Curriculum Vitae

Personal information

Floriana Miraglia

Work experience

1. Employer: Agenzia Italiana del Farmaco_AIFA
    - Start date: Oct 2019
    - End date: current position
    - Position: Assessor
    - Activities: Evaluation of module 3 sections of pharmaceutical dossiers submitted for marketing authorisation variations under national procedures, as well as MRP (Mutual Recognition Procedure) and DCP (Decentralised Procedure) when Italy acts as RMS (Reference Member State) and CMS (Concerned Member State). Evaluation of impacted Product Information.
    - Country: Italy

2. Employer: STM Group Srl
    - Start date: Oct 2017
    - End date: Oct 2019
    - Position: QP/RP
    - Activities: QP for Secondary packaging activities in GMP area and issuing of confirmation of partial manufacturing according to GMP Annex 16 requirements. Responsible Person for the local warehouse (Third party warehousing activities including controlled drugs).
      Contact management with customer for both Warehouse and manufacturing plant facilities
      Quality Management System responsible according to ISO 9001).
    - Country: Italy

3. Employer: University of Naples “L. Vanvitelli”
    - Start date: June 2017
    - End date: Oct 2017
    - Position: Pharmacist
    - Activities: Uploading of university suppliers’ contract in SAP. Review of tender specifications related to the items to be supplied. Product codes harmonization in a management system.
    - Country: Italy

4. Employer: Farmaimpresa Group
    - Start date: Jan 2017
    - End date: Jun 2017
    - Position: Quality Consultant
    - Activities: Technical Files preparation for Class I and II Medical Devices. Definition of Risk analysis according to ISO 14971 requirements.
      Support for Quality Management System Processes (Audit to suppliers and customers, complaint and CAPA managements)

- Country: Italy

5. Employer: Hospira Italia S.r.l.
    - Start date: Dec 2011
    - End date: Dec 2016
    - Position: Regulatory Affairs Associate Sr., Quality Manager and QP
    - Activities: Quality Management System Responsible (according to ISO 9001) and Qualified Person (according to article n° 52 – Legislative Decree n°219 - April 24th 2006).
        Co-ordination of the local warehouse/secondary packaging site to manage batch processing priorities and subsequent release on the market (through SAP), according to business priorities.
        Responsible of Medical Devices at Country level.
        Responsible of complaint processing, investigation and CAPA resolution within the three business units (Biological, pharma and medical devices).
        Technical Support for requests on Medical Devices received by the customers. Supervision/coordination of service/support for serialized and non-serialized Medical Devices distributed by the Company.
        Team member of European Audit team to guarantee the compliance of TPM.
        Responsible of specific training on internal procedures and implementation/deployment of Corporate procedures.
        Supporting to the regulatory department in maintenance of the existing Marketing Authorization and coordination with the Company European headquarters for the submission of variations and/or new Marketing Authorization according to various European procedures used.
        Cooperation with the Medical Department for scientific medical responses to customers' queries and in training activities.
        Regulatory/Compliance evaluator in B2B business process for drug products approved according to National procedure.
        From April 2014 to December 2015 member of the Supervisory Board according to Decree 231/2001.
    - Country: Italy

6. Employer: Gaba Vebas (Colgate Palmolive Group)
    - Start date: May 2011
    - End date: Dec 2011
    - Position: Scientific Affairs Manager
    - Activities: Contact management and collaboration with dentistry and/or university hospitals KOL in the North of Italy. Responsible of Scientific presentations and training courses for specific groups of professionals and/or university students. Training activities for sales force, coaching to agents in the field. Marketing support for the design, development and construction of promotional materials (for Cosmetics and Medical Devices); analysis of competitors strategy.
        Quality Management activities related to business processes and pharmacovigilance/surveillance activities for Pharmaceutical products, cosmetics and Medical Devices distributed by the Company. Responsible of issuing the Technical Files according to Decree 93/42/CE and subsequent modification. Responsible of Quality Management System maintenance and compliance to ISO 13485 and 9001.

