Beth Brown, Ph.D.

Senior Manufacturing Consultant

Core Competencies

- Executive Leadership
- Biologics Manufacturing
- Combo Devices
- Inhalation Development
- Live Biotherapeutic Products
- Oral Bacterial Capsules
- Bioprocessing
- Lyophilization

Professional Summary

Dr. Brown brings formulation, process development, pharma, biotech, drug device and drug delivery technology expertise to our clients including development of biologics from toxicology studies, through IND enabling studies, Clinical Phase studies, draft provisional patents and the marketing technical and business assessment for commercial dosage forms. Her career roles focused on novel science, revolutionary and evolutionary next generation products and the establishment of business processes. She has developed first-in-the-world oral bacterial capsule therapy platform including product and manufacturing processing.

- Utilized novel applications of bioprocessing, lyophilization, pharmaceutical encapsulation and packaging technologies.
- Authored regulatory submissions and two provisional patents for oral bacterial capsule therapy platform.
- Bioanalytical test method development and validation, PMA-qPCR, gene sequencing.

Dr Brown is experienced in later phase BLA submission activities and has worked directly with Quality and Manufacturing Directors to set up commercial manufacturing suites and quality control laboratories.

Prior to joining DSI, Dr. Brown served as Director Research and Development for Rebiotix, a clinical stage biotechnology company founded to revolutionize the treatment of debilitating diseases by harnessing the power of the human microbiome. She is past editorial board member for Drug Delivery Technology and hold a Six Sigma Black Belt.

Education

Ph.D.	Pharmaceutics	University of Michigan
M.S.	Pharmaceutics	University of Michigan
B.S.	Pharmacy	Purdue University

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Professional Experience

DS INPHARMATICS **2017 – present**

Experienced drug delivery technical leader utilizing scientific fundamentals to educate, design strategic and tactical development plans for new products and technology

- CMC Consultant for a start-up pharmaceutical company, leading the development of a biological actives, authored IND, Clinical Phase I and Phase IIa; draft provisional patents; led market, technical and business assessment for commercial dosage form.
- Creates strategic plan, develops regulatory 510k strategies, authors 510k, oversees biocompatibility/consensus standard testing, and authors patents for non-prescription product line.
- Authors IND CMC submissions for small and large molecule product.
- Author ANDA for a sterile biologic injectable solution (First to File).
- Authors analytical method validation reports for animal health oral tablet products.
- Provides strategy for the development and manufacturing as well as regulatory submission for small molecule injectable suspension.
- Defines process and conducts new technology assessment in support of next generation product research & development selection and acquisition target recommendations.

REBIOTIX, Inc. – Roseville, MN **2015 – 2017**
Rebiotix Inc. is a start-up, clinical stage biotechnology company founded to revolutionize the treatment of debilitating diseases by harnessing the power of the human microbiome.

Director, Research and Development
Reported to the Vice President of Technical Operations and Business Development. Member of the Senior Leadership Team. Responsible for the creation of pharmaceutical and analytical development functions including laboratories. Developed first-in-the-world oral bacterial capsule therapy platform including product and manufacturing process in 9 months.

- Utilized novel applications of bioprocessing, lyophilization, pharmaceutical encapsulation and packaging technologies.
- Authored regulatory submissions and provisional patents for oral bacterial capsule therapy platform.
- Bioanalytical test method development and validation, PMA-qPCR, gene sequencing.

American Medical Systems, Inc. – Minnetonka, MN **2013 – 2015**
American Medical Systems, Inc. (AMS)- now part of Boston Scientific- is a $500MM company who provides medical solutions that restore the pelvic health of men and women worldwide. AMS is a world-class leader in advanced medical technologies.

Principal Research Scientist, Research and Development
Reported to the Sr. Vice President of Research and Development. Led a multi-disciplinary team for drug/device combination product remediation and implementation of 21CFR 4. Pharmaceutical development and DFSS consultant for the company. New product concept generation, selection, and assessment.

- Technical lead and Program Manager for InhibiZone® analytical methods development and validation, process optimizations (reduce manufacturing cost by 60%), process qualifications, PMA filing, and 21CFR 4 compliance plan for multiple implants.
- Taught DFSS principles and deploys DFSS using tools and methodology for new product development and remediation.

Pharmaceutical & Medical Device Consultant – Twin cities, MN **2012 – 2013**

Experienced drug delivery technical leader utilizing scientific fundamentals to educate, design strategic and tactical development plans for new products and technology

- Taught Quality by Design principles and deployed QbD through the use of tools, methodology, and product development project planning for $900MM pharma company.
- Instructed on the scientific fundamentals and experimental approach to understanding protein drug stability, its performance and interaction with a novel device for a $34B company.

Gilead Sciences, Inc. – Seattle, WA **2011 – 2012**

A $8.4B research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines. Therapeutic areas of focus include HIV/AIDS, hepatitis, serious respiratory, cardiovascular and metabolic conditions, as well as cancer and inflammation.

Senior Research Scientist II, Formulation and Process Development

Recruited by and reported to the Vice President of Formulation and Process Development. Responsible for managing a multi-disciplinary department of scientists, medical device engineers, engineering firms, and consultants. Oversaw technical and regulatory product development for new chemical entity (NCE) inhalation (nebulizer, pMDI – pressurized metered dose inhaler, DPI – dry powder inhaler) drug/device products. Forecasted and managed a $4MM department budget.

- Advanced drug/device combination projects both strategically and tactically to meet development and regulatory milestones including an IND submission.
- Executed technical assessments for quality change controls and conducted cross-functional department training to support commercial inhalation devices.
- Improved the department technical capability through performance management and staff development.
- Managed Gilead new inhalation technology including the drafting of patent application work plans.

