

Curriculum Vitae

Personal information **Audrey Sultana**

Work experience

1. Employer: Malta Medicines Authority
 - Start date: 092011
 - End date:
 - Position: Clinical Assessor
 - Activities: Assessment of European and National procedures as well as variations and renewals Assessment of Bioequivalence studies Provision of scientific and regulatory advice Alternate member of the Scientific Advice Working Party Observer at the Pharmacokinetic Working Party Member of the Prescription Status Working Group 2012_ Present day
 - Country: Malta
2. Employer: MHRA (UK)
 - Start date: 012008
 - End date: 082011
 - Position: Pharmaceutical Assessor
 - Activities: Pharmaceutical assessment of new applications for, or variations to, Marketing Authorisations, including the preparation and updating of good quality assessment reports, within target assessment times. Supporting and managing the progress of all European procedures including Centralised, MRP and DCP applications where UK is Rapporteur, Co_rapporteur, RMS or CMS or where a voluntary assessment is required. Provision of scientific advice to applicants and of expert advice for the Centralised Procedures and European working parties Mentoring Scientific Specialists within the assessment team. Training in Transformational Leadership by the Oxford Group.
 - Country: United Kingdom
3. Employer: EMA
 - Start date: 032007
 - End date: 122007
 - Position: Contract Agent
 - Activities: Secretariat of the Biologicals Working Party Administration of the Biological Centralised Procedures including Scientific Advice.
 - Country: United Kingdom
4. Employer: Arrow Pharm Malta Ltd
 - Start date: 052003
 - End date: 052004
 - Position: QA Analyst
 - Activities: QA and QC control in the start up of the pharmaceutical company Validation of the purified and potable water system Validation of the first product in order to obtain the Manufacturing License and GMP certificate
 - Country: Malta

Education and training

1. Subject: School of Pharmacy London
 - Start date: 092005
 - End date: 092006
 - Qualification: MSc in Drug Delivery
 - Organisation: Drug delivery, Pharmaceuticals, Pharmacology, Pharmacokinetics Thesis: "Taste Masking of a solution of sodium benzoate" (using the ASTREE Electronic Tongue)
 - Country: United Kingdom
2. Subject: University of Malta
 - Start date: 092000
 - End date: 062005
 - Qualification: Bachelor of Pharmacy
 - Organisation: Thesis: "Validation of a new pharmaceutical manufacturing site"
 - Country: Malta

Additional information

Publications

Projects

Centralised Generic Products: Clinical Assessment Aripiprazole Accord –Marketing Authorisation Application Aripiprazole Sandoz –Marketing Authorisation Application Aripiprazole Zentiva –Marketing Authorisation Application Atosiban SUN – inc. Quality Marketing Authorisation Application Busulfan Fresenius Kabi –Marketing Authorisation Application Capeticabine SUN –Marketing Authorisation Application Darunavir Krka –Marketing Authorisation Application Duloxetine Mylan –Marketing Authorisation Application Efavirenz/ Emtricitabine/Tenofovir Krka –Marketing Authorisation Application Emtricitabine/Tenofovir Krka –Marketing Authorisation Application Lopinavir/Ritonavir Mylan –Marketing Authorisation Application Ritonavir Mylan –Marketing Authorisation Application Tenofovir Zentiva –Marketing Authorisation Application Voriconazole Accord –Marketing Authorisation Application Envarsus –Hybrid Marketing Authorisation Application 90 DCP RMS Procedures since starting my position as assessor but with the UK MHRA and with the Malta Medicines Authority.

Memberships

Alternate Member of the Scientific Advice Working Party Observer at the Pharmacokinetic Working Party Member of the Malta College of Pharmacy Practice Member of the Royal Pharmaceutical Society of Great Britain Registered

Other Relevant Information