

**NEAL G. ANDERSON, Ph.D.**

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**SUMMARY**

Synthetic Organic Chemist with 35 years of experience in chemical process R & D. Experienced in laboratory research, scale-up, and technology transfer to ensure optimal product quality. Results-oriented, with 12 hands-on manufacturing start-ups of drug substances and intermediates. Design and implementation of practical, cost-saving processes. Consultant to the pharmaceutical, biotech, and fine chemicals industries. Author of widely-used process chemistry text and experienced instructor of courses on chemical process development.

**PROFESSIONAL EXPERIENCE**

**ANDERSON'S PROCESS SOLUTIONS**

**1997 – Present**

Formed Anderson's Process Solutions for consulting and training with pharmaceutical, biotech, and fine chemicals companies.

- Consulting internationally to pharmaceutical, biotech and CRO/CMO companies on efficient development of processes to make drug substances and intermediates. Assisted in preparing the API / CMC portion of regulatory filings, focusing on process descriptions, specifications, and impurities such as mutagens (genotoxins).
- Prepared and presented short courses internationally on practical process research and scale-up to more than 1500 participants from more than 160 companies.
- Wrote *Practical Process Research & Development* (Academic Press; 2<sup>nd</sup> edition 2012, 1<sup>st</sup> edition 2000).
- Courtesy faculty appointment, Department of Chemistry, University of Oregon, 2012 - 2016.

**E. R. SQUIBB & SONS / BRISTOL - MYERS SQUIBB, New Brunswick NJ  
Chemical Process Technology**

**1979 - 1997**

**Principal Scientist**

**1989 - 1997**

Developed and monitored manufacturing processes of key intermediates of captopril (Capoten®, \$1.5 B peak annual sales), fosinopril sodium (Monopril®) and others to ensure optimal product quality and profitability. Researched alternative pathways to IND candidates for preparation of clinical supplies. Mentored MS chemist, assisting with his promotion to entry-Ph.D. level. Served as in-house consultant for process development.

- Demonstrated in a timely fashion that the processes for the manufacture of aztreonam intermediates could be used to prepare intermediates for an epimeric drug candidate, thus potentially decreasing development time. Coordinated efforts of four people.
- Expeditiously developed and scaled up new processes (Fischer indolization, chlorination) for drug candidates. Helped demonstrate process ruggedness on scale.
- Served as resource to BMS chemists and engineers. Helped train recently hired chemists in process development, including in-house presentations. Assisted BMS Manufacturing, Quality Control, and Technical Registration Resources in identifying impurities, based on process experience. Advised BMS Analytical R & D on optimizing derivatizations for GC assays. Assisted with process optimization to remove trace impurities in drug candidates. Authored conception records for alternative processes.

- Chaired interdepartmental task force to determine the source and removal of key trace impurities in bulk captopril. Advised manufacturing colleagues in Puerto Rico on process alterations to successfully optimize manufacturing operations.
- Initiated work on PTC applications and showed that PTC provides a safe effective alternative to the use of NaH / DMF or K<sub>2</sub>CO<sub>3</sub> / DMF for two processes to prepare an API and drug candidate.
- Redeveloped manufacturing process for the manufacture of a fosinopril sodium intermediate, to ensure all batches exceeded specifications. Successfully introduced process to manufacturing.
- Responsible for development and successful manufacturing startups of three processes at BMS Ireland facilities. Solved startup problems on the floor.
- Received President's Award and Spot Awards in recognition of achievements.

**Group Leader****1987 - 1989**

Supervised research activity in Chemical Process Technology by evaluating quality and impact of approaches. Directed 7 chemists (5 Ph.D.s) in the timely development and startup of processes.

- Chaired Project Team for aztreonam (\$155 MM annual sales), in interdisciplinary approaches to solving manufacturing problems.
- Introduced an optimized captopril process (productivity improved by 30%) and processes for new fosinopril sodium intermediates.

**Senior Research Investigator****1984 - 1987**

Performed process research and development for new products. Directed two chemists.

- Initiated and developed simplified process for the manufacture of captopril (\$3.7 M annual savings).
- Responsible for development and successful manufacturing startups of four fosinopril sodium and aztreonam processes at Squibb facilities in Ireland. Solved startup problems on the floor.
- Initiated process research for formation of new salt of aztreonam intermediate. Batch processing time was cut by 30% by eliminating use and recovery of one solvent.
- Helped introduce modern NMRs and HPLCs. Redesigned evaluation form for interviewing candidates. Hosted seminar programs, which featured prominent academicians.

