Curriculum Vitae

Personal information

Chiara Acone

Work experience

1. Employer: Medicines Evaluation Board Agency (MEB)
    - Start date: 092021
    - End date:
    - Position: Quality Assessor
    - Activities:
    - Country: Netherlands
2. Employer: Kyowa Kirin
    - Start date: 022021
    - End date: 072021
    - Position: Associate Director Regulatory Affairs
    - Activities: Regulatory Affairs Lead in multi_disciplinary project teams. Develop and execute regulatory strategies. Liaison with Regulatory Authorities (EMA and/ or competent authorities) and preparation of meetings with Regulatory Agencies (e.g. pre_submission meeting and scientific advice). Manage various regulatory applications including variations to Marketing Authorization Applications and Preparation of PIP Modifications.
    - Country: Netherlands
3. Employer: Kiadis Pharma
    - Start date: 122018
    - End date: 012021
    - Position: Associate Director Regulatory Affairs _ RA CMC Lead
    - Activities: Regulatory Affairs CMC Lead in multi_disciplinary project teams. Participate in the design of the Kiadis Pharma product strategy for Cancer Immunotherapeutics (i.e. development of Regulatory strategy and pathways). Develop and execute regulatory strategies. Liaison with Regulatory Authorities (Health Canada, FDA, EMA and/ or competent authorities) and preparation of meetings with Regulatory Agencies (e.g. pre_submission meeting and scientific advice). Manage various regulatory applications (e.g. ODDs, MAA, CTAs and Annual Reports); coordination, preparation and modification of Marketing Authorization Dossier, IND and IMPDs, including reviewing and writing of CMC sections. Provide regulatory support during quality audits, GDP and GMP Inspections. Develop SOPs and drive/provide support to processes continuous improvements projects.
    - Country: Netherlands
4. Employer: Teva Pharmachemie
    - Start date: 082013
    - End date: 112018
    - Position: Team Leader _ Senior Regulatory Affairs Officer
    - Activities: Team leader; responsible for setting priorities, planning and coordinating activities of a team of three Regulatory Affairs Officers and one Assistant. Coaching and motivating team members. Creating of departmental goals and involved in recruitment of new staff. Manage Life Cycle activities relating to licensed products (Oncology and Respiratory) in Europe and other major markets (APAC, Canada, CIS, Japan, LATAM, SEE and US). Act as regulatory point person for (global) project teams on selected projects. Provide regulatory advice within the framework of the company's Change Control procedure. Develop the regulatory strategy and manage the preparation of technically complex regulatory submissions which require extensive interaction with departments outside of Regulatory Affairs (including third_parties) for commercial products (e.g. dossier updates/remediation, addition of new drug substance manufacturers, material and formulation changes). Prepare CMC sections of the dossier of new products developed by other Teva sites and manufactured in Haarlem. Co_ordinate in and out site change projects. Co_ordinate and prepare responses to Health Authorities' deficiencies. Provide regulatory support for business development projects (Including INDs and NDAs). Support product launches. Perform due diligence activities. Maintain knowledge of regulatory requirements up_to_date and communicate changes in regulatory information to project teams and senior management in a timely manner. Liaise with European Submission Centers and Market Regulatory Affairs groups on Regulatory activities. Until March 2016 responsible for submissions in EU (DCP, MRP and national procedures. Provide regulatory support during quality audits and GMP Inspections. Develop SOPs and drive/provide support to processes continuous improvements projects
    - Country: Netherlands
5. Employer: Novartis Vaccines & Diagnostics (NV&D)
    - Start date: 042013
    - End date: 072013
    - Position: RA Franchise Senior Specialist, Flu Franchise
    - Activities: Prepare, coordinate and having responsibility for the preparation of regulatory submissions such as clinical trials applications, IND submissions, variations, renewals, support for marketing applications in EU (Centralized Procedure). Act as regulatory point person for (global) project teams on selected projects, draft regulatory sections of project plans and Scientific Advices. Provide regulatory advice within the framework of the company's Change Control procedure.
    - Country: Netherlands
6. Employer: Teva Pharmachemie
    - Start date: 012008
    - End date: 032013
    - Position: Regulatory Affairs Officer
    - Activities: Manage Life Cycle activities relating to licensed products in Europe and other

major regions. Act as regulatory point person for global project team on selected projects. Provide regulatory advice within the framework of the company's Change Control procedure. Develop the regulatory strategy and manage the preparation of technically complex regulatory submissions which require extensive interaction with departments outside of Regulatory Affairs for commercial products (e.g. dossier updates/remediation, batch size increases, addition of new drug substance manufacturers and dossier updates). Co_ordinate in and out site change projects. Evaluate New Potential API sources. Provide regulatory support for business development projects (Including INDs and NDAs). Responsible for submissions in EU (DCP, MRP and national procedures). Co_ordinate and prepare responses to Health Authorities' deficiencies. Maintain knowledge of regulatory requirements up_to_date and communicate changes in regulatory information to project teams and senior management in a timely manner. Liaise with (other) European Regulatory Affairs & Corporate groups on Regulatory issues. Provide regulatory support during quality audits and GMP Inspections. Develop SOPs and drive/provide support to processes continuous improvements projects.
    - Country: Netherlands
7. Employer: Solvay Pharmaceuticals
    - Start date: 072007
    - End date: 112007
    - Position: Sr Pharmaceutical Engineer/PAT(Process Analytical Technologies)
    - Activities: Involvement in development of PATs
    - Country: Netherlands
8. Employer: Organon NV
    - Start date: 092006
    - End date: 032007
    - Position: Internship as part of the "Leonardo da Vinci program Unipharma Graduates 2", promoted by University of Rome "La Sapienza" and Noopolis
    - Activities: Study of demixing potential and segregation tendency of powders and granules
    - Country: Netherlands

Education and training

1. Subject: University of Naples "Federico II", Faculty of Pharmacy
    - Start date: 091999
    - End date: 102005
    - Qualification: Master Degree in Pharmaceutical Chemistry and Technologies
    - Organisation:
    - Country: Italy
2. Subject: University of Naples "Federico II", Faculty of Pharmacy
    - Start date: 122005
    - End date: 122005
    - Qualification: Qualification as Pharmacist
    - Organisation:
    - Country: Italy
3. Subject: BIG Register
    - Start date: 082022
    - End date: 082022
    - Qualification: Qualification as Pharmacist
    - Organisation: Qualification as Pharmacist in the Netherlands (BIG number: 19910450217); Initial registration 2008
    - Country: the Netherlands

Additional information

Publications

Projects

Memberships

Other Relevant Information