

CURRICULUM VITAE

Francis X. McConville

QUALIFICATIONS

- 35 years in chemical process engineering, technology transfer and process scale-up
- Specializing in bulk API process development, biocatalysis and asymmetric resolution
- Author, training instructor and chemical engineering consultant

EXPERIENCE

Scientific Update, East Sussex, United Kingdom

Training Course Instructor March 2004 - present

- Author and instructor of 3-day training course “*Secrets of Batch Process Scale-Up*” designed for chemical industry R&D professionals. Presented some 50 times to date throughout Europe and the U.S., including in-house at several major pharmaceutical manufacturers.

IMPACT Technology Development, Inc., Devens MA

Senior Engineering Consultant/Project Leader Sept 2003 - present

- Providing process engineering expertise and project management assistance to U. S. and international clients, including system and process design and development, documentation, startup and troubleshooting, and expert witness testimony in IP matters.

FXM Engineering and Design, Worcester MA

Self-Employed Consultant March 2001 - 2010

- Wrote, designed and self-published *The Pilot Plant Real Book*, a practical handbook for development chemists and engineers in the pharmaceutical and fine chemical industries. Now in its fifth printing (2nd Edition).
- Contributor to 5th edition (2005) of *Kirk-Othmer Encyclopedia of Chemical Technology* and author of numerous articles and chapters in industry trade publications and texts.
- Reviewer for ACS publication *Organic Process Research and Development*.

Sepracor, Inc., Marlborough, MA

Supervisor, Kilo-Lab 1996 - 2001

- Established 50-L scale kilo-lab, including design, layout, installation, IQ/OQ and start-up.
- Operated kilo-lab, including training, raw material sourcing, batch records, SOP's and other documentation, led Haz-Op reviews.

Senior Process Engineer 1992 - 2001

- Transferred bulk API processes to metric-ton scale at several pilot and manufacturing sites in Canada, Europe and Asia as key member of technology transfer teams.
- Helped develop, document, transfer, install and startup pilot and commercial plant in Osaka, Japan utilizing proprietary membrane-based biocatalytic process.
- Principle team member in installation and startup of pilot system for novel immobilized biocatalytic production of bulk antibiotic in Taipei, Taiwan.
- Developed several proprietary asymmetric resolution routes for API intermediates, from research through pilot production, process optimization and economic evaluation.

Francis X. McConville

EXPERIENCE

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- Organized and set up multi-gram-scale cGMP manufacturing laboratory. Assisted in development of company-wide cGMP guidelines and SOP's.

Process Engineer 1987 - 1992

- Developed, optimized and scaled up several novel membrane-based biocatalytic processes for chiral APIs and intermediates.

Dept. of Chemical Engineering, WPI

Research Assistant 1986 - 1987

- Explore computer interface for control of bacterial fermentation, microbiology, energy charge determinations, experimental apparatus design/development.

Dept. of Biology and Biotechnology, WPI

Teaching Assistant - 1985-1987

- Courses included Advanced Microbial Genetics, Advanced Cell Biology, Fermentation Biology, Fermentation Engineering, and general biology courses.

New England Renewable Fuels, Inc., Littleton MA

Process Chemist / Assistant Engineer 1981 - 1984

- Helped develop and optimize biocatalytic process for hydrolysis and fermentation of ligno-cellulosic agricultural wastes at lab and pilot scales.
- Helped design and construction of 5000 gal/day machine oil repurification (ultrafiltration) plant. Installation, startup, O&M manuals and drawings, licensing application preparation and technical liaison with regulatory agencies.

Worcester Foundation for Experimental Biology, Shrewsbury MA

Research Assistant 1976 - 1979

- Measured levels of key neurotransmitter in brain tissue of developing rats on restricted diets by spectrofluorometric and other analytical techniques.

EDUCATION

Worcester Polytechnic Institute, Worcester, MA

- M.Sc. in Chemical Engineering, 1987
- M.Sc. in Biotechnology, 1987
- B.Sc. in Chemistry, with Distinction, 1976

ADDITIONAL

Other Experience and Professional Training

- XP installations and intrinsically safe wiring
- Fermentation, asymmetric crystallization
- HPLC, GC, IR, UV, React-IR, TGA, DSC and other standard analytical techniques
- Served on Sepracor Safety Committee
- Bulk Pharmaceutical Drying, 1997 (Scientific Update, UK)

Francis X. McConville

ADDITIONAL

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- Auditing of GMP Manufacturing Sites, 1988 (Barrett's)
- Coaching for Managers, 1998 (Boston University)
- Hazwoper/Hazmat/OSHA First Responder
- Chemical Development and Scale-Up, 1995 (Scientific Update)
- In-House GMP Training Sessions (Sepracor)

