

CURRICULUM VITAE

RICHARD F. BERGSTROM, R.Ph., Ph.D.

Professor of Pharmaceutical Sciences and Director of Research Alliances

Butler University College of Pharmacy and Health Sciences
Indianapolis, IN



Adjunct Professor of Medicine

Division of Clinical Pharmacology
Indiana University School of Medicine, Indianapolis, IN

PK/PD and Clinical Pharmacology Expertise and Consulting

RFBergstrom PK/PD Consulting LLC
Anson Group, Indianapolis, IN
YourEncore, Indianapolis, IN
B2S Consulting, Indianapolis, IN

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Education:

Doctor of Philosophy (1980)

The University of Michigan, College of Pharmacy
Professor: Dr. John G. Wagner

Master of Science (1977)

Butler University, College of Pharmacy

Bachelor of Science in Pharmacy (1973) Suma Cum Laude

University of Pittsburgh, School of Pharmacy
Taylor University (1967 - 1970) Major: Chemistry

High School Diploma

Iroquois Area High School (1967) Cum Laude
Erie, PA

Current Academic Appointments:

Butler University College of Pharmacy and Health Sciences (2010-present)
Professor of Pharmaceutical Sciences and Director of Research Alliances

Indiana University School of Medicine (1985 to present)
Adjunct Professor of Medicine Division of Clinical Pharmacology (2009-present)
Adjunct Assistant Professor of Pharmacology and Toxicology (1985-2008)

Current Consulting Appointments:

RFBergstrom PK/PD Consulting, LLC (2009-present)
Principal: Richard F. Bergstrom, Ph.D.
Various clients including Centurion Clinical Research (2009); Eli Lilly and Company (2010); and EMD Millipore, the Life Science division of Merck KGaA of Germany (2010-2011)

YourEncore (2009-present) www.yourencore.com
Expert in PK/PD Biopharmaceutics and Clinical Pharmacology
Completed multiple short-term assignments for various companies including Eli Lilly and Company (2009-2010, 2011-) and Roche (2010)

The Anson Group LLC (2009-present) www.ansongroup.com
11460 N Meridian St Suite #150
Carmel, IN 46032-4409 Phone (317) 569-9500
Completed short term project work for small biotechnology companies including Marcadia Biotech (2009-2010)

B2S Consulting LLC (2011-present) www.b2s-stats.com
Indianapolis, IN
Ongoing and completed short-term assignments for various companies and clients including Stemline Therapeutics (2011-present)

Prior Employment and Experience:

Eli Lilly and Company (1973-2008)
Research Fellow and other Research Titles
Global Pharmacokinetics Pharmacodynamics and Trial Simulations
Lilly Research Laboratories

Licensure and Qualifications:

Registered Pharmacist: Indiana: Certificate number 13001 (inactive) 1973
Staff Member of the Lilly Laboratory for Clinical Research 1980 – 2002
Biopharmaceutics, Clinical Pharmacology, Pharmacokinetics, and Pharmacodynamics
IND, NDA, and CTD preparation, submission, approval and product commercialization

Awards, Honors, and Professional Activity:

Honor Societies:

Sigma Xi (1988)

Phi Lambda Upsilon Honorary Chemical Society (1978)

Rho Chi Honorary Pharmaceutical Society (1972)

Honors and Awards:

AAPS Distinguished Service Award (2004)

Lilly Research Laboratories President's Recognition Award (1999)

Fellow American Association of Pharmaceutical Scientists (1993)

FDA Commissioner's Special Citation CANDA Guidance (1993)

University of Michigan AFPE Manufacturing and Industrial Pharmacy Fellow (1979)

University of Pittsburgh Merck Award (1973)

University of Pittsburgh Outstanding Achievement in Pharmaceutical Chemistry (1973)

Professional Organization Memberships and Activities:

APhA	American Pharmacists Association www.apha.org	1981 →
	APS Academy of Pharmaceutical Sciences • Chair PPDM Midwest Regional Meeting (1984)	1981 – 1986
AAPS	American Association of Pharmaceutical Scientists www.aaps.org • Membership (Charter Member 1986 – present) • Primary Section: PPDM • PPDM Section Abstract Screener • PPDM Executive Committee • Strategic Planning Committee (1993) • Program Committee Chair (1995) • Executive Council Member at Large (1996-1998) • President (1999-2001) • Chair Publication Board (2001-2002) • Nominations Committee (2002) • Fellows Task Force (2002) • Nominations Program Review Team (2004) • Fellows Selection Committee (2006 – 2008)	1986 →
IODG	Indiana Ohio Discussion Group www.aaps.org/inside/discussion_groups/iodg/index.asp • Founding Committee (1987), Chair (1988-89)	1987 →
ACCP	American College of Clinical Pharmacology www.accp1.org	1989 →
ASCPT	American Society for Clinical Pharmacology and Therapeutics www.ascpt.org	1990 →
ISSX	International Society for the Study of Xenobiotics www.issx.org	2010 →

