Regulatory Affairs Manager | EU Procedures and Lifecycle

FIRSTNAME LASTNAME

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Profile

Regulatory Affairs Manager with seven years of experience in human medicines, covering EU centralised, decentralised and national procedures. Owns variations, renewals and labelling for a portfolio of 30 products and prepares eCTD submissions. Main contact for the national competent authorities BfArM and Paul-Ehrlich-Institut.

Career highlights

- Managed about 120 variations a year with no rejected submission.
- Coordinated a decentralised procedure with Germany as reference member state, approved in 13 member states.
- Introduced a labelling tracker that halved the time to implement safety-related text changes.
- Led regulatory due diligence for two product acquisitions.

Professional experience

Regulatory Affairs Manager **January 2022 to present**
Mid-sized pharmaceutical company (example) Bonn, Germany

- Plan and submit variations, renewals and PSUSA outcomes for 30 products.
- Prepare and validate eCTD sequences and handle questions from authorities.
- Maintain SmPC, package leaflet and labelling in line with QRD templates.

Regulatory Affairs Specialist **April 2019 to December 2021**
Regulatory consultancy (example) Cologne, Germany

- Compiled Module 1 and 3 documents for generic applications.
- Published eCTD sequences for clients.
- Tracked procedures in the regulatory information management system.

Education

University of Bonn. Master of Drug Regulatory Affairs (M.D.R.A.), 2021 | State examination in pharmacy, 2018

Further training

EU variations regulation update (2025) | eCTD 4.0 readiness (2025)

Languages

German (native) | English (business fluent)

Core competencies

EU procedures (CP, DCP, MRP, national) | Variations and renewals | eCTD | Labelling and QRD | SmPC and PIL | BfArM and PEI | Regulatory due diligence | RIM systems | Lifecycle management | CMC Module 3

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