DNA BRIDGES, INC.

BIOPROCESS AND MANUFACTURING AT A GLANCE

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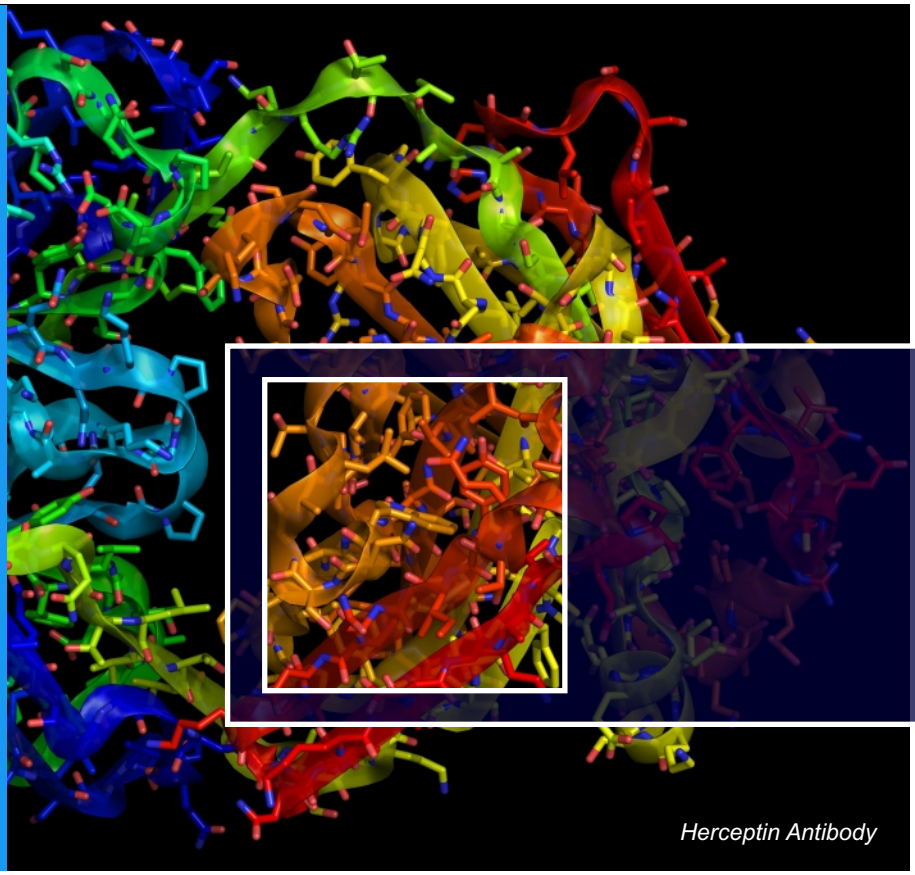

Herceptin Antibody

Seasoned Scientific and Business Talent

DNA Bridges, Inc. is a leading corporate development firm that leverages seasoned scientific and business talent in the life sciences, device and pharmaceutical industries to *bridge science and products*.

FROM DISCOVERY TO LAUNCH

Our team has developed and supported the commercialization of products with combined sales over $10 billion USD. These include Herceptin, Xolair, Activase, Raptiva and Kogenate.

We Understand Today's Complex Markets

We understand how to succeed in today's dynamic Life Science Industry, with its complex markets and regulatory environment.

Services

- ❑ Bioprocess troubleshooting and process development guidance
- ❑ Technology, facilities and equipment evaluation
- ❑ Due diligence for development programs
- ❑ Due diligence for process and manufacturing related IP
- ❑ Contract vendor arrangements and management
- ❑ Management of process/technology transfer and its implementation
- ❑ Project management: CMC and Drug Development
- ❑ CMC regulatory submission preparation and review
- ❑ Corporate and technology positioning

Expertise

- ❑ Process development utilizing mammalian, E. coli and yeast hosts
- ❑ Manufacturing strategies
- ❑ Expression technologies and cell line development strategies
- ❑ Downstream process development
- ❑ Biopharmaceuticals manufacturing, pre IND through commercial
- ❑ Facilities layout, design and evaluation
- ❑ Broad range of experience with biologics development, including monoclonal antibodies, growth factors, cytokines and the clotting cascade

Bioprocess and Manufacturing Client Profiles

- Biotechnology companies
- Pharmaceutical companies
- Early stage biotechnology companies
- Multi-national companies
- Biosimilar companies
- Law firms
- Venture capitalists

DNA BRIDGES®, INC.

