Abstract: CURRICULUM VITAE

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I joined Cook Pharmica as the Director of Scientific Affairs in May, 2006 and became the Vice President of Scientific Affairs and Chief Scientific Officer in February, 2008. Cook Pharmica LLC is a new company dedicated to cell culture contract manufacturing. I established a Process Development group of 26 scientists, (five PhDs, three MSs, eight BSs, ten AA or HS). The group executed or had in process six distinct process development and/or scale-up contracts.

As a Research Fellow for Eli Lilly and Co., Indianapolis, IN, I was the senior scientific leader for manufacturing support of six major biotechnology products in the marketplace, Xigris®, Humulin®, Humalog®, Humatrope®, Forteo® and Recombinant Human Glucagon with sales approaching $3.5 billion per annum.

27 plus years of experience in the development and manufacture of recombinant proteins have provided many opportunities. As a leading member of the teams for the scale-up and manufacturing support of the initial Human Insulin production using the chain route (Humulin®), Human Insulin using the proinsulin process (Humulin®), Human Growth Hormone (Humatrope®), Recombinant Human Parathyroid Hormone (1-34) (Forteo®), Factor IX and several monoclonal antibodies and conjugates I have extensive experience in process design, development, scale-up, and manufacturing, including the quality aspects and CMC requirements of these activities. Additionally, responsibilities in project management for the development of several protein products, management of a protein process development group and management of several manufacturing technical support groups have provided breadth to my technical depth.

Nine years experience developing lecture materials and lecturing at professional training seminars offered by the ASME BioProcess Technology Seminar Series and the Society for Bioprocessing Professionals BioProcess Institute (including participating in an in-house training session for Amgen, Rhode Island) have provided extensive experience in training members of the biotech community. I am a founding member and Vice President of the Board of Directors of the Society for Bioprocessing Professionals(SBP).

My post-doctoral training was at the Harvard Medical School, Department of Physiology after receiving a Ph.D. degree from the University of Minnesota, Department of Biochemistry in 1978. My BA in Chemistry was earned from St.Olaf College, Northfield, Minnesota in 1973.

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Education:	Degree:	Year:	Field/Specialty:
University of Minnesota Minneapolis, Minn.	Ph.D.	1978	Biochemistry
St. Olaf College Northfield, Minn.	BA.	1973	Chemistry

Citizenship: USA

Memberships:

- ISPE, 2006-07
- ISPE Biotech COP (transition team member for SBP incorporation into ISPE), 2006
- Vice-President and Institute Director, Society of Bioprocessing Professionals, 2001-2007

Teaching and Training Experience:

- ASME BioProcess Technology Seminars, Instructor/Lecturer/Course Director: "BioProcess Scale-up," 1996, 1997, 1998, 1999, 2000, 2001, 2002.
- Society of BioProcessing Professionals, Instructor/Lecturer/Course Director: "Purification Scale-up for Bioprocess Systems," 2003.
- Society of BioProcessing Professionals, Instructor/Lecturer/Course Director/Institute Director: "BioProcess Development and Scale-up for Downstream Purification," 2004, 2005, 2006, 2007.

Research and Professional Experience:

2006 - 6/2008 Director of Scientific Affairs, Cook Pharmica LLC
Vice President of Scientific Affairs and CSO, Cook Pharmica LLC
Responsibilities: Participate in Leadership Team for company, lead a process development group consisting of cell culture development, downstream purification development and analytical development and represent the company in technical discussions with potential clients. Assisted in the technical aspects of at least 20 responses to RFPs. The Development group consists of 5 PhDs, 1 senior BS level (30 yrs experience), 3 MS level associates, 8 BS level associates, and 10 AA or high school level associates.

2001 - 2006 Research Fellow, Large Molecule Network, Manufacturing Science and Technology, Eli Lilly & Co.
Responsibilities: Oversee the re-development of a new human insulin manufacturing process and the technical aspects of a new rhPTH(1-34) manufacturing campaign, of hGH operations in the UK, of human insulin and of lispro human insulin operations. This includes a direct group of 3 PhD's, 7 associates, 2 engineers and 4 technical assistants and an extended group of approximately 120 PhDs and associates.

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Frederick S. Larimore, PhD

1997 - 2001 Sr. Research Scientist, Biosynthetic Technical Services, Eli Lilly & Co.
Responsibilities: Oversee the technical aspects of Recombinant Human Parathyroid Hormone(1-34) (rhPTH(1-34)) process development, technical transfer to manufacturing and manufacturing. This includes regulatory submission preparation, responses to regulatory agencies, hosting pre-approval inspections, process and cleaning validation protocol preparation and execution and completing all the development and manufacturing activities associated with providing launch materials.

