

Ronald C. Bates, Jr.
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EDUCATION:

Ph.D. Chemical and Biochemical Engineering, University of Maryland, Baltimore County, August 1999

Dissertation: "Development of a Novel Chromatofocusing Method for Protein Separation"

Advisor: Professor Douglas D. Frey.

B.S. Chemical Engineering, Economics Minor, Rensselaer Polytechnic Institute, May 1993.

EXPERIENCE:

Vice President, CMC: Immunovant (remote), November 2020 – present

Lead Drug Substance, Drug Product, Device, Packaging/Labeling, Analytical Development, Quality Control, Stability, and Supply Chain activities at various CDMOs. Led several CDMO selection processes.

Managed growth of CMC group from 5 to 25 FTE, not including temporary employees and consultants.

Established and Managed Budget (>\$25M/year) and Contracts for CMC.

Developed and Implemented Stability, Cell Bank, Specification, and Validation Directives.

Established methodology for analyzing data to support shelf-life determination and process parameter classification.

Developed commercialization timeline and budgetary needs for lead molecule including development/characterization studies, manufacturing schedule, stability requirements, validation timelines (QTPP, CQAs, Process Control Strategy, shipping, internal and CMO protocols), clinical trial packaging/labeling/shipping forecast/delivery, and appropriate head count models to support.

Lead development of back-up molecule: transfer of amino acid sequence, selection of cell line and generation of cell banks, drug substance, formulation, and drug product development, analytical method development and qualification, tox material generation and shipment to vendor, drug substance and drug product clinical material generation and shipment to warehouse.

Supported filing of IND amendments and IMPDs to support clinical trials. Led CMC activities at the End of Phase 2 meeting with the FDA.

Director: Bristol-Myers Squibb, August 2013 – October 2020

Managed Drug Substance Manufacturing Sciences & Technology group (~70 FTE) responsible for commercial support of biological moieties including PV/PPQ, regulatory filings, audit support, campaign monitoring, manufacturing support, raw material and consumable strategies and implementation, deviation remediation, technical transfer, continuous improvement, and next generation process development and characterization at several internal and external manufacturing sites

Member of Global Drug Substance MS&T Senior Leadership Team

Member of Syracuse Senior Leadership Team with membership on site change control and IRB councils, site strategic and continuity planning, community outreach, executive safety council, audit preparation, supply chain, operational excellence, etc.

Managed headcount, capital, and expense budgets totaling over \$10,000,000 annually.

Led Manufacturing Technology activities to support Syracuse operations.

Led MS&T activities (protocols, investigations, reports) for the PPQ/ commercial approval of 3 molecules at 3 sites.

Managed resources and provided support for regulatory filings, questions, and audits leading to the approval of 3 molecules by world-wide health authorities for 2 internal and 2 external sites.

Supported technical transfer of 4 late-stage and commercial molecules to internal and external manufacturing sites.

Developed and implemented a PIP and satellite program for Syracuse and CMO commercial manufacturing support.

Led commercialization of next generation process (risk assessments, scale-down models, and protocols) to meet an aggressive timeline. Led subsequent PPQ and filing resulting in an approved process that is 500% more productive.

Successfully integrated in-process analytical testing group into MS&T, increasing productivity and communication between submitters and testers. Established "walk-up" HPLCs to increase productivity saving 1 FTE/year.

Oversaw operations and subsequent closure of 500-L Development Pilot Plant.

Chair, Biotech Talks seminar series

Co-lead of New Technology Task Force Governance Team responsible for soliciting, funding, and monitoring new technology projects within Process Development and MST with an \$1,000,000 annual budget.

Chair, Process Development/MS&T Summit Series

Past co-chair internal development and commercial technical governance body

Past member of Biologics Specifications Committee responsible for setting specifications for all biological moieties.

Director: Allergan, February 2011 – August 2013

Managed process development, manufacturing science, and stability groups responsible for development, improvement, characterization, technical transfer, and monitoring for early- and late-stage biological moieties.

