RAO CHILAMKURTI, PHD

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DRUG DEVELOPMENT AND MANUFACTURING CONSULTANT

Expertise in Process Development and Validation to Ensure Product Approval and Launch

Injectable Products Development | Technology Transfer | Process Validation
NDA & ANDA Quality Review | Stability Evaluation

R&D leader with proven knowledge in parenteral product development. Focus on solving technical and manufacturing challenges through quality tools to enable on time approval and product launches. Build relationships with global manufacturing plants and supply chain partners to ensure successful technology transfer. Highly focused on results and cross-functional collaboration. Learn quickly and ramp up into new projects.

Areas of Expertise and Selected Accomplishments:

- Developed generic and proprietary injectable products in flexible plastic containers, prefilled syringes, and glass vials for global markets.
- Delivered expert review of Quality Modules for NDA / ANDAs and strategies for responding to deficiencies and corporate research leadership (CRL) to ensure product approval.
- Led functional teams for formulation and process development, and technology transfer of new products to market in the US, Canada, and Europe.
- Recognized as Subject Matter Expert (SME) for technology transfer and process validation of drug products for the US, Canada, and Europe.
- Worked extensively with client pharma companies (B2B) in developing and manufacturing proprietary drugs, including development proposals and strategies, monitoring studies, regulatory submissions, and product launch.

PROFESSIONAL EXPERIENCE

BAXTER HEALTHCARE CORPORATION, Round Lake, IL

Senior Advisor / Principal Scientist 2011 – 2023

Served as senior technical SME in manufacturing process development and technology transfer for multiple drug development project teams. Member of R&D management team.

- Advised teams on project technical direction and resolution of technical challenges of injectable drugs, ensuring on-time regulatory file submissions and approval.
- Liaised between pharma R&D and 4 different manufacturing plants in the US and Europe, facilitating technology transfer and product launches, resulting in over 12 product approvals during past 10 years.
- Collaborated proactively with contract manufacturing organizations in the US and China, resolving manufacturing hurdles and facilitating technology transfer.
- Created strategies for determining stability batch sizes, process validation / commercial batch sizes based on market demand, ensuring compliance to regulatory and GMP requirements.
- Designed process development and scale-up studies for numerous products, including improvements to existing product processes.
- Developed and implemented process validation plans (including European and Canadian requirements for submission), Concurrent Validation and Continued Process Verification (Stage 3), leading to approval and launch of several products.
- Interacted with API suppliers at their facilities, DCAT and CPhI meetings and one-on-one discussions, facilitating identification of technically and economically suitable API suppliers.
- Provided expert review of quality modules for NDA / ANDAs and strategies for responding to deficiencies and CRLs, resulting in several NDA / ANDA, EU, and Canadian approvals.

BAXTER HEALTHCARE CORPORATION (Continued)

Senior Director, Pharmaceutical Technology 2004 – 2011

Managed Pharmaceutical Technology / Process Development department and API Sourcing function with more than 15 employees. Oversaw process development, scale up, process validation, CMC / CTD section development, and technology transfer to plants in the US, Puerto Rico, and Europe. Global R&D Leadership team member, providing project and process guidance.

- Developed and validated manufacturing processes and launched several new drug, nutrition, and renal products in the US, Canada, Europe, and Asia. Examples include premixed injections: Nexterone (amiodarone), Cardene (Nicardipine, Chirocaine; and injections Clinolipid, Clinisol, and Extraneal dialysis solution.
- Served as R&D lead for BioPharma (Contract Development & Manufacturing) franchise, interacting extensively with pharma client companies to set and track development strategies and goals.
- Led API sourcing function, ensuring timely sourcing and supply of APIs, contracts for generic drug business based in Baxter New Jersey facilities.
- Implemented continuous improvement program, reducing development time significantly (development start to stability: 9 to 12 months from 12 to 15 months).
- Integrated R&D activities through site acquisition (Baxter Bloomington) and consolidation of R&D (New Providence and Cherry Hill R&D facilities).
- Headed R&D for Baxter US Compounding business, directing method validation, drug compatibility, and stability evaluation of numerous admixed drug solutions in facilitating setting stability dating in the US, Europe, Canada, and Australia.

Prior roles at Baxter Healthcare Corporation:
Held several positions with increasing responsibility, including senior research associate, scientist, senior scientist and director in pharmaceutical development, formulation science, and drug delivery.

EDUCATION

Doctor of Philosophy (PHD), Pharmaceutics, University of Rhode Island, Kingston, RI
Master of Science (MS), Pharmaceutics, University of Rhode Island, Kingston, RI
Bachelor of Science (BS), Pharmacy, Banaras Hindu University, Varanasi, India

SOFTWARE SKILLS

Microsoft: Excel, PowerPoint, Word

HONORS AND AWARDS

Received multiple awards, including: Customer First, Corporate Technical, Outstanding Contribution, Outstanding Commercial Success, Technical Achievement

PROFESSIONAL AFFILIATIONS

Parenteral Drug Association
Founding Member of Midwest Validation Discussion Group

PATENTS, PUBLICATIONS, AND PRESENTATIONS

Several publications in peer-reviewed journals and presentations in national and international conferences.
Two patents, including “Premixed Formulation of Piperacillin Sodium and Tazobactam Sodium Injection”, resulting in injectable commercial product that has been on market for over 25 years.