

# BARRETT E. RABINOW, PHD

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## PHARMACEUTICAL CONSULTANT

### Leverages Creativity and Scientific Expertise in Analyzing R&D Opportunities

Versatile, creative Ph.D. Pharmaceutical Scientist provides strategic and subject matter consulting expertise in R&D and sterile manufacturing. Known for collaborative communication with teams, expert process translation, and achieving resolution to pervasive pharmaceutical issues.

Adept at speaking and presenting on complex scientific topics. Innovative patent-holder, frequently published in numerous journals and delivering professional papers. Known both as a collegial organizer of multi-functional teams to attack nebulous problems, and as an independent contributor of novel solutions.

### Resolve Root Cause & CAPA Issues | Process Improvement | R&D Acquisition Analysis Comprehensive Program Plan Development

## PROFESSIONAL EXPERIENCE

### **BAXTER HEALTHCARE CORPORATION**, Round Lake, IL

*Medication Delivery Division*

#### **Baxter Distinguished Scientist**

**2006 – 2016**

Developed global technical vision for new product / process design, incorporating multiple disciplines and has broad business applications. Evaluated numerous business opportunities from technical and patent perspective. Provided broad multi-disciplinary knowledge of advanced fields. Energized and mentored technical talent. Led technical feasibility analysis of new, unproven technologies.

- Developed concept, and executed animal studies demonstrating reduction of toxicity for key product with small, simple design change; issued patent.
- Devised major drug delivery platform, used for 6 HIV drugs in development by major pharmaceutical company.
- Created nanosuspension drug formulation platform, treating antimicrobial infections normally resistant to non-formulated drugs; issued patent.
- Attracted 9 clients and clinical production, growing business by conducting 75 technical sales presentations.
- Conceived rapid testing approach for IV solutions expediting change control, reducing stability testing, showing compliance with Good Distribution Practices, and minimizing testing for elemental impurities, and leachables. Presented to Medicines and Health Care Regulatory Agency (MHRA) who endorsed concept.
- Troubleshoot complex corrosion issue affecting manufacturing process, and implemented it for key product line.

#### **Senior Director**, Strategic Technical Development

**1999 – 2006**

Led corporate troubleshooting teams and task forces of industry-wide organizations for the most serious chemical problems of high commercial impact. Developed novel methods, leading-edge techniques to solve problems. Negotiated favorable outcomes for company and industry with FDA.

- Improved manufacturing processes resolving pH and particulate issues, retiring imminent product recall issues for major, strategic product lines.
- Developed industry position / white paper and presented to FDA on storage labeling, saving millions of dollars in unnecessary costs.

## ADDITIONAL RELEVANT EXPERIENCE

### **BAXTER HEALTHCARE CORPORATION**, Round Lake, IL

*Medication Delivery Division*

#### **Director**, Strategic Technical Development

- Identified anti-adhesion as a therapeutic concept, eventuating in a product.

#### **Director**, Chemistry R & D

- Identified source of contaminant affecting 17 plants, allaying worldwide regulatory concern.
- Launched IV container extractable program that has become the standard of the industry.

**BAXTER HEALTHCARE CORPORATION** (Continued)**Associate Director**, Analytical & Technical Services

- Reformulated company's most lucrative drug, satisfactorily retiring an imminent FDA recall.

**Manager**, Analytical & Technical Services

- Resolved pervasive field issue of color formation in product, without reformulation.

**Supervisor**, Amino Acid Analysis

- Increased batch analysis rate 50 fold, eliminating log jam in product release.