Editorial Boards and Reviewer:

Clinical Pharmacology and Therapeutics (Editorial Board 2006-2007)
Journal of Antimicrobial Agents and Chemotherapy (Editorial Board 1983-1991)
Journal of Pharmaceutical Scientists (reviewer)
Pharmaceutical Research (reviewer)
AAPS Journal (reviewer)
AAPS PharmSci Tech (reviewer)

Teaching Activities:

Indiana University School of Medicine
Clinical Pharmacokinetics (F-813) taught every other year 1984 →
Physiologic Disposition of Drugs (F-836) taught every other year 1985 →

Expertise and Experience:

- Biopharmaceutics
- Clinical Pharmacology (Phase 1-4)
- Pharmacokinetic
- Pharmacodynamics
- Drug-Drug Interactions
- Special Populations pediatric, elderly, renal, hepatic
- Bioavailability/Bioequivalence
- Dosage Form Design and Line Extensions
- Biopharmaceutics Drug Development Strategies and Planning
- PK/PD Analyses Population and Noncompartmental Analyses
- Clinical Study Report Authorship
- CTD and Submission Document Authorship
- Regulatory Agency Interaction and Response Documents
- Briefing Documents
- Advisory Committee Meetings
- Phase 1-4 Regulatory Meetings United States, Canada, Europe, Japan

Technical Experience:

- Noncompartmental Analysis (WinNonlin)
- Compartmental Models (WinNonlin)
- Graphical Analysis and Result Illustration (Sigma Plot)
- Statistical Descriptive Analysis and Assessment (SAS, JMP)
- Simulation and Predictions (Excel)
- Population Pharmacokinetics (NONMEM strategy and consulting, nontechnical)

Research and Experience:

Research activities over three decades were conducted as a staff member of the Lilly Laboratory for Clinical Research and at the Lilly Corporate Center Indianapolis, IN. I have expertise in clinical pharmacology study design, conduct, analysis, and reports. I have developed excellent collaboration skills by conducting research endeavors across Lilly research sites and with external partnerships for 30 years. I am experienced as a principal investigator, collaborator, and/or research advisor with a focus on integrating PK/PD aspects into clinical research either as the primary study objective or as a secondary objective. My research experience spans the broader aspects of PK/PD across the wide spectrum of drug discovery-development-commercialization of drug products. Specifically, my experience includes a major role in the pharmacokinetics, pharmacodynamics, and clinical trials for CYMBALTA™ (duloxetine), ZYPREXA™ (olanzapine), PROZAC™ (fluoxetine HCl), and AXID™ (nizatidine). With each of these as well as others projects I have had the responsibility to design and analyze a full range of PK/PD, biopharmaceutics, and metabolism studies. My core competencies include the ability to perform appropriate PK/PD analysis, to prepare detailed study reports, and to integrate key information into submission summary documents. My regulatory expertise includes preparation of the biopharmaceutics application summary, and the common technical document for new drug applications in the United States, Europe, Japan, and Asia. Enabling activities include setting registration strategy, having interactions with regulatory agencies, writing drug labeling and negotiating post-approval commitments. The scope of my research includes compounds in different therapeutic classes including oncolytic, cardiovascular, anticonvulsant, analgesic, anti-inflammatory, antiulcer, antidepressant, antipsychotic, and endocrine drugs. I have managed projects at all stages of research including discovery, development, registration, and post-launch commercialization. The greatest depth and the strength of my experience is focused in the area of neuroscience projects during registration and commercialization phases. Regarding my skills as a classical pharmacokineticist, my expertise includes utilizing noncompartmental pharmacokinetic models to answer fundamental research questions, defining compartmental and/or physiologically-based models to understand advanced pharmacokinetic and pharmacodynamic properties, and applying these models to perform clinical trial simulation. My endeavor is to use the results from each of these to guide and direct the application of knowledge and information toward more efficient research and utilization. Early on I developed a series of computer programs for noncompartmental pharmacokinetic analyses growing out of a need for standardized methodologies that is now suitably accomplished using well-established industry-standard software. My professional career also involves teaching graduate level courses in pharmacokinetics and pharmacodynamics and being heavily involved in the leadership of the American Association of Pharmaceutical Scientists.

Publications and Presentations: (bibliography available upon request)

Abstracts and Posters: >60

Peer Reviewed Publication: >40

Book Chapters: 4

Invited Presentations: >10