Strategic Manufacturing Worldwide, Inc.

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Scott M. Wheelwright, Ph.D.
Statement of Qualifications

Vaccine Technology

Dr. Wheelwright has considerable experience in the field of vaccine development and manufacturing. His 22 years of experience in the development and production of biological products includes product development for sub-unit vaccines, process development and manufacturing of recombinant antigenic proteins, and process development and manufacture of various viruses. While at Abbott Laboratories, Dr. Wheelwright participated in the development of one of the first large scale operations for the production of HIV; while at Chiron Corporation, Dr. Wheelwright participated in the development and manufacture of Herpes and HIV sub-unit vaccines; while at Calydon Corporation, Dr. Wheelwright designed, built and operated a facility for production of genetically modified adenovirus.

Animal Facility Design and Construction

Dr. Wheelwright has participated in the design, construction and operation of animal facilities. While at Calydon Corporation, Dr. Wheelwright led the design and installation of a facility for animal studies. While at Scios Inc., Dr. Wheelwright managed the upgrade and operation of an AAALAC accredited animal facility that housed multiple species of rodents and rabbits.

Additional Experience

International

2005 Supported technology transfer of biopharmaceutical production process for Japanese client from US company to Contract Manufacturing Organization (CMO) in Japan. Responsible for US contacts and for compliance review of Japanese CMO.

2005 Conducted compliance audit of vaccine manufacturer in India in preparation for license applications and planned sales to World Health Organization.

2005 Conducted compliance audit of Japanese pharmaceutical manufacturer as part of due diligence process for potential license by US firm.

1998-2002 Led business development activity in Japan seeking partners for cancer products and sustained release contract development projects.

1994-1998 Led technology transfer team for outsourcing of recombinant peptide to European CMO for cardiovascular product now in commercial production.

1992-1998 Led product development team that filed license application in Japan for wound healing product. Led development program with Japanese partner.

1983 Post-doctoral research in Germany.

1973-1975 Resident in Japan. Developed Japanese language speaking and reading ability.

Outsourcing and Technology Transfer

2005 Assisted client company with process development and manufacture of product proteins at contract firms.

2005 Assisted client in identifying contract development firm for novel protein.

2005 Assisted client in obtaining protein from plasma source.

1996-1998 Led team transferring production technology for recombinant protein to Japanese partner.

1996-1997 Led technology transfer team for in-sourcing of recombinant protein to company pilot plant as a means to defray overhead.

1994-1998 Led technology transfer team for outsourcing of recombinant peptide to European CMO for cardiovascular product now in commercial production.

1987-1992 Transferred 21 new processes from multiple research and development groups into fermentation and purification manufacturing operations; reduced technology transfer time (measured from the receipt of research protocol to the submission of regulatory package) from two years to six months.

Auditing, Compliance and Training

2005 Conducted compliance audit of vaccine manufacturer in India in preparation for license applications and planned sales to World Health Organization.

2005 Conducted compliance audit of Japanese pharmaceutical manufacturer on behalf of US firm as part of due diligence process for potential license.

2005 Conducted compliance audit of Japanese contract manufacturer on behalf of Japanese firm.

2005 Conducted compliance audit of US contract manufacturer on behalf of US firm.

2005 Conducted GMP training for employees of vaccine manufacturing plant in India.

Construction

2000-2002 Led construction of 8000 square foot (800 square meter) cGMP aseptic manufacturing plant for commercial production (licensed by State of California).

1998-2000 Constructed cGMP cell culture and purification facility for manufacture of virus products (licensed by State of California).

1994-1996 Led design and construction of 30,000 square foot laboratory for research and development.

1992-1998 Refurbished 7000 square foot cGMP fermentation and purification facility for manufacture of recombinant products (licensed by State of California).

Manufacturing and Development

2002-2004 Built operations group of PhDs, engineers and technicians from 20 to over 50 (approximately one half of company total) in the areas of molecular biology, cell culture, production, process development, quality control and facilities; manufactured and supplied to clinical trials over 100 individual patient-specific therapies.

2000-2003 Established manufacturing and QC groups in support of pharmaceutical products, including materials handling, product assembly, aseptic filling, raw materials testing and product testing.

1998-2000 Optimized cell culture process for production of active virus, scaled up process and implemented the process in manufacturing, transferred four products from research into manufacturing, hired and trained development and manufacturing staff (approximately one-third of company).

1992-1998 Developed production process for recombinant peptide for congestive heart failure, transferred process to Europe and scaled up process to 3000L batch size for manufacturing (product is now in commercial production); led interdisciplinary project team for development of wound healing protein product, including preparation of the CMC section for filing of NDA for this product in Japan in 1996 (this NDA was approved and the product is now marketed in Japan).

1991 Published monograph on protein purification.

1987-1992 Produced four licensed products in full cGMP compliance and with consistent high quality (as documented by annual audits from FDA CBER); scaled up or developed de novo 9 purification processes for recombinant proteins, including the first commercial Hepatitis C antigens and a Herpes Simplex Virus vaccine.