Led Biologics Development team for pre-clinical/Phase I biological moiety.

Participated on Biologics Development steering committee responsible for development projects strategy, timelines, resource allocation and conflict resolution, CMC team representation, and budgets.

Supported technical transfer activities to external CMO and internal manufacturing sites.

Authored and reviewed regulatory submissions.

Managed stability program for non-commercial biological moieties (cell banks, drug substances, drug products, reference standards, key impurities). Created lifecycle management document to map key stability expectations across the drug development and commercialization lifetime. Developed stability analysis methodology SOP.

Developed and implemented high throughput screening for cell line selection, resin screening, process optimization, and process characterization reducing development time by > 6 months.

Led validation and licensure team for next generation process that was 1000% more productive: developed strategy for characterization and validation (including documentation requirements), timelines, and implementation.

Supported technical transfer activities to external CMO and internal manufacturing sites.

Managed process development annual operating budget of \$3,000,000.

Senior Manager: Allergan, May 2007 – January 2011

Managed downstream process development and manufacturing science group responsible for development, improvement, technical transfer, and monitoring of processes for early- and late-stage biological moieties.

Managed stability group responsible for developing and executing drug substance and product stability program.

Developed and implemented high throughput cell line selection, resin screening, and process optimization.

Developed and implemented a statistically-based process for process characterization and validation for biologics.

Led technical transfer, process characterization, and process validation teams for 1000% more productive next generation process including cell bank selection, manufacture, and stability monitoring, DOE range finding studies for inoculation, fermentation, harvest and downstream steps, impurity challenge studies, process control strategy, stability strategy.

Provided technical support to manufacturing operations (internal and external CMOs) including SOP and batch record review, investigations (scientific and experimental), process trending, and change recommendations.

Represented process team on CMC working group and managed process development project budget.

Authored and reviewed regulatory submissions including IND, IMPD, sBLA, and briefing documents.

Managed purification group budget (capital, expense and compensation totaling ~ \$1 million/year).

Implemented LEAN and 5S tools and an atmosphere of continuous improvement into development team.

Managed document control group responsible for establishing and maintaining document procedures, templates, and systems and technical writing/editing for development, procedural and regulatory documents.

Manager/Senior Manager: Bristol-Myers Squibb, March 2003 – May 2007

Managed process development group responsible for development and improvement of recovery and purification processes for late-stage biological moieties.

Provided technical guidance and support to manufacturing operations and manufacturing deviation investigations.

Led cross-functional team including manufacturing, cell culture, recovery, and downstream development and technical services to identify root cause of harvest operation issue. Authored final report.

Led cross-functional team including cell culture and downstream development to compile potential root causes for OOS result during long-term stability studies (LTSS). Authored final report.

Developed and transferred the harvest and purification process for a Phase III biological molecule to manufacturing.

Provided guidance and floor support to manufacturing operations during technical transfer and routine operations.

Provided technical and managerial support for process validation efforts including viral clearance studies, impurity challenge studies, scale-down activities, DOE range finding studies, process validation master plan, SOP authoring and reviewing, report authoring and reviewing.

Authored and reviewed CMC Sections of IND, BLA, sBLA and MAA and Downstream Process Validation reports.

Managed and planned purification group budget (capital, expense, project and compensation).

Managed recruiting of supervisor and junior-level scientists.

Established and chaired Biotechnology Development Team seminar series for junior scientists to present their work.

