Daniel Seth Torok, Ph.D.

Senior Drug Substance Consultant

Core Competencies

- Pilot Plant Operations
- Process Chemistry
- Person in Plant
- CMO Selection
- Process Optimization
- Custom Synthesis of APIs
- Yield Improvement
- High Potency API
- Tech Transfer

Products

- Neratnib ®
- Losartan®
- Montelukast®
- Grapiprant®
- Capromorelin®

Professional Summary

Dr. Torok leads our development team with more than 16 years' experience in process development, manufacturing, and synthetic chemistry. He is highly proficient in technology transfers to internal and external manufacturers for scale up and commercial cGMP manufacturing, including injectable grade APIs.

Dr. Torok is a skilled problem solver and troubleshooter within the API industry, including customer relations, production, shipping scheduling, sourcing, purchasing and inventory management. He has a strong aptitude for customer/contractor communication, API manufacturing, and GMP compliance as well as cost estimation and budget tracking.

Prior to joining DSI, Dr. Torok served as Project Manager, Production Chemistry for Lonza. He holds a Ph.D. in Organic Chemistry from the University of Iowa and an undergraduate degree in chemistry from Bowling Green State University.

Education

Ph.D.	Organic Chemistry	University of Iowa, Advisor: W. J. Scott
M.S.	Organic Chemistry	University of Arizona
B.S.	Chemistry	Bowling Green State University

Professional Experience

Design Space Inpharmatics, LLC **2007 - Present**

Senior Drug Substance Consultant

- Project management of multidisciplinary teams of internal and external resources in pre-NDA CMC development,
- Manages clients' API contractors, including overseeing of costing, sourcing, manufacturing and quality assurance issues in cGMP settings,
- Manages and organizes resources for writing and submission of CMC NDA fillings, including authoring, QA checking and editing of DS and DP Mod 3 sections,
- Works within and manages multidisciplinary teams to create and manage CMC timelines to guide clients in development which leads to accepted NDA fillings within available budgets.

Lonza **2006 - 2010**

Project Manager, Production Chemist Manager

- Responsible for all communication between production site and Pharmaceutical customer occupying >80% of the capacity of the US facility,
- Responsible for process optimization leading to profitability of product portfolio,
- Directed, organized, and advised multidisciplinary production teams on customer requirements as well as technical issues, including QA, QC, manufacturing, and development,
- Worked closely with comptrollers in project budgeting,
- Worked closely with Quality Assurance and Regulatory affairs in the filing and administration of DMF/CMC affairs.

Hovione **2002 - 2006**

Team Leader, R&D

- Prioritized and organized team resources on a project-to-project basis,
- Served as scientific/technical liaison with customers,
- Performed cost analyses for proposals,
- Designed and carried out process optimization and route scouting projects,
- Carried out tech transfers both within and outside of company,
- Served as team leader for the introduction of the first highly active compound produced at Hovione,
- Supported customer needs in development of CMC sections of NDAs,
- Created IOPs and SOPs for opening of new facility.

Lonza **1998 - 2002**

Group Leader, Process Development

- Oversaw and supervised 2-4 B.S./M.S. chemists on various projects as required,
- Led and supervised all activities within the Process Development Department,
- Served as technical transfer liaison between U.S and Swiss sites for three major processes,
- Served as direct technical contact with customers on two major processes,
- Responsible for introduction of data logging and lab automation capabilities,
- Improved process of intermediate to decrease cycle time by 40% while increasing yield by 5%,
- Stabilized and improved both quality and yield (30% increase) of API by providing a robust method for obtaining a kinetic polymorph of the final intermediate,
- Served as process development representative on various multidisciplinary teams.

American Cyanamid **1995 - 1998**

Research Chemist, Process Development

- Increased yield of manufacturing process more than 4% resulting in > $1,000K/year savings,
- Developed methodology to stabilize process and allow for smooth control in plant,
- Improved isolation/crystallization procedure, allowing for the isolation of consistent quality product required for formulation,
- Participated in design team for simulation and engineering of 2.5 ton/year dedicated facility.

National Institutes Of Health **1993 - 1995**

Postdoctoral Fellow, Medicinal Chemist

- Synthesized enzyme inhibitors in the Kynurenine pathway on 50g scale for invitro testing,
- Discovered a novel series of heteroaromatic analogs with high antimalarial activity,
- Optimized a route to produce antimalarial compounds efficiently and cost effectively for invivo testing.

University Of Iowa – Department Of Microbiology (Dr. David Gibson Lab) **2004 - 2006**

Postdoctoral Associate, Synthetic Chemist

- Discovered new mechanism in the biotransformation of polyaromatic hydrocarbons using strains of pseudomonad putida,
- Introduced simpler and more time efficient methods for isolation of metabolites.