EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Alessia Calzolari

Work experience

1. Employer: AIFA
   - Start date: 012010
   - End date:
   - Position: GMP Senior Inspector/API Junior Inspector
   - Activities: Finished products & API GMP inspections
   - Country: Italy
2. Employer: Hospira Italia Srl
   - Start date: 012008
   - End date: 122009
   - Position: Technical Manager
   - Activities: Working in an International Team with EMEA headquarter in UK and Corporate office in Lake Forest (IL) (USA), he was responsible for the Italian suppliers (APIs & FPs) qualification (25%); Responsible for GMP _ GDP compliance (30%); Working with the US Supply Chain Corporate Office as well as the Nijmegen (NL) Supply Chain EMEA headquarter he was responsible for products demand (more than 200 items including drugs & medical devices) (45%). Qualified as: SAP Supervisor (Modules WM – IM – APO & Business Warehouse).
   - Country: Italy
3. Employer: Hospira Italia Srl
   - Start date: 012006
   - End date: 122007
   - Position: Regulatory Affairs Manager
   - Activities: Reporting to the Regulatory Affairs Director, working in an International Regulatory Affairs team with headquarter in UK, he was responsible for drafting the documentation for supporting Marketing Authorisation Application ANDA either via MRP/DCP or Centralised procedures (biosimilar); Variations, Line extensions, Price application. Drafting of Quality Expert Reports. Responsible of the Italian scientific service (registered on AIFA Convegni & Congressi web platform). Responsible for drugs Traceability as requested by Italy Minister of Health (files MOV, FAT & SFR): working with US IT department (IL _Lake Forest) he has developed/validated the SAP transactions for producing traceability files requested by MOH.
   - Country: Italy
4. Employer: Mayne Pharma Italia Srl
   - Start date: 072001
   - End date: 122005
   - Position: Regulatory Affairs Officer
   - Activities: Reporting to the Regulatory Affairs Manager, working in an International Regulatory Affairs team with headquarter in UK, he has actively collaborated in drafting the documentation for supporting Marketing authorisation application (abridged application) for generic drugs either via National or MRP/DCP; Variations, Line extension, Price application. Responsible of scientific service. Supporting Pharmacovigilance Manager in drafting PSURs as well as ADEs reports.
   - Country: Italy
5. Employer: Alfa Intes Srl
   - Start date: 102000
   - End date: 072001
   - Position: Head of Production
   - Activities: Ensuring that drugs are produced and stored according to the GMP; approving the instructions relating to production operations and to ensure their strict implementation; to ensure that the production records are evaluated and signed; to check the maintenance of production department; to ensure that the appropriate validations are done.
   - Country: Italy
6. Employer: Alfa Intes Srl
   - Start date: 042000
   - End date: 092000
   - Position: Quality Control Analyst
   - Activities: Performing chemical analysis of starting materials, packaging materials, and intermediate, bulk and finished products; to ensure that all necessary testing were carried out; drafting specifications, sampling instructions, test methods and other Quality Control procedures; dry heat & vapour steam sterilisation cycles qualification (qualified as KAYE Validator user).
   - Country: Italy

Education and training

1. Subject: NAPLES UNIVERSITY FEDERICO II
   - Start date: 091991
   - End date: 031998
   - Qualification: Bachelor's + Master's degree Chemistry
   - Organisation: Thesis Title: "Sinthesis of giraffe brain ribonuclease into heterologous systems ". The DNA sequence of the brain giraffe RNAase has been cloned either in E.coli (in order to produce enough protein for studying the primary/secondary structure) or into eukaryotic cells (CHO) (with the aim of studying glycosilation structure of the protein).

- Country: Italy

2. Subject: La Sapienza Univesity & AIFA _ ROME
   - Start date: 122013
   - End date: 102014
   - Qualification: Master in Drug Regulatory Affairs Science
   - Organisation: MAA (Pre clinical, Clinical and Quality). Post marketing activities (Pharmacovigilance); HTA, Drug prices & reimbursement strategy.
   - Country: Italy

Additional information

Publications

Projects

Italian medicinal gas working group coordinator ATMP Italian GMP Inspector Group

Memberships

Other Relevant Information

Presentations ▪ Main audit findings during medicinal gas manufacturers GMP inspections – AIFA – Rome Italy 16/03/2011 ▪ Medicinal gas: CTD vs production compliance _ AIFA – Rome Italy 09/11/2011 ▪ Contamination Control – AIFA – Rome Italy 02_05_2012 ▪ Medicinal gas: a review of all major findings during inspections – AFI Rome 15/11/2012 ▪ Oral solid dosage: product development & production _ AIFA – Rome Italy 17/06/2013 _ PIC API Expert cyrcle, Strasburg 19_22/10/2015 "Case study of a joint API Inspection" _ AFI Qualified Person Meeting _ Rome 01/12/2015 "Data integrity: the point of view of Health Authority" _ AIFA Training course for GMP Inspector: "Data Integrity: the most relevant oservation ascertained during inspection" _ Rome 22/01/2016 _ AFI Training course on Data Integrity: "Data Integrity: specific consideration for paper – based systems" _ Rome 11/05/2017 _ AFI Training course on Data Integrity: "Data Integrity: specific consideration for paper – based systems" _ Milan 18/05/2017 _ GMP for ATMP – AIFA Rome 12/03/2018 _ GMP for ATMP – ISS Rome 10_13 June 2019