Wantanee Phuapradit, Ph.D.

Senior Drug Product Consultant

Core Competencies

- Formulation Development
- Process Validation
- CMO transfer
- Due Diligence
- Person in Plant
- CMO Selection
- GAP Analysis
- Project Management
- Process Scale-up

Professional Summary

Dr. Phuapradit confidently leads, directs, and makes decisions on a large drug product development portfolio in an entrepreneurial setting through all phases including early-stage product selection, product development, technology transfer, regulatory submission, FDA approval and commercialization. A Leader of high-performing scientific and technical cross functional teams of pharmaceutical development scientists and other related CMC functions has built strong internal and external networks.

She provides committed and inspiring leadership, stewardship and advocacy, striving for compound and manufacturing process knowledge development, continuous improvement, acceleration, risk assessment and mitigation, resource allocation and support. She ensures an effective Target Product Profile is in place which defines product characteristics and performance expectations to inform pharmaceutical development success.

Dr. Phuapradit holds a Ph.D. in Pharmaceutics with over 30 years of experience in pharmaceutical oral dosage development, scale-up, technology transfer of generics, 505b2 and new chemical entities. Accolades include over 20 patents, 10 publications, and over 20 presentations/speaker events all specializing in pharmaceutical excellence.

Education

Ph.D.	Pharmaceutics	St. John's University
M.S.	Pharmaceutics	St. John's University
B.S.	Pharm. Sciences (Honors)	Chulalongkorn University

Professional Experience

Design Space InPharmatics, LLC **2021 - Present**

Senior Drug Product Consultant

- Responsible for ensuring adequate transition plans to transfer knowledge to commercial manufacturing,
- Maximizes alignment, cooperation, input, decision making, commitment and synergy, of Pharmaceutical Development Team members to ensure their technical contributions meet and exceed program objectives.

Tulex Pharmaceuticals, **2019 -2020**

Senior Vice President
Chief Scientific Officer

- Spearheads the company's project portfolio selection, intellectual property development, research & development and regulatory functions.

Kashi BioSciences **2011 - 2019**

Senior Vice President, Formulation Research & Development

- Develops and implements comprehensive, compound-specific, development strategies and tactics to meet the project needs that incorporate all elements across the drug substance, drug product, analytics, quality, regulatory, and clinical material space,
- Extensive knowledge and track records of pharmaceutical development and regulatory pathways for generic/505b2/NCE,
- Effectively transforms formulation ideas/concepts into clear development strategies (IP/Regulatory/Technical) while accurately managing budget,
- Develops stable, robust and bioequivalent products based on scientific driven approaches,
- Ensures efficient development timelines leading to FTF, successful execution of PE/ANDA batches, high quality ANDA submission based on QbD,
- In-depth knowledge on the formulation characterization, IVIVR development for achieving bioequivalent drug products,
- Participates in critical review of provisional and non-provisional patent applications supporting 505b (2) projects,
- Evaluates in-license opportunity and provide critical decision making.

Barr Laboratories/ Teva Pharmaceuticals **2007 - 2011**

Senior Director, Formulation Research & Development

- Worked on numerous complex generics oral solid dosage forms development,
- Specialized in oral controlled release dosage form development,
- Mentored formulation scientists with respect to science and technology,
- Served as a Subject Matter Resident Expert of the Formulation R&D Team,
- Established the critical manufacturing processes for robustness and successful technology transfer to production,
- Analyzed and resolved technical complexities related to manufacturing, stability and bioavailability,
- Had ability to effectively utilize discriminating in-vitro test methods for bioequivalence assurance,
- Ensured the formulations developed, meeting all defined target profiles,
- Ensured that the regulatory documents are prepared in a timely manner.

Hoffman La Roche **1989 - 2007**

Senior Research Leader

- Led oral formulation development team and mentored scientists in handling challenging projects with respect to science and technology,
- Exhibited a leadership role on a global level in oral dosage form research and development,
- Developed oral dosage forms for toxicology and clinical studies and the market, including line extension,
- Was an expert in designing solid dosage form and manufacturing procedures; provides general expertise on solid dosage forms unit operations and techniques, cGMPs and regulatory issues related to oral products,
- Designed experiments to evaluate excipients interactions with new molecular entities and the effects of critical processing parameters on formulation stability,
- Identified and validated significant research opportunities for new drug delivery systems,
- Ensured appropriate technical, scale-up, and production strategies and timelines are in place to meet clinical supply and registration needs, and ensures production, technology transfer, validation and regulatory outcomes, meet or exceeds industry standards,
- Prepared scientific manuscripts for internal and external publication, and patent applications,
- Monitored the manufacture of clinical batches at external contractors or other Roche affiliates,
- Ensured that the documentation and maintenance of the laboratories and equipment are in accord with corporate and departmental SOPs,
- Superior writing skills capable of articulating complex scientific issues in clear, concise and accurate reports and regulatory documentation.

Research Experience

- Drug Absorption Enhancement
- Controlled Release Drug Delivery Systems
- Colonic-Targeted Drug Delivery Systems
- Powder and Tablet Technologies
- Micro-precipitation Technology
- Fine Particle Coating Technology
- Hot Melt Granulation Technology
- Specialized Drug Delivery Systems for BCS Class 2, 3 and 4 Compounds
- Stabilized Amorphous Formulation
- Fluid Bed Technology
- Spray Drying Technology
- Lipid Delivery Systems
- Designs of Experiment (DoE)
- Quality by Design and Design Space