - Country: Malta
3. Employer: Medicines Authority
 - Start date: 022015
 - End date: 052018
 - Position: Head (Quality, International and EU Affairs)
 - Activities:
 - Country: Malta
4. Employer: Medicines Authority
 - Start date: 102014
 - End date: 022015
 - Position: Pharmacist
 - Activities:

Supporting the Quality Manager to:

Ensure that processes needed for the Quality Management System are established, implemented and maintained.

Report to top management on the performance of the QMS and any need for improvement.

Liaise with the external assessment body on all matters related to the external accreditation process.

Ensure that records are established and maintained to provide evidence that the Quality Management System is being followed and that there is a system in place for the identification, storage, protection, retrieval, retention time and disposition of such records.

Ensure that the performance of the Quality Management System is reviewed at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review means assessing opportunities for improvement and the need for changes to the Quality Management System.

Ensure that Quality Objectives are set by top management for measuring the performance of the Quality Management System and that these are regularly reviewed.

Ensure that all new staff are inducted into the requirements of the Quality Management System related to their own roles and responsibilities and provide updated training as necessary.

Ensure that there is periodic and regular assessments of any customer complaints, any deviations and any corrective and preventive actions, and that consequent improvements are identified and implemented.

Ensure that an internal audit programme is adopted to verify that the Quality Management System conforms to planned arrangements and is effectively implemented and maintained. Ensure that appropriate action is taken when this is not the case.

Co_ordinate continual improvements of the Quality Management System, ensuring that evidence of corrective and preventive actions taken are recorded and reviewed.

Supporting the Licensing Directorate in:

Co_ordination of Mutual Recognition and Decentralised Procedures where Malta is a Concerned Member State including the processing of post authorisation procedures such as variations, renewals and withdrawals.

5. Employer: V.J. Salomone Pharma Ltd.
 - Country: Malta
 - Start date: 112009
 - End date: 102014
 - Position: Regulatory Affairs Officer / Deputy Responsible Person
 - Activities:

Responsible for all issues concerning Health Regulation in line with the importation of pharmaceutical and medical devices and anything related to the importation, selling and distribution of pharmaceutical and medical devices

Responsible for safeguarding product users against potential hazards arising from poor distribution practices

Ensures that the conditions of the Wholesale Dealer's Licence are met and that the guidelines on Good Distribution Practice are complied with

Responsible for the support of all licensing activities

Responsible for the translations of product information of centrally authorised products for new registrations, variations, renewals and MAH transfers

Responsible for the support of registration of new pharmaceuticals and medical devices for introduction into the Maltese market, and the maintenance of all registered products

Responsible for management and maintenance of post_licensing activities in line with local legislation and company specific requirements including all pharmacovigilance issues

- Country: Malta
6. Employer: Actavis Malta
- Start date: 032008
 - End date: 102009
 - Position: Quality Control Specialist
 - Activities:

To review and approve production (tableting and packaging) documents in compliance with Good Manufacturing Practice

To review and approve printed packaging material specifications

To review and approve/reject printed packaging material

To compile Product Quality Review Reports following the reviewing of tableting documents

To ensure that all deviations noted are adequately investigated and documented

To write company Quality Control Standard Operating Procedures

To train company employees on issues that fall under their responsibility

- Country: Malta
7. Employer: Medical Plaza Pharmacy
- Start date: 082008
 - End date: 112012
 - Position: Community Pharmacist (Part_Time)
 - Activities:

Working according to legal and ethical guidelines to ensure the correct and safe supply of medical products to the general public

Maintaining and improving people's health by providing advice and information

Selling over_the_counter medical products and instruct patients on the use of medicines and medical devices

- Country: Malta

Education and training

1. Subject: University of Malta
 - Start date: 102014
 - End date: 092017
 - Qualification: Doctorate of Pharmacy
 - Organisation:
 - Country: Malta
2. Subject: University of Malta
 - Start date: 102013
 - End date: 062014
 - Qualification: Master of Pharmacy
 - Organisation:
 - Country: Malta
3. Subject: University of Malta
 - Start date: 092003
 - End date: 062008
 - Qualification: Bachelor of Pharmacy (Honours)
 - Organisation:
 - Country: Malta
4. Subject: Junior College
 - Start date: 092000
 - End date: 062002
 - Qualification: Matriculation Certificate
 - Organisation:
 - Country: Malta
5. Subject: St. Dorothy's School
 - Start date: 091993
 - End date: 062000
 - Qualification: School Leaving Certificate
 - Organisation:
 - Country: Malta
6. Subject:
 - Start date: 102014
 - End date: 082015
 - Qualification: The following training was provided by the Medicines Authority
 - Organisation:
 - Country:
7. Subject:
 - Start date: 122014
 - End date:
 - Qualification: The following training was provided by the Malta Competition and Customer Affairs Authority

- Organisation:
 - Country: Malta
8. Subject:
- Start date: 022015
 - End date: 042015
 - Qualification: The following training was provided by the University of Malta / CTP Systems
- Integrated Competences
- Organisation:
 - Country: Malta

Additional information

[Publications](#)

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