CURTIS A. SEIZERT, PH.D.

CMC CONSULTANT AND PROCESS CHEMIST

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PROFESSIONAL PROFILE

- Accomplished process chemist with seven years of experience across all stages of small-molecule API pharmaceutical development
- Proficient in organizing and authoring regulatory filings, including commercial marketing applications (NDA and MAA), and developing drug substance regulatory strategies
- Utilizes extensive knowledge of FDA, EMA, and ICH guidelines and process chemistry techniques to develop effective, data-driven control strategies
- Values collaboration, both within CMC and with external stakeholders
- Proven expertise in vendor selection and management to deliver results quickly and efficiently

WORK EXPERIENCE

SEIZERT CMC SOLUTIONS, Providence, RI — 03/2024 – Present

Principal Consultant

- Performed CMC due diligence review and gap assessment for an in-license candidate Phase 2 JAK2 inhibitor
  - Identified gaps in the development work performed for the asset
  - Highlighted paths forward to improve control of impurities and key research activities to perform prior to registration
  - Worked with quality consultant to provide recommendations on key IND updates

EQRX INTERNATIONAL, Cambridge, MA — 11/2021 – 10/2023

Senior Manager, Drug Substance Process Development

- Contributed to delivering high-quality, cost-effective pharmaceutical products as a drug substance SME for commercialization of an in-licensed third-generation EGFR inhibitor
  - Led the drug substance submission strategy; author of key drug substance sections in the marketing application, including S.2.2, S.2.6, and S.3.2
    - Oversaw robustness (DoE) studies and modeled results with Minitab; used models to implement process controls
    - Organized mutagenic impurity information and addressed gaps to ensure M7 compliance.
    - Provided written responses to regulator questions and worked with Regulatory CMC and CMC teams to develop response strategies
    - Developed the company strategy for the N-nitrosamine risk assessment and evaluation; oversaw confirmatory testing
  - Collaborated with quality to ensure a successful drug substance process validation
  - Oversaw the tech transfer to a European second supplier and process optimization, resulting in an anticipated >30% COGs reduction
  - Led development efforts for new route to key regulatory starting material, 25% reduction in COGs
  - Worked with stakeholders to manage supply chains for raw materials
- drug substance lead on phase III CDK4/6 inhibitor
  - Created a development plan to ensure submission-readiness for the drug substance
  - Analyzed vendor results on an API polymorph study to understand solid form characteristics and impacts on the drug product
  - Developed an M7 strategy, including in silico evaluation and Ames testing
- Led CMC development and route scouting of preclinical candidates
  - Authored RFPs and engaged vendors for drug substance research projects and production campaigns
  - Assessed vendor-proposed routes and independently proposed alternatives
  - Worked with drug development teams to begin CMC development in parallel with final stages of DC nomination
  - Collaborated with stakeholders to assemble preclinical and phase 1 development plan

SPERO THERAPEUTICS, Cambridge, MA 04/2020 – 10/2021

Senior Scientist, Process Development

- Played a critical role in the development and optimization of the manufacturing process in collaboration with the CMC team in late stage and pre-commercialization for an oral antibiotic, including NDA preparation
  - Authored the pre-NDA type C brief on regulatory starting materials
  - Collaborated with CDMO on robustness studies and helped oversee successful PPQ
  - SME and author of key drug substance NDA sections and source documents. Performed a gap assessment
  - Led cross-functional collaboration on impurities and control strategies and engaged with toxicology consultants for M7-compliant mutagenicity evaluation
- Served as drug substance lead for a mid-stage peptide antibiotic potentiator
  - Collaborated with analytical and drug product leads to create a CMC development plan for phase III readiness, anticipating the needs of future regulatory filings and budgetary requirements
  - Began research on process revisions aimed at COGs reductions and addressed potential regulatory hurdles associated with the phase I process
  - Engaged vendors for drug substance research projects and production campaigns.
  - Oversaw process research work conducted by Asian CDMO
- Created series of approachable, low-key presentations to familiarize and refresh the CMC team on various aspects of regulatory control strategies

RAYBOW US (PHARMAGRA LABS), Brevard, NC 01/2017 – 04/2020

Group Leader, Chemical Process Development (07/2019 – 04/2020)

Research Chemist, Organic Synthesis (01/2017 – 07/2019)