1984-1987 Designed and installed a process to harvest HTLV-III (HIV) virus from cell culture as a member of the team that brought the first commercial AIDS test to market; developed in vitro cell culture method for monoclonal antibody production, including novel tissue culture systems, cell metabolism studies, assay optimization and stability studies; scaled up the purification of multiple monoclonal antibody products and developed fermentation methods for recombinant bacteria.

Strategic Planning

2005 Preparing strategic plan for development and manufacturing of therapeutic proteins.

2004 Prepared strategic plan for development and manufacture of patient specific therapy for non-Hodgkins lymphoma.

2001 Prepared strategic plan for manufacture of drug delivery implant.

2000 Prepared strategic plan for development and manufacturing of therapeutic viruses.

Corporate Leadership

2004-2005 Founding CEO of consulting firm with focus on biotechnology manufacturing and bringing products to market.

2002-2004 Vice President of operations for biotechnology startup that successfully completed IPO.

2000-2002 Vice President of operations for pharmaceutical drug delivery startup that successfully completed IPO.

1998-2000 Vice President of operations and quality for biotechnology startup that was purchased by mid-sized biotechnology company.

Products and Indications

Cancers: Lymphoma, leukemia, prostrate, liver, breast
Vaccines and Viruses: HIV, Herpes, Hepatitis A, B and C, adenovirus
Other Indications: Congestive heart failure, dermatological ulcers, drug delivery, chronic pain, multiple sclerosis
Devices: Diagnostics, implantable pump

Education

1983 Post-Doctoral Research, Max Planck Institute for Biophysics, Frankfurt, Germany, under the direction of Dr. Wolfgang Pusch.

1982 Ph.D. Chemical Engineering, University of California, Berkeley, California, under the direction of Dr. Theodore Vermeulen.

1978 B.S. Chemical Engineering, University of Utah, Salt Lake City, under the direction of A. Lamont Tyler.

Publications

Wheelwright, S.M., and J.A. Asenjo, "Economic analysis of downstream processes," in Handbook of Downstream Processing, K.H. Kroner and N. Papamichael (eds.), John Wiley & Sons, New York (in press).

Wheelwright, S.M., and J.A. Asenjo, "Strategies for process design," in Handbook of Downstream Processing, K.H. Kroner and N. Papamichael (eds.), John Wiley & Sons, New York (in press).

Wheelwright, S.M. and H. Kosaku, "Changes to the Japanese Pharmaceutical Affairs Law," BioProcess International, 3(1):14-16 (2005).

Baker, S. and S.M. Wheelwright, "Financially Based Modeling of Recovery Process Alternatives," BioProcess International, 2(5) (2004).

Wheelwright, S.M. and S. Yamamoto, "Protein Purification: Process Design," Kagaku Kogaku 65(9):498-499 (2001). In Japanese.

Wheelwright, S.M., "Economic and cost factors of bioprocess engineering," in Processing and Preservation of Biotechnological Products, K.E. Avis and V. Wu (eds.), Interpharm Press, Buffalo Grove, Illinois (1996).

Wheelwright, S.M., "Commercializing Biotech Products," Bio/Technology 12:877-880 (1994).

Wheelwright, S.M., Protein Purification: Design and Scale up of Downstream Processes, 228 pp, John Wiley & Sons, New York (1991). (Now in third printing.)

Wheelwright, S.M., "The design of downstream processes for largescale protein purification," Journal of Biotechnology 11:89-102 (1989).

Burke, R.L., G. Van Nest, N.B. Gervase, C. Goldbeck, D. Dina, P. Brown, S. Wheelwright, and G. Ott, "Development of an HSV subunit vaccine: effect of adjuvant composition and antigen dose", in Vaccines for Sexually Transmitted Diseases, Butterworth Scientific, Ltd., Guildford, UK (1989).

Wheelwright, S.M., "The impact of downstream recovery operations on upstream production methods: vertical integration and process optimization," in Biotechnology Research and Applications, J. Gavora et al. (eds.), Elsevier Applied Science, London (1988).

Wheelwright, S.M., "Designing downstream processes for largescale protein purification," Bio/Technology 5:789-793 (1987).

Wheelwright, S.M., J.M. Vislocky, and T. Vermeulen, "Adiabatic adsorption with condensation: prediction of column breakthrough behavior using the BET model," in Fundamentals of Adsorption, A.L. Meyers and G. Belfort (eds.), Engineering Foundation, New York (1984).

Wheelwright, S.M., "Multivariant ion exchange: applications of weak-electrolyte resins," Ph.D. dissertation, University of California, Berkeley (1982).

Wheelwright, S.M., "Solubilization of Utah Oil Shale Kerogen," B.S. thesis, University of Utah, Salt Lake City (1978).