

Curriculum Vitae **Howard L. Levine, Ph.D.**

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EDUCATION

1978 Ph.D., Chemistry
University of Chicago, Chicago, IL

1975 B.S., magna cum laude, Chemistry
University of Southern California, Los Angeles, CA

PROFESSIONAL EXPERIENCE

1994 – present President and Principal Consultant
BioProcess Technology Consultants, Inc., Acton, MA
Founder of a consulting company providing full service CMC consulting to the biopharmaceutical industry.

1991 – 1994 Vice President, Manufacturing Operations (1992 – 1994);
Vice President Product Development (1991 – 1992)
Repligen Corporation, Cambridge, MA
Responsible for process development, manufacturing and engineering.

1986 – 1991 Director, Pilot Plant Operations
Xoma Corporation, Berkeley, CA
Supervised development, scale-up, and validation of manufacturing processes for monoclonal antibodies.

1984 – 1986 Senior Process Scientist
Amgen, Inc., Thousand Oaks, CA
Developed and scaled-up manufacturing processes for recombinant products produced in *E. coli* and mammalian cell culture.

1980 – 1984 Scientist
Genentech, Inc., South San Francisco, CA
Purified and characterized human proteins produced in *E. coli* and yeast by recombinant DNA.

Curriculum Vitae
Howard L. Levine, Ph.D.

1978 – 1980 Post-Doctoral Research Fellow
Chemical Laboratories, Harvard University, Cambridge, MA
Conducted structure-function studies of Orotidine-5'-phosphate Decarboxylase.

AWARDS AND HONORS

1999 Publisher's Award, Advanstar Publications
1991 Fred Simon Award, Parenteral Drug Association
1978 Marc Perry Galler Prize, University of Chicago
1976 – 1978 National Research Service Award, NIH
1975 American Institute of Chemists Award, University of California
1975 Phi Beta Kappa, University of Southern California

BOARD MEMBERSHIPS

Strategic Advisory Board, Acretia, Inc.
Strategic Advisory Board, NexBio, Inc.
Strategic Advisory Board, DSM Biologics
Scientific Advisor, IBC BPI Conference
Editorial Advisory Board, Biopharm Magazine
Editorial Advisory Board, Bio/Pharmaceutical Outsourcing Report

PROFESSIONAL ASSOCIATIONS

American Chemical Society
American Institute of Chemical Engineers
 Treasurer, Northern California Section, 1988 – 1989
 Vice Chairman, Northern California Section, 1989 – 1990
 Chairman, Northern California Section, 1990 – 1991
International Society of Pharmaceutical Engineering (ISPE)
 Member, Boston Area Chapter Advisory Board, 1992 – 2002
Parenteral Drug Association
 Member, Biotechnology Task Force, 1988 – 1992
 Chairman, Biotechnology Task Force, 1990 – 1992

SELECTED PRESENTATIONS

“The Use of Critical Process Analysis to Reduce Risk and Increase Biologics Product Quality,”
 presented at FIP Quality International 2007 Conference: Critical Process Parameters in the
 Manufacture of APIs, Biologicals, Tablets, and Parenterals, London, UK (November 27, 2007)

“The Future of Viral Validation,” presented at IBC Process Validation for Biological Conference,
 Carlsbad, CA (February 26, 2007)

“Successfully Managing Biopharmaceutical Manufacturing Outsourcing,” presented at IQPC Contract
 Manufacturing Conference, San Diego, CA (November 2005).

“Biologics Contract Manufacturing: A Buyer’s Perspective,” workshop presented at DCAT Sourcing Primer for Chemical and Pharmaceutical Procurement Professionals, Newark, NJ (November 2005).

“The State of Biomanufacturing Capacity – Do We Finally Have Enough?” presented at IBC BioProcess International Conference, Boston, MA (September 2005).

“Ensuring Complete and Efficient Process Validation within a CMO-Sponsor Relationship,” presented at IBC Outsourcing, Contracting, and Partnering Conference, San Diego, CA (March 2005).

“Recent Advances in Cell Culture Technology: Improvements in Biopharmaceutical Production and Cost,” presented at International Knowledge Millennium Conference, Hyderabad, India (November 2004).

T.C. Ransohoff and H.L. Levine, “Assessing Strategic Options for Biologics Manufacturing,” presented at SRI World Antibody Summit, Philadelphia, PA (July 2004) and IBC Bioprocess International Conference, Boston, MA (October 2004).

“The Impact of the EU Clinical Trials Directive and Other Recent Regulatory Changes on the Manufacture of Biopharmaceuticals,” presented at Terrapinn bioLOGIC Europe 2004, Geneva, Switzerland (June 2004).

“Analysis of Biologics Manufacturing Capacity,” presented at Marcus Evans Manupharma Congress, Boston, MA (April 2004).

