Brian A. Dow, Ph.D.

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Summary

- 7 years' combined professional experience in Pharmaceutical R&D and regulatory affairs
- Dossier author responsible for 70+ Module 2/3 submissions, Health Authority Responses, Investigator Brochures, and US FDA and EMA Scientific Advice Briefing Packages

Industry Experience

JANSSEN RESEARCH & DEVELOPMENT, LLC (Johnson & Johnson) **Feb. 2016 - Present**
CMC Regulatory Dossier Author, Senior Scientist

- Internal regulatory subject matter expert for novel platforms, including continuous manufacturing, antibody drug conjugates, and cell & gene therapy technologies
- Lead CMC dossier teams, including with external partners, to develop regulatory strategy and clinical trial application content for 70+ submissions in the US and EU
- Pioneered use of ICH S9 and Haber's Law for impurities specifications in a high dose early development oncology program
- Collaborated with Non-Clinical Safety group to develop innovative, viable solution to justify higher dosing than toxicologically qualified
- Maintain, update, and develop CMC regulatory content strategy and best practices for Phase 1-3 IND/IMPDs, BLA/MAAs, investigator brochures, and briefing books

Johnson & Johnson Advanced Therapy Policy Team Member **May 2020 – Feb. 2021**

- Represent Janssen CMC in Johnson & Johnson cell and gene therapy strategy and policy forum

Cell and Gene Therapy Dossier Intelligence Forum Leader **Jan. 2018 – Feb. 2021**

- Lead Cell & Gene therapy commenting efforts on 7 US, EU, and Brazilian Health Authority guidances and legislations
- Develop and maintain regulatory intelligence databases, including laws, guidances, designations, product approvals, EPARs, FDA Summary Bases for Regulatory Actions, and health authority questions and responses
- Collaborate with GRA and CMC functional areas to develop CMC IND/IMPD and BLA/MAA dossier content outlines and templates

Regenerative Medicine Advanced Therapies GRA Rotation **Jan. 2018 – Feb. 2019**

- Performed industry benchmarking and competitive intelligence activities on the FDA RMAT designation
- Developed and maintained international guidance and legislation intelligence database to support publication in the Journal of the National Academy of Medicine

ALLIANCE FOR REGENERATIVE MEDICINE **April 2020 – Feb. 2021**
Regulatory CMC Task Force Member

- Provided recommendations on "CMC Flexibility" in PDUFA VII comment letter and inclusion in 21st Century Cures Act, v2.0
- Provided proactive comments to FDA guidance on CMC considerations for Human Somatic Cell Therapy INDs

UNIVERSITY OF CENTRAL FLORIDA COLLEGE OF MEDICINE **Aug. 2011 – May 2016**
Doctoral Candidate

- Studied antibody misfolding and instability in Light Chain Amyloidosis

BOEHRINGER-INGELHEIM VETMEDICA, PHARMACEUTICAL R&D **Jan. 2009 – Aug. 2011**
Analytical, Formulations, and Stability Scientist

- Performed compendial stability testing on 7 marketed products and supported novel formulation development for Semintra® registration

Education

Doctor of Philosophy, Biomedical Sciences
University of Central Florida, College of Medicine, Orlando, FL

Bachelor of Science, Biotechnology with minor in Chemistry
Missouri Western State University, St. Joseph, MO

Certificate, Terrorism and Counterterrorism (edX, Inc. Online Course)
Georgetown University, Washington, District of Columbia

Certifications & Trainings

FDA Human Drug Review and Approval Basics, Food and Drug Administration
Chemistry, Manufacturing, and Controls Perspective of the IND, Food and Drug Administration
Biologics Review, Food and Drug Administration
FDA eCTD Overview and Submission, Food and Drug Administration

Languages

English
Spanish
Brazilian Portuguese

Professional Memberships

American Association of Pharmaceutical Scientists
Chairman of Career Development Committee
Sub-chair of Regulatory Sciences Abstract Screening Committee

Drug Information Association

Presentations

Application of ICH S9 and Haber's Law for Impurities Specifications in a High Dose Early Development Oncology Program
Drug Information Association Global Annual Meeting and CMC Leaders Level 1 meeting

FDA RMAT Competitive Intelligence Benchmarking and Analysis
GRA Hot Topics Forum and BCMA CAR-T GRA Team Meeting

Careers in Science Symposium Invited Speaker
University of Central Florida College of Medicine

Regulatory Affairs 102: Essential of Regulatory Compliance for Pharmaceutical Scientists
American Association of Pharmaceutical Scientists (eCourse)
(https://www.pathlms.com/aaps/courses/4693)