CURRICULUM VITAE

P. SARITHA DEVI

New Bowrampet, Near Bachupally, Hyderabad,
Cell: 9848845499
Email: saritha.adusumilli123@gmail.com

OBJECTIVE:

To associate myself with an organisation that provides me an opportunity to use my professional knowledge, technical skills and interpersonal skills to be part of a team that works dynamically towards the growth of the organisation.

EDUCATIONAL QUALIFICATION:

- **M.Pharmacy** (Pharmaceutical Biotechnology) (82%) with distinction in **Jawaharlal Nehru Technological University** - December 2009.
- **B.Pharmacy** with distinction (72.6 %) from **Shadan College of Pharmacy**, Hyderabad, Affiliated to Jawaharlal Nehru Technological University, Hyderabad - August 2002.
- **Intermediate** with 84% from Board of Intermediate Education, Hyderabad, Andhra Pradesh-April 1998
- **S.S.C** with 80% from the Board of Secondary Education, Andhra Pradesh, Hyderabad - June 1996.

CAREER PROFILE:

20 years of experience in Pharma (parenterals and oral solid dosage forms) and Biotech industries (vaccines and biotherapeutic products) and looking for better prospects in Regulatory Affairs department. Well versed with MAA application, Variations, Annual reports and queries responses to Europe, South Africa, South Korea, WHO prequalification and ROW markets.

KEY ACCOMPHLISHMENTS:

- Successfully registered anticancer products in MHRA, Europe, South Korea, South Africa, Malaysia, Russia and in Ukraine from CTD template initiation.
- Lead the team for submissions for Indian CTA (Phase I/II, Phase III), NDA, WHO PSF submission and Variation approvals for combination vaccines.
- Achievements: Successfully registered two vaccines in CDSCO and WHO prequalified and registered in around 30 countries subsequently.
- Contributed for revision of Post Approval Change guideline and Drugs and Cosmetic act rules for vaccines.
- Preparation of exhaustive registration pathway and gap analysis to help exports to project annual planning.
- Registration of vaccines in Mexico by responding for queries, pre-audit documents and facilitation of audit.

CORE REGULATORY SKILLS:

- Project execution
- CTD format development and submission management
- Registration and maintenance
- Variations and Annual reports submission
- Post-marketing activities such as PSURs
- Regulatory intelligence
- Technical review and responding skills
- Multiple task management Skills
- Consulting activities and professional relationship management
- Staff and resourcement management
- Efficient technical writing in english
- Customer focussed working and sense of urgency
- Critical thinking and problem solving
- Worked in the matrixed organization
- Constructive and motivational feedback to direct reports.

Key responsibilities in current and earlier organisations have been detailed further.

Period: Jun 2019 – Till date

Working as **Manager** in Regulatory Affairs Department in **SP Accure Labs Private Ltd.,** since **June 2019 to till date.**

KEY JOB REPONSIBILITIES:

- Regulatory Strategy: Responsible for providing regulatory intelligence inputs for obtaining fast track approval in global markets.
- Submissions and Approvals: Project lead/drive for CTD and eCTD MAA submissions for anti cancer small parenterals and Oral solid dosage forms for global registration in MHRA, Europe, South Korea, South Africa, GCC, ASEAN, CIS and LATAM markets in appropriate submission type.
- HA requests: Developed and implemented plans for timely response for Health Authority (HA) requests.
- Prepared briefing packages and lead the HA technical meetings.
- Gap assessment and mitigation: Identified gaps and issues if any for the submissions and responses and coordinated with functional teams for neccessary fulfillment of these gaps.
- Managed the direct reports (7 to 10 team members) by setting objectives, mentoring and training the team with regular review suggestions and feedback for improvement.
- Assessed change controls for regulatory impact and developed variation packages as per EMEA guidelines.
- Revised the labels as needed for HA approvals with best available resources and HA comments.
- Review documentation (e.g., stability data, specifications, for adequacy to support MAA.

Period: September 2017 –Jun 2019:

Worked as **Manager - Quality and Regulatory handling the responsibilities of** QA, QC, Regulatory Affairs Department in **Siflon Drugs and Pharmaceuticals Pvt. Ltd.** since **September 2017 to Jun 2019.** A pioneer for Veterinary Medicinal products manufacturing Oral liquids, Tablets and dry powders formulations.

