PRAMO MUTTUCUMARU

Senior Director

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ABOUT ME

- Highly skilled regulatory professional with extensive pharmaceutical industry experience.
- Proven track record in executing regulatory strategies across all phases of drug development.
- Strong leadership, organizational, team-working, strategic thinking, communication, technical competence, and line management skills.
- Excellent knowledge of European procedures, especially the Centralised Procedure.
- Expertise in CTAs, ODAs, PIPs, CHMP, and national scientific advice.
- Established connections with key regulatory agencies: EMA, MHRA, BfArM, ANSM, MPA, MEB, DKMA, FAMHP, Swissmedic, TGA.
- Held Global Regulatory Lead (GRL) roles, developing and implementing regulatory strategies in the US, Canada, Switzerland, Australia, and the EU.
- Extensive experience as a European Regulatory Lead (EURL).
- Broad therapeutic area experience, including oncology, hematology, gastroenterology, pain management, anti-infectives, women's health, respiratory, and rare diseases.

EDUCATION

BSc (Hons) in Pharmacology & Biochemistry
University of Aston, Birmingham UK

Experience

May 2024 - Present
Ozack ApS I Copenhagen Denmark

Senior Director

Regulatory consultant for both pharmaceutical and biotechnology companies.

March 2016 - January 2024
Shionogi I London UK

Executive Director Regulatory Affairs Europe

Responsibilities

- Led pre-MAA activities for a new chemical entity in Pain/Gastroenterology (Rizmoic, naldemedine, a PAMORA).
- Key role in preparing and submitting a MAA via the Centralised Procedure.
- Led preparation of responses to questions, ensuring successful regulatory approval with a strong label (CHMP Positive Opinion Dec 2018, European Commission Decision Feb 2019).
- Prepared, submitted, and supported approval of post-approval measures, PAS studies, PSURs, RMP updates, Type 1A, Type 1B, and Type II variations.
- Oversight of all approved products and development compounds (4 approved, 3 late-stage, 3 early-stage).
- Supporting EU Regulatory Strategy Leads within my team in developing and executing regulatory strategies
- EU Regulatory Strategy Lead for 3 development compounds, including one in a rare disease area and one in-licensed product.
- Prepared for implementation of EU CTR and EMA systems (IDMP).
- Coordinated preparation, submission, and support of PIPs and PIP modifications.
- Led activities for preparing and submitting CTAs, responding to regulatory agencies, and maintaining applications.
- Included Clinical Investigation Notification (CIN) for a medical device and the first CTA for Shionogi under the EU CTR.
- Reviewed and assessed regulatory documents for potential acquisitions, identifying strengths, weaknesses, risks, and further information needed.
- Managed a team of 6 regulatory professionals.

September 2013 - August 2014
Celgene Europe Limited I Uxbridge UK

Regulatory Affairs Director

Responsibilities

- Provided strategic regulatory guidance to Global Project Teams, European and Global Commercial Teams and developed optimal regulatory strategies
- Provided oversight to development and execution of submission strategies in EU and Switzerland
- Provided oversight and direction for all regulatory activities for products in the therapy area, for established products and compounds in development

LANGUAGE

English	Full Professional Proficiency

ADDITIONAL INFORMATION

Professional Memberships

- Member of TOPRA (MTOPRA)

Additional professional activities

- Chair of TOPRA CRED Clinical Development working party which has organised and run a two-day course on early to late stage clinical development every 2 years since 2007. These have been very successful, including the most recent one in October 2023
- Member of ABPI Regulatory Science Board Sponsored Group (BSG) while at Shinogi.

June 2011 - August 2013

Gilead Sciences International | Cambridge UK

International Regulatory Affairs Director

Responsibilities

- Provided strategic regulatory guidance to Global Project Teams, European and Global Commercial Teams
- Provided oversight and direction for all regulatory activities in support of a number of development compounds at different stages of development. This included a late-stage compound for which pre-MAA activities were initiated
- A member of the Regulatory International Leadership Team (ILT) and actively participated in the running of the department (strategic and operational)

July 2008 - March 2011

Genzyme Europe Research | Cambridge UK

Regulatory Affairs Europe Director

Responsibilities

- Managed timelines, budgets and resources
- Drove regulatory strategies for key activities (2 new indications) and provided oversight of all regulatory activities (several Type II variations, Scientific Advice, PIP and renewals) for the therapy area
- Member of site Management Team and EU Regulatory Affairs Management Team
- Provided regulatory input for Due Diligence activities

June 2001 - June 2008

Wyeth Europa | Berkshire UK

Regulatory Affairs Europe Director

Responsibilities

- Global Regulatory Lead (GRL) and Haemophilia Project Team representative for recombinant FVIII and FIX products (2 biologicals), with responsibility for coordinating regulatory strategy and activities globally for these busy products
- European Regulatory Lead for an oncology product in advanced renal cancer (Torisel, temsirolimus,), filed via the Centralised Procedure. Obtained European Commission approval in 13 months, following two rounds of questions
- Managed the regulatory aspects of assigned projects at different stages of development, including major applications that included:
  1. Scientific advice to national agencies and CHMP
  2. Paediatric Investigational Plans
  3. MAAs, variations and line extensions
  4. The preparation, submission and maintenance of pan-European clinical trial applications

November 1992 - May 2001

Glaxo SmithKline R&D | Middlesex UK

Regulatory Project Manager, Regulatory Affairs Europe

Responsibilities

- Worked on a NCE in the gastrointestinal area (Lotronex, alosetron) for IBS for nearly 7 years, from pre-Phase II onwards
- Submitted an EU MAA via the centralised procedure. Provided leadership, direction and oversight for all activities required for preparation and submission of the application and preparation of responses to the Day 120 list of questions. The application was withdrawn by the Company in Europe, Canada, Australia and Switzerland before the responses to questions could be submitted
- Supported products across a number of other therapeutic areas (anti-emesis, neuromuscular, anaesthesia, dermatological and cardiovascular)
- Global Regulatory Lead for several projects. Represented Europe and Rest of World on International Product Development Teams for a range of products in exploratory and full development
- Provided regulatory input for Due Diligence activities.