Anirudha Munje
Holding Permission to work in Germany

Regulatory Affairs
(Submission Publishing - 9 Years exp)

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Germany Job Seeker Visa

JOB SKILLS

- Accomplished regulatory affairs professional with extensive experience in pharmaceutical compliance and **lifecycle management**.
- Successfully managed and submitted **500+ complex** regulatory dossiers, including **MAAs,** with a **99% approval** rate over five years.
- Well-versed in **data consolidation and quality checks**, ensuring accuracy and compliance
- Streamlined the urgent conversion of **9 sequences** from **NEES to eCTD** format within a day using Insight Publisher, ensuring lifecycle maintenance and facilitating approval.
- Adept at using regulatory tools like **Insight Publisher, Veeva Vault RIM, Mono eCTD**.
- Experienced in publishing and submissions via **Swissmedic, CESP, MHRA,** and **EMA**.
- Proven track record as a **Submission Manager** for Swiss submissions, managing full lifecycle and client communication.
- Demonstrates **strong organizational skills, creative thinking**, and effective team management.

TOOLS & TECHNOLOGIES

Technical Skills	Insight Publisher | Veeva-vault | Docubridge | life-cycle Management |Mono eCTD Office | SmartDesk | ISI Toolbox | CESP | MHRA| EMA | Swissmedic | PDF Bookmarking & Hyperlinking | NEES | CTA | EURS - Lorenz eValidator | Variations |MDR
Functional Skills	Regulatory Submissions |Document Management | Compliance | Team Collaboration | Project & People Management | Communication.

EXPERIENCE

Mar 2020 – Present

Sr. Regulatory Affairs Associate
Parexel International Private Limited, Bangaluru, India

- Efficiently manage regulatory submissions using **Insight Publisher** for **National, Swiss**, **MRP-DCP, CP, PSUSA** ensuring eCTD and NEES compliance and dispatching to CESP, MHRA, EMA, and Swissmedic.
- Consolidate **biweekly data** for Swiss and National projects, ensuring timely updates.
- Conducting QC for MRP-DCP and project-specific tasks, including Veeva archival QC, report extraction, and analysis. Assisting in **CAPA** development.
- Driving the entire **lifecycle** as Submission Manager, from initial screening in **Veeva-Vault** to binder creation, timely delivery through consistent client communication.
- **Coordinate** and schedule client meetings to ensure project success.
- **Orchestrated** a Swiss project with a team of 6, achieving a **20% boost** in efficiency and **cutting delivery time by 15%.**
- Addressed training sessions for internal teams on regulatory requirements and best practices, improving compliance awareness and **reducing submission errors by 25%**

Achievements

- **Established uniformity** of XML title in SCP (Submission Content Plan) with the approval of the client, helping to reduce publishing and overall submission process to the health authority. This **ensures timely submission**.

May 2016 – Mar 2020

Senior Process Associate
Tata Consultancy Services Pvt. Ltd., Pune, India

- Publicized the preparation and submission of **CSRs, AE reports,** and **promotional** materials for **U.S. submissions**, ensuring compliance with FDA guidelines.
- Implemented **standardized formatting** across Modules 2 to 5 of the CTD, enhancing document consistency and regulatory adherence.
- Generated compliant PDFs and XML backbones, ensuring accurate submissions and successful validation with **EURS - Lorenz eValidator.**
- Managed critical regulatory documents (IMPDs, IBs, DSURs, PSURs, Protocols) with precise pagination, bookmarking, and hyperlinking using **ISI Toolbox** and **SmartDesk.**
- Established a Clinical Study Report **Data Redaction** Project, focusing on document redaction and retention to ensure data privacy and compliance.

Achievement

- Appointed as a **key person** in CSR publishing and QC process**, boosting submission efficiency** and reducing errors.

sep 2015 – May 2016

Regulatory Trainee
Elite Institute of Pharma, Pune

- Contributed to the **development of DMFs** and managed country-specific dossier submissions for Vietnam, Ghana, and Thailand, ensuring local regulatory compliance.
- Corresponded with regulatory authorities to **secure product licensing** and ensure adherence to pharmaceutical compliance standards, facilitating **timely market entry**.

Nov 2013 – Sep 2015

Pharma Marketing (Medical Representative)

- H & H Pharma LLP, Danone Nutricia Pvt. Ltd & Claris Lifesciences Pvt. Ltd.

PROJECTS

Master's Project:

- Title - Creating Stable Oil/Water Pickering Emulsions Using Pluronic-17r4.

CERTIFICATIONS

May 2024

- Medical Device Regulation

EDUCATION

Sep 2012- May 2013

- Master of Science (Formulation Science) — University of Greenwich, United Kingdom

Sep 2008- Aug 2011

- Bachelor of Pharmacy — University of Pune, India

LANGUAGE

English – Fluent
German – Completed A1, Pursuing A2

PERSONAL SKILLS

- Honest, **hardworking**, & loyal team player, **adaptable** to achieve business demands.
- Self-motivated performer, **strong organizational skills, creative thinker**, **flexible** & **technologically competent** to achieve any project milestone.
- **Helping**, **managing** & **planning** the development activities of the team.
- Provide updates to top **management** and **co-ordinate** with the team.
- **Managing** and **tracking** the release plan to ensure successful completion of delivery goals.