- Prepared API DMF open part and responded for Ireland queries for API.
- Submitted site registration documents for international registration for formulation plant.
- Worked for WHO GMP and Schedule M application, faced audits and further responses.
- Contributed for facility renovation and instruments upgradation for GMP and quality compliance and achieved grant of these certificates for the facility and products involved.
- Sucessfully, renewed Mfg. license for next five years vide online application by responding to queries given by laisioning local drug authority.
  - Trained and implemented Core QA SOP for establishing the quality systems in Siflon Group and structured the QA and QC operations.
  - Subsequently coordinated for Change control and deviation writing practices.
  - Managed the quality team for their works assigned (7 members).
  - Assessed the gaps and activities pending for audit preparedness.
  - Trained and Implemented SOPs for Basic QC activities, Coordinated for installation of new instruments including HPLC and procurement of working standards.
- Planned and coordinated for stability study initiation for some new products.
- Documentation support for conduct of Method validation studies and review of Specifications and Testing Procedures for these products

Period: AUGUST 2006 – September 2017:

Worked as **Senior Manager** in Regulatory Affairs Department in **Shantha Biotechnics Private Limited**, a Sanofi Company, since **May 2007 -September 2017**

KEY JOB REPONSIBILITIES:

- Regulatory Strategy: Responsible for providing regulatory strategy and project milestones, timelines for obtaining fast track approval in CDSCO and WHO prequalification for vaccines
- Submissions and Approvals: Project lead/drive for CTD CTA and MAA submissions for bacterial, viral and recombinant vaccines for CDSCO Approval and WHO prequalification and global registration in African, ASEAN, CIS, Pacific Asian and LATAM markets.
- HA requests: Developed and implemented plans for timely response for Health Authority (HA) requests and prepared briefing packages for HA technical meetings (CDSCO and WHO, Geneva).
- Gap assessment and mitigation: Identified gaps and issues if any for the submissions and responses and coordinated with functional teams for neccessary fulfillment of these gaps.
- Managed the direct reports - 5-7 team members by setting objectives, mentoring and training the team with regular review suggestions and regular feedback for talent improvement.
- Assessed change controls for regulatory impact and developed annual reports and variation packages and further requests as per CDSCO and WHO variation guidelines.

- Revised the labels as needed for HA approvals with best available resources and HA comments.
- Worked for revision of Post Approval Change guideline of CDSCO for Biological products.
- Worked for revision of Drugs and Cosmetic Act rules with related to Biological products.
- Designed many initial tracking formats including change control logs for quick and detailed regulatory assessment of changes
- Summarising the Highlights of New / revised Regulatory guidelines for quick reference of RA team and Functional teams.

Period: AUGUST 2006 – MAY 2007:

Officer (Grade 1) in Regulatory Affairs - Exports Department in **Indian Immunologicals Limited** during the period **August 2006 – May 2007**.

KEY JOB REPONSIBILITIES:

- Preparation and Submission of CTDs and Technical dossiers for Viral vaccines, rDNA vaccines and combination vaccines.
- Preparation and Submission of responses to regulatory Authorities.

Period: FEBRUARY 2003 - AUGUST 2006:

Senior Officer in Drug Regulatory Affairs Department in **Gland Pharma Limited, February 2003 till August 2006.**

KEY JOB REPONSIBILITIES:

- Submission of technical dossiers for registration of small molecule parenterals
- Preparation and Submission of Plant master files for parenteral facility registration.
- Submission of DMF Type II and Certificate of suitability for small molecules API.
- Review of below mentioned documents for small molecule parenterals:
    - Filter validation protocols and reports
    - Method validation protocols and reports
    - Stability study protocols and reports
    - Specifications and Test methods
    - Batch manufacturing records
    - Country specific artworks

ACADEMIC PROJECTS ACCOMPLISHED:

Phytochemical and pharmacological investigation of species lantana camara linn.

Phytochemical and pharmacological investigation of Allicin (Garlic Extract), and development of Allicin microspheres, awarded Grade A accreditation by JNTU.

PROFESSIONAL TRAININGS ATTENDED:

Attended the training on ‘Submission of eCTDs to EU and US markets’ conducted by Take Solutions.

COMPUTER SKILLS:

MS-office (Word, Excel, Powerpoint), eCTD software, Internet tools, Coral draw software (updation of existing packaging material).

STRENGTHS:

Sincere, Good quality review, Good communication skills, flexible, adaptability, strong interpersonal skills, Quick learner, proactive, positive attitude and problem solving ability.

PERSONAL DETAILS:

Name	:	Potluri Saritha Devi
Father’s Name	:	Potluri Balagangadhar Tilak
Date of Birth	:	16-09-1980
Marital Status	:	Married
Nationality	:	Indian
Languages Known	:	Telugu, English, and Hindi

REFERENCE: Will be provided on request.