PATENTS/ PUBLICATIONS/ ARTICLES

- McConville, F. and Kessler, S. "Scale-Up of Mixing Processes: A Primer" in Chemical Engineering in the Pharmaceutical Industry, R&D to Manufacturing, ed. David J. am Ende, AICHE / Wiley, 2011
- McConville, F. "Scale-Up Dos and Don'ts" in Chemical Engineering in the Pharmaceutical Industry, R&D to Manufacturing, ed. David J. am Ende, AICHE / Wiley, 2011
- McConville, F. "Functions for Easier Curve fitting", *Chemical Engineering* 115 (13) p 48, Dec 2008
- McConville, F. "Tips for Drying Active Pharmaceutical Ingredients", *Process Heating* 14 (11) p 26, Nov 2007
- McConville, F. "A Bit of Extra Effort Can Prevent Grief During Scale-up", *Chemical Engineering* 113 (5) p 38, 2006
- Wilkinson, M. and McConville, F. "Is Your Process Scaleable?" *Pharm. Formulation & Quality*, 7 (7) p24, 2006
- McConville, F. X., Article: *Pilot Plants* in Kirk-Othmer Encyclopedia of Chemical Technology, 5th Edition, 2005
- McConville, F. X., The Pilot Plant Real Book, 2nd, ed., FXM Engineering & Design, Worcester MA, 2006.
- Fang, Q. K., Grover, P., Han, Z., McConville, F. X., Rossi, R., Olsson, D., Kessler, D., Wald, S., and Senenayake, C. Practical Chemical and Enzymatic Technologies for (S)-1,4-benzodioxan-2-carboxypiperazine intermediate in the synthesis of (S)-doxazosin mesylate. *Tetrahedron: Asymmetry* 12 (2001) 2169-2174.
- Roger P. Bakale, Charles P. Vandenbossche, Francis X. McConville, Philomen de Croos, Jorge Lopez, Michael Sizensky, Yue Fang, Chris H. Senenayake and Stephen A. Wald. Poster Presentation: A Highly Efficient Resolution and Direct Coupling Process for Large-Scale Manufacture of the Antispasmodic (S)-Oxybutynin Hydrochloride, 37th National Organic Symposium, Montana State University, Bozeman, MT, 2000.
- Hong, Y., Bakale, Roger P., Fang, Q. K., Kiang, T., Han, Z., McConville, Francis X., Senenayake, Chris H., Wald, S. Synthesis of enantiomerically pure desmethylzopiclone and determination of its absolute configuration. *Tetrahedron: Asymmetry* 11 (2000) 4623-4627.
- Bakale, Roger P., Lopez, Jorge L., McConville, Francis X., Vandenbossche, Charles P., Senenayake, Chris Hugh. Synthesis of Optically Active Cyclohexylphenylglycolate Esters. US Patent Nos. 6140529, 5973182.
- Bakale, Roger P., Lopez, Jorge L., McConville, Francis X., Vandenbossche, Charles P., Senenayake, Chris Hugh. Synthesis of Optically Active Cyclohexylphenylglycolic Acid and its Esters. European Patent No. 99953250.0-2103, U.S. Pat's Nos. 0177456, 0211646.
- Jorge L. Lopez, Francis X. McConville and Stephen A. Wald: Practical Considerations for the Design of Crystallizations used for the Separation and Enrichment of Enantiomeric Mixtures. American Institute of Chemical Engineers, National Meeting, Los Angeles, CA, November 17, 1997.
- McConville, F. X., Lopez, J. L., Wald, S. A. Enzymatic resolution of ibuprofen in a multiphase membrane reactor. 1990. *Biocatalysis* 167-77. Ed. Abramowicz, Daniel A. Can Nostrand Reinhold, N.Y.

Francis X. McConville

**PATENTS/
PUBLICATIONS/
ARTICLES**
(continued)

- McConville, F. X., J. E. Miller, D. DiBiasio. Poster: Ethanol Fermentation by Immobilized *S. Cerivisiae*: Application of Dimensional Analysis. Abstract #O-22 Proc. 86th Ann. Meet. A. S. M. March, 1986, Washington. DC.
- McConville, F. X., J. E. Miller, P. J. Weathers, M. Goldberg. Pilot studies in ethanol production from apple pomace. New Eng. Biotech. Assoc. Ann. Meeting, Worcester MA, March 1985.
- Miller, J. E., P. J. Weathers, F. X. McConville, M. Goldberg. Saccharification and ethanol fermentation of apple pomace. 1982. Biotechnology and Bioengineering Proc. IV Symp. On Biotechnology in Energy Production and Conservation 12:183-191.
- Miller, M., J. P. Leahy, F. McConville, P. J. Morgane, O. Resnick. 1978. Utilization of C-14-tyrosine in brain and peripheral tissues of developmentally protein malnourished rats. Brain Res. Bull. 3 (6):681-686.
- Miller, M., J. P. Leahy, F. McConville, P. J. Morgane, O. Resnick. 1977. Phenylalanine utilization in brain and peripheral tissues during development in normal and protein malnourished rats. Brain Res. Bull. 2 (3):189-196.
- Miller, M., J. P. Leahy, F. McConville, P. J. Morgane, O. Resnick. 1977. Effects of protein malnutrition on tryptophan utilization in brain and peripheral tissues. Brain Res. Bull. 2 (5):347-354.
- Ciaccio, P. R., J. V. Ellis, M. E. Munson, G. L. Kederis, F. McConville, and J. M. Duclos. 1976. Ligand Binding to Metalloporphyrins. II. The equilibrium between iron III tetraphenylporphyrin chloride and imidazole in various media. J. Inorg. Nucl. Chem. 38 (10):1885-1889.

-Feb 26, 2015