**NORWEGIAN-AMERICAN HOSPITAL**, Chicago, IL**Director**, Chemistry**BAXTER AWARDS**

- Outstanding Innovation Award for Nanosuspension Formulation of Indibulin, 2004
- Outstanding Innovation – Control of Itraconazole Nanosuspension Through Polymorph Control, 2003
- Outstanding Technical Achievement Award – Premix Pipeline Strategic Development Team, 1998
- Annual Outstanding Technical Achievement Award – Resolution of ----- Particulate Matter Issue, 1998
- Annual Outstanding Technical Achievement Award – Resolution of ----- pH Issue, 1998
- Annual Outstanding Technical Achievement Award – Heparin Dextrose Warehouse Temperature Study, 1996
- Honorable Mention Award – Innovative Regulatory Strategies, 1995
- Outstanding Technical Achievement Award – LVP Stability & Storage Conditions Position, 1994
- Scientific Contribution Award – Innovative Analytical Methodologies for Drug Development, 1992
- Distinguished Problem Solving, 1992
- Outstanding Technical Contribution – Admixed Chemotherapeutic Agents in Travenol Containers, 1985
- Baxter-Travenol Technical Achievement Award – Synthroid® Reformulation, 1983

**PROFESSIONAL ACTIVITIES**

- Parenteral Drug Association – Committee on Aluminum Methodology
- Health Industry Manufacturers' Association – Consultant and point presenter to FDA on issues of aluminum methodology, toxicology, and formulations for large volume parenteral solutions, osmolarity and stability storage labeling issues
- Association for the Advancement of Medical Instrumentation – Consultant on aluminum methodology and appropriate levels in dialysis solutions
- International Standards Organization – Consultant on approach to systematize evaluation of leachables from medical devices
- Journal of Pharmaceutical Sciences – Reviewer

**EDUCATION**

- **Doctor of Philosophy (PhD)**, Physical-Organic Chemistry, University of Chicago, Chicago, IL
  - Postdoctoral Fellowship in Clinical Chemistry, National Institutes of Health (NIH), Michael Reese Medical Center, Chicago, IL
  - Postdoctoral work in Electrochemistry, University of Chicago, Chicago, IL
- **Master of Science (MS)**, Organic Chemistry, University of Chicago, Chicago, IL
- **Bachelor of Arts / artium baccalaureus (AB)**, Cornell University, Ithaca, NY, Graduated *cum laude* with Distinction in all Subjects and Honors in Chemistry

**PATENTS, UNIVERSITY LECTURES & PUBLICATIONS**

- 14 Patents
- 4 University Lectures
- 41 Publications and Book Chapters

## REPRESENTATIVE PATENTS

- US 6,309,723. October 30, 2001. Propofol Formulation with Enhanced Microbial Characteristics.
- US 8,067,032. November 29, 2011. Method for preparing submicron particles of antineoplastic agents.
- US20100290983A1. Pub. Nov 18, 2010. Compositions and Methods for Drug Delivery.
- US 8,263,131. September 10, 2012. Method for treating infectious organisms normally considered to be resistant to an antimicrobial drug.
- US 8,617,467. December 31, 2013. High-pressure sterilization to terminally sterilize pharmaceutical preparations and medical products. EP1663321B1, Pub. August 29, 2012.
- US 8,686,036. April 1, 2014. Methods of Controlling Heart Rate While Minimizing / Controlling Hypotension.
- US 9,044,381. June 2, 2015. Method for delivering drugs to the brain.

## UNIVERSITY LECTURES

- University of Illinois College of Pharmacy, Course 594:
  - "Special Topics in Biopharmaceutical Development"
    - "Overview of Drug Development"
    - "Biopharmaceutical considerations of injectable dosage forms"
    - "Resolving formulation and manufacturing problems with parenteral pharmaceuticals"

