**Jason M. LePree, R.Ph., Ph.D.**

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**Pharmaceutical Development Leader**

Technical project leader with comprehensive background in disciplines of Analytical Sciences, Preformulation / Material Characterization and Formulation Sciences. Drives pharmaceutical development of branded and generic products at several companies from preclinical (early-stage development) through Phases 2 or 3 (late-stage development).

Adept in formulation specialties, including solid-oral dosage forms (with specialization in lipid-based formulation of low solubility compounds with poor bioavailability) and Sterile Products for IV, SC, IM, nasal and ophthalmic administration. Expertise in analytical specialties, including chromatography, dissolution and solid-state analysis, and material characterization. Recognized as being dedicated, collaborative leader with excellent interpersonal skills, and a teacher / mentor to less experienced scientists and team members.

**Project Management | Analytical Method Development & Validation** **| Laboratory Set-Up**

**CRO/CDMO Management |Solid-State Chemical Analysis | Thermal Activity Monitoring |Topical, Parenteral Formulation Development & Manufacture (Small Molecule and Peptide)**

**| Six Sigma Green Belt|Module 3 Author | Solid-Oral Formulation Development & Manufacture | Educator / Professor**

**Professional Experience**

**Boehringer Ingelheim Animal Health (Site closure Dec 2025)** North Brunswick, NJ

July 2023 to Present

**Principal CMC Technical Development Lead and Senior Associate Director in Analytical Pharmaceutics/Preformulation (Dual Roles)**

Direct technical development projects resulting in the creation of a robust product and complete CMC technical package to ensure successful global regulatory approvals by relevant health authorities and scale-up and industrialization of the finished product. Maintain project timelines and budgets for all CMC activities.

Serve as a member of the Core Project Team (CT) with delegated responsibilities in the areas of Analytical, Formulations, Process, Regulatory CMC, Packaging and Operations to work globally and cross-functionally to drive the development of new product development projects from development to launch as the leader of Technical Development Teams.

Lead Physical Characterization Group in Analytical Pharmaceutics to guide Preformulation, Quality by Design and Material Characterization disciplines. Guide and standardize worldwide preformulation activities in Boehringer Ingelheim animal health by leading a Preformulation working group of scientists from Chemical Process Development, Physical Chemistry, Formulation and Analytical Chemistry.

Recent accomplishments included A) writing and submission of Module 3 sections for drug product for a long-acting injectable product for Brazil, Mexico, Uruguay, Argentina and several other Latin American countries. B) Completed submission all Module 3 sections for drug substance and drug product for a long-acting injectable product for Brazil, Mexico, Uruguay, Argentina and several other Latin American countries. C) design and execution of a formulation mixture design experiment to identify a composition that provides 6-month sustained release in rat and dog models; in addition, developed an APP IV-based dissolution method that is predictive of in-vivo performance.

**Viatris Eye Care Division (Formerly Oyster Point Pharma, acquired Jan 2023)** North Brunswick, NJ

Aug 2021 to July 2023

**Director, CMC Development and Project Management**

Direct cross functional teams to drive development of late-stage drug products. Oversights include Analytical Methods Development, Validation, Verification and Scale-up and Transfer of Manufacturing Processes for solutions and ointments. Responsible for maintaining project guidelines and budgets. Accomplishments:

* Guided analytical work at CRO necessary for Post Approval Commitments, including Nitrosamine Method Development and Validation for testing of commercial product.
* Extractables and leachables work for primary packaging including HDPE bottles and nasal spray pumps and in-process manufacturing components.
* Transfer of analytical methodologies between multiple CRO sites, including technical troubleshooting of methods for assay and impurities, preservative content assay and nasal spray testing.
* Manufacturing Process Scale-up and transfer for an ophthalmic ointment.
* Guiding analytical work in-house and at CRO for nasal spray pumps needed for Prior Approval Supplements to respond to changes in nasal spray pump design.
* Authored and received approval of work from FDA for Post Approval Commitment responses for Nitrosamine Method Development and Validation

**FERRING PHARMACEUTICALS (R&D closed Dec 2020)**, Parsippany, NJ 2018 to 2020

**Associate Director, Pharmaceutical Sciences, Pharmaceutical Development**

Served as CMC Project Lead, with specialty in Formulation Science, oversaw external formulation feasibility and development activities for US and global projects to ensure delivery of prototypes and products with high scientific quality. Met the needs of patients who relied on company’s medicines.