1993 - 1997 Sr. Research Scientist, Biosynthetic Technical Services, Eli Lilly & Co.
Responsibilities: Oversee the technical aspects of biosynthetic human insulin manufacturing and transfer a new peptide hormone from development to manufacturing. This includes technical direction, but not administration, of upto 21 associates and technicians.

1992 - 1993 Director, Biopharmaceutical Development, Eli Lilly & Co.
Responsibilities: Form a group of 85 scientists, associates and technicians from the Parental Products Research and Development Group and the Bioanalytical Development Group. (This included hiring 30 new employees.) The assignment for the division is to form a team-based group for the development of protein and macromolecular new products and for the technical support of existing proteins. An additional assignment was to remain as the Project Manager for the Humulin Cartridges Project. Duration: 6 months.

1992 Director, Parenteral Products Research and Development, Eli Lilly & Co.
Responsibilities: Manage a group of 35 Pharmaceutical Scientists, associates and technicians. The primary function of the group was the development of new parenteral products. An additional assignment was to remain as the Project Manager for the Humulin Cartridges Project. Duration: 6 months.

1991 - 1992 Manager, Development Projects Management, Eli Lilly & Co.
Responsibilities: Manage 3 protein development projects. This included coordinating the activities of manufacturing, process development, parenteral product development, regulatory and analytical development to ensure appropriate timelines were constructed and adhered to during the development process. In addition, it required interfacing with strategic facilities planning and the manufacturing sites to ensure facilities were available for the production of the products upon regulatory approval. Duration: 15 months.

1989 - 1990 Director, Diagnostics Manufacturing Technical Support, Hybritech, Inc. (a wholly owned subsidiary of Eli Lilly & Co.)

Responsibilities: Manage a group of 35 scientists, associates and technicians. The group was responsible for the technical support of diagnostics manufacturing. The activities of the group included development activities to support continuous improvement, problem solving and trouble-shooting in manufacturing. Duration: 17 months.

1987 - 1989 Manager, Diagnostics Process Development, Hybritech, Inc. (a wholly owned subsidiary of Eli Lilly & Co.)
Responsibilities: Manage a group of 20 scientists, associates and technicians. The group was responsible for the characterization and improvement in the processes used in the manufacture of diagnostic products. Duration: 29 months.

1987 Research Scientist, Manufacturing Technical Consultant, Hybritech, Inc. (a wholly owned subsidiary of Eli Lilly & Co.)
Responsibilities: Originally specified as a temporary assignment of 3-6 months, the assignment was to evaluate and provide technical direction for monoclonal antibody manufacturing at the newly acquired subsidiary of Hybritech, Inc. Duration: 3 months.

1982 - 1986 Senior Scientist, Team Leader, Biosynthetic Human Insulin Technical Services, Eli Lilly and Company.
Responsibilities: Provide technical leadership for a team of associates and technicians. The group grew from 9 in 1982 to 18 in 1985. Initially the responsibilities were for the front end of the manufacturing process, from killed broth to materials prepared for insulin formation. The last 18 months of the assignment included all aspects of the manufacturing process. In addition to the manufacturing support activities the group was responsible for the support of the pilot plant and the development scientists working in the pilot plant and for the technical support of the engineers designing and constructing major manufacturing plant renovations. Duration: 51 months.

1981 - 1982 Senior Scientist, Biosynthetic Human Insulin Development, Eli Lilly and Company.
Responsibilities: Develop a new process for the production of human insulin. Duration: 16 months.

1979 - 1981 Research Fellow, Department of Physiology, Harvard Medical School.
Mentor: Dr. Alfred L. Goldberg. Isolation and Characterization of the ATP-Dependent Protease in *E. coli.*

1978 Research Specialist, Department of Biochemistry, University of Minnesota.
Mentor: Dr. Robert J. Roon. Isolation of Transport Proteins in *Saccharomyces cerevisiae.*

Presentations:

Larimore, F. S., Keynote Address “Upstream and Downstream Processing, A Question of Balance,” Millipore BioForum 2008, Tokyo, Japan, 9/08.

