



Judit Bartis

SUMMARY

Pharmaceutical professional, trained as an inorganic chemist, with broad experience in drug development, especially in analytical and formulation development. A creative problem solver with excellent analytical and communication skills.

PROFESSIONAL EXPERIENCE

PHARMACEUTICAL CONSULTANT: 2009-Present

- Managing drug development activities including chemical and bio-analytical methods, formulations, and manufacturing of drug products.
- Leading the transition of the new drug candidates from research into development.
- Defining the strategy for advancing products to achieve successful IND submissions.

PEAR TREE PHARMACEUTICALS, Cambridge, MA; 2008-2009

Director, CMC

- Formulated and implemented CMC development strategies for clinical programs to meet aggressive timelines and control costs.
- Directed all development activities including analytical, formulation, and manufacturing of the drug product at CMO. Prepared CMC budget and timelines. Identified suppliers and contract facilities for clinical trial material and negotiated contracts.

ARQULE, Inc., Woburn, MA; 2006-2008

Manager, Product Development

- Managed product development activities including formulation, manufacturing process, analytical method development, QC, technology transfer and scale-up for three drug development programs.
- Led a team of four scientists and managed the activities at CRO/CMOs
- Conducted solid state characterization of new chemical entities for formulation studies.

PRAECIS PHARMACEUTICALS, Waltham, MA; 2003-2005

Associate Director, Pharmaceutical Development

- Successfully developed a suspension formulation as line extension for the marketed drug product. Supervised a group of three scientists.
- Identified and developed new test methods to evaluate and predict the physical stability of the sterile suspension formulation. Established stability programs and evaluated impurity profiles.
- Conducted DOE to optimize formulation and manufacturing process variables that led to a significant increase in the physical stability of the drug product.
- Oversaw successful manufacturing process scale-up and technology transfer activities to CMO. Worked closely with vendors to ensure the selection of most suitable equipment and packaging components.



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MILLENNIUM PHARMACEUTICALS, Cambridge, MA: 2002-2003

Senior Manager, Process Development (Clinical Manufacturing), Biologics

- Managed and coordinated CMC development activities for an antibody based drug products in Phase I development.
- Selected third party suppliers and oversaw activities at contract facilities.
- Led the formulation and analytical method development activities for a radiolabeled antibody.

BRISTOL-MYERS SQUIBB (formerly DuPont Pharmaceuticals): 1997-2002

Medical Imaging Division, Billerica, MA

Senior Research Scientist, Development (2000-2002)

Research Scientist, Discovery Chemistry (1998-2000)

Visiting Research Scientist, Discovery Chemistry (1997-1998)

Formulation and Analytical Development

- Conducted formulation and analytical method development for radiolabeled biologically active molecules leading to rugged pharmaceutical dosage forms. Supervised three scientists and a co-op student.
- Evaluated the stability of the drug product and identified degradation products. Identified problem on solid-state stability of API and defined the appropriate storage conditions.
- Conducted radio-analytical method development and qualification to meet regulatory requirements. Prepared CMC sections for IND submission.

Discovery Chemistry

- Responsible for the preparation and analytical testing of radiolabeled new drug candidates for pre-clinical evaluation. Supervised and trained BS/MS level scientists.
- Optimized formulations that improved the purity and the stability of the final drug product.
- Developed HPLC analytical and preparative methods for characterization and purification of small molecules and peptides.
- Evaluated the radiolytic degradation of small biologically active molecules and identified degradation products by LC-MS.
- Developed a novel process for radiolabeling of HYNIC derivatized peptides with rhenium radioisotopes using ternary ligand system.

EDUCATION

M.B.A. High Technology Program, Northeastern University, Boston, MA

Ph.D. in Analytical/Inorganic Chemistry, City University of New York, NY

B.S. in Chemistry and Physics, University Babes-Bolyai, Cluj, Romania