* Led long-acting injectable PLGA-based decapeptyl peptide product, driving formulation development from preclinical stage at lab scale to Phase 3 at commercial scale.
  + Designed custom manufacturing equipment and guided manufacturing site selection, while managing CMC budgets and timelines.
* Technical manager of external and internal labs, ensuring ensure delivery of R&D, Pilot Scale, and Commercial Scale Batches.
* Oversaw staff development and provided training and oversight to colleagues in external labs.
* Directed design of experiment studies for process robustness, identifying critical process parameters and impact of their variation on product critical quality attributes.
* Authored 3.2.P.2, 3.2.P.3, 3.2.P.7 sections for an injectable fertility product.

**GATTEFOSSÉ USA**, Paramus, NJ & Lyon, France 2016 to 2018

**Senior Principal Scientist 2018**

**Pharmaceutical Applications Laboratory Manager 2016 to 2018**

Established the North American Technical Center of Excellence Application Laboratory to support oral and topical lipid-based formulation development, processing, analysis, and characterization for external clients and internal projects and presented seminars to customers and scientific audiences to promote use of Gattefossé excipients and build/maintain customer base. Hired, trained and cultivated laboratory staff.

* Spearheaded activities for review, cost negotiation, procurement, installation, and qualification of analytical instrumentation and processing equipment with over $750K budget, including pH Stat, MDSC, X-polarized light microscope with hot stage, stereoscope, UPLC, Dissolution Bath, Rheometer, Dynamic Light Scattering Particle Sizer, Thermal Activity Monitor, Automated Franz Diffusion Cell system), HME, comill, mixers, homogenizers, and a high shear granulator.

• **ABON PHARMACEUTICALS**, Northvale, NJ 2015 to 2016

**Distinguished Research Fellow, Formulation Research & Development**

Led Preformulation and Solid State / Physical Characterization Laboratory. Performed DSC, TGA, PXRD, SEM, TAM, and Water Sorption Analysis studies for Scientists or mentored Scientists to effectively utilize techniques to assist formulation development or characterize and troubleshoot formulations.

* Served as technical guide for formulation design of solid oral and sustained release parenteral dosage forms, including extended-release osmotic tablets, matrix tablets, and coated pellets and tablets for solid oral dosage forms, PLGA microspheres, and micronized API for long-acting injections.

**ELITE PHARMACEUTICALS**, Northvale, NJ 2014 to 2021

**Consultant, Scientific Affairs 2015 to 2018, 2021**

Provided technical oversight for Analytical R&D, Formulation R&D, and Quality Control Guided analytical method development and validation for various tablet and capsule formulations.

* Acted as technical advisor for formulation of immediate release and controlled release opioid and antagonist solid oral dosage forms.
* Performed dynamic water sorption-desorption studies on active pharmaceutical ingredients and finished drug product formulations for data-driven formulation development.
* Authored 3.2.P.2 Pharmaceutical Development sections for multiple ANDAs

**Vice President, Scientific Affairs 2014 to 2015**

Oversaw In-vitro lab assessment testing of Abuse Resistant Opioid Formulations for NDA filling of SEQUESTOX.

* Designed, implemented, and managed in-vitro challenge tests for abuse resistant narcotic formulations.
* Created, executed, and oversaw pre-formulation / characterization studies to support development of immediate release and sustained release abuse resistant formulations and provide technical insight.

**CAPSUGEL**, Pearl River, NY 2013 to 2014

(Site closure announcement Oct 2014, Site closed Jan 2015)

**Principal Scientist, Formulations Research and Development**

Directed Preformulation laboratory and Preformulation activities, including solid state analyses, excipient compatibility studies, oxidative, and hydrolytic screening studies for API (Nutraceuticals) and drug product.

