Padmamalini Srinivasan
L403, Atrium, 22 Kalakshetra Road,
Thiruvanmiyur, Chennai-600041
India

Ph: +91-9967362041 (email: spadmamalini@gmail.com)

CURRICULUM VITAE

Sr Incubation Professional - Start up, IIT Madras incubation cell, Chennai
May 2019 – Oct 2021

1. Supported the entrepreneur community for incubation, mentoring deep technology ventures utilizing AI, Data analytics, ML, Robotics, etc. Assess the product market fit, business models and facilitate with incubation for availing services.

2. Assistance to incubation cell for building and forging partnerships with academia, investors for early stage, mentors, government institutions for funding, grants, other incubators for startups to leverage.

ARD (Manager), Monolom Pharma India (Formerly Perrigo API India Pvt Ltd), Ambernath Mumbai Feb, 2016 to Jun, 2018

1. As Head of ARD, led API Analytical Research delivering increased responsibilities, managing all levels of people and priorities on day-to-day activities.

2. Successfully **filed three DMFs** and led a 20-member team involved in analytical **method development and validation**, data analysis, fixing specification limits and standard test procedures based on in-house and USP/EP pharmacopeia.

3. Facilitated analytical Project progress to completion, delivered presentations and communication of key issues and strengthening future steps to Israel team for successful method transfers with respect to RM spec/STPs, IPC, intermediates, API, Scale up support, justification of specifications including validation of methods.
4. Guidance to team members for HPLC/GC/titration Method development and validation of APIs at conceptual level. Complete Characterization of around 60 reference standards sourced in-house/ vendors with superior documentation procedures.
5. Support ARD planning activities for SRD team to process optimization, reference sample, and analytical activities for QBD (DOE), specification justification, Kilo lab and GMP campaign and lab stability.
6. Reporting and interpretation of data for reference standard characterization.
7. Guidance to carry over studies and leveled validation, planning for batch readiness and testing and reporting. Assisted the team in evaluation of genotoxic impurities, its risk assessment and determination.
8. Documentation including feasibility Reports, specification, and MOAs, DMF submission with relevant content and stylized formats.
9. Phase dependent analytical method transfers to commercial plants for QC testing with good success rates. Approval of testing plans, sample readiness, timing , resolved gaps and rectification with supporting hand-wetting exercise at commercial plants.
10. Coordinated efforts for regulatory filing between SRD, QA, CRO, RA and plant – Understanding and addressing queries, concise planning of experiments, and harmonization of pharmacopeia methods.

11. Team building, Recruitment, Training and Orientation of team members. Created procedures for set up of new Analytical lab and coordination with vendors and readiness for qualification of equipment and instruments.
12. Routine Laboratory maintenance and ensured good laboratory practices. Maintained relevant compliance mechanisms.
13. Co-ordinated with external testing partners for outsourcing activities and its daily management.

Principal Scientist, Mumbai	**Zoetis Pharmaceutical Research India Pvt Ltd, Jun 2006 - Dec, 2015**

1. Supervisory experience in **stability lab operations** in R&D facility with IQ, OQ,PQ of the instruments, and periodic calibration of instruments, **Reference standards management, LIMS, SAP.**
2. Global coordination and management of stability studies lab activities contracted at third party vendors at US, EU, India and Australia.
    a. Supported numerous large registration stability programs globally for the testing of API and DPs and monitored activities with regards to drafting protocol, scheduling, readiness, packaging, data review with robust documentation procedures
    b. Both API and DP Sample requirement, bracketing and matrixing proposals, post approval stability protocols right from development, registration and commercial stages. Trending of data and abnormalities checking.
    c. Skilled in anticipating issues upfront, efficiently facilitated investigations and root - cause analysis, through structured problem-solving methods
3. Scientific drafting stability experience in the technical filing aspects of chemistry, manufacturing and controls (CMC) of API, tablets, topical solution, injectable and rendered the relevant documentation for regulatory approvals on time. Reviewed the other technical portions with correlation to stability batches for physical and chemical trends.
4. Created and implemented the development of reference standard supply model for supply to CROs and centralized storage for all India centric projects for local requirements.

Research Associate	**Orchid Chemicals, Chennai**	**Mar 2001 - May, 2006**
Analyst	**Cipla Bangalore**	**Mar 1997 – May, 2000**

1. Developed chromatographic methods with shorter run times and easily accessible rugged columns, built a system for a thorough data review of validation reports and release and stability data.
2. Performed in-process analysis of Cephalosporin and generic drug products in Orchid in the earlier days.
3. Adequacy and Accuracy Validation data reviews of Assay, Related substances by HPLC, residual solvents, pXRD, titrimetry in Orchid.
4. Assigned quality attributes to fix the specification for release and shelf life and created a process for the specification setting and recognized Subject matter expert in Orchid. Assisted in preparing a guideline for setting specifications.

5. **<u>At Cipla</u>**, hands on experience in HPLC, dissolution testers, UV, IR and KF titrators and exposure to many seminars in technical and lab compliance systems, Good understanding in chromatography and other analytical techniques.

CORE COMPETENCIES

<u>Behavioral Competencies: -</u>

1) Adheres to timelines to meet project milestones.
2) Demonstrated ability to work in Project management framework
3) Ability to work in multiple projects and deliver oral presentations.
4) Demonstrates adequate oral and written communication skills.
5) Concentrates on specific to details.
6) Know to use MS Office tools including fair knowledge in MS Project

ANALYTICAL EQUIPMENT EXPOSURE

1) HPLC (Agilent, Waters)
2) GC (Agilent)
3) IR
4) UV Spectrophotometer (Perkin Elmer)
5) Polarimeter (Perkin Elmer)
6) Autotitrator (Metler)
7) Karl fisher Instrument(KF) (Metler)

ACADEMIA/CERTIFICATIONS

*Certificate course in **Regulatory affairs** from IPM, Mumbai in Oct, 2015.*

*Executive MBA in **Business analytics** from IIM, Calcutta in Aug, 2009.*

*M.Tech in **Modern methods of Chemical analysis** from I.I.T-Delhi in Dec 1996.*

*M.Sc. in **Chemistry** from **I.I.T-Chennai** in May 1995.*

*B.Sc in **Chemistry** from **Madras University** in May 1993*

IT SKILLS

- Proficient in LABWARE LIMS, SAP-QM, MS Office, Statistical evaluation of stability data

PERSONAL DETAILS

Date of Birth : 22nd Feb 1973

Linguistic Abilities : English, Hindi & Tamil

Relocation : Possible