

## *CURRICULUM VITÆ*

### **RODOLFO PINAL, Ph.D.**

Purdue University  
Department of Industrial and Physical Pharmacy  
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West Lafayette, IN 47907  
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#### **EXPERIENCE:**

2009-Present	Associate Professor
2003-2009	Assistant Professor

Department of Industrial and  
Physical Pharmacy  
Purdue University

#### **Research:**

Leading and conducting graduate level research in the study of some of the most prevalent problems encountered during pharmaceutical product development, such as solubility, solubilization and drug delivery, from the theoretical framework provided by the properties of liquid (fluid and amorphous) mixtures. Drug-polymer and drug-lipid mixtures as systems for improved solubility, dissolution and drug delivery are among current research projects.

#### **Solubility, solubilization and drug delivery of liquid mixtures and amorphous systems**

- Methods for enhancing oral bioavailability of poorly soluble active compounds
- Relationship between chemical structure and physical properties responsible for the solubility of drugs
- Development of amorphous formulations with improved drug solubility
- Stabilization of amorphous formulations through the study, modeling and control of molecular mobility

#### **Study of polymeric excipients and their interactions in pharmaceutical systems**

- Investigation of the effect of polymer-plasticizer interactions on the mechanical and mass transport properties of pharmaceutical polymers
- Dispersions of drug microparticles in polymeric films as drug delivery systems
- Production of spatially dispersed, stable nanocrystals for delivery of highly insoluble anticancer drugs via transcytosis
- Development of polymeric strip films containing immobilized, spatially dispersed API micro- and nano-particles

#### **Pharmaceutical Processing**

- Influence of excipient raw material physical properties on the quality attributes products made by roller compaction
- Use of acoustic emission for the continuous monitoring and control of pharmaceutical manufacturing processes
- Matrix assisted co-crystallization (MAC). Use of hot-melt extrusion for the production of formulated co-crystals in a scalable/continuous process

### **Prefabricated (modular) dosage forms**

- Guide the development of a new technology for the design and manufacture of pharmaceutical dosage forms
- Research and development on working parts based on desired function (ID/anti-counterfeiting, solubilization, crystallization inhibition, chemical stabilization, etc.)
- Blueprint design and 3D assembly of integrated dosage forms prototypes
- Comparative performance testing against commercial benchmark products

### **International Activities:**

2013- Present. Visiting Professor, Shenyang Pharmaceutical University, Shenyang, China

- Teach general aspects of pharmaceutics and physical characterization of solids to graduate and undergraduate students
- Teach theoretical and formulation aspects of solubility and solubilization of drugs
- Cover physical characterization of pharmaceutical solids in training courses designed for industrial scientists working in the Chinese pharmaceutical industry
- Serve as co-advisor of Masters' and Ph.D. students in the department of Pharmaceutics

2014 – Summer Faculty on Pharmaceutical Technology, Universidad de Los Andes, Bogota, Colombia.

- Solubility, solubilization and drug release from liquid mixtures and amorphous systems.

2015 - Present. Graduate thesis evaluation committee. Faculty of Pharmacy. Universidad Nacional de Colombia, Bogota, Colombia.

- Serve in graduate examination committee and thesis oral defense

### **Teaching:**

Teaching of undergraduate and graduate level courses on Pharmaceutics, Pharmaceutical Technology and Drug Delivery.

<b>Code</b>	<b>Course</b>	<b>Role</b>
IPPH 100	Pharmaceutical Science Orientation	Instructor
IPPH 471	Parenteral Products	Instructor
IPPH 562	Manufacturing Processes	Instructor
IPPH 587	Pharmaceutical Solids	Instructor
IPPH 521	Drug Development	Instructor
IPPH 690A	Solids Discussion Group	Instructor
PHAD 690	Introduction to Pharmaceutical Sciences Research	Instructor
IPPH 590	Applied Thermodynamics	Instructor
PHRM 828	Dosage Forms I	Instructor
PHRM 829	Dosage Forms II	Instructor
PHRM 866	Biotechnology and Advanced Parenteral Products	Instructor
AGRY 544	Environmental Organic Chemistry	Instructor

Code	Course	Role
ABE 591	Microparticulate Systems, Surface Properties & Performance	Instructor