* Created and validated / verified lipolysis testing procedures for lipid-based formulations for selection of candidate formulations for in-vivo studies.
* Devised a predictive stability screening technique for anti-oxidative effectiveness used in solid lipid particle formulations.
* Provided novel application of DSC to determine how processing would affect the solid-state chemistries of solid lipid particles.

**ABON PHARMACEUTICALS**, Northvale, NJ 2011 to 2013

**Research Fellow, Formulation Research & Development**

Orchestrated Preformulation and Solid State / Physical Characterization Laboratory, including DSC, TGA, PXRD, SEM, TAM, and Water Sorption Analysis. Performed studies for scientists or guided scientists to effectively utilize techniques to benefit formulation development work or characterize and troubleshoot formulations.

* Co-developed and authored Module 3 ANDA sections for Abon’s first approved injectable product (Clofarabine).
* Formulated and scaled up controlled release tablet formulation for a muscle relaxant from lab scale to bio-batch.

**PENWEST PHARMACEUTICALS**, Patterson, NY 2007 to 2011

(Acquired by Endo Pharmaceuticals Summer 2010 and site closed April 2011)

**Director, Preformulation and Formulation, Non-Solids**

Served as CMC project lead for drug substances and formulations supporting orphan diseases, such as Friedreich’s Ataxia. Formulator for capsule-filled liquid formulations and topicals.

* Developed lipid-based formulations of drug candidate, A0001 for preclinical studies (IV and oral formulations), and Phase I and Phase II studies (oral formulations).
* Wrote drug product and drug substance sections for Phase I and Phase II INDs and Phase II IMPDs.
* Championed CMC team, including representatives from Analytical Sciences, Quality Assurance, Formulations, Non-solids, Quality Control, and Contract Research Organization (CRO), ensuring drug substance and drug product were available for preclinical and clinical trials.
* Guided research efforts of CRO, confirming delivery of API used in preclinical studies with targeted level of a key impurity used in Preclinical and Phase I studies.

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**Additional Experience**

Oversaw development and validation of methods for Assay, Impurity, Volatile Organic Compounds, Water Content, and Dissolution testing of drug substances and drug products, including tablets and capsules with progressive roles from bench Chemist to Group Leader of Analytical Sciences at the following companies:

**PARKE-DAVIS**, Morris Plains, NJ, **Senior Scientist**

**BOEHRINGER-INGELHEIM**, Ridgefield, CT, **Senior Scientist, Principal Scientist**

**HOFFMANN-LAROCHE**, Nutley, NJ, **Principal Scientist**

Developed and validated analytical methods for commercial products including Accutane and Versed while working at method development and validation specialist in quality control.

**NOVARTIS**, East Hanover, NJ, **Research Fellow**

**Academic Experience**

**LONG ISLAND UNIVERSITY**, Rockland County Campus, NY 1998 to 2018

**Adjunct Professor of Pharmacy**

Instructor for PHS 972, Pharmaceutical Analysis & PHS 701, Physical Chemistry & PHS 832, Pharmacokinetics.

**LONG ISLAND UNIVERSITY**, Rockland County Campus, NY 2012 to 2014

**Part-Time Program Director**

Oversaw student recruitment activities. Devised Outcomes Assessment plans for Middle States Review. Served as student advisor.

**ARNOLD AND MARIE SCHWARTZ COLLEGE OF PHARMACY**, Brooklyn, NY 1996 to 1998

**Assistant Professor of Pharmaceutics**

Graduated 3 MS students with research topics regarding retention mechanisms in RP-HPLC and complexation studies between fluoride and amino acids with 9 to 12 credit semester teaching loads.

