Curriculum Vitae

Personal information

Marie Valentin

Work experience

Since Sept 2023 World Health Organization Geneva, Switzerland

Team Lead, Facilitated Product Introduction

- Manage and coordinate the technical activities of the Facilitated Product Introduction Team (FPI) Team: coordinate work plans, budget and resources, reporting to donors and resources mobilization, support regulatory system strengthening activities.

- Manage, strengthen and expand the WHO Collaborative Registration Procedure as a reliance mechanism to facilitate and speed-up registration of quality-assured medical products in countries.

- Coordinate other reliance pathways, mechanisms and approaches to facilitate product introduction in countries and regions: support and promote global health procedures in collaboration with the European Medicines Agency and Swissmedic and regional joint assessment procedures (ASEAN and in Regional Economic Communities in Africa).

- Support capacity building in countries for marketing authorization assessment and reliance mechanisms, including in case of public health emergency: support the implementation of the reliance concept, including in case of emergency and relevant training and capacity building for marketing authorization assessment in countries.

May 2019 – Aug 2023 World Health Organization Technical Officer

- Regulatory System Strengthening by supporting and providing technical support to WHO Member States National Regulatory Authorities and Regional Regulatory Harmonization Initiatives in regulatory matters related to medical products.

- Promote regulatory reliance, cooperation, convergence, harmonization and work-sharing in the area of medical products through the provision of technical expertise and assistance in guidelines development.

- Support improved access to essential medicines more specifically focused on products that are needed for high disease burden in low- and middle-income countries.

- Secretariat for the WHO paediatric regulatory network, a global network of regulators and other interested stakeholders supporting the availability of quality assured medical products for children. Regulatory lead of the Global Accelerator for Paediatric formulations (GAP-f), a WHO led-network which goal is to enhance coordination between partners for an optimal development of formulations for children in need.

- Participate in National Regulatory Authority (NRA) benchmarking as well as in the Regional Regulatory Harmonization Initiatives as part of the WHO regulatory systems strengthening programme.

Oct 2010 – Apr 2019 European Medicines Agency Regulatory Affairs Officer

London, UK

- Provision of regulatory and procedural advice in relation to the development, evaluation and surveillance of medicinal products for human use from early development to post-marketing.

- Provision of regulatory support to the Committee for Medicinal Products for Human Use (CHMP) and its associated Working Parties and expert Groups, the Committee for Orphan Medicinal Products (COMP) and the Paediatric Committee (PDCO)

- Responsible for ensuring co-ordination in the application and interpretation of legislation to the operations of the EMA in co-operation with legal colleagues and where necessary the European Commission.

- Provision of regulatory and procedural guidance in compliance with community legislation to Agency staff, all the Human Scientific Committees and their working parties.

- Responsible for the development of regulatory and procedural guidance through internal and external Standard Operating Procedures and Guidance documents.

Mar 2009 – Aug 2010

Sep 2008 – Feb 2009 Gilead Sciences Ltd., Great Abington, UK

Manager, HIV Products

Associate Manager, Clinical Trial Liaison

- Maintenance of a centralised licence:

o Prepare and manage the relevant variations, line extensions and follow-up measures.

o Ensure the licence is maintained in accordance with MAH responsibilities.

o Provide regional input into the regulatory strategic plan.

- Management and coordination of regulatory activities for several development compounds.

- Support for preparation and management of relevant Paediatric Investigational Plans.

- Coordination and advising role with regards to clinical trial regulatory activities.

- Management of clinical trials across Europe (HIV/AIDS, chronic hepatitis, respiratory diseases and oncology).

- Project management and liaison with Regulatory Authorities, clinical teams and local affiliates.

- Regulatory strategy, responses to questions, amendment and notifications.

- Labelling review.

PPD, Great Abington, UK

Apr 2007 – Sep 2007 Regulatory Affairs Manager

Feb 2006 – Mar 2007 Senior Regulatory Executive

- Clinical trials management:

o Preparation and management of clinical trial applications for the EU and rest of world (mainly New Zealand, Russia, South Africa).

o Investigational Medicinal Product Dossiers (IMPDs) writing and reviewing.

o Regulatory strategy, responses to authorities and labelling preparation.

o Preparation and submission of amendments and notifications.

o Regulatory consultancy to local and internationally based clients.