#### **Administration:**

- Director of Graduate Studies. Academic advisor to new graduate students. Develop development program of individual graduate students in preparation to join a research group/advisor. Review and revise the Graduate Studies handbook for the department. 2016 – Present.
- Undergraduate Curriculum Council 2019 - Present
- Chair, Graduate Admissions Committee, Industrial and Physical Pharmacy. Evaluate application materials for students wanting to pursue a Ph.D. degree in the department. Conduct one-to-one interviews with applicants. Assess applicants' scientific and academic qualifications for admission to the department. Vote on admission/non admission of student applicants. 2006 - 2016.
- Director, NSF-I/UCRC Purdue Dane O. Kildsig Center for Pharmaceutical Processing Research (CPPR). 2005 – 2018 - Present.
- Director, NSF-I/UCRC Dane O. Kildsig Center for Pharmaceutical Processing Research (CPPR). 2005 – 2018.
- Associate Director, Center for Pharmaceutical Processing Research (CPPR). 2004.
- Chair, Faculty Search Committee, Endowed Professorship, Department of Industrial and Physical Pharmacy. 2010.
- Assessment Committee, College of Pharmacy. 2010 – Present
- Graduate Fellowships Committee, 2004 – Present
- Faculty Council, 2012-2014
- SWOT (strengths, weaknesses, opportunities and threats) Analysis Task Force, 2014-2015
- University Grievances Committee, 2015 – 2018
- Professional Outcomes Task Force, 2015
- University Advisory Committee on Equity, 2017 – Present
- PharmD Program Admissions committee, chair 2022
- PharmD Program Admissions committee, 2022 – Present

#### **Theses directed:**

Chen Mao, Ph.D. 2006. Structural relaxation and molecular mobility in organic amorphous pharmaceutical compounds. Purdue University.

Fabrice Gusching, M.S. 2006. Antiplasticization of pharmaceutical polymers (Antiplasticisation des polymères à usage pharmaceutique), Université Louis Pasteur, Strasbourg, France. Co-advisor.

François-Xavier Diringer, M.S. 2007. Influence of moisture on the ability of microcrystalline cellulose to form tablets. Université Louis Pasteur, Strasbourg, France. Co-advisor.

Sai Prasanth Chamarthy, Ph.D. 2007. The different roles of surface and bulk effects on the functionality of pharmaceutical materials. Purdue University.

Carole Bucher, M.S. 2008. Assessment of the distribution of API microparticles in polymeric films. Université Louis Pasteur, Strasbourg, France. Co-advisor.

Michelle K. Papp, Ph.D. 2009. Application of acoustic emission to the monitoring of pharmaceutical unit operations. Purdue University

Nathan A. Boersen, Ph.D. 2009. The development of roller compacted formulations using multivariate and dimensional analysis. Purdue University.

Ji-Young Kim, Ph.D. 2009. Hydrotropic solubilization of poorly soluble drugs. Purdue University.

Maria Elisa Luque. M.S. 2010. Toward the development of an ontological framework for drug-loaded film manufacture. Dept. of Chemical Engineering. Co-advisor.

Ryan J. McCann. PhD. 2011. Investigating the density distribution of roller compacted ribbons. Purdue University.

Andrew Otte, Ph.D 2011. From milling to particle engineering: formulations for dry powder inhalers.

Xin Chen. PhD 2012. Solubility estimation and rapid structural characterization of small molecule drugs in polymers. Purdue University. Co-advisor.

Bo Zhou. PhD 2012. Development of laminate based, prefabricated dosage forms – Formulation, processing and characterization. Purdue University.

Yan Zhang. Ph.D. 2012. Kinetic driving effects of phase transformations in mechanically activated powders. Purdue University.

Kevin Boksa. PhD. 2014. Matrix-assisted cocrystallization: the simultaneous production and formulation of pharmaceutical cocrystals using melt extrusion. Purdue University.

Yang Song. Ph.D. 2015. Acid-base interactions in amorphous solid dispersions: Formulation strategy for tyrosine kinase inhibitors. Purdue University. Co-Advisor.

Jing Ling. Ph.D. 2017. Crystallization control using fabricated polymeric materials. Purdue University.

Hwee Jing Ong. Ph.D. 2018. Drug solubilization by means of a surface-modified biopolymer enabled by hot melt extrusion. Purdue University.

Mario Cano-Vega. 2019. Ph.D. Quality by Design approach to develop 3D Integrated Pharmaceuticals for personalized medicine. Purdue University. Co-Advisor.

<b>1999-2003</b>	<b>Research Leader (Solid-State Pharmaceutics)</b>
<b>1997-1999</b>	<b>Principal Scientist (Solid-State Pharmaceutics)</b>
<b>Pharm. and Anal. R&amp;D</b>	
<b>Hoffmann-La Roche</b>	

Physical characterization of solids and Particle Technology. Supervisory responsibility for the group's activities and capabilities: X-ray powder diffraction, DSC and hot stage microscopy, TGA/IR, SEM, Image Analysis, particle size by Laser diffraction and Dynamic Light Scattering, Hygroscopicity (microbalance), Microcalorimetry (TAM), BET gas adsorption and gas pycnometry.