“Biopharmaceutical Manufacturing Strategy – To Make or Buy?” Guest lecture presented at MIT Sloan School, Cambridge, MA (November 2003).

“An Introduction to Biopharmaceutical Manufacturing,” presented at DCAT Continuing Education Class, Newark, NJ (November 2003).

T.C. Ransohoff, P. Latham, and H.L. Levine, “The Use of Economic Models to Support Biopharmaceutical Capital Decisions,” presented at Recovery for Biologics XI, Banff, Canada. (September 2003).

“The Capacity Crunch – Reality or Myth,” presented at IBC Conferences Production Economics and Manufacturing Strategies of Biologicals, Brussels, Belgium (June 2003).

“Identifying, Qualifying, and Selecting Outsourcing Partners,” presented at Barnett International Biomanufacturing Outsourcing Conference, Boston, MA (March 2003)

SELECTED PATENTS AND PUBLICATIONS

W. Kerns and H.L. Levine, Antiviral Proteins with Improved Properties and Methods Thereof. US Patent Application PCT/US04/033230, filed April 6, 2006.

T.C. Ransohoff and H.L. Levine “A Method for Forecasting Industry-wide Biopharmaceutical Manufacturing Capacity Requirements,” in Advances in Large Scale Biopharmaceutical

Manufacturing and Scale-Up Production, 2nd edition (E. Langer, Ed.), Institute for Science and Technology Management, Washington, DC (2008).

S.D. Jones, F.J. Castillo, and H.L. Levine “Advances in the Development of Therapeutic Monoclonal Antibodies,” *BioPharm International* 96 – 114 (September 2007).

R.E. Thompson, S.D. Jones, S.M. Magil, and H.L. Levine “Validation of Recovery and Purification Processes,” in *Validation of Pharmaceutical Processes*, 3rd edition (J. Agalloco and F.J. Carleton, Ed.) Informa Healthcare, New York, NY pp 455 – 472 (2007).

P.M Seymour, H.L. Levine, and S.D. Jones, “Successful CMO Selection: CMC Strategies for Outsourcing Biopharmaceutical Product Manufacturing,” Supplement to *BioProcess International* 26 – 29, (September 2006).

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

S.D. Jones and H.L. Levine, “Managing Biopharmaceutical Vendor Identification and Selection Through Use of a Request for Proposal,” *American Pharmaceutical Outsourcing*, 6, 18 - 24, (2005).

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

S.D. Jones and H. L. Levine, “Biotech Emerges in India: A Changing Business and Legal Environment Drives the Expansion,” *BioExecutive* 50 – 53, (May 2005).

S.D. Jones and H. L. Levine, “You Can Outsource Manufacturing but Not Responsibility Managing Biopharmaceutical Manufacturing Outsourcing,” *BioExecutive* 46 – 51, (March 2005).

T.C. Ransohoff, R.E. Mittendorf II, and H.L. Levine, “Forecasting Industry-wide Biopharmaceutical Manufacturing Capacity Requirements” in *Advances in Large Scale BioManufacturing and Scale-up Production* (E. Langer, Ed.), ASM Press, New York, New York and Institute for Science and Technology Management, Washington, DC, p 619 – 668 (2004).

S.D. Jones and H.L. Levine, “Impact of the EU Clinical Trials Directive and Other Recent Regulatory Changes on the Manufacture of Biopharmaceuticals,” *Preclinica*, 2, 1 – 4 (2004).

A.S. Rathone, P. Latham, H.L. Levine, J. Curling, and O. Kaltenbrunner, “Costing Issues in the Production of Biopharmaceuticals,” *BioPharm International*, 17, 46-55 (2004).

T.C. Ransohoff and H.L. Levine, “Capacity Requirements for Biopharmaceuticals – The Shortage That Never Was,” *Bioprocess News*, D&MD Publications, March (2003).

