

CURRICULUM VITAE

Francis X. McConville

6 Intervale Road
Worcester, MA 01602
508-752-1563

- QUALIFICATIONS**
- 28+ years in chemical process engineering, technology transfer and scale-up
 - Specializing in bulk API process development, biocatalysis and asymmetric resolution
 - Author, training instructor and self-employed engineering consultant

EXPERIENCE

Scientific Update, East Sussex, United Kingdom

Training Course Instructor March 2004 - present

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

IMPACT Technology Consultants, Lincoln MA

Senior Engineering Consultant Sept 2003 - present

- Providing process engineering expertise to several U.S. clients, including system and process design, documentation, startup and troubleshooting.

FXM Engineering and Design, Worcester MA

Self-Employed Consultant March 2001 - present

- 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 third printing (2nd Edition).
- Contributor to 5th edition (2005) of *Kirk-Othmer Encyclopedia of Chemical Technology*.
- Reviewer for ACS publication *Organic Process Research and Development*

Sepracor, Inc., Marlborough, MA

Supervisor, Kilo-Lab Operations 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 and Europe as key member of technology transfer teams.
- Helped develop, document, transfer, install and startup pilot and commercial plants in Osaka, Japan utilizing proprietary membrane-based biocatalytic process.

Francis X. McConville

EXPERIENCE

(continued)

- 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.
- 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 API 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 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

Francis X. McConville

ADDITIONAL

Other Experience

- XP installations and intrinsically safe wiring
- Enzyme fermentation, asymmetric crystallization
- HPLC, IR, UV, Reacts-IR, TGA, DSC and other standard analytical techniques
- Served on Sepracor Safety Committee

Other Professional Training

- Bulk Pharmaceutical Drying, 1997 (Scientific Update, UK)
- 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 Sepracor GMP Training Sessions
- Member, former club officer, Toastmasters International

PATENTS/ PUBLICATIONS/ ARTICLES

- McConville, F. "A Bit of Extra Effort Can Prevent Grief During Scaleup", Chem. Eng., 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*, FXM Engineering & Design, Worcester MA, 2002.
- Fang, Q. K., Grover, P., Han, Z., McConville, F. X., Rossi, R., Olsson, D., Kessler, D., Wald, S., and Senanayake, 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. Senanayake 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., Senanayake, 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., Senanayake, 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., Senanayake, Chris Hugh. Synthesis of Optically Active Cyclohexylphenylglycolic Acid and its Esters. European Patent No. 99953250.0-2103, U.S. Pat's Nos. 0177456, 0211646.

Francis X. McConville

**PATENTS/
PUBLICATIONS/
ARTICLES**

(continued)

- 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.
- 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.