



Dr. Florin Muraru, MD, MBA

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EXECUTIVE PROFILE

Executive Regulatory Leader with an MD and MBA, offering extensive experience in global development strategies for complex therapeutic areas, including Oncology, Neurology, Metabolic, Cardiovascular and other indications for large and small molecules.

Driven by an entrepreneurial mindset, I specialise in elevating Regulatory Affairs from a traditional support function into a core business partner, recognised by internal and external stakeholders. As a proactive solution finder and out-of-the-box thinker, I reshape legacy processes to ensure regulatory roadmaps are tightly integrated with nonclinical, clinical, CMC, and commercial goals, ultimately driving true business value.

My leadership approach is rooted in empowerment and mentorship. I build lean, agile, and highly autonomous groups capable of navigating complex health authority negotiations (FDA, EMA, China) and delivering on multiple, parallel high-priority submissions under aggressive timelines. By fostering a culture of collective problem-solving, I empower office-based as well as geographically dispersed, remote personnel to align their efforts directly with the organisation's mission while maintaining the highest quality standards.

Additionally, I am deeply engaged in regulatory intelligence and policy shaping, actively evaluating digital trends and innovations to guarantee my department remains future-ready and optimally positioned to secure early patient access.

CORE COMPETENCIES

- **Launch Acceleration & Strategy:** End-to-End Roadmap (US, EU, China, RoW), Accelerated Approval Pathways, Orphan Drug Designations, Commercial Alignment, Regulatory development and Life cycle management activities, Regulatory submissions (IND, CTAs, MAAs, NDAs and BLAs).
- **Process & Operating Model Transformation:** Workflow Redesign, Scalable Regulatory Hub Models, Enterprise Leadership & Cross-Functional Integration (R&D, Clinical, CMC, Commercial, Government Affairs)
- **Therapeutic Expertise:** Oncology, Metabolic, Cardiovascular, Immunology, Neurology, Orphan & Pediatric Indications.
- **Team Building & Leadership:** Restructuring International Teams, Mentoring & Growing Talent, Agile/Lean Operating Models, Cross-Functional Matrix Leadership, Elevating Regulatory Influence
- **Digital Readiness & Innovation:** Technology Scouting, AI/Automation Evaluation, Trend Education

PROFESSIONAL EXPERIENCE

Group Head of Global Regulatory Affairs

Helsinn Group | Lugano, Switzerland | Oct 2022 – Present

Lead corporate regulatory and policy strategies for clinical and commercial portfolios across the US, EU, China, and RoW, advising the executive team on regulatory risks and opportunities.

- Updated the company's regulatory processes, which expedited approval routes and secured new product registrations ahead of schedule.

- Led important scientific advice meetings and negotiations with major health authorities (FDA, EMA, China), successfully defending key commercial assets worth \$40 million in the US.
- Changed older, rigid processes into a lean, more agile working model. Mentored the team to operate with high independence and flexibility, firmly positioning Regulatory as a collaborative, main partner to R&D and commercial teams
- Drove regulatory intelligence projects to track EU/US policy changes and evaluate and implement new digital tools to shape efficient work, allowing the team to focus on strategic aspects.
- Educate leadership and teams on technology trends, fostering a culture of experimentation and building the foundational readiness required for future adoption.

Senior Director Global Regulatory Strategy / Head of Regulatory Operations

Innovent Biologics (Europe) | Bern, Switzerland (Remote) | Nov 2020 – Oct 2022

Built and led US, European, and Rest of World regulatory operation team to support rapid worldwide expansion for a high-growth biotech, overcoming the challenges of a completely remote role

- Reshaped and directed RoW regulatory strategy for the Oncology, Ophthalmology, Immunology, and Metabolic franchises, were ensuring all development plans were fully integrated with commercial objectives to maximise asset value.
- Designed regulatory approaches for early and late-stage portfolios, managing various submissions, INDs, BLAs and finding solutions for adapting and optimising the EU-US-RoW plans, increasing the chances of success. For example, redesigning and adapting the ongoing clinical trials to meet the evolving regulatory requirements.
- Acted as a key member of the R&D Leadership Team, ensuring the Regulatory department had a strong voice in prioritising the portfolio by balancing regulatory rules with commercial objectives, providing creative regulatory approaches for meeting the organisational goals.
- Conducted critical negotiations with regulatory authorities to advance development programs, providing scientific and technical guidance to bridge R&D and commercial expansion goals.