- R.E. Thompson and H.L. Levine, "Assessing the Benefits and Risks of Internal Manufacturing vs. Outsourcing Production of Biological Clinical Material," *American Pharmaceutical Outsourcing*, 1, 7-15 (2002).
- H.L. Levine and F.J. Castillo, "Validation of Biopharmaceutical Processes," in *Biotechnology: Quality Assurance and Validation* (K.E. Avis, C.M. Wagner, and V. Wu, Eds.), Interpharm Press, Buffalo Grove, Illinois, p. 51 (1998).
- Biotechnology Task Force, Parenteral Drug Association, (H.L. Levine, chairman). "Industry Perspective on the Validation of Column-Based Separation Processes for the Purification of Proteins," *J Parenteral Sci and Tech*, 46, 87 (1992).
- H.L. Levine, T.C. Ransohoff, R.T. Kawahata and W.C. McGregor, "The Use of Surface Tension Measurements in the Design of Antibody-Based Product Formulations," *J Parenteral Sci and Tech*, 45, 160 (1991). [Awarded PDA Paper of the Year, 1991]
- T.C. Ransohoff and H.L. Levine, "Large Scale Purification of Monoclonal Antibodies," in *Purification and Analysis of Recombinant Proteins* (R. Seetharam and S.K. Sharma, Ed.), Marcel Dekker, New York, p. 213 (1991).
- T.C. Ransohoff, M.K. Murphy and H.L. Levine, "Automation of Biopharmaceutical Purification Processes," *Biopharm Magazine*, 3, 20 (1990).
- H.L. Levine, "High Performance Adsorption Separations," in *Frontiers in Bioprocessing* (S. Sikdar, M. Bier and P. Todd, Eds.), CRC Press, Boca Raton, p. 303 (1990).
- E.N. Fish, K. Bannerjee, H.L. Levine, N. Stebbing, "Antitherpetic Effects of a Human Alpha Interferon Analog, IFN-alpha Con₁, in Hamsters," *Antimicrob Agents Chemother*, 30, 52 (1986).
- J.M. Davis, M.A. Narachi, H.L. Levine, N.K. Alton, and T. Arakawa, "Conformation and Stability of Two Recombinant Human Interferon-alpha Analogs," *Int J Peptide and Protein Res*, 29, 685 (1987).
- R.A. Hitzeman, D.W. Leung, L.J. Perry, W.J. Kohr, H.L. Levine, and D.V. Goeddel, "Secretion of Human Interferons by Yeast," *Science*, 219, 620 (1983).
- R.A. Hitzeman, D.W. Leung, L.J. Perry, W.J. Kohr, H.L. Levine, and D.V. Goeddel, "Secretion of Human Interferons by Yeast," in *Biotechnology and Biological Frontiers* (P.H. Abelson, Ed.), AAAS, New York, p. 21 (1984).
- R. Wetzel, H.L. Levine, J. Hagman and J. Ramachandran, "Human Leukocyte Interferon Has No Structural or Biological Relationship to Corticotropin," *Biochem Biophys Res Comm*, 104, 944 (1982).
- R.A. Hitzeman, D.W. Leung, L.J. Perry, W.J. Kohr, F.E. Hagie, C.Y. Chen, J.M. Lugovoy, A. Singh, H.L. Levine, R. Wetzel and D.V. Goeddel, "Expression, Processing, and Secretion of Heterologous Gene Products by Yeast," *Proceedings of the Berkeley Workshop on Recent Advances in Yeast Molecular Biology: Recombinant DNA*, University of California Press, Berkeley, p. 173 (1982).

- R. Wetzel, H.L. Levine, D.A. Estell, S. Shire, J. Finer-Moore, R. M. Stroud and T.A. Bewley, "Structure-Function Studies on Human Leukocyte Interferon," in *Interferons* (T. Merigan, R. Friedman, and C.F. Fox, Eds.), UCLA Symposium XXV on Molecular and Cellular Biology, Academic Press, New York, p. 365 (1982).
- T.A. Bewley, H.L. Levine and R. Wetzel, "Structural Features of Human Leukocyte Interferon A as Determined by Circular Dichroism Spectroscopy," *Int J Peptide and Protein Res*, 29, 93 (1982).
- R.A. Hitzeman, F.R. Hagie, H.L. Levine, D.V. Goeddel, G. Ammery, and G.D. Hall, "Expression of a Human Gene for Interferon in Yeast," *Nature*, 293, 717 (1981).
- R. Wetzel, L.J. Perry, D.A. Estell, N. Lin, H.L. Levine, B. Slinker, F. Fields, M.J. Ross and J. Shively, "Properties of a Human Alpha Interferon Purified from *E. coli* Extracts," *J Interferon Res*, 1, 318 (1981).
- H.L. Levine, R.S. Brody and F.H. Westheimer, "The Inhibition of Orotidine-5'-phosphate Decarboxylase by 1-(5'-phospho- β -D-ribofuranosyl) Barbituric Acid, 6-Azauridine-5'-phosphate, and Uridine-5'-phosphate," *Biochemistry*, 19, 4993 (1980).
- H.L. Levine and E.T. Kaiser, "Stereospecificity in the Oxidation of NADH by Flavopapain," *J Am Chem Soc*, 102, 343 (1980).
- E.T. Kaiser, H.L. Levine, T. Otsuki, H.E. Fried, and R. Dupreya, "Studies on the Mechanism of Action and Stereochemical Behavior of Semisynthetic Model Enzymes," *Adv Chem Ser*, 191, 35 (1980).
- H.L. Levine, Y. Nakagawa, and E.T. Kaiser, "Flavopapain: Synthesis and Properties of Semisynthetic Enzymes," *Biochem Biophys Res Comm*, 76, 64 (1977).