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Frederick S. Larimore, PhD

Larimore, F. S., "Development, Scale-up, and Technical Transfer of Purification Processes," Wyeth Internal Vaccine Development Technical Forum, Durham, NC, 5/08.
Larimore, F. S., "Utilizing Quality by Design and Design Space for Continuous Improvement." Interphex, Philadelphia, PA, 3/08.
Larimore, F. S., IBC Panel Discussion on the Future of Chromatography, IBC, BioPharm Conference, Boston, MA, 11/07.
Larimore, F. S., "The Future of Process Development," Interphex, New York, NY, 3/07.
Larimore, F. S., "The Future of Process Development," ISPE Midwest Chapter Meeting, Indianapolis, IN, 9/06.
Larimore, F. S., "BioProcess Development Issues" and "BioProcess Development Case Study," ISPE 'Closing the Knowledge Gaps: Process Development Symposium,' Arlington, VA, 6/06.
Larimore, F. S., "BioProcess Development Issues" and "BioProcess Development Case Study," ISPE 'Closing the Knowledge Gaps: Process Development Symposium,' Arlington, VA, 6/05.
Larimore, F. S., Weisman, D., Siwak, M., Brunkow, R., "BioProcess Development and Scale-up of Downstream Puritifcation," SBP Institute, San Francisco, CA, 5/05.
Larimore, F. S., Weisman, D., Siwak, M., Brunkow, R., "BioProcess Development and Scale-up of Downstream Puritifcation," SBP Institute, Cambridge, MA, 9/04.
Larimore, F. S., "Basics of Biotechnology," FDA Investigator Training, Invited Speaker, Rockville, MD, 2/04.
Larimore, F. S., "Validation Expectations for Chromatography Resins and Columns," IBC "Validation for the Production of Biologicals" Conference, Munich, Germany, 12/03.
Larimore, F. S., "Chromatography Media and Process Control," Society of Bioprocessing Professionals (SBP) In-house Chromatography Training Program, Amgen, Inc., Providence, RI, 11/03.
Larimore, F. S., "Enhancing Manufacturing Capacity and Productivity," IBC's International Antibody Production & Downstream Processing and Multisource Biologics, Invited Speaker, Basel, Switzerland, 10/03.
Larimore, F. S., Brunkow, R., Hilgert, M., Kahn, D., Raghunath, B., "Purification Scale-up for Bioprocessing Systems," SBP Institute, Washington, D.C., 8/03.
Larimore, F. S., "Insulin Comparability," PDA Comparability Conference, Invited Speaker, 2/03.
Hilgert, M. D., Larimore, F. S., Xie, Y., Mun, S., Wang, N.-H. L., "Continuous Size Exclusion Chromatography for Separation of Insulin from a Multicomponent Mixture," AIChE Meeting, 11/02.
Larimore, F. S., "FDA Expectations about Column Lifetimes and Resin Reuse," IBC's Well Characterized Biologics Conference, Invited Speaker, 10/02.
Larimore, F. S., "Insulin Comparability," ICH Q5E: Establishing the Comparability of Biotechnology/Biologic Products, Invited Speaker, 9/02.
Larimore, F. S., Brunkow, R., Hilgert, M., Siwak, M., "BioProcess Scale-up," ASME BioProcess Technology Seminars, Instructor/Lecturer, 10/02.
Larimore, F. S., Brunkow, R., Hilgert, M., Siwak, M., "BioProcess Scale-up," ASME BioProcess Technology Seminars, Instructor/Lecturer, 10/01.
Larimore, F. S., Brunkow, R., Hilgert, M., Siwak, M., "BioProcess Scale-up," ASME BioProcess Technology Seminars, Instructor/Lecturer, 11/00.
Larimore, F. S., Brunkow, R., Hilgert, M., Siwak, M., "BioProcess Scale-up," ASME BioProcess Technology Seminars, Instructor/Lecturer, 10/99.
Larimore, F. S., Miner, D., Bird, T., "Comparability Protocols Applied to Insulin Changes," IBC "Strategic Use of Comparability Studies and Assays for Well-Characterized Biologicals" Conference, Invited Speaker, 6/99.
Larimore, F. S., Miner, D., Bird, T., "Comparability Protocols Applied to Insulin Changes," PhRMA Regulatory SubCommittee Meeting, Invited Speaker, 4/99.
Larimore, F. S., "PTH: The Process That Could, But Didn't", Biosynthetic R&D Seminar Series, Invited Speaker, 1999.
Larimore, F. S., Maloney, A., Busse, S., McDonough, J., Rajagopalan, N., "PreNDA Review of rhPTH(1-34) CMC section of NDA," Presentation to FDA, 12/98.