- Played a pivotal role in driving innovation, ensuring operational excellence, and fostering collaboration with clients in biotech to develop and optimize drug substance manufacturing processes
  - Designed and implemented process for first-in-human trials
    - Optimized chemistry, identified impurities, and prepared an IND-enabling TOX batch
    - Developed in-process and release methods for intermediates and drug substances
    - Authored batch records and other documentation, led GMP manufacturing
  - Optimized and transferred commercially viable second-generation drug substance routes
    - Led the team through process development and demonstration, significantly improving yields, decreasing solvent use and reagent excess, and preparing tox batches
    - Identified analytical gaps and developed discerning methods for in process control and intermediate release
    - Facilitated process transfer to a European CMO
  - Developed a second-generation regulatory starting material process.
    - Developed and optimized chemistry and developed analytical methods for in-process control and product release
    - Facilitated process transfer to an Asian CMO
- Led development of in-house best practices for scale-up, safety, and efficiency
  - Designed flow-control systems for process use of air-sensitive materials and solvent dispensing
  - Trained chemists on process chemistry goals and techniques
  - Revised solvent transfer and dispensing practices to minimize air contact and static buildup
  - Retrofitted and prepared documentation for cGMP use of the pressure reactor and basket centrifuge

EDUCATION

Ph.D., Organic Chemistry, COLORADO STATE UNIVERSITY, Fort Collins, CO (2015)

- Advisor: Eric Ferreira
- Dissertation: The Application of a New Methodology to Complex Molecule Synthesis: Studies Toward the Synthesis of Pordamacrine A and Liphagal

B.A., Chemistry, WASHINGTON UNIVERSITY, St. Louis, MO (2009)

- Research Advisor: Vladimir Birman

SPECIALIZED TRAINING

Chemical Development and Scale-Up in the Fine Chemical and Pharmaceutical Industries
- Scientific Update, 2023

Understanding Polymorphism and Crystallization Issues in the Pharmaceutical Industry
- Scientific Update, 2023

Introduction to Design of Experiments
- Synolostats, 2023

Practical Management of Impurities and Development of Effective and Comprehensive Control Strategies
- Scientific Update, Dr. Andrew Teasdale, 2020

Process Validation
- ECA Academy, Dr. Line Lundsberg-Nielsen, 2020

PEER-REVIEWED PAPERS

- **Pordamacrine A – synthetic studies, difficulties, and our motivation for exploring the Ireland-Claisen rearrangement of boron ketene acetals**. Seizert, C. A.; Ferreira, E. M. Tetrahedron, **2017**, 73, 4186 – 4194.
- **Pt catalysis enables concise syntheses of frondosin B and liphagal**. Huynh, K.; Seizert, C. A.; Allegretti, P. A.; Ozumerzifon, T. J.; Ferreira, E. M. Organic Letters, **2017**, 19, 294 – 297.
- **An Examination of the Scope and Stereochemistry of the Ireland-Claisen Rearrangement of Boron Ketene Acetals**. Seizert, Curtis A.; Ferreira, Eric M. Chemistry A European Journal, **2014**, 20, 4460-4468.
- **Molecular scaffolds with remote directing groups for selective palladium-catalyzed C-H bond functionalizations**. Stache, Erin E.; Seizert, Curtis A.; Ferreira, Eric M. Chemical Science, **2012**, 3, 1623-1628.
- **A Cope rearrangement-based route to hexahydroazulenes**. Seizert, Curtis A.; Bumbu, Valentina B.; Birman, Vladimir B. Organic Letters, **2010**, 12, 3472-3475.

SELECTED PRESENTATIONS

- **What Matters and What Doesn't in ICH M7**
  CMC group informational presentation, EQRx, December 2022
- **The Road to Maeocrystal V**
  Departmental literature presentation, Colorado State University, Department of Chemistry, April 2013.
- **Transmetalation in Cross Coupling Reactions**
  Departmental literature presentation, Colorado State University, Department of Chemistry, July 2011.
- **Coordinative Unsaturation in Transition Metal Catalysis**
  Research group literature presentation, Colorado State University, Department of Chemistry, July 9, 2011.
- **Cope Rearrangement Route to Hexahydroazulenes**
  New Reactions and Methodology, 237th National ACS meeting, Salt Lake City, March 2009.

AUTHORED WEBPAGES

- **Perfluorobutanesulfonyl Fluoride**
  Wikipedia. https://en.wikipedia.org/wiki/Perfluorobutanesulfonyl_fluoride
- **Leaving Group**
  Wikipedia. https://en.wikipedia.org/wiki/Leaving_group

INTERESTS AND ACTIVITIES

- Cooking and baking bread.
- Precision machining and toolmaking, mechanism design, and dimensional metrology.
- Heat treatment and metallurgy of steels.
- Woodworking and welding to build furniture, cabinetry, and other things made of wood or metal