

Curriculum Vitae

James V. Blackwell, Ph.D. M.B.A.

Address: Bioprocess Technology Consultants, Inc.
289 Great Road, Suite 303
Acton, MA 01720
Phone: 978-266-9112
Fax: 978-266-9152
E-mail: jblackwell@bioprocessconsultants.com

EDUCATION

2003 M.B.A. and M.S., Technology Management
University of Maryland, Adelphi, MD

1992 Ph.D., Chemical Engineering
Northeastern University, Boston, MA

1987 M.S., Microbiology
The Ohio State University, Columbus, OH

1983 B.S., Chemical Engineering
The Ohio State University, Columbus, OH

PROFESSIONAL EXPERIENCE

2007-present Senior Consultant
2005 – 2007 Consultant
BioProcess Technology Consultants, Inc., Acton, MA
Technical operations and business consulting to the biopharmaceutical industry with specific expertise in cell culture and fermentation process development, manufacturing, product commercialization, and cost modeling and analysis.

2003 – 2005 Sr. Manager, Technical Operations
Abbott Corporation, Worcester, MA
Responsible for technical support for Humira[®] manufacturing. Served on site validation review board and quality management teams.

1996 – 2003 Process Engineer III, Manufacturing Technical Support (1999-2003)
Process Engineer II (1996-1999)
Genzyme Corporation, Cambridge, MA
Provided technical support to Cerezyme[®], Fabrazyme[®], and Hylumed[®] manufacturing and other late-stage clinical programs.

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1992 – 1996 Research Scientist (1995-1996)
 Associate Scientist (1992-1996)
 Repligen Corporation, Cambridge, MA
 Developed and scaled-up manufacturing processes for recombinant products
 produced in *E. coli* and mammalian cell culture.

AWARDS AND HONORS

2003 Phi Kappa Phi, University of Maryland
1996 – 2003 Several internal awards, Genzyme Corporation
1978 National Merit Scholarship/Honors Program, The Ohio State University

BOARD MEMBERSHIPS

Editorial Advisory Board, Pharmaceutical Processing

PROFESSIONAL ASSOCIATIONS

International Society for Pharmaceutical Engineering (ISPE)
 Chair, Process and Product Development Community of Practice Steering Committee, 2005 -
 present
 President, Boston Area Chapter, 2003 – 2004
 Vice President, Boston Area Chapter, 2002 – 2003
 Secretary, Boston Area Chapter, 2001 – 2002
 Board of Directors, Boston Area Chapter, 2000 – 2001
 Member, 1992 – present

SELECTED PRESENTATIONS

Bio-processing – Chem. E's in Technology Development, presented at American Institute of Chemical Engineers Boston Section (April 2006)

The Impact of the EU Clinical Trials Directive and Other Recent Regulatory Changes on Process Development and the Manufacture of Biopharmaceuticals, presented at ISPE Current Trends in Biotech Manufacturing Technology and Process Development, Tampa, FL (February 2006)

Removal of Mycoplasma from Cell Culture Media by Filtration – An end user perspective, presented at IBC's Scaling-Up from Bench to Clinic & Beyond, Durham, NC (August 2003)

Use of Mass Off-Gas Analysis in a Large Scale Perfusion Cell Culture Process, presented at IBC's Bioprocess Control Parameters, Bethesda, MD (October 2001)

An Integrated Activity-based Framework for Making Decisions in Biotechnology Manufacturing Processes, presented at IBC's Production and Economics of Biopharmaceuticals, La Jolla, CA (November 2000)

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Large-scale Perfusion Cell Culture for Routine Manufacturing of Proteins, presented on behalf of Richard Schoenfeld at IBC's Production and Economics of Biopharmaceuticals, La Jolla, CA (November 2000)

Application of Process Modeling and Statistical Process Control Techniques to the Optimization of Bio-Processes, presented at American Institute of Chemical Engineers Annual Meeting, Chicago, IL (November, 1996)

Control Problems & Solutions Encountered in Scale-up of Recombinant *Escherichia coli*, presented at ISPE Advances in Biotechnology: Process Development and Facility Planning, Design, Construction, ELA, IND, PLA, Requirements and Validation, Westborough, MA (May 1995)

Fermentation Optimization of Expression of Recombinant Proteins in *Escherichia coli* using a T7 RNA Polymerase Transcription System, presented at Recent Advances in Fermentation Technology '95, San Diego, CA (November 1995)

Scale-up of *Escherichia coli* Producing Recombinant Platelet Factor-4 in a Fed-batch Process, presented at Society of Industrial Microbiology Annual Meeting, Boston, Massachusetts (August 1994)

Metabolic Studies of Platelet Factor-4 Producing *Escherichia coli* in Continuous Culture, presented at Society of Industrial Microbiology Annual Meeting, Boston, MA (August 1994)

Production of Human Rec-Creatine Kinase/MB in *Escherichia coli*, presented at Society of Industrial Microbiology Annual Meeting, Boston, MA (August, 1994)

Characterization and Modeling of the Hall Jet-loop Bioreactor, presented at American Institute of Chemical Engineers Annual Meeting, Miami Beach, FL (November 1992)

High Cell Density Cultivation of *Streptomyces* C5, presented at American Society of Microbiology Annual Meeting, Atlanta, GA (March 1986)

PUBLICATIONS

Rosin, L.J. (Interviewer), The Next Five Years- and More: Industry Leaders Weigh in on the Future, BioProcess International (October 2007)

Blackwell, J.V., Levine, H.L. and Ransohoff, T. (Editor: Langer, E.S), 4th Annual Report and Survey: Biopharmaceutical Manufacturing Capacity and Production: An In-Depth Industry Analysis, Institute for Science and Technology Management (June 2006)

Blackwell, J.V., Levine, H.L. and Ransohoff, T. (Editor: Langer, E.S), 3rd Annual Report and Survey: Biopharmaceutical Manufacturing Capacity and Production: An In-Depth Industry Analysis, Institute for Science and Technology Management (June 2005)