- Country: Italy

7. Employer: Abbott Srl
    - Start date: Feb 2009
    - End date: May 2011
    - Position: MS&T Regulatory Support
    - Activities: Preparation of CTD dossier (modules 2 and 3) to support finished products registration and renewal. Preparation of technical documentation to support the submission of regulatory variations and to reply to deficiency letters and declarations/evidence required for renewals and new registrations. Preparation and revision of Finished Products and API materials specification in accordance with the main European guidelines. Request for CPP and GMP certificates.
    - Country: Italy

8. Employer: Bristol Myers Squibb
    - Start date: Jan 2008
    - End date: Feb 2009
    - Position: Regulatory Affairs Support
    - Activities: Preparation and review of documents required for international dossiers submission (CTD, Annual Report and DMF) for finished products and the APIs manufactured at the site. Revision and preparation of the documentation for type I/II variations and for marketing authorizations renewal. Preparation of answers to Deficiency Letters received by the FDA and/or other regulatory agencies. Request for CPP Certificates for Export and GMP certificates. Gap analysis and regulatory impact assessment for finished products transfer from other sites. Responsible of issuing the Site Master File related to the Pharmaceutical and Chemical Plants in accordance with EMEA and regulatory guidelines.
    - Country: Italy

9. Employer: Janssen-Cilag
    - Start date: Feb 2007
    - End date: Dec 2007
    - Position: Quality control analyst – stability studies
    - Activities: Quantitative/qualitative analysis on finished products manufactured in the plant. Drafting and updating of the documentation related to the stability studies. Stability samples management and preparation of "Stability Study Report" according to Regulatory requirements.
    - Country: Italy

10. Employer: Keryos Spa
    - Start date: Nov 2005
    - End date: Nov 2006
    - Position: Medical Scientific Advisor
    - Activities: information to general practitioners, pneumologists, cardiologists, urologists and diabetologists, contributing to promote new brands in the assigned territory. Definition and monitoring of the major clients (Specialists, General practitioners and private and public pharmacists). Definition of promotional and training projects for clinicians to promote the corporate image.
    - Country: Italy

11. Employer: Chiesi Farmaceutici
    - Start date: Jan 2005
    - End date: Nov 2005
    - Position: Medical Scientific Advisor
    - Activities: Medical information to general practitioners, pneumologists, cardiologists, urologists and diabetologists , contributing to promote new brands in the assigned territory. Definition and monitoring of the major clients (Specialists, General practitioners and private and public pharmacists).Definition of promotional and training projects for clinicians to promote the corporate image.
    - Country: Italy

12. Employer: Bracco Imaging SpA
    - Start date: Mar 2004
    - End date: Dec 2004
    - Position: Researcher
    - Activities: Synthesis, isolation and characterization of intermediates of pharmaceutical interest (amino-poliols used in contrast agents) deepening and improving knowledge in these areas. Partecipation in regular meetings with colleagues from the American headquarters to present the status of the research.
      Tools: HPLC, NMR, mass spectrometry, UV, IR, common laboratory equipments and consumables.
    - Country: Italy

13. Employer: IRCCS Neuromed
    - Start date: Nov 2003
    - End date: Jan 2004
    - Position: Practitioner
    - Activities: S DNA and proteins extractions from organs of mice, electrophoresis on agarose gel and polyacrylamide, polymerase chain reaction (PCR), Western and Northern blotting, immuno-histochemical assays, colors, optical microscopy and fluorescence spectrophotometric analysis and use of the cryostat.
    - Country: Italy

Education and training

1. Subject: University Guglielmo Marconi
    - Start date: Apr 2024
    - End date: On Going
    - Qualification: II Level Master in “Clinical Research and Medical Affairs: Drugs and Medical Devices”.
    - Organization:
    - Country: Italy

2. Subject: CRAsecrets.com, Yghea CRO
    - Start date: Oct 2017
    - End date: Oct 2017
    - Qualification: "CRA Mission" (CRAsecrets.com, Yghea CRO) 48 hours compliant with Ministerial Decree 15 Nov 2011
    - Organization:
    - Country: Italy

3. Subject: Certiquality
    - Start date: 2016
    - End date: 2016
    - Qualification: Auditor of quality management systems according

to UNI EN ISO 9001:2015.
- Organization:
- Country: Italy

4. Subject: CERMET
   - Start date: 2011
   - End date: 2011
   - Qualification: Auditor of quality management systems according to UNI EN ISO 9001:2003.
   - Organization:
   - Country: Italy

5. Subject: University of Naples (Italy) - Federico II
   - Start date: Oct 1998
   - End date: Jul 2003
   - Qualification: Degree in Pharmaceutical Chemistry and Technology". Final mark: 110/110 cum laude. Dissertation: "Immunomodulants Glycosphyngolipids: stereoselective synthesis of Agelasfina analoguos compounds".
   - Organization:
   - Country: Italy

Additional information

Publications

Projects

Memberships

- April 2012: Recognition released by Italian MoH to be a Qualified Person according to article n° 52
Legislative Decree n°219 - April 24th 2006.
- December 2003: Professional qualification as Pharmacist achieved at "FEDERICO II University, Naples".

Other Relevant Information