EXHIBIT 1

MICHAEL W. GLACKEN, Sc.D.

Senior Consultant

+1.325.864.0698 (m)
mglacken@bdo.com

Profile

A biochemical engineer with over 27 years of experience in bioprocess manufacturing and strategic CMC development of biopharmaceutical products. Experienced in cell culture process development, rapid supply of proteins for discovery, and CMC regulatory strategy for recombinant proteins and monoclonal antibody products. Participated in the development of over 20 biological products, including the commercialization of two of these products.

Experience

BioProcess Technology Consultants, Inc./BDO 2014-Present
Senior Consultant

Author & reviewer for CMC sections of several client BLAs

Assisted several clients in developing process characterization and process validation strategies;

Author & reviewer of PVMP, PC & PPQ protocols and PC & PPQ reports for several clients. Assisted in scale-down model design, PC DOE design and data review.

Person-in-plant for several late stage and commercial manufacturing campaigns, including an ADC.

Joule Unlimited Technologies, Bedford MA & Hobbs, NM 2010-2014
Vice President, Development Operations, Hobbs, NM (2013-2014)
Vice President, Bioprocessing (2011-2013)
Sr. Director, Bioprocessing, (2010-2011)

Site leader for Joule's Demonstration facility for the outdoor R&D of photosynthetic processes to produce fuels. Led the experimental photobioreactor development program at Joule's R&D facility in Bedford, MA

Millennium Pharmaceuticals, Cambridge, MA 2004-2010
Senior Director, Bioprocess Development (2009-2010)
Director, Bioprocess Development (2006-2009)
Associate Director, Bioprocess Development (2005-2006)
Senior Scientist II, Bioprocess Development (2004-2005)

Led the Bioprocess Development group responsible for the outsourcing, process development, process characterization and process validation of the Entyvio drug substance process. Team Leader for the CMC development, including regulatory strategy, of Vedolizumab (Entyvio). Millennium CMC lead for Adcetris partnership with Seattle Genetics. Responsible for the process development and supply of clinical trial material for numerous other biologics.

Xcellerex LLC, Marlborough, MA 2003-2004
Vice President, Process Development Technology and Services

Developed high throughput tools to enable the rapid screening of the bioprocess design space for therapeutic proteins manufacturing.

EMD Pharmaceuticals, Lexington, MA 2002-2003
Manager, Cell Culture Process Development

Led team responsible for developing a Phase III mammalian cell perfusion bioreactor process and successfully transferring this process to a CMO.

Millennium Pharmaceuticals, Cambridge, MA 2001-2002
Director, Process Development Technologies

Developed high throughput tools to enable the rapid screening of the bioprocess design space for therapeutic proteins manufacturing.

Michael W. Glacken Consulting 1998-2001
Principal

Clients served: Genentech, Immunex, Millennium, BIO, Formatech, Applied Process Technologies, Schering Plough, Allergan, Avigenics, Merck, Eli Lilly, Protein Design Labs, Dow AgroSciences, SemBioSys, Genetics Institute, BASF, Centocor, Genzyme, Bayer, Atlantic Biopharmaceuticals, M.I.T., Bristol Myers Squibb and Genzyme Transgenics

Bristol Myers Squibb Pharmaceutical Research Institute, Seattle, WA 1993-1997
Associate Director, Department of Bioprocess Research

Led mammalian cell culture STR and microbial fermentor bioprocess development to supply protein therapeutic candidates for discovery research. Responsible for transferring processes to clinical manufacturing group. Led technology advancement for cellular protein expression in mammalian, *E. coli* and *P. pastoris* cell lines. Improved CTLA4Ig (Orencia) titers 20-fold for the clinical manufacturing group.

SmithKline Beecham Pharmaceuticals, King of Prussia, PA 1990-1993
Senior Investigator, Department of Bioprocess Sciences

Developed STR process for the first large scale GMP animal cell culture production campaign at SB to support human clinical trials. Optimized and started-up large scale Prostak microfiltration unit to clarify supernatant from the 1000L STR. Led group responsible for GMP and research cell banking, cell line testing, medium development and cell line evaluation and development.

Rice University, Houston, TX 1987-1990
Assistant Professor of Chemical Engineering

Supervised research thesis of five graduate students (3 M.S., 2 Ph.D.). Taught undergraduate Plant Design and senior lab courses, and graduate Biochemical Engineering course. Wrote or co-wrote three peer reviewed grants that received funding totaling $280,000.

Education	**Massachusetts Institute of Technology, Cambridge, MA** ***Sc.D., Biochemical Engineering***	1987
	University of Maryland, College Park, MD ***B.S., Chemical Engineering***	1976

Recent Presentations

Glacken MW and Connolly J. Managing Process Characterization and Validation on a Breakthrough Therapy Program. Presented at BPT-West; 2019 Mar 13; Santa Clara, CA.

Glacken MW. Process characterization: It's not a science project. Presented at BPT-West; 2017 Mar 01; San Francisco, CA.

Glacken MW. Are there drivers left for further process optimization in cell line development? Presented at IBC's Sixth Annual Cell Line Development and Engineering Conference, Keynote address; 2010 Jun 21-23; San Francisco, CA.

Glacken MW. Managing a biologics supply chain using a fully outsourced manufacturing model. Presented at IBC's BioProcess International Conference; 2008 Sep 23-26; Anaheim, CA.

Glacken MW. Identification of important process engineering problems requiring joint efforts of biologists & engineers. Presented at IBC's BioProcess International Conference; 2005 Sep 19-22; Boston, MA.

Glacken MW. High throughput biopharmaceutical process development. Presented at BIO International Convention; 2004 Jun 6-9; San Francisco, CA.

Glacken MW. Plant transgenics vs. animal transgenics vs. CHO bioreactor culture: An objective comparison for monoclonal antibody production. Presented at IBC's Eighth International Conference: Antibody Production and Downstream Processing; 2002 Feb 13-15; San Diego, CA.

Full publication list is available upon request

Recent Publications

Glacken MW. Efficacious transfer of bioprocesses to CMOs: The role of process history in establishing clear transfer criteria. BioPharm Int. 2010 Mar;23(3): 54-9.

Full publication list is available upon request

EXHIBIT 2

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.