Upsher-Smith Laboratories – Maple Grove, MN **2008 – 2011**

USL was a privately-held specialty pharmaceutical company- now part of Sawai Pharmaceutical Co., Ltd.- focused on the development, manufacture and marketing of drug products to treat epilepsy and Parkinson's disease. Commercial portfolio also includes cardiology, dermatology, and women's health products.

Director, Pharmaceutical Development

Recruited by and reported to the Vice President of Pharmaceutical Sciences and Project Management. Responsible for the leadership of 30 scientists including consultants and contractors within Pharmaceutical Development and Drug Delivery. Oversaw technical and regulatory product development activities for greater than 10 NDA, ANDA, OTC, and nutraceutical product development programs (conventional oral solid, controlled release oral solid, oral soft gelatin, nasal, and semi-solid dosage forms). Forecasted and managed departmental budget exceeding $10MM.

- Progressed research and development projects both strategically and tactically to meet development and regulatory milestones resulting in multiple IND and ANDA submissions.
- Developed recruitment plan to fill the Pharmaceutical Sciences' gaps in skills and expertise for NDA development. Created semi-virtual resourcing plan, increased the capacity of the department 3-fold and improved technical proficiency.
- Updated department infrastructure to support cGMP manufacturing and implemented Quality by Design to establish efficient and competitive product development. Key contributor to the establishment of Corporate Stage Gate Process for NDA product development.
- Performed technical due diligence on several product candidates which resulted in the licensing of Phase 3 product opportunity.

CIMA LABS, Inc., subsidiary of Cephalon, Inc. – Brooklyn PArk, MN **2005 – 2008**
(now Teva Pharmaceutical Industries Ltd.)
CIMA LABS was a drug delivery company engaged in the development and manufacture of prescription and over-the-counter products based upon its proprietary, orally disintegrating (OraSolv® and DuraSolv®), oral transmucosal, solubilization, taste-masking, tamper-deterrent, and custom release drug delivery technologies.
Senior Manager of New Technology
Recruited by and reported to the Vice President of Business Development and Technical Operations. Leader for all in-licensing and acquisition activities for Cephalon drug delivery. Supported business development to reach third party drug delivery business revenue goals.

- Identified and managed market research firm and led an internal cross-functional team to develop a new drug delivery technology strategic plan resulting in the identification of key technology areas for the Cephalon/CIMA LABS portfolio.
- Identified, supported and recommended multiple product and technology licensing/acquisitions through the evaluation and analyses of drug delivery technology information which included, technical, clinical, regulatory, financial and intellectual property.
- Built relationships with universities and research institutes resulting in joint research projects.
- Led team to prioritize Cephalon Drug Delivery intellectual property which defined the technology research projects for the portfolio.
- Participated in business development activities to attract new partner business. This included, serving as technology presenter at conferences and at partner companies, technical writing, and contributing to the CIMA LABS re-branding and web site redesign team.

3M– Drug Delivery Systems - Maplewood, MN **1996 – 2005**
3M is a $27 billion dollar international company that develops innovations for healthcare, display and graphics, consumer and office, transportation, electronic and communication, and safety transportation businesses. 3M Drug Delivery Systems offers inhalation and transdermal drug delivery technology including a full range of feasibility, development and contract manufacturing capabilities for pharmaceuticals.
Global Technical Project Leader **2004 – 2005**
Responsible for global technical management of the 3M/MicroDose dry powder inhaler (DPI) co-development and marketing collaboration. Developed and executed strategy and tactical plans for global dry powder inhaler capabilities including partner project plans utilizing Design for Six Sigma methodology.

Division Design for Six Sigma (DFSS) Black Belt **2003 – 2004**
As the Division's first technical DFSS black belt, trained teams on methodology and established working knowledge of tools, processes, and project management to conduct competitive product and technology development programs utilizing Market Analysis and Segmentation, Voice of Customer, Quality Function Deployment, Concept Generation, Design of Experiments, Design for Manufacturability, Critical Parameter Management (CPM), Technical Transfer and Control Plans. Projects included the delivery of macromolecules and advanced transdermal systems.

Senior Pharmacist, Advanced Research Specialist **1996 – 2003**
Studied the compatibility of protein/peptide APIs in pMDIs and completed DPI technology evaluation which resulted in bringing new DPI device technology to 3M. Led immune response modifier NCE pMDI feasibilities; key contributor to molecule screening and selection resulting in several records of invention.
Solved several complex technical challenges (drug product manufacturing, stainless steel compatibility, and device component fabrication) with novel, patentable solutions.

PROFESSIONAL AND CIVIC AFFILIATIONS

TeamWomenMN Leadership Mentor (2012 - 2016)
Co-Chair for $100,000+ Non-Profit Auction (2012 - 2014)
Drug Delivery Technology - Editorial Board Member (2006 – 2012)
LifeScience Alley - Track Chair for Annual Conference (2008 – 2011)
Member of Industrial Advisory Board for Center for Pharmaceutical Processing Research (2008 – 2011)

AWARDS

Finalist for Valiant Explorer Leader in Health Care Award, Minnesota Business Magazine (2015)
Certification for Design for Six Sigma Black Belt (2004)
Recipient of the Golden Step Award for Qvar® (2004)
Recipient of the 3M Discover Grant (2001)
Recipient of the 3M Circle of Technical Excellence Award for Technical Championing (2000)

PRESENTATIONS AND PUBLICATIONS

Over 40 presentations and publications on scientific research, pharmaceutical product and drug delivery technology development, and leadership. List available upon request.