EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

PERSONAL INFORMATION

Chiara Acone

WORK EXPERIENCE

September 2021- Present

Quality Assessor

Medicines Evaluation Board Agency (MEB) (Netherlands)

February 2021-July 2021

Associate Director Regulatory Affairs

Kyowa Kirin (Netherlands)

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.

December 2018-January 2021

Associate Director Regulatory Affairs - RA CMC Lead

Kiadis Pharma (Netherlands)

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.

August 2013-November 2018

Team Leader - Senior Regulatory Affairs Officer

Teva Pharmachemie (Netherlands)

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 companys 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

April 2013-July 2013

RA Franchise Senior Specialist, Flu Franchise

Novartis Vaccines & Diagnostics (NV&D) (Netherlands)

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 companys Change Control procedure.

January 2008-March 2013

Regulatory Affairs Officer

Teva Pharmachemie (Netherlands)

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 companys 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.

July 2007-November 2007

Sr Pharmaceutical Engineer/PAT(Process Analytical Technologies)

Solvay Pharmaceuticals (Netherlands)

Involvement in development of PATs

September 2006-March 2007

Internship as part of the Leonardo da Vinci program Unipharma Graduates 2, promoted by University of Rome La Sapienza and Noopolis

Organon NV (Netherlands)

Study of demixing potential and segregation tendency of powders and granules

EDUCATION AND TRAINING

September 1999-October 2005

Master Degree in Pharmaceutical Chemistry and Technologies

University of Naples Federico II, Faculty of Pharmacy (Italy)

December 2005-December 2005

Qualification as Pharmacist

University of Naples Federico II, Faculty of Pharmacy (Italy)

August 2022-August 2022

Qualification as Pharmacist

BIG Register ()

Qualification as Pharmacist in the Netherlands (BIG number: 19910450217); Initial registration 2008

ADDITIONAL INFORMATION

Expertise

Publications

Projects

Memberships

Other Relevant Information