**Research Investigator****1979 - 1984**

Performed independent research and development on novel, specialized projects.

- Developed and introduced key steps for aztreonam:  $\beta$ -lactam formation, oxidation of intermediates, and isolation of aztreonam. Simplified manufacturing processes, thus increasing reliability and ultimately profitability.
- Responsible for development and successful manufacturing startups of five aztreonam processes at Squibb facilities in Ireland and Puerto Rico. Solved startup problems on the floor.
- Altered process for nadolol (Corgard®, \$150 MM annual sales) to enable optimal profitability. Initiated and developed an aqueous process for nadolol penultimate, which decreased batch time by eliminating a cosolvent. Process was later filed with FDA.

**McNEIL PHARMACEUTICAL, Spring House, PA**  
**Post-Doctoral Fellow, Chemical Research****1977 - 1979**

Investigated medicinal and process chemistry of pyrrole acetic acids, and other exploratory research.

- Developed new process for Tolectin® intermediate, helping J&J to ward off foreign competition.
- Developed first chemical preparation of a Zomax® metabolite, key for NDA filing.

**PUBLICATIONS**

Anderson, N. G., *Practical Process Research & Development – A Guide for Organic Chemists*; 2<sup>nd</sup> edition; Academic Press: San Diego; 2012. (ISBN: 9780123865373; see <http://store.elsevier.com/product.jsp?isbn=9780123865373&requestid=113257>). Translated into Japanese.

Anderson, N. G., *Practical Process Research & Development*; Academic Press: San Diego; 1<sup>st</sup> edition; 2000. (ISBN 0-12-059475-7; see <http://www.elsevierdirect.com/ISBN/9780120594757/Practical-Process-Research-and-Development>). Translated into Japanese, Chinese, and Korean languages.

Anderson, N. G.; Nelson, T. D. "API Cost of Goods: Discovery to Early Development," Chapter 4 in *Early Drug Development – Bringing a Preclinical Candidate to the Clinics*; Giordanetto, F., Ed.; Methods and Principles in Medicinal Chemistry Series – VCH Wiley; 2018; pp 49 - 72.

Weissman, S. A.; Anderson, N. G. "Design of Experiments (DoE) and Process Optimization. A Review of Recent Publications," *Org. Process Res. Dev.* **2015**, *19*, 1605.

Anderson, N. G. "Using Continuous Processes to Increase Production." *Org. Process Res. Dev.* **2012**, *16*, 852.

Anderson, N. G.; Burdick, D. C.; Reeve, M. M. "Current Practices of Process Validation for Drug Substances and Intermediates." *Org. Process Res. Dev.* **2011**, *15*, 162.

Haney, B. P.; Mason, P.; Anderson, N. G. "Response to the Comments by Bercu and Callis on our Communication 'Controlling the Genotoxins Ethyl Chloride and Methyl Chloride Formed During the Preparation of Amine Hydrochloride Salts from Solutions of Ethanol and Methanol'." *Org. Process Res. Dev.* **2009**, *13*, 921.

Yang, Q.; Haney, B. P.; Vaux, A.; Riley, D. A.; Heidrich, L.; He, P.; Mason, P.; Tehim, A.; Fisher, L. E.; Maag, H.; Anderson, N. G. "Controlling the Genotoxins Ethyl Chloride and Methyl Chloride Formed During the Preparation of Amine Hydrochloride Salts from Solutions of Ethanol and Methanol." *Org. Process Res. Dev.* **2009**, *13*, 786.

Anderson, N. G. "The Impact of Process Chemists and Engineers on Green Chemistry." *Org. Process Res. Dev.* **2008**, *12*, 1019.

Anderson, N. G. "Process Research: How Much? How Soon?" Chapter 2 in *The Art of Drug Synthesis*; Johnson, D. S.; Li, J. J., Eds.; Wiley: New York; 2007; pp 11-28.

Anderson, N. G. "Developing Processes for Crystallization-Induced Asymmetric Transformation." *Org. Process Res. Dev.* **2005**, *9*, 800.

Anderson, N. G. "Assessing the Benefits of Direct Isolation Processes." *Org. Process Res. Dev.* **2004**, *8*, 260.

