Prasad Gullapalli, Ph.D.

Senior Drug Product Consultant

Core Competencies

- Oral Dose Formulation
- Process Development
- Person in Plant
- CMO Selection
- Supply Chain
- Scale-up
- Clinical Trial Material
- Commercial Manufacturing
- Gastro-Retentive CR

Professional Summary

Dr. Gullapalli is skilled in the development and execution of CMC strategies for New Chemical Entities (NCEs) and for product line-extensions of existing molecules using patentable novel drug delivery technologies. He has over 20 years of experience developing strategies to respond to agency drug product inquires and representing clients during Preapproval Inspections (PAI), conducting investigations on Quality Events (QEs), and implementing Corrective and Preventive Actions (CAPAs).

- Built in-house oral dosage formulation and process development capabilities and personnel expertise (drug substance (DS) characterization, pre-formulation, analytical, and clinical & preclinical formulations) to complement the outsourcing model of early to late-stage product development and cGMP manufacturing at CROs & CDMOs,
- Expertise in immediate/Controlled Release (IR/CR) Tablets & Capsules, liquid-filled soft gel & hard capsules (SEDDS/SMEDDS/aqueous & nonaqueous solubilized dosage forms), and nanocrystal dispersions (NCD),
- Hands-on experience in both Biotech/Pharma and Contract Research Development & Manufacturing Organization (CRO & CDMO) sides of drug product (DP) development, selecting CROs & CDMOs, negotiating timelines and logistics and providing oversight (person-in-plant) of all supply chain management activities for clinical programs.

Before joining DSI, Dr. Gullapalli served as Head of Formulations at Dart Neuroscience and similar roles with Elan, Chiron and Purdue Pharma. He is RAC certified and earned his Ph.D. in Pharmaceutics from the University of Tennessee. He has eleven Patents/Applications and over 30 Publications/ Presentations.

Education

Ph.D.	Pharmaceutics	University of Tennessee
M. Pharm.	Pharmacology	Andhra University
B. Pharm.	Pharmacology	Kakatiya University

Prasad Gullapalli, Ph.D.

Senior Drug Product Consultant

Professional Experience

DS InPharmatics/Consultant — 2019 - Present

Senior Drug Product Consultant

- Providing consulting services in the areas of drug product development, manufacturing, testing, and intellectual property (IP).

Dart NeuroScience, LLC — 2014 - 2018

Director, Head of Formulations (CMC Formulation, Pre-formulation & Analytical)

- Built in-house drug substance (DS) characterization, pre-formulation, analytical, and oral dosage form development capabilities and personnel expertise to complement company's outsourcing model for later-stage development,
- Managed in-house product development and outsourced process scale-up/CTM manufacturing activities for the clinical programs,
- Authored/reviewed/approved batch records, protocols, development reports, and IND documentation,
- Designed and executed drug product (DP) development strategies for several NCEs resulted in successful filing of 6 INDs/amendments and production of Phases 1 and Phase 2 clinical supplies using commercially viable formulations and scaled-up manufacturing processes,
- Selection of NCEs with optimal biopharmaceutical properties, polymorphs, and salts.

Pharmaceutics International, Inc. (PII) — 2011 - 2014

Vice President, Drug Product Development & Manufacturing

- Led R&D staff of 13 responsible for designing, developing, and producing oral drug products for NCEs and existing molecules using novel Nanocrystal Dispersion (NCD), Liquid-filled Soft & Hard Capsule, and IR/CR Tablet/Capsule technologies,
- Responsible for Product Development Reports (PDRs) and CMC documentation for regulatory filings,
- Managed manufacturing staff responsible for manufacturing clinical and commercial scale products in cGMP environment in support of clients' programs,
- Developed/executed formulation and process development protocols using QbD, Master Production Records (MPRs) and process optimization/validation protocols,
- Represented clients during FDA PAIs and addressing FDA inquiries.

Elan Pharmaceuticals **2006 - 2011**

Associate Director, Formulation & Process Development

- Developed in-house oral dosage forms, development capabilities/technical expertise, managed in-house development and outsourced process scale-up/CTM manufacturing activities at CDMOs in support of Élan's Alzheimer's NCE programs,
- Designed and executed CMC development strategies: innovative Nanocrystal Dispersion formulation approach with improved bioavailability for the poorly soluble compound ELND006, Gastro-Retentive Controlled Release (GRCR) formulation approach for compound ELND005 with GIT site-specific absorption characteristics, and identification of a stable crystalline form for the difficult to crystallize compound ELND007.