FRANKA JÜRGENS

Senior Global Regulatory Affairs Manager | CMC Professional

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CORE COMPETENCIES

- Global Regulatory Strategy
- European & International Regulatory Affairs
- Health Authority Interaction & Scientific Advice
- CMC Strategy & Lifecycle Management
- Regulatory Intelligence & Risk Assessment
- Cross-functional Leadership & Stakeholder Management
- Technology Transfer & Change Management
- US / EU / RoW Regulatory Activities
- eCTD Documentation & Publishing
- GMP Compliance & Quality Systems

PROFESSIONAL EXPERIENCE

InfectoPharm Arzneimittel und Consilium GmbH | Senior Regulatory Affairs Manager | 2025

- Lifecycle management of marketed medicinal products in the DACH region
- eCTD dossier maintenance and regulatory documentation activities
- Quality expert for dossier review prior to submission
- Cross-functional coordination with QA, manufacturing and development teams

Midas Pharma GmbH | Regulatory Affairs Manager | 2023–2025

- Regulatory lead for EU and US markets supporting global Regulatory Strategy and lifecycle activities
- Management of variations and publishing for submissions
- Supported Scientific Advice activities for a combination product
- ANDA-related regulatory activities for a cardiovascular injection product
- Coordination with CMOs, CROs and international stakeholders
- Support of Health Authority interactions and regulatory strategy implementation

Merz Pharmaceuticals GmbH | Senior Regulatory Affairs Manager | 2022

- Strategic planning and execution of variations
- Project leadership within cross-functional regulatory activities
- Authoring of QAAs
- KPI management and process optimization

Wörwag Pharma GmbH | Regulatory Affairs Manager CMC | 2020–2022

- Project leadership for regulatory and technology transfer initiatives
- Development and implementation of Regulatory Strategies supporting lifecycle optimization
- Cross-functional Leadership across QA, manufacturing and development functions
- Technology transfer activities and regulatory support

PharmaLex GmbH (Boehringer Ingelheim Project) | Regulatory Affairs Consultant | 2016–2020

- Global regulatory support for veterinary medicinal products
- Lifecycle management and Regulatory Strategy implementation across international markets
- Health Authority interaction support and global submissions
- Cross-functional Leadership and coordination of international stakeholder groups

EDUCATION

BSc in Analytical and Pharmaceutical Chemistry

CERTIFICATIONS

Certificate in Quality Management

LANGUAGES

German (native), English (fluent), Russian (intermediate), Polish (beginner)

SOFTWARE

DocuBridge, Extedo, Lorenz, TrackWise, HubSpot, SalesForce, Microsoft Office