Research Scientist/Senior Research Scientist: Pfizer, Inc., February 1999 – March 2003

- Supervised two research groups responsible for purification process method development, process scale-up, and delivery of bulk drug substance for discovery, development, and manufacturing colleagues using separation techniques including high pressure liquid chromatography (HPLC) with various stationary phases (chiral, silica, reversed phase, cyano), medium pressure chromatography (silica, hydrophobic), simulated moving bed (SMB) chromatography with both chiral and achiral stationary phases, supercritical fluid chromatography (SFC), filtration, precipitation, crystallization, and liquid-liquid extraction.
- Scaled-up laboratory purification schemes to the pilot scale and provided technical and analytical assistance during the purification campaigns.
- Developed an automated chiral and reversed-phase analytical chromatographic method development software package. Improved existing logic to more efficiently analyze chromatograms and propose future plans. Developed logic for and assisted in the implementation of preparative method development using artificial intelligence for both chiral and reversed-phase chromatographic systems.
- Involved with matrix teams involving members from all stages of the drug development process focused to either bring drug product into clinical trials (Phase I and Phase II) or improve existing manufacturing processes.
- Established and chaired Bioprocess Research and Development Departmental Safety Committee, set agenda for monthly safety committee meetings, ran quarterly development safety meetings, member of other departmental safety committees across company.

Graduate Assistant: University of Maryland, Baltimore County, September 1993 – February 1999

- Developed and optimized novel chromatofocusing systems for the separation, purification and identification of peptide and protein mixtures using numerous weak-base stationary phases and traditional ion-exchange chromatography buffering species.
- Developed a computer model based on local equilibrium analyses to predict effluent pH profiles using simple buffering species and a weak-base stationary phase.
- Developed a theoretical solution predicting protein peak shapes in a chromatographic column using known and experimentally determined physical parameters.
- Assisted in the teaching of two senior level classes, Chemical Engineering Lab and Process Design.
Activities: development of Chemical Engineering Laboratory curriculum, exam development and grading, assembling and monitoring unit operation labs and demonstrations.

ACTIVITY IN THE SCIENTIFIC COMMUNITY

- Member, Scientific Committee, HIC/RPC, 2016 – present
- Editorial Board Member and reviewer, Biotechnology Journal, 2012 - present
- Scientific Advisor, BioProcess International Conference Series, August 2018- present
- Speaker: Increased Bioburden Excursions in an Aging Facility. Technology's Evolution and Impact on Manufacturing Symposium, Evaluating Biopharma, December 2021.
- Speaker: Case Study: Raw material issue derails PPQ, causes 2-year process delay. Pharma Shifts to Biologics Symposium, Evaluating Biopharma, October 2021.
- Participant: Roundtable on "Creating Value for Biopharmaceutical Organizations with a Real-World Evidence Strategy", Innovaccer Host, September 2020
- Chair: Roundtable on "Mitigating Challenges with Raw Material Supply Chains at Biomanufacturing and Cell & Gene Therapy Strategy Meeting, June 2020.
- Board Member, BPI Europe Leadership Boardroom, April 2016.
- Reviewer: Journal of Chromatography B (2009-present); Chemical Engineering Science (2020); Analytical Chemistry (2008-2013); Biopolymers (2007); Biotechnology Progress (2009); Electrophoresis (2006); Industrial and Engineering Chemistry Research (2008); Journal of Biochemical and Biophysical Methods (2006 – 2007).
- Panel Member, Single-Use Process Development Symposium, BPI Conference, October 2011
- Panel Member, Bottlenecks in Downstream Processing Symposium, BIO International Convention, June 2011
- Member, Scientific Committee, ISPPP, 2004 and 2006.
- Chair or Co-Chair, numerous international conventions including ACS, ISPPP, HIC/RPC, BPI Europe, Bioprocessing Summit, etc.

LEADERSHIP ROLES:

Executive Sponsor Syracuse BMS Pacific-American Network underrepresented group, January 2018 – October 2020
Sponsor/Chair BMS Development/MS&T Summit Series, March 2018 – October 2020
Co-lead, BMS New Technology Task Force, January 2015 – October 2020
Lead, BMS Biotech Talks seminar series, June 2014 – October 2020
Member, BMS Biologics Specification Committee, January 2015 – December 2019
Co-chair, BMS Integrated Bioprocess Technical Review committee, January 2018 – December 2018
Member, Allergan Biologics Development Steering Committee, April 2011 – July 2013
Development Lead, Allergan CMC Project Team, January 2009 – July 2013
Process Representative, Allergan CMC Working Group, April 2008 – January 2009
Member, BMS Large-Scale Cell Culture Facility Start-up Team, November 2005 – May 2007
Councilor, ACS Council Committee on Project Seed, February 2003 - December 2005
Member, BMS Integrated Development Team, March 2003 - December 2004
Chair, Pfizer Bioprocess Research and Development Safety Committee, August 2002 – March 2003
Associate, ACS Council Committee on Project Seed, February 2002 – February 2003
Member, Pfizer Pharmaceutical Sciences Project Teams, Summer 1999 – March 2003
Graduate Student Association (GSA) Treasurer, Spring 1998 – Spring 1999
Undergraduate Advisor (through UMBC Advising Center), Summer 1994 – Summer 1998
GSA Financial Committee Member, Fall 1996 – Spring 1999
Captain UMBC Ice Hockey Team, Fall 1997 – Spring 1999
Graduate Student Association Senator, Biochemical Engineering Department, Fall 1993 - Spring 1998

AWARDS AND AFFILIATIONS:

Member American Chemical Society, 1990 - present
Member Parental Drug Association, 2009 – present
BMS Ovation Award September 2020
BMS Encore Award for Belatacept US/EMA/ROW filing December 2019
Yellow Belt Certification June 2016
Allergan Award for Excellence, August 2008 and September 2008
Technical Operations Achievement Award, Bristol-Myers Squibb, November 2006
Abatacept BLA IMPACT Spot Plus Award, Bristol-Myers Squibb, October 2004
Selected by Bioprocess Department Management to present at 1st Annual Chemical Research and Development Global Science and Technology Forum, June 2002
SEXTANT Team Award, Pfizer, Inc., Spring 2001
UMBC Biochemical Regulatory Engineering Program Track Concentration Certification, May 1998
Selected to represent UMBC at the 1988 Mid-Atlantic Biochemical Engineering Consortium, March, 1988
Captain's Award, UMBC Ice Hockey, 1997-1998
Most Valuable Player, UMBC Ice Hockey, 1995-1996
Dean's List of Distinguished Students at RPI, Fall 1989 - Spring 1993
Represented RPI at the 6th National Conference of Undergraduate Research, Spring 1992
Honor Initiate of Delta Tau Delta Fraternity, Spring 1990
National Honor Society, May 1989
First Team All-Western Massachusetts Ice Hockey Defensemen, 1988-1989
Second Team All-Western Massachusetts Ice Hockey Defensemen, 1987-1988

SELECTED PUBLICATIONS and PRESENTATIONS:

Publications

Troubleshooting A Failed Process Performance Qualification: Lessons Learned, Ron Bates, Outsourced Pharma, January 24, 2022.
PDA Technical Report No. 60-3. Process Validation: A Lifecycle Approach Annex 2: Biopharmaceutical Drug Substance Manufacturing, May 2021.
Theresa Scharl-Hirsch, Ves Lesins, Ron Bates, and Alois Jungbauer, The characteristics of a robust biomanufacturing process: production of an Fc-fusion protein over a 15-year period, in preparation.
Doug Frey, Yang Liu, Sevda Deldari, Ryan Swanson, Chittoor Narahari, Ronald Bates, Sanchayita Ghose, Zhengjian Li, Methods of Isolating a Protein, US Application Number 17/433584, filed 24 Feb 2020.
A. Lewis, A. Lee, N. Lamon, TW. Carone II, R. Bates, and R. Ludwig, Methods of Making a Protein, US Application Number 63/066127, filed 14 Aug 2020.
Yang Liu et al., Evaluation of chromatofocusing as a capture method for monoclonal antibody products, *Journal of Chromatography A*, 1568 (2018) 108-122.
Hui Xiang, Derek Chan and Ronald Bates. Minimization of Freeze/thaw-induced Protein Aggregation and Optimization of a Drug Substance Formulation Matrix, BioPharm International, Volume 28, Issue 8, pp 30-37, August 1, 2015.

