UTTAM PRAJAPATI

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Experienced regulatory affairs professional for more than 6 years seeking a challenging role in the pharmaceutical industry. Proven expertise in navigating complex regulatory landscapes, ensuring compliance, and facilitating product approval. Goal-oriented and skilled in regulatory submissions, coordination with authorities, and strategy development.

INTEREST

- Regulatory affairs Specialist
- Labelling
- Data Scientist
- Data Analyst

SKILLS

- **Regulatory Knowledge:** Strong understanding of regulatory guidelines and frameworks.
- **Submissions Management:** Proficiency in preparing, reviewing, and managing regulatory submissions, Familiarity with eCTD.
- **Compliance and Quality Assurance**: Ability to ensure compliance with regulatory standards and guidelines, including GMP, GLP and ICH guidelines. Strong attention to detail in QA and auditing processes.
- **Communication and Collaboration:** Excellent verbal and written communication skills to effectively interact with cross-functional teams, regulatory authorities, and external stakeholders. Ability to present complex regulatory information clearly and concisely.
- **Regulatory Intelligence:** Proactive in monitoring and staying up-to-date with evolving regulations, guidelines, and industry trends. Strong research and analytical skills to assess the impact of regulatory changes on product development and commercialization.
- **Project Management:** Proficient in managing multiple projects simultaneously, setting priorities, and meeting deadlines. Effective organizational and time management skills in a fast-paced regulatory environment.
- Adaptability and Flexibility.
- Problem-Solving and Decision-Making.
- Cross-Functional Collaboration.
- Data analysis and interpretation, Machine learning knowledge.
- Data visualization using tools like Tableau, Power BI, or Python libraries.
- Data cleaning and analysis using Excel, MySQL, R-Programming or Python libraries.
- Ability to generate insights and communicate findings effectively.

CERTIFICATE AND TRAINING

- Data Science Pro
- eCTD & CTD Preparation & Submission Course

EXPERIENCE

➢ ACCORD HEALTHCARE UK (INTAS PHARMACEUTICALS LTD) 19/09/2022 - TILL DATE

QA/RA Research Associate

Market: Europe, UK

- Working on Module-1, 2, 3 documents.
- Develop and review labeling documents (PIL, Packaging Info) to ensure compliance with European and UK regulations.
- Compile, assess, and manage Module 3 quality documentation in accordance with European (CTD) structure, ensuring that quality information meets European and UK regulatory standards.

- Contribute to the development of regulatory strategies for labeling and quality documentation submissions, considering the distinct requirements of both the European and UK markets.
- Collaborate on labeling changes and variations, maintaining compliance.
- Stay updated on evolving European and UK labeling and quality guidelines.
- Facilitate cross-functional collaboration for accuracy and consistency.
- Coordinate with partners for external labeling and quality information.
- Provide training to enhance internal teams' understanding of Module 1, 2, 3 requirements.

➢ SWISS PARENTERALS LTD. 17/01/2022 - 10/09/2022

International Regulatory Affairs

Market: RoW, LATAM, ASEAN

- Prepare and review Module-1 documents, including cover letter, application form, and administrative information.
- Developing and Reviewing product packaging material artworks (i.e. Carton, Foil, Label and Package Inserts) and SPC.
- Review and assess the accuracy and completeness of non-clinical and clinical data in Module-2 submissions.
- Prepare and review Module-3 documents, including quality, safety, and efficacy data.
- Review and assess the accuracy and completeness of product specifications, manufacturing processes, and analytical methods inline with latest Pharmacopeia and MVR, BMR, BPR.
- Compilation of Tender Dossier for different countries.
- Coordinate with cross-functional teams to ensure timely completion of Module-3 submissions.
- Ensure compliance with applicable regulations and guidelines.

➢ ZYDUS LIFESCIENCES 28/06/2017 - 13/01/2022

Corporate Quality Assurance

Market: USA, Europe, RoW, Domestic

- Working on Module-3 and ICH Quality guidelines.
- Ensure that all Quality documents are accurate, complete, and comply with relevant regulatory requirements, ICH guidelines and other Quality documents (i.e. SOP/BMR/BPR/DMF/MVR/ MSDS/ Manufacturer COA).
- Collaborate with cross-functional teams, including Quality Assurance, Regulatory Affairs, and Research and Development, to ensure compliance with pharmacopoeial standards.
- Staying up-to-date with changes to pharmacopoeial standards (i.e. IP, USP, BP, Ph. Eur.) and guidelines and provide guidance on the impact of these changes on the company's products and processes.
- Participate in internal and external audits related to pharmacopoeial standards and guidelines.
- Prepare and submit comments to pharmacopoeial authorities on proposed revisions to pharmacopoeial standards and guidelines.
- Identify opportunities for continuous improvement and make recommendations to enhance the company's compliance with pharmacopoeial standards.

EDUCATION

I have completed my post-graduation in Master of Science with a specialization in Organic Chemistry from Jaipur National University. Prior to that, I pursued my graduation and obtained a Bachelor of Science degree with a major in Chemistry from Gujarat University.

Uttam Prajapati