Responsible for identifying and devising methods for the measurement and monitoring of physical properties/parameters critical for the development of a given specific product or process. Responsibilities include the physical characterization of active ingredients, final dosage forms and intermediate blends. Work with formulation and process development scientists in troubleshooting powder technology issues of processability such as flowability, granulation and dissolution during development and technology transfer.

Leader of the Integrated Solid-State Strategy Team among international development centers for various projects. Designed and instituted methodology necessary for evaluating the physical attributes and stability for an amorphous formulation technology used in clinical trials. Work with Chemical Synthesis designing and implementing crystal polymorph screening strategy for new chemical entities during preclinical development and Kilo-lab production. Responsible for writing the IND and NDA sections on crystal polymorphism.

Provide official characterization data to Analytical groups on drug substances and formulations for GLP and cGMP qualification. Responsible for the regulatory compliance of the Solid State Pharmaceutics laboratory. Responsible for the development and validation of physical testing methods for regulatory submission and transfer to Quality Management for testing during production. Responsible, in the capacity of System Owner, for the Computer System Validation plan and implementation as dictated by 21CFR Part 11 for

instrumentation in the Solid State Pharmaceutics Laboratory. Technical Team Leader for preclinical activities (CMC section) of international project. Coordinate activities among scientists in the U.S., Germany and Switzerland, integrating Discovery Pharmacology, chemical supply, formulation and manufacturing, Toxicology and Pharmacokinetics.

**1993-1997**  
**Pharmaceutical R&D**  
**Hoffmann-La Roche**

**Principal Scientist**  
**Sterile Dosage Forms**

Developed injectable formulations for Phase 00 and Phase 0 studies. Worked in the solubilization and formulation of organic molecules to support Drug Discovery, early Toxicology and Pharmacokinetics. Setup the capability for injectable emulsion technology in the group to support proof-of-concept efforts in Discovery.

Specific assignments: Parenteral development team leader for a polypeptide molecule in Phase II/III. Formulation research and GLP manufacture, compatibility testing with manufacturing process/materials. Formulation development and manufacture of IND-enabling stability lots, issue Directions for Manufacture of cGMP clinical supplies and complete transfer of the manufacturing process for clinical supplies to the manufacturing department. Coordinate clinical supply manufacturing and analytical (stability, release, and cleaning assessment) activities with CMC leader for regulatory submissions and shipment to the clinic. Formulation scientist responsible for small molecule, line extension product. Manufacture of ANDA-enabling stability lots. Primary container selection studies, stopper extractables, tubing and filter membrane compatibility studies. Development of a manufacturing process suitable for trade lots. Preparation of Research Directions for technology transfer, scale-up and manufacture of exhibit lots. International Team Leader for project focused on the identification and evaluation of new technologies for drug delivery and drug development.

**1991-1993**  
**1990-1991**  
**Pharmaceutical R&D**  
**Hoffmann-La Roche**

**Senior Scientist (Preformulation)**  
**Research Associate (Preformulation)**

Physicochemical characterization of new drug candidates. Development of stability-indicating methods, HPLC, TLC, UV/IR and Fluorescence spectra. Stability screening in solution and solid state, pH-solubility profile, pH-stability profile and kinetics, pK<sub>a</sub> determination. Salt selection studies for new drug candidates. Photodegradation and drug-excipient compatibility studies, accelerated stability. Solubility/solubilization and partitioning studies. Developed a method for measuring partition coefficients using solid phase extraction.

Also responsible for studies intended to address issues specific to discovery or development programs: QSAR studies to support drug discovery, studies on drug sorption to valve-gaskets to support aerosol development, compaction studies to support solid-dosage form formulation.

**1988-1990**  
**Soil Science Department**  
**University of Florida**  
**Gainesville, Florida**

**Post-Doctoral Research Associate**  
**(Research on the fate and transport of organic compounds in complex mixtures)**

Responsible for all major technical aspects of the project: designing and conducting experiments, planning of future work, preparing and presenting progress reports to the sponsoring agency.

Analytical (HPLC) method development, chemical and scintillation counting analyses in multi-component, multi-phasic matrices, extensive measurements of solubility/partitioning in miscible and immiscible solvent mixtures, and of sorption/partitioning to natural and synthetic polymers. Computer modeling of data; developed and published a model to predict solubility of organic compounds in non-ideal solvent mixtures.

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