Jennifer Ton, Hemant Patel, Ronald Bates, and Wajdie Ahmad. Process and System for Obtaining Botulinum Neurotoxin, Patents: WO/2011/008713, 2011; US 8,129,139 B2 2012; 8,324,349 B2 2012; 8,357,541 B2, 2013, US 8,927,229 2015, US 8,932,827 2015.

Disposable Downstream Processing – A Time and a Place for Everything. Ronald Bates, BioPharma Asia, Vol 3 Issue 4 (2014) 4-16.

Downstream Processing: Is the Death of Protein A Chromatography Imminent?, Ronald Bates, Chapter in 11th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production, April 2014 BioPlan Associates, Inc.

Workplace Stress and Job Satisfaction among Biologics Development Professionals. H. Xiang, S. Coleman, M. Johannsson, and R. Bates, Health, 6 (2014) 1790-1802.

Host cell protein analysis – comparison of methods. A.L. Tscheliesnig, J. Konrad, R. Bates, and A. Jungbauer, Biotechnology Journal, Vol 8, Issue 6 (2013) 655-670.

Jennifer Ton, Ronald Bates, Ji Zheng, Phillip Nguyen, Timothy O'Neill. Stabilization of Therapeutic Agents to Facilitate Administration, Patent WO/2011/075500, 2011.

Kirk Leister et al. Compositions and Methods for Producing a Composition, Patent WO/2007/076032, 2007.

Ronald Bates, "Chapter 13. Downstream Processing", in *Cell Culture Technology for Pharmaceutical and Cell-Based Therapies*. Biotechnology and Bioprocess Series Volume 30, CRC Press, 2006.

Mark Guinn, Ronald Bates, Glenn Wilcox, Benjamin Hritzko, Teri Shanklin, and Sam Guhan, "Chapter 10. Isolation Methods II: Column Chromatography," in *Handbook of Isolation and Characterization of Impurities in Pharmaceuticals (Separation Science and Technology, Volume 5)*, Satinder Ahuja and Karen Alsante, ed., Elsevier, Inc., Academic Press: 2003.

D. Frey, R. Bates, C. Narahari, "Chromatofocusing", in *Encyclopedia of Life Sciences*, McMillan Publishers, 2001.

High-Performance chromatofocusing using linear and concave pH gradients formed with simple buffer mixtures. I. Effect of buffer composition on the gradient shape. R. Bates, X. Kang and D. Frey, Journal of Chromatography A, Vol. 890 (2000), pg. 25-36.

High-Performance chromatofocusing using linear and concave pH gradients formed with simple buffer mixtures. II. Separation of proteins. X. Kang, R. Bates and D. Frey, Journal of Chromatography A, Vol. 890 (2000) 37-44.

Quasi-Linear pH Gradients for Chromatofocusing Using Simple Buffer Mixtures: Local Equilibrium Theory and Experimental Verification. Ron Bates and Doug Frey, Journal of Chromatography A, Vol. 814 (1998) 43-54.

Dean Vortices with Wall Flux in a Curved Channel Membrane System. 4. Effect of Vortices on Permeation Fluxes of Suspensions in Microporous Membranes. K.Y. Chung, R. Bates and G. Belfort, Journal of Membrane Science, Vol. 81 (1993) 139-150.

Effects of Dean Vortices on Membrane Fouling. R. Bates, K. Y. Chung, and G. Belfort, National Conference of Undergraduate Research Proceedings 6th Edition, 1992.

Selected Presentations

Learning Opportunities During Commercial Manufacturing, Ron Bates, Presented at Bioprocessing Summit, Boston, MA, August 2019.

Integration of Disposables into a Stainless Steel Facility. Ron Bates, Presented at BioProduction Conference, Dublin, Ireland, October 2018.