Anderson, N. G. "Practical Use of Continuous Processing in Developing and Scaling Up Laboratory Processes." *Org. Process Res. Dev.* **2001**, *5*, 613.

Rosso, V. W.; Lust, D. A.; Bernot, P. J.; Grosso, J. A.; Modi, S. P.; Rusowicz, A.; Sedergran, T. C.; Simpson, J. H.; Srivastava, S. K.; Humora, M. J.; Anderson, N. G. "Removal of Palladium from Organic Reactions by Trimercaptotriazine." *Org. Process Res. Dev.* **1997**, *1*, 311.

Anderson, N. G.; Coradetti, M. L.; Cronin, J. A.; Davies, M. L.; Gardineer, M. B.; Kotnis, A. S.; Lust, D. A.; Palaniswamy, V. A. "Generation and Fate of Regioisomeric Sidechain Impurities in the Preparation of Fosinopril Sodium." *Org. Process Res. Dev.* **1997**, *1*, 315.

Anderson, N. G.; Ary, T. D.; Berg, J. A., et al. "Process Development of 5-Fluoro-3-[3-[4-(5-methoxy-4-pyrimidinyl)-1-piperazinyl]propyl]-1*H*-indole Dihydrochloride." *Org. Process Res. Dev.* **1997**, *1*, 300.

Anderson, N. G.; Ciaramella, B. M.; Feldman, A. F.; Lust, D. A.; Moniot, J. L.; Moran, L.; Polomski, R. E.; Wang, S. S. Y. "Process Development for the Preparation of a Monopril Intermediate by a Trimethylsilyl-Modified Arbuzov Reaction." *Org. Process Res. Dev.* **1997**, *1*, 211.

Anderson, N. G.; Lust, D. A.; Colapret, K. A.; Simpson, J. H.; Malley, M. F.; Gougoutas, J. Z. "Sulfonation with Inversion by Mitsunobu Reaction: An Improvement on the Original Conditions." *J. Org. Chem.* **1996**, *61*, 7955.

Anderson, N. G.; Carson, J. R. "Synthesis and Biological Activity of 5-(4-Chlorobenzoyl)-4-(hydroxy-methyl)-1-methyl-1-*H*-pyrrole-2-acetic Acid, a Major Metabolite of Zomepirac Sodium." *J. Med. Chem.* **1980**, *23*, 98.

Anderson, N. G.; Lawton, R. G. "Intramolecular Photochemical Closure to 4-Tryptophan-substituted Tiglate Derivatives." *Tetrahedron Lett.* **1977**, *22*, 1843.

## **PRESENTATIONS**

"Route Selection" and "Reagent & Solvent Selection," invited lectures at the 2<sup>nd</sup> International School of Process Chemistry, Gargnano Italy, April 8 – 11, 2018.

"Looking Ahead from Academia to Pharma: The Importance of Interdisciplinary Thinking," invited lecture at the University of Victoria, March 25, 2015 and the University of Manchester, 4 December 2015.

"Avoiding Potholes in Process Development," lectures in San Francisco, Chicago, Boston & San Diego, sponsored by Regis Technologies, 2014 – 2015.

"Continuous Reactions and Beyond," invited lecture at the AMRI Chemical Development Symposium, Albany NY, October 3, 2013.

"Some Current R&D Challenges in the Pharmaceutical Industry," keynote lecture, Northwest Regional Meeting, American Chemical Society, Corvallis, Oregon, July 22, 2013.

"Ask the Experts: The uses, challenges and benefits of flow chemistry to optimize drug development" *Future Medicinal Chemistry* September 2012, *4(14)*, 1779 (doi:10.4155/fmc.12.106).

Lectures on process chemistry at the University of Oregon, summer 2012 and summer 2013.

"Controlling Genotoxic Impurities in APIs," invited lecture at the Fourth Drug Innovation and Technology Seminars, Shanghai, China, December 9, 2011.

"Case Studies on the Development of Two Drugs, the 1980s and Today," invited lecture at the University of Wisconsin at Madison, October 5, 2011.

"Development of APIs — Efficiencies for a New Decade," Pre-Conference Workshop presented at Cambridge HealthTech Institute's Symposium on Process Chemistry, Philadelphia PA, June 1, 2011.

"Process Validation from the Standpoint of an Organic Chemist, or Examples of What Can Go Wrong When Implementing Processes On-Scale," lecture recorded for Lehigh University's Chemistry Department, June 30, 2010.

