

SARITHA MALLEPOOLA

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Hyderabad, India 500049

SUMMARY

Well-versed in drug and device regulatory affairs, and the scientific aspects of new and biologic drug development. Skill sets in Regulatory Intelligence, Competitive Intelligence, Project Management, Research Analysis and Analytics in regulatory and scientific fields. Proficient in strategizing and establishing goals tailored to specific resources. Engaged in collaborative efforts with automation and technology teams to integrate knowledge management within the regulatory field. Skilled in setting the tone from the top as a leader, fostering partnership approach, and creating an environment that empowers and motivates employees. Proficient in delivering multiple end-to-end projects and solution development with strong exposure as well as an understanding of Life Sciences concepts/processes. Experience in CTD module documentation, including technical requirements such as bookmarking, hyperlinking, and cross-referencing.

SKILLS

- Drug Regulatory Affairs
- Device Regulatory Affairs
- Process Improvement
- Project Management
- Team Management
- Research & Development
- Regulatory Impact Assessment
- Regulations/Guidance
- Global labeling requirements
- CMC Change Control Requirements
- Biologic Regulatory Affairs
- Cell and Gene Therapies
- Regulatory Documentation
- People Management
- Consumer Healthcare
- Ingredients Requirements
- Building Metadata

EXPERIENCE

ASSOCIATE DIRECTOR | 06/2018 to 03/2024

MakroCare - Hyderabad, Telangana

- Managed the Regulatory Intelligence department, overseeing comprehensive regulatory summaries, updates, and guidance documents worldwide for various product categories including pharmaceuticals, biologics, medical devices, and consumer healthcare.
- Extensive hands-on experience in crafting regulatory summaries for a diverse range of products across the US, EMEA, and APAC regions.
- Sound knowledge on regulatory affairs including CMC change control
- Giving training to the subordinates with respect to drug and device regulations or guidelines
- Provide leadership in the development of research and analytics areas in regulatory and scientific fields
- Lead team in planning and setting up resource-specific goals
- Work with automation and technology teams to align knowledge management
- Strategize sources and literature for scientific, clinical, and diagnostic areas
- Serve as research expert and act as a liaison with other relevant teams
- Guide and support scientific team for project-related matters and sharing of best practice
- Provide mentoring and supervision to teams, to ensure execution of plans is consistent with corporate and department objectives

- As a part of local management team to contribute ideas, suggestions, strategies Responsible for all employees in group based on solid line for all deliverables and dotted lines for Administration Responsible to support Pre-sales, Bid Management, RFIs etc.,
- Attending and handling various demos with clients
- Working with automation team in applying artificial intelligence for regulatory and clinical affairs
- Managing people related to multiple departments (drugs, device, consumer healthcare & tool development team).
- Utilized knowledge and experience to excel in medical writing, focused on CTD module, End note citations and bibliography.
- Comprehensive understanding of relevant technical requirements for electronic registration submissions (eCTD) - Bookmarking, hyperlinking, cross referencing etc.
- Knowledge on electronic submissions
- Managed the development of new team members through training, mentoring and ensuring quality of data collected.
- Crafted informative and persuasive content for white papers.
- Collaborated closely with team members to ensure successful project execution.
- Demonstrated strong expertise in summarizing regulatory information for pharmaceuticals, medical devices, and consumer healthcare products.
- Demonstrated strong expertise in preparing regulatory requirements for clinical trials, registration/market authorization approvals, labeling requirements including UDI, safety reporting, post-approval changes and import/export requirements.
- Conducted secondary research on consumer care products and gathered regulatory requirements from authority websites to enrich database as per client specifications.
- Gathered regulatory updates on Asia, Europe, USA, Latin America, and other nations worldwide from diverse authority websites to compile newsletters.
- Prepared granularized metadata based on the requirements of the project
- Utilized knowledge to develop effective business proposals.

QUALITY ANALYST, BIOMEDICINE | 06/2013 to 06/2018

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- Leading a team of twelve involved in research and analysis of biomarkers responsible for a disease or treatment
- Work allocation, preparing work reports, query solving, mentoring and Root cause analysis of errors made by team members
- Quality checking of the analysis done by team members and giving appropriate feedbacks and taking feedback sessions
- Analyze comprehensive biomarker intelligence in relation to drug discovery, patient stratification, translational medicine, or drug repositioning
- Providing the information of key biomarker uses at every stage of drug research and development including disease risk detection, diagnosis, target identification, proof-of-mechanism, proof-of-concept, treatment/ safety monitoring and outcome measurement, covering all therapeutic areas.

