Curriculum Vitae

Personal information

Claudia Bernardini

Work experience

1. Employer: Italian Medicines Agency AIFA
   - Start date: 112002
   - End date: 102010
   - Position: Quality Assessor Senior
   - Activities: ☐ Assessor for the evaluation of the Module 3 (CTD) of the Registration Dossiers submitted under National and Mutual Recognition Procedures. ☐ Contact point for Mutual Recognition, Variations and Referral Procedures. ☐ Marketing Authorization Regulatory Affair Expert throughout the current Italian and European legislation. ☐ Regulatory assistance for the submission of new Marketing Authorization Applications. ☐ Advanced Therapies
   - Country: Italy
2. Employer: Italian Medicines Agency AIFA
   - Start date: 102010
   - End date: 022015
   - Position: GMP Inspector Junior and member of the General Direction Segretariate
   - Activities: • Inspection for the evaluation of Good Manufacturing Practice Compliance of Active Substances (API) Manufacturers • Inspection for the evaluation of Good Manufacturing Compliance of medicinal products, gases Manufacturers, Advanced Therapies Manufacturer. • Follow_up activities to oversee the resolution of Inspection deviations from GMP for Active substances, medicinal gases , medicinal products and Advanced Therapies Manufacturers • Evaluation of extension applications for medicinal products manufacturing Ghost writer for the General Director
   - Country: Italy
3. Employer: Italian Medicines Agency AIFA
   - Start date: 022015
   - End date: 042017
   - Position: medical information and advertising Assessor ; GMP Inspector Junior
   - Activities: •Evaluation of documents about medical information and advertising Inspection for the evaluation of Good Manufacturing Compliance of medicinal products, gases Manufacturers, Advanced Therapies Manufacturer. • Follow_up activities to oversee the resolution of Inspection deviations from GMP for Active substances, medicinal gases , medicinal products and Advanced Therapies Manufacturers
   - Country: Italy
4. Employer: Italian Medicines Agency AIFA
   - Start date: 042017
   - End date: 022023
   - Position: GMP Inspector Senior and GCP Inspector Senior
   - Activities: Inspector GMP • Inspection for the evaluation of Good Manufacturing Compliance of medicinal products, gases Manufacturers, Advanced Therapies Manufacturer. • Follow_up activities to oversee the resolution of Inspection deviations from GMP for Active substances, medicinal gases , medicinal products and Advanced Therapies Manufacturers and Inspector GCP • Inspection for the evaluation of Good Clinical Practice in Clinical Studies • Follow_up activities to oversee the resolution of Inspection deviations
   - Country: Italy

Education and training

1. Subject: University of Perugia (PG)
   - Start date: 091985
   - End date: 091994
   - Qualification: Degree
   - Organisation: Bachelor in Pharmaceutical Chemistry and Technology
   - Country: Italy
2. Subject: University of Camerino
   - Start date: 091994
   - End date: 111995
   - Qualification: degree
   - Organisation: Bachelor in Pharmacy
   - Country: Italy
3. Subject: University of Pisa
   - Start date: 091996
   - End date: 022000
   - Qualification: PhD
   - Organisation: PhD in Pharmaceutical Chemistry and Technology
   - Country: Italy
4. Subject: University of Perugia
   - Start date: 091999
   - End date: 072002
   - Qualification: Specialization
   - Organisation: Specialization in Hospital Pharmacy
   - Country: Italy
5. Subject: University of Camerino

- Start date: 092002
- End date: 062007
- Qualification: Master Executive
- Organisation: Bioethic
- Country: Italy

6. Subject: University of Sacro cuore _ Policlinico Gemelli
   - Start date: 012015
   - End date: 032016
   - Qualification: Master Executive
   - Organisation: Health Technology Assessment
   - Country: Italy

Additional information

Publications

Projects

Memberships

European Medicines Agency (EMA) London: 1. Alternate delegate to the Co_ordination Group for Mutual Recognition and Decentralised Procedures (CMDh) London 2. Alternate member to the Quality Working Party (QWP) London European Directorate for the Quality of Medicines (EDQM) Stransburg 1. Alternate delegate to the plenary meeting of EDQM

Other Relevant Information