Larimore, F. S., “Comparability Protocols Applied to Insulin Changes,” PhRMA Regulatory SubCommittee Meeting, Invited Speaker, 11/98.
Larimore, F. S., Brunkow, R., Hilgert, M., Siwak, M., "BioProcess Scale-up,” ASME BioProcess Technology Seminars, Instructor/Lecturer, 10/98.
Larimore, F. S., Bird, T., Miner, D., Frank, B., "Comparability Protocol for BHI Manufacturing,” Presentation to FDA, 6/98.
Larimore, F. S., “Process Monitoring,” California Separation Science Society, Invited Speaker and Session Leader, 1/98.
Larimore, F. S., Brunkow, R. “Adopting Strategies for Efficiently maximizing Commercial Production of a Bulk BioProduct,” IIR Conference “Developing Strategies for Fast and Efficient Technology Transfer in the Pharmaceutical and Biotech Industry”, Invited Speaker, 1/98.
Larimore, F. S., “BHI Capacity”, Biosynthetic R&D Seminar Series, Invited Speaker, 1998.
Larimore, F. S., Brunkow, R., Hilgert, M., Siwak, M., "BioProcess Scale-up,” ASME BioProcess Technology Seminars, Instructor/Lecturer, 9/97.
Larimore, F. S., Brunkow, R., Hilgert, M., Siwak, M., "BioProcess Scale-up,” ASME BioProcess Technology Seminars, Instructor/Lecturer, 10/96.
Larimore, F. S., “BHI Production”, Biosynthetic R&D Seminar Series, Invited Speaker, 1996.
Larimore, F. S., Lloyd, Y., Maloney, A., Davis, G., Frank, B., "Recycles and Reworks in BHI Manufacturing Process,” Presentation to FDA, 12/94.

Abstracts/Posters:

Anderson, B., Allen, G., DeVoe, P., Sundboom, J., Mangold, M., Maskalick, D., Shrewsbury, D., Larimore, F. S., “Utlizing Statistical Design of Experiment for Column Chromaotgraphy,” Lilly EXPO, 1999.
Mangold, M., Henry, J., DeVoe, P., Anderson, B., Larimore, F. S., “Characterization of PTH Fusion Reference Standard for One Milliliter Micro-transformations,” Lilly EXPO, 1999.
Sundboom, J., Larimore, F. S., Brunkow, R., Kahn, D., DeVoe, P., Anderson, B., Mangold, M., “Moisture Adjustment of Bulk rhPTH(1-34) Powder,” Lilly EXPO, 1999.

Regulatory Reports and Technical Reports:

Larimore, F. S., “Manufacturing History Report: Human Insulin,” 2006.
Larimore, F. S., “Biosynthetic Human Insulin; Proinsulin Derived CMC API Process Description,” 2005. (Updated the CMC API Manufacturing Section of the NDA.)
Larimore, F. S., “Discussion of Critical Process Parameters,” 2004.
Larimore, F. S., “Membrane and Filter Lifetime Strategy,” 2004.
Larimore, F. S., “Chromatography Resin and Column Lifetime Strategy,” 2003.
Larimore, F. S., Response to CPMP Questions, United States Questions, European Union Questions, Australian Questions, Swiss Questions, Canadian Questions for Forteo Submission, 2001-2002.
Larimore, F. S., “rhPTH(1-34) Active Pharmaceutical Ingredient Process Validation Summary Report,” 2001.
Larimore, F. S., “rhPTH(1-34) Active Pharmaceutical Ingredient Development History Report Summary,” 2001.
Larimore, F. S., “rhPTH(1-34) Active Pharmaceutical Ingredient Process Development History Report,” 2001.
Larimore, F. S., “Active Pharmaceutical Ingredient Manufacturing CMC section for rhPTH(1-34) NDA,” 2000.
Larimore, F. S., Miner, D., Bird, G., Frank, B., “Draft Comparability Protocol for BHI,” submitted to the FDA, 6/98.
Larimore, F. S., ”Blend 10- Pre-Approval Supplement to BHI NDA”, submitted to FDA, 1996.
Larimore, F. S., White, R., Kaiser, R., “NorValine Report,” prepared for the BHI Annual Report, 1995.
Larimore, F. S., “Forward Processing Criteria and Recycles- Changes Being Effected Supplement to BHI NDA,” submitted to FDA, 1995.

Kelly, G., Larimore, F. S., "Converting Beef Iletin DMF to NDA- Pre-Approval Supplement for Beef Iletin," submitted to FDA, 1995.

Annual Reports to FDA:

BHI: 1994, 1995, 1996, 1997
a-Glucagon: 1995, 1996, 1997