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International Pharma: First Entry Into Biologics

Challenge: An international pharmaceutical company with interest in biologics development contracted DNA Bridges, Inc., along with other outside consultants, to assist their company in evaluating competitive strengths and gaps in their biologics development infrastructure. Personnel expertise, worldwide manufacturing facilities, vendors and contractors, and technical know-how were key areas to be evaluated. DNA Bridges' expertise in biologics development and manufacturing, as well as intellectual property, were employed in the assessment.

Our Approach: The DNA Bridges team provided specific recommendations to strengthen and solidify the client's ability to develop and manufacture New Biologic Entities (NBEs).

Actions:

- Evaluated present facilities, personnel, hardware, technical readiness and vendor utilization on a worldwide basis
- Established development and production estimates for a 20-year window considering anticipated technological advances for the industry
- Reviewed the client company's competitiveness with respect to process development and intellectual property
- Provided a report detailing biologic development and manufacturing gaps within the organization
- Made specific recommendations for internal resource and asset allocation and where outside contractors could be used

Results: The client company established an implementation plan for strategic biologic development and manufacturing and began reorganization of facilities, sites and personnel.

This plan included:

- Significant capital investment for development and manufacturing facilities
- Strategies for optimal site and personnel use
- Development of strategic and technical awareness within the client organization with respect to biologics development

Getting the IND Back on Track

Challenge: A private biopharmaceutical company faced both process and manufacturing issues during the development of its lead product, resulting in the delay of their IND submission. The company needed help troubleshooting aggregation issues, undesirable heterogeneity during processing and instability after product formulation. They also required assistance interacting with the vendor contracted to manufacture the product.

Our Approach: DNA Bridges, Inc. was engaged to evaluate the process and manufacturing plans, then troubleshoot pre-IND development process issues and recommend corrective actions to the contract vendor.

- Evaluated development data and procedures to determine likely causes of process issues and recommend corrective actions
- Interacted with the manufacturing vendor to plan, test, evaluate and implement solutions
- Recommend new assays to monitor and troubleshoot product homogeneity, consistency and stability
- Developed timeline and budget recommendations that minimized time and funds needed to get the IND back on track

Results: Troubleshooting was successful. A process was established for manufacturing scale-up evaluation which was consistent with the company's IND plan and timeline objectives.

- Product heterogeneity, product aggregation and near term stability were significantly improved and controlled
- Product yield requirements and specifications for release were met at the test scale
- The improved manufacturing process was ready for scale up testing for the IND

DNA BRIDGES® INC.

Cori Gorman, PhD, MBA | Cori@dnabridges.com
Antibody Therapeutics, Cell Line Development, Protein Expression

L. Gene Burton, PhD | L.Gene@dnabridges.com
Chemistry, Process Development,
Manufacturing & Control for Protein Biologics

Dave Vetterlein, PhD | Dave@dnabridges.com
CMO Arrangements, Process Development, GMP Manufacturing

THE COMPANY WE KEEP...

Cori Gorman, PhD, MBA | Vector Production, Cell Line Development and Protein Expression

With over twenty-five years experience in biotechnology, Dr. Gorman has worked in all aspects of the industry, from strategic planning to developing infrastructure. She has helped early stage companies raise over $100 million USD in both private and government funds and has closed over 35 partnerships. The sales of marketed therapeutics developed in part by Dr. Gorman exceeds $2 billion USD. Her experience in the biotechnology industry includes a ten-year period as a scientist at Genentech where she is recognized as a pioneer in the development of monoclonal antibody therapeutics and has co-authored several INDs. Dr. Gorman helped develop of a number of marketed products including Herception, Kogenate, Activase, Xolair, and Raptiva. Following her tenure at Genentech, she co-founded two biotech start-ups including Valentis, which launched a successful IPO. Dr. Gorman is currently on the Scientific Advisory Board for Takeda San Francisco and the Dean's Leadership Council at Washington State University. Under her direction, DNA Bridges, Inc. has expanded its reach beyond the U.S. into Europe, Australia and South America.

