Curriculum Vitae

Personal information

Sara Camilleri

Work experience

1. Employer: Medicines Authority
   - Start date: 012022
   - End date:
   - Position: Senior Quality Assessor, Licensing Directorate
   - Activities:

   Assessment of Module 3 (Drug Product) of dossiers submitted as Article 8 (line extension) or Article 10 Marketing Authorisation applications

   Assessment of EMA Scientific Advice applications

   Peer review of junior assessors (variations)

   Alternate member of the Quality Review of Documents committee of the European Medicines Agency

   National contact person for the Name Review Group of the European Medicines Agency

   Chair of Assessors' Technical Meetings within the Medicines Authority

   - Country: Malta
2. Employer: Health Products Regulatory Authority
   - Start date: 072018
   - End date: 062019
   - Position: Pharmaceutical Assessor, HPAR
   - Activities:

   Assessment of Module 3 (Drug Product) of dossiers submitted as Article 8 and Article 10 Marketing Authorisation applications (tablets, orodispersible tablets, oral solutions)

   Mentoring of new assessors
   - Country: Ireland
3. Employer: Medicines Authority
   - Start date: 092015
   - End date: 062018
   - Start date: 072019
   - End date: 122021
   - Position: Quality Assessor, Licensing Directorate
   - Activities:

   Assessment of Module 3 (Drug Product) of dossiers submitted as Article 8 (line extension) or Article 10 Marketing Authorisation applications

   Alternate member of the Quality Review of Documents committee of the European Medicines Agency

   National contact person for the Name Review Group of the European Medicines Agency

   Chair of Assessors' Technical Meetings within the Medicines Authority

   Secretariat of the Borderline Classification Committee within the Medicines Authority

   Member of the Prescription Status Working Group within the Medicines Authority

   - Country: Malta
4. Employer: Medicines Authority
   - Start date: 022010
   - End date: 092015
   - Position: Senior Pharmacist, Licensing Directorate
   - Activities:

Co-ordination of Mutual Recognition and Decentralised procedures where Malta is Reference and Concerned Member State, including post-authorisation procedures

Co-ordination of Centralised procedures where Malta is Rapporteur

Co-ordination of Paediatric Worksharing procedures where Malta is Rapporteur

Co-ordination of Clinical Trial Applications

Alternate member of the Quality Review of Documents committee of the European Medicines Agency

Processing of national procedures (variations, renewals, withdrawals, transfers and line extensions)

Secretariat of the Borderline Classification Committee within the Medicines Authority

Writing of Standard Operating Procedures for the Licensing Directorate

Processing of applications in accordance with Article 126(a) of Directive 2001/83/EC

- Country: Malta

5. Employer: Medicines Authority
   - Start date: 072008
   - End date: 022010
   - Position: Pharmacist, Licensing Directorate
   - Activities:

Processing of national procedures (variations, renewals, withdrawals, transfers and line extensions)

Secretariat of the Borderline Classification Committee within the Medicines Authority

Writing of Standard Operating Procedures for the Licensing Directorate

Processing of applications in accordance with Article 126(a) of Directive 2001/83/EC

   - Country: Malta

6. Employer: Government Pharmaceutical Services
   - Start date: 112005
   - End date: 072008
   - Position: Pharmacist, Office of the Responsible Person
   - Activities:

Writing / updating of Standard Operating Procedures

Dealing with medicinal product recalls and defect reports

Liaising with the Medicines Authority

Providing information on medicinal product registration procedures / legislation within the EU

Ensuring Good Distribution Practice within the Government Pharmaceutical Services

   - Country: Malta

7. Employer: Arrow Pharm (Malta) Limited
   - Start date: 092005
   - End date: 112005
   - Position: Technical Services Officer
   - Activities:

Assisting in the preparation of validation protocols and reports

Updating of Batch Manufacturing Documents following validation

Updating of company monographs and methods as per pharmacopoeial updates

Assisting in preparation of testing methods / specifications in accordance with product registration dossiers

   - Country: Malta

Education and training

1. Subject: University of Malta
   - Start date: 092000
   - End date: 062005
   - Qualification: Bachelor of Pharmacy (Honours)
   - Organisation:
   - Country: Malta
2. Subject: International Centre for Parliamentary Studies
   - Start date: 052013
   - End date:
   - Qualification: Professional Certificate in Regulatory Affairs
   - Organisation:
   - Country: United Kingdom
3. Subject: Kings College, London
   - Start date: 052012
   - End date: 042016
   - Qualification: Postgraduate Diploma in Drug Development Science
   - Organisation: Drug Development Pharmacology, Regulatory Affairs, Exploratory Development, Preclinical and Clinical Development, Drug Safety and Ethics, Health Technology Assessment, Marketing
   - Country: United Kingdom

Additional information

Publications

Projects

Memberships

Other Relevant Information