## REPRESENTATIVE PUBLICATIONS

- Barrett Rabinow, Jane Werling, Alison Bendele, Jerome Gass, Roy Bogseth, Kelly Balla, Paul Valaitis, Audrey Hutchcraft, Sabine Graham. Intra-Articular (IA) Ropivacaine Microparticle Suspensions Reduce Pain, Inflammation, Cytokine and Substance P Levels Significantly More than Oral or IA Celecoxib in a Rat Model of Arthritis. Inflammation. Volume 38, Issue 1 (2015), Pages 40-60.
- McKee J, Rabinow B, Daller J, Brooks B, Baumgartner B and Rohatgi P. An enantiomerically pure formulation of esmolol attenuates hypotension and preserves heart rate control in dogs. *Anesthesiology*. 121(6):1184-93 (2014).
- S. Lee, E. Chess, B. Rabinow, G. Ray, C. Szabo, B. Melnick, R. Miller, L. Nair, E. Moore. NMR of heparin API: investigation of unidentified signals in the USP-specified range of 2.12-3.00ppm. *Anal Bioanal Chem*, 399 (2011). pp.651-662.
- Jeff McKee, Barrett Rabinow, Chyung Cook and Jerry Gass. Nanosuspension Formulation of Itraconazole Eliminates the Negative Inotropic Effect of SPORANOX® in Dogs. *Journal of Medical Toxicology*: Volume 6, Issue 3 (2010), Page 331-336.
- B. Rabinow, "Nanosuspensions for Parenteral Delivery", ch. 2 in *Nanoparticulate Drug Delivery Systems*, eds. Deepak Thassu, Michel Deleers, Yashwant Pathak, Informa Healthcare, New York, 2007.
- B. Rabinow, J. Kipp, P. Papadopoulos, J. Wong, J. Glosson, J. Gass, C-S Sun, T. Wielgos, R. White, C. Cook, K. Barker, K. Wood. Itraconazole IV nanosuspension enhances efficacy through altered pharmacokinetics in the rat. *Int. J. Pharm.*, 339:251-260 (2007).
- B. Rabinow and M. Chaubal, "Injectable Nanoparticles for Efficient Drug Delivery", ch. 8 in *Nanoparticle Technology for Drug Delivery*, ed. Ram B. Gupta and Uday B. Kompella, Taylor & Francis, New York, 2006.
- B. Rabinow, M. Chaubal, J. Kipp, "Excipient Selection and Criteria for Injectable Dosage Forms", ch. 16 in *Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems.*, eds. A. Katdare and M. Chaubal., Informa Healthcare, New York, 2006.
- B. E. Rabinow and T. J. Roseman, "Plastic Packaging Materials", ch. 54, Remington: *The Science and Practice of Pharmacy*, 21st ed., Lippincott Williams & Wilkins, Philadelphia, Pa. 2005.
- B.E. Rabinow, Nanosuspensions in Drug Delivery. *Nature Reviews Drug Discovery* 3:785-796 (2004).
- B. E. Rabinow, et. al, Biomaterials with Permanent Hydrophilic Surfaces and Low Protein Adsorption Properties, *J. Biomat. Sci., Polymer Ed.*, 6:91 (1994).
- D.R. Jenke, E.K. Chess, D Zietlow, and B. E. Rabinow, Model for Estimating the Accumulation of Solutes Leaching from Polymeric Containers into Parenteral Solutions. *Int. J. Pharm.*,78:115 (1992).
- B. E. Rabinow, et al., Characterization of Cisplatin Degradation as Affected by pH and Light. *Amer. J. Hosp. Pharm.*, 48:1500 (1991).
- B. Rabinow, et al., Aluminum in Parenteral Products: Analysis, Reduction, and Implications for Pediatric TPN. *J. Parenteral Science & Technology*, 43:132 (1989).
- B. Rabinow, R. Payton, and N. Raghavan, A Novel Radiotracer Method for the Precise Determination of Water Vapor Transmission Rate Characteristics of Packaging Systems. *J. Pharm. Sci.*, 75:808 (1986).
- B. Rabinow, "Contribution of the Trace Metal Contaminants in the Dialysis Concentrate to Dialyzing Fluid," in *Issues in Hemodialysis*, The Association for the Advancement of Medical Instrumentation, 1981, pp. 34-40.