Dr. Gorman has an outstanding record of achievement in basic research and drug development. She is an inventor on nine issued patents in the fields of gene expression and delivery and gene therapy. Dr. Gorman developed the CAT assay, which was the industry standard for more than twenty years. With over 10,000 citations, she is recognized as one of the most highly cited people in her field in the past two decades. She has used her knowledge to chair a number of sessions on business models and financing for early stage companies at the BIO and BIO-Europe conferences and she has been a guest lecturer for the 'business of biotechnology' course at Yale and Haas Business School, UC Berkeley. Dr. Gorman has received several fellowships from such organizations as the American Cancer Society, the National Cancer Institute, the European Molecular Biology Organization and NATO.

Gene Burton, PhD | Chemistry, Process Development, Manufacturing & Control for Protein Biologics

Gene Burton, Ph.D., has more than 22 years of biotechnology industry experience, working in various roles in biotechnology company management, including recombinant drug process and product development and as well as a seasoned protein chemist. Most recently, he was VP of Product Development and Process Sciences at Receptor BioLogix, Inc., a startup company in the oncology space working in the HER family system of receptors. Prior to the role at Receptor BioLogix, he spent over 17 years at Genentech, Inc. and 5 years at Bayer Corporation, primarily focused on recombinant protein purification, process design and manufacturing implementation at scale, for pre-IND, IND and BLA drug candidates. He also helped direct the purification design and small-scale production of over 50 different research proteins as well as contributing to the development of two different drug screening programs. He was instrumental in the development program of a drug candidate from its inception to completion of Phase III, acting as either project team leader, CMC team leader or its process development manager, over the course of the project's history.

In addition to his industry experience, Dr. Burton served as an assistant professor and adjunct assistant professor at The Rockefeller University. He completed 2 postdoctoral studies: one with Dr. Stanford Moore at The Rockfeller University, working on ribonuclease inhibitors, and a second with Dr. Eric Shooter at Stanford University working on nerve growth factor. Dr. Burton is a member of the ASBMB, Society for Neuroscience and the AAAS, with more than 50 peer-reviewed publications and 5 patent applications or issues. He has a B.S. in Chemistry from Montana State University and a Ph.D. in Biochemistry from Michigan State University.

Dave Vetterlein, PhD | CMO Arrangements, Process Development, GMP Manufacturing

David Vetterlein, PhD, brings over 25 years of biotechnology experience in the areas of bioprocessing and protein manufacturing. Most recently, Dr. Vetterlein worked in numerous capacities at ICOS Corporation. At ICOS, he built a clinical manufacturing facility and developed the infrastructure needed to support a pipeline of biologic products at a production scale of up to 3,000L. This included hiring and staff management for process engineering, project management, upstream and downstream process development and cGMP manufacturing through Phase III development in preparation for commercial launch. Additionally, Dr. Vetterlein established a very successful contract manufacturing business at ICOS, completing more than 25 different projects from yeast, CHO and E.coli origin and developing many novel biologic manufacturing processes and characterization methods. In 2007, the ICOS biologics division was sold to CMC Biopharma of Copenhagen and Dr. Vetterlein became Chief Science Officer, focusing on process troubleshooting, originating new process technologies, and establishing the conceptual design for a large-scale commercial manufacturing facility.

Prior to ICOS, Dr. Vetterlein worked at Genentech for 10 years as a Senior Scientist where he developed processes for manufacturing of vaccines, antibodies and other proteins. He is a member of the Amgen Bioprocess Advisory Board at Keck Graduate Institute of Applied Life Sciences in Claremont, CA and in 2009 he became an adjunct faculty member. Dr. Vetterlein earned in PhD in Biology (Biochemistry) from the University of California at Santa Barbara, where he utilized biophysical methods to study the kinetic and allosteric properties of a cytoplasmic enzyme.

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