SENIOR RESEARCH ANALYST, IDRAC | 06/2011 to 06/2013

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- Daily monitoring of new releases and related regulatory information content from the US FDA website and other regulatory sources
- Providing inside source for drug approval information; drug's overview, its regulatory history, related Adcomm bulletin coverage, post-marketing/phase 4 commitments, pediatric studies, market competition, and in the pipeline

- Preparing competitive intelligence reports on a daily basis by performing secondary research about the performance of a product across the globe
- Updating company and drug records, from a range of publicly available sources like scientific research journals, Company Worldwide websites, poster and paper presentations, conferences including Bio Partnering Europe, BioPharm America, Asia, and Korea, clinical trial registries

RESEARCH ANALYST, CIS | 06/2008 to 06/2011

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- Curation of clinical trials information and integration with other scientific and competitive intelligence
- Creating clear and concise customized English scientific abstracts
- Providing dynamic executive summaries on the current status of and future trends in drug therapy, which included providing drug information in a single, flexible resource that can help to drive innovation and support earlier decision-making
- Analysis/extraction of information from life science and biomedical articles, assigning appropriate descriptors and writing informative summaries based on profiles and guidelines submitted by clients based within the pharmaceutical industry
- Updating pharmacovigilance data such as adverse events caused by the client product, the adverse event that is to be treated, drug or therapy given for the treatment of a particular adverse event, co-existing diseases, dosage and route of administration, drug interactions, and concomitant medications
- Writing reports for chemistry, pharmaceuticals, pharmacokinetics, pharmacology, clinical, safety, and regulatory information of pharmaceutical products depending upon the client's requirement
- Providing essential chemical and pharmacological information, and the development status of bioactive compounds in the drug pipeline
- Providing data from experimental and clinical studies that delineate the absorption, distribution, metabolism and excretion (ADME) profile of a drug.

ASSOCIATE RESEARCH ANALYST, DDF | 06/2007 to 06/2008

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- Writing, editing, and reconciling high-quality medical and scientific communications including abstracts, literature reviews, and manuscripts
- To prepare competitive intelligence reports on a daily basis by performing secondary analysis about the new drugs, associated companies, their pipeline, and other related information
- Perform in-depth Pipeline Analysis of products in Research & development and contact the companies for the same
- Analyzing, interpreting, and reporting key information from clinical study reports
- Generate competitive intelligence reports on various products in preclinical and clinical stages
- Provide complete information of drugs and their safety profiles to the customers using data from online sources including, press releases, meeting reports, journals, etc
- To analyze and add all the types of deals related to the Merger and Acquisition deals, spin-offs, company bankrupts, research contracts, manufacturing, supply & marketing deals into the company records and update the drug records accordingly
- Writing abstracts and manuscripts for drugs, biologicals, and medical devices using data from conferences
- To prepare as well as analyze reports for pharmaceutical companies including a detailed description of R&D as well as marketed products portfolio and analyst forecasts from various sources
- Research on novel drugs to keep the database updated with all the latest information available

- Updating the drug record with generic names, research codes, and other names and current development status using various online sources
- Data retrieval from scientific databases like IMS, clintrials.gov, trial trove, Science Direct, PubMed
- Organizing and Indexing document-level classifications to serve as a concise, informative summary of the contents
- Responsible for mentoring new hires and doing a quality check of their work.

EDUCATION

Sri Bharathidasan University, Tamil Nadu
M.Sc. Microbiology
01/2003

PROFILES

- <https://www.linkedin.com/in/saritha-mallepoola-2292062a/>

PERSONAL INFORMATION

- Date of Birth: 06/17/1979
- Marital Status: Married

LANGUAGES

- English
- Hindi
- Telugu

AWARDS AND ACCOMPLISHMENTS

- Won "You Shine" Award for my active involvement in ViSTAAR tool development.
- Done Six Sigma Project for merging biomarker and gene records
- Received "STAR OF THE MONTH" awards for maintaining quality and efficiency.
- Successfully completed and implemented Six Sigma project in quality scoring methodology.
- Worked with Barcelona counter parts in implementing new quality scoring methodology.
- Successfully trained new recruits and was appreciated for the smooth knowledge transfer within a short span of time.

CERTIFICATIONS

- eCTD and CTD Preparation & submission