**Education**

* **Doctor of Philosophy (Ph.D.)**, Pharmacy (Pharmaceutics), University of Wisconsin-Madison, Madison, WI
  + Thesis Title: Solvent and Pressure Effects on the Decarboxylative-Dichlorination of N-Chloro-alpha-Amino Acids in Binary Aqueous-Organic Cosolvent Systems: The Phenomenological Model Applied to Chemical Reaction Rates
* **Master of Science (MS)**, Pharmacy (Pharmaceutics), University of Wisconsin-Madison, Madison, WI
  + Thesis Title: The Solubility of Naphthalene in Binary Aqueous-Organic Cosolvent Mixtures: An Investigation of the Phenomenological Model
* **Bachelor of Science (BS)**, Pharmacy, Rutgers University College of Pharmacy, Piscataway, NJ
  + Graduated with highest honors and participated in the College of Pharmacy Honors Program

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**Awards**

* PMA Pre-doctoral Fellowship Award
* Syntex Research Fellowship Award
* Women’s League of Rutgers University Scholarship Award

**Publications & Presentations**

Abstracts of Presentations:

* LePree, J.M.; Dave, M. “Characterization of API stability via Ultra-High Pressure Liquid Chromatography (UPLC) and Thermal Activity Monitoring (TAM)”, NERDG 2018.
* Dave, Masumi; LePree, J.M. “A Systematic Approach to Lipid-Based Formulation Development for a Poorly Soluble API, Fenofibrate”, AAPS Annual Meeting 2017.
* LePree, J.M.; Williams, H.D. “Lipid Multiparticulates (LMPs) for Improving Intestinal Absorption of Low Solubility Compounds: In Vitro Digestion (Lipolysis) as a Tool to Support Formulation Design and Mechanisms of Solubilization” AAPS Annual Meeting 2014.
* LePree, J.M.; Sun, Y.; Salageanu, J.; Heald, S.; Hawi, A. “In vitro and In vivo testing of Lipid-Based Dosage Forms for A0001”, Northeast Regional Discussion Group-AAPS, 2010.
* LePree, J.M. “Application of Chemiluminescent Nitrogen Specific Detection to Impurities Analysis of Drug Substance”, Eastern Analytical Symposium, 2002.
* LePree, J.M.; Fett, J.J.; MacNeil, T.M.; Hokanson, G.C. “Robustness Testing of a Dissolution Procedure” Pharm. Res. 13 (1996) s-45.
* LePree, J.M.; Cancino, M.E. “Application of the Phenomenological Model to Retention in Reversed-Phase High Performance Liquid Chromatography (RP-HPLC).” Pharm. Res. 14 (1997) s-377.

White Papers:

* LePree, J.M.; “LIPID-BASED DELIVERY - Are Lipid-Based Drug Delivery Systems in Your Formulation Toolbox?” Drug Development and Delivery, Issue: October 2017, Posted Date: 9/29/2017.

Journal Articles:

* LePree, J.M.; Connors, K.A. “Hydrolysis of Drugs” Encyclopedia of Pharmaceutical Technology, Marcel Dekker, New York, 2001; 1506-1513.
* LePree, J.M.; Cancino, M.E. “Application of the Phenomenological Model to Retention in Reversed-Phase High Performance Liquid Chromatography (RP-HPLC)” J. Chromatogr. A. 829 (1998) 41-63.
* Brown, M.C.; LePree, J.M.; Connors, K.A. “Pressure and pH Dependence of the Kinetics of Decarboxylative-Dechlorination of N-Chloro-l-Alanine” Int. J. Chem. Kinetics 28 (1996) 791-797.
* LePree, J.M.; Connors, K.A. “Solvent Effects on Chemical Processes. 11. Solvent Effects on the Kinetics of Decarboxylative-Dechlorination of N-Chloro Amino Acids in Binary Aqueous-Organic Solvents” J. Pharm. Sci. 85 (1996) 560-566.
* LePree, J.M.; Mulski, M.J.; Connors, K.A. “Solvent Effects on Chemical Processes. Part 6. The Phenomenological Model Applied to the Solubility of Napthalene and 4-Nitroaniline in Binary Aqueous Organic Solvent Mixtures” J. Chem. Soc. Perkins Trans. 2 (1994) 1491-1497.