Julius Vincenz Weidlich

Interim Regulatory Affairs & Program Manager (PMP) | Interim Regulatory Program Lead

USA, permanent residence permit for Germany
+49 170 839 1243 · Julius.weidlich@gmail.com
linkedin.com/in/juliusweidlich
Froelingstr. 49, 61348 Bad Homburg, Hessen, Germany

PROFESSIONAL SUMMARY

Pharmaceutical companies looking for a more efficient use of time and resources on regulatory projects benefit from combining Regulatory Affairs expertise and program leadership in a single, accountable role — rather than coordinating two separate external specialists. I provide exactly that. As an Interim Regulatory Affairs & Program Manager with 20+ years in the pharmaceutical industry, I combine 9 years of hands-on Regulatory Affairs experience across 100+ markets with 8 years of PMP-certified project and program leadership. At Viatris, I led a portfolio of approximately 20 parallel Lifecycle Management programs across cross-functional teams of 10–25, accelerating project timelines by 10–20%. Available on short notice for interim mandates — particularly relevant as the EU Pharmaceutical Reform reshapes regulatory processes from 2026 onward.

CORE COMPETENCIES

Interim Regulatory Affairs Management • Interim Program & Project Leadership • IND/NDA/MAA Submission Support • Variations & Renewals (MRP, DCP, CP, NP) • Lifecycle Management (LCM) • CMC Project Leadership • Regulatory Strategy • CTD/eCTD • Cross-Functional Leadership • Stage-Gate Governance • RAID & Critical Path Management • Portfolio Prioritization • Budget Planning • Stakeholder Engagement • Change Control • GxP/GMP Awareness • Business Case Development

WORK EXPERIENCE

SR. PROJECT MANAGER, GLOBAL KEY BRANDS & PORTFOLIO EXPANSION

January 2017 – October 2025

Viatris (MEDA Pharma GmbH & Co. KG), Bad Homburg, Germany

Position ended due to company-wide restructuring.

- Led a diverse portfolio of approx. 20 global R&D and lifecycle projects, including reformulations, CMC updates, regulatory variations, and market expansions. Directed cross-functional teams of 10–25 members across R&D, Regulatory, QA, Supply Chain, Manufacturing, Market Access, Global Marketing, SC, Finance, etc. and Regional Affiliates.

Key Achievements

- Delivered 20+ global LCM (new formulations, reformulation, development) and portfolio expansion initiatives, ensuring regulatory compliance and uninterrupted supply across 100+ markets.
- Accelerated project timelines by 10–20% through critical path control, RAID-based risk management, and proactive issue resolution.
- Strengthened governance by preparing high-impact decision materials and driving alignment with senior leadership, enabling faster go/no-go decisions.
- Improved transparency and reporting accuracy by maintaining project data in centralized systems, reducing reporting time.
- Supported Global Marketing in developing business cases for new market entries, contributing to multiple successful commercial expansions.
- Prevented delays in at-risk projects by identifying resource constraints early and implementing cross-functional mitigation plans.

SPECIALIST CORPORATE DRUG REGULATORY AFFAIRS

June 2009 – December 2016

Viatris (MEDA Pharma GmbH & Co. KG), Bad Homburg, Germany

- Led the preparation and submission of regulatory variations and renewals across EU, APAC, CIS, MEA and LATAM markets, ensuring 100% compliance with evolving regulations.
- Managed end-to-end lifecycle activities for over several products in over 100 countries, supporting market continuity and alignment with local authority requirements.

- Contributed to the development of an internal Regulatory Information Management System (RIMS), improving team efficiency and documentation accuracy.
- Acted as primary liaison with health authorities for assigned products.

HEAD OF PRODUCT MANAGEMENT (Parallel Import / Parallel Distribution) December 2005 – May 2009

AxiCorp Pharma GmbH, Friedrichsdorf, Germany

- Planned and executed commercial product launches across EU markets, achieving 90% on-time launch rate.
- Managed end-to-end product lifecycle including label creation and manufacturing instructions.
- Led a team of six, improving departmental productivity and exceeding performance goals through targeted mentoring and KPI-driven leadership.
- Implemented budget planning processes for staff and materials, achieving cost savings while maintaining operational excellence.
- Spearheaded strategic planning initiatives, aligning departmental objectives with company growth targets and expanding product portfolio access.

SPECIALIST CORPORATE DRUG REGULATORY AFFAIRS April 2005 – December 2005

Viatris Pharma GmbH & Co. KG, Bad Homburg, Germany

- Supported global regulatory submissions and lifecycle management efforts, with a focus on label and variation documentation.

EDUCATION

Medical Technologist for Laboratory Analysis / Medical Technical Laboratory Assistant (MTLA)

Robert-Gustav-Hufnagel-Schule – Staedtische Kliniken, Offenbach; 2000 – 2003. State certified (Regierungspräsidium Darmstadt), October 2003

CERTIFICATIONS

- Project Management Professional (PMP), Project Management Institute (PMI) — certified March 2024
- Certified Associate of Project Management (CAPM), PMI — certified June 2023
- Medical (Sales) Representative, Chamber of Industry and Commerce (IHK) — certified 2008

PROFESSIONAL MEMBERSHIPS

- TOPRA — The Organisation for Professional Regulatory Affairs
- PMI — Project Management Institute
- DDIM — Dachgesellschaft Deutsches Interim Management

SKILLS

Languages: English (native speaker) | German (native speaker) | French (basic) | Spanish (basic)

Software: MS Office (Word | Excel | PowerPoint), MS Project | OnePager (Gantt Tool)

MTLA Skills: Proficient in laboratory techniques including microbiology, clinical chemistry, hematology, and immunology. Experienced in operating laboratory equipment and conducting diagnostic tests. Knowledgeable in quality control and laboratory safety protocols.

PROFESSIONAL DEVELOPMENT

- Continuously updated skills through professional certifications and training programs.
- Actively participated in industry conferences and workshops to stay abreast of the latest trends and best practices in project management and pharmaceutical regulations.

PERSONAL INTERESTS

Basketball • Sports • Reading • Cooking • Arts