"Successful Approaches for Controlling Genotoxins in APIs," invited lecture at the AMRI Chemical Development Symposium, Albany NY, Aug. 26, 2009.

"Demystifying Process Chemistry," Pre-Conference Workshop presented at Cambridge Healthtech Institute's Mastering Process Chemistry Symposium, Philadelphia PA, November 17, 2008, and October 15, 2007.

Invited lectures at Oregon State University, as part of the Industrial Chemistry course, April 7 – 11, 2008.

"Process Validation from the Standpoint of an Organic Chemist," invited lecture at the AMRI Chemical Development Symposium, Albany NY, Sept. 28, 2007 and Cambridge Healthtech Institute's Mastering Process Chemistry Symposium, Philadelphia PA, Oct. 16, 2007.

Invited lectures at the AMRI Chemical Development Symposium, Albany NY (May 5, 2005 and May 8, 2003); at the Siegfried Symposium on Successful Drug Development in the Biotech Industry, San Diego, CA (April 3-4, 2003); at the ACS ProSpectives Symposium on Process Chemistry in the Pharmaceutical Industry, San Juan, Puerto Rico (February 2-5, 2003); at Queens College (September 22, 1999), Lehigh University (July 27, 1999), UC / Santa Barbara and UC / Riverside (February 1995), and SUNY / Binghamton (November 6, 1985).

In-house and public courses (some through American Chemical Society) presented internationally on process research & scale-up since 1998.

### **PATENTS**

Patel, R. N.; Banerjee, A.; Nanduri, V. B.; Goldberg, S. L.; Johnston, R. M.; Tully, T. P.; Szarka, L. J.; Swaminathan, S.; Venit, J. J.; Moniot, J. L.; Winter, W. J.; Anderson, N. G.; Lust, D. A.; Crispino, G.; Srivastava, S.K. "Enzymatic Oxidative Deamination Process." (Bristol-Myers Squibb Co.) U. S. 6,515,170, 2003.

Anderson, N. G.; Deshpande, R. P.; Moniot, J. L. "Method for preparing N-substituted heterocyclic derivatives using a phase-transfer reagent." (Bristol-Myers Squibb Co.) U. S. 6,162,922, 2000.

Anderson, N. G.; Bennett, B. J.; Feldman, A. F.; Lust, D. A.; Polomski, R. E. "Process for the Direct Isolation of Captopril." (E. R. Squibb & Sons.) U. S. 5,026,873, 1991.

Anderson, N. G.; Cimarusti, C. M.; Lust, D. A. "Process for Stereochemically Inverting a Hydroxy Function of an Ester by a Modified Mitsunobu Reaction Process." (E. R. Squibb & Sons.) U. S. 4,912,230, 1990.

Anderson, N. G.; Anderson, C. F. "Delta Form of Aztreonam and Preparation Thereof." (E. R. Squibb & Sons.) U. S. 4,826,973, 1989.

Anderson, N. G.; Carson, J. R. "Process for Preparing Pyrrole-2-acetic Acids." (McNeil Laboratories Inc.) U.S. 4,284,562, 1981.

**AFFILIATIONS & PROFESSIONAL ACTIVITIES**

Co-chair for the 2016 Organic Reactions & Processes Gordon Research Conference.

Organized Process Chemistry Symposium at Northwest Regional Meeting of the American Chemical Society, Corvallis, Oregon, July 22, 2013. Technical advisor for Process Chemistry symposia presented by Cambridge HealthTech.

Reviewer for manuscripts submitted to *Journal of Organic Chemistry*, *Organic Process Research and Development*, and other journals.

Member - American Chemical Society; member of ACS Division of Organic Chemistry and Industrial & Engineering Chemistry Division

Teaching assistant for biochemistry laboratory course, University of Illinois, summer 1972.

**EDUCATION**

Ph.D., University of Michigan, Interdepartmental Program in Medicinal Chemistry, December 1977; conducted research under Professor R. G. Lawton in the Chemistry Department. Education funded by full traineeship from the National Institutes of Health.

B.S. with honors, University of Illinois, June 1972; Honors Biology major with chemistry minor. James Scholar throughout with admission to Phi Kappa Phi and Phi Eta Sigma.

"Psychology of Supervision," Middlesex County College, Edison, New Jersey, 1982 (grade of "A").

Recertified for successful completion of S-212, Wildland Fire Chain Saws (US Bureau of Land Management), January 2015.