Global Regulatory CT Opx Team Leader

CSL Behring | Bern, Switzerland | Aug 2018 – Oct 2020

Provided operational leadership for products in development, driving rapid alignment with multiregional regulatory requirements.

- Reorganised the Clinical Trial Regulatory team into a highly collaborative unit, optimising resource allocation to meet strict deadlines and empowering team members to operate independently.
- Developed and implemented interdepartmental procedures for the seamless rollout of the EU Clinical Trial Regulation, coordinating cross-functional collaboration for timely deliverables.
- Managed and oversaw operational aspects of regulatory activities, complex submissions (MAAs, INDs and BLAs) associated with product development, ensuring harmonisation with regulatory requirements for various categories of products, including a gene therapy product under development.

Associate Director Regulatory Affairs

PAREXEL Consulting Regulatory | Cambridge, UK | Jun 2014 – Jul 2018

Built up and led an international regulatory organisation of >90 FTEs across multiple regions, supporting >120 products, 430 international clinical trials, and >1,000 monthly submissions.

- Designed and rolled out an innovative, scalable Regulatory Hub model that optimised resource allocation across Oncology, Cardiovascular and Neurology portfolios, significantly reducing external vendor costs.
- Streamlined internal processes and SOPs, establishing KPIs and training programs that improved cross-departmental collaboration and adherence to regulatory timelines.
- Acted as the Regulatory Lead for biotech clients, giving direct advice, supporting and developing Orphan Drug Designations tactics, Paediatric Plans, fast-track and breakthrough designations.
- Managed worldwide regulatory strategies for Oncology, Cardiovascular, Ophthalmology, and Neurology, leading Pre-INDs and IND meetings, and scientific advice meetings with the MHRA, BfArM, and ANSM.

Senior Consultant Regulatory Affairs

Parexel Regulatory Consulting | Berlin, DE / Bucharest, RO / Uxbridge, UK | Jul 2008 – Jun 2014

- Coordinated regulatory submissions for multinational clinical studies spanning Europe, APAC, MEA, and LATAM.
- Oversaw and worked as International regulatory lead for >15 Phase 1-2 clinical trials and >20 Phase 3 programs across 30+ countries, leading cross-functional teams to enable seamless project execution and facilitating multinational scientific advice meetings.

Head of Drug Regulatory Affairs Department

F. Hoffmann-La Roche | Bucharest, Romania | Jan 2004 – Jun 2008

- Oversaw regulatory compliance and market access for a portfolio of 38 EU and national registered products.
- Directed departmental integration during the EU accession period and implemented a six-month project model to support transferring to Centralised Procedures (CP) of the local registered products, restructuring workflows for improved service delivery.
- Managed pricing, reimbursement, and market access during the successful launch of major new products.

Group Product Manager (Marketing and Sales) / Business Manager

F. Hoffmann-La Roche | Bucharest, Romania | Sep 1995 – Dec 2003

- Instrumental in developing the cardiology, metabolism-obesity, and dermatology portfolios, driving significant sales growth and market penetration, with marketing and commercial objectives.
- Led the highly successful launch and post-launch commercial activities for two major products: Xenical and Dilatrend (carvedilol).
- Managed a team of 10 Medical Representatives, bridging the gap between clinical data and commercial market execution.

EDUCATION

- **Master of Business Administration (MBA)** | 2005 – 2007

Telfer School of Management at the University of Ottawa

- **Professional Diploma in Management** | 1998 – 2000

Open University

- **B.Sc. in General Medicine / Medicine Doctor (MD)** | 1995

University of Medicine and Pharmacy „Gr T. Popa”, Iassy, Romania

ASSOCIATIONS & INDUSTRY INVOLVEMENT

- **TOPRA** (The Organisation for Professionals in Regulatory Affairs) – Member, Regulatory Intelligence SPIN Steering Group
- **RAPS** (Regulatory Affairs Professionals Society) – Member
- **DIA** (Drug Information Association) – Member

LANGUAGES

- **English:** Fluent / Full Professional Proficiency
- **Italian:** Professional Working Proficiency
- **French:** Intermediate / Conversational
- **German:** Basic / Elementary
- **Romanian:** Native