Disposable Manufacturing – Case Study from BMS. Ron Bates, Presented at BPI Europe 2016, Vienna, Austria, April 2016.

Integration of Control Strategy, Process Validation and Lifecycle Management for Biologics Process Validation. Ronald Bates, Joseph Shiminsky, and Brendan Hughes, Presented at DIAs CMC Workshop 2015, Bethesda, MD, April 2015

Disposable Processing – A Time and a Place for Everything. Ronald Bates, Presented at 9th HIC/RPC Bioseparation Conference, Sliema, Malta, March 2015.

Current Best Practices in the Definition of Process Parameters for Development of Control Strategies. Ronald Bates, Presented at CMC Strategy Forum Europe, Sorrento, Italy, 2014.

Challenges with Disposables in Downstream Processes, Ronald Bates, Presented at Peptalk, Palm Springs, CA, 2014.

A Risk-Based Approach to an Extractables and Leachables Testing Strategy. Ronald Bates, Presented at Peptalk, Palm Springs, CA, 2013.

Establishing Process Design Space from Concept to Implementation, A Case Study. Derek Chan, Hui Xiang, and Ronald Bates, Presented at IBC's 18th Annual Process Validation & Continuous Verification, Huntington Beach, CA, 2013.

Implementation of Single-Use Technology in Laboratory- and Manufacturing-scale Downstream Processing. Ronald Bates, Presented at BPI Annual Conference, Long Beach, CA, 2011.

Application of QbD and PAT Methods to an *E. coli* Protein Purification Process Development Project. Ji Zheng, Phillip Nguyen, David Didio, Johnney Wu, Pam Cifra, and Ronald Bates, Presented at BPI Annual Conference, Long Beach, CA, 2011.

Prevention of Freeze/Thaw Induced Protein Aggregation and Optimization of a Drug Substance Matrix. Hui Xiang, Derek Chan, and Ronald Bates, Poster Presented at BPI Annual Conference, Long Beach, CA, 2011.

Attacking the Next Biomanufacturing Bottleneck: Downstream Processing. Ronald Bates, Presented at 2011 BIO International Convention, Washington DC, 2011.

High throughput screening approach to identify ideal conditions for protein chromatography. Dennis Coss and Ronald Bates, Presented at 239th ACS National Meeting, San Francisco, CA, 2010.

Prokaryote Platform Process: Perils, Pitfalls, Payback. Ronald Bates, IBC's Non-Antibody Protein Therapeutics Development & Production, Carlsbad, CA, 2009.

Case Study: The Effect of Protein Solubility on the Development of a Hydrophobic Interaction Chromatography Step for a Glycosylated Antibody-Fusion Protein. Ronald Bates, Junfen Ma, Rachel Ozer, Presented at Recovery XII, Litchfield, AZ, April 2006.

Chromatographic Scale-up of Pharmaceutical Compounds. Ronald Bates, Presented at Preptech 2002, Gothenburg, Sweden, May 2002.

Chromatofocusing of Proteins Using Simple Buffer Mixtures to Generate Quasi-Linear pH Gradients. Ronald C. Bates, Douglas D. Frey, Presented at ISPPP '99, Delray Beach, Florida, November 1999.

Protein Separation and Purification using Novel Chromatofocusing Methods. Ron Bates and Doug Frey, Presented at ACS National Meeting, Boston, MA, August 1998.

Local Equilibrium Prediction of Linear pH Profiles Using a Weak-Base Adsorbent and Simple Buffering Species. Ron Bates, Doug Frey, and John Strong, Poster presented at ACS National Meeting, San Francisco, CA, April 1997.

Protein Separation and Purification Using Novel Chromatofocusing Methods. Doug Frey, John Strong, and Ron Bates, Poster presented at ACS National Meeting, New Orleans, LA, March 1996.

The Effects of Dean Vortices on Membrane Fouling. Ron Bates, Kun Yong Chung and Georges Belfort, Poster presented at 6th National Conference of Undergraduate Research, Minneapolis, MN, March 1992.