- Project management and liaison with clinical teams, clients and Regulatory Authorities.

- Marketing authorisations: maintenance activities in Europe (variations and renewals).

- Business development: proposals and bid defences.

Nov 2002 – Dec 2005 Cambridge Regulatory Services Saint Ives, UK

Regulatory Affairs Consultant

- Marketing authorisations: dossier compilation, preparation of module 3, quality and clinical overall summaries, dossier up-date, CTD conversion, work on SPCs, labelling and leaflets.

- Regulatory procedures: variation files, marketing authorisation transfers, appeal documents, involvement in several MRPs and orphan drug applications.

- Project management and liaison with clients, Regulatory Authorities and experts.

- Clinical trial applications: CTA and IMPDs.

- Regulatory intelligence, responses to client regulation queries and translation.

- Work at clients' sites.

Jan – Sep 2002 Laboratoire Aventis, Paris, France Internship

- Management of marketing authorisations (centralised procedure, mutual recognition procedure).

- Preparation of variation files and price and reimbursement files.

- Assessment of promotional documents, leaflets and packaging materials.

May – Aug 2001 Laboratoire Besins international, Paris, France

Internship

- National licensing procedures and mutual recognition procedure.

- Assessment of promotional documents, leaflets and packaging materials.

Jan 2001 GYD Institute – France

- Enrolment and monitoring activities for a pharmaco-economic study in Paris (visits to doctors).

2000 – 2001 Central Pharmacy, Hospital of Lyon – France

- Management of temporary status medicines (released by the French Agency for medicines).

- Dispensation of medicines.

1997 – 2001 Regular work in pharmacies

Education and training

Feb 2005 School of Pharmacy – Université Claude Bernard – Lyon 1 – France

- Doctorate in Pharmacy: Study of the Directive 2001/20/EC (clinical trials) and its implementation in the UK.

2001 – 2002 Pharmaceutical Industry Institute – Lyon (IPIL) – France

- One-year postgraduate degree in Regulatory Affairs and Medicines Regulation (D.E.S.S.).
- Specialisation in pharmaceutical documentation.

Business School of Lyon (EM Lyon).

- Management and marketing course.

1995 – 2002 School of Pharmacy – Université Claude Bernard – Lyon 1 – France

- Six years of pharmaceutical studies with honours.
- Credits "Industrial orientation", "Physico-chemistry and galenic development" and "Biomedical English".

Additional information

Publications

1. Reliance: a smarter way of regulating medical products - The IPRP survey

Published on 23 December 2020

Petra Doerr, Marie Valentin, Nobumasa Nakashima, Nick Orphanos, Gustavo Santos, Georgios Balkamos & Agnes Saint-Raymond

https://www.tandfonline.com/doi/full/10.1080/17512433.2021.1865798

2. Pediatric COVID-19 Therapeutics. Seizing the Right Research and Development Opportunities to Accelerate Access for Children

Published in January 2022

Morin, Sébastien PhD; Lallemant, Marc MD; Garcia-Prats, Anthony MD; Lewis, Linda; Watkins, Melynda BSc Chem; Giaquinto, Carlo MD; Valentin, Marie PharmD; Penazzato, Martina PhD; Reeder, John C. PhD

https://journals.lww.com/pidj/Fulltext/2022/01000/Pediatric_COVID_19_Therapeutics__Seizing_the_Right.11.aspx

3. From paediatric formulations development to access: Advances made and remaining challenges

Published on 18 May 2022

Catherine Litalien, Sophie Bérubé, Catherine Tuleu, Andrea Gilpin, Émilie Kate Landry, Marie Valentin, Robert Strickley, Mark A Turner

https://pubmed.ncbi.nlm.nih.gov/35229891/

4. Reliance is key to effective access and oversight of medical products in case of public health emergencies

Published on 9 August 2022

Agnes Saint-Raymond, Marie Valentin, Nobumasa Nakashima, Nick Orphanos, Gustavo Santos, Georgios Balkamos & Samvel Azatyan

https://www.tandfonline.com/doi/full/10.1080/17512433.2022.2088503

Projects

Memberships

Other Relevant Information