CHRIS WILEY

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PROFESSIONAL SUMMARY

Results-oriented project leader with more than a decade of experience in drug product development and a proven track record of multiple successful clinical and commercial approvals for several complex drug modalities, including AAV-based gene therapy, CAR-T cell therapy, mAbs, ADCs, and vaccines. Skilled in drug product formulation, process development, process validation, and strategic regulatory planning, guiding projects through the development lifecycle from the regulatory toxicology stage through commercial launch. Proven ability to manage diverse projects with conflicting priorities while consistently meeting aggressive timelines and maintaining unwavering quality standards. Excels at simplifying complex technical information for diverse audiences to bridge the gap between technical and non-technical stakeholders.

SKILLS

- Drug Product Development
- Understanding of cGMPs, ICH, EMA, and PDMA requirements
- Technology Transfer
- Process Validation
- Coaching and Mentoring
- Regulatory Submission Authoring and Strategy
- Continuous Improvement
- Risk Assessment
- CMO/CDMO Management
- MS Office Suite (Project and Visio)
- Cross-Functional Team Leadership

EDUCATION

Bachelor of Science: Biochemistry, 2013
University of Missouri - Columbia - Columbia, MO

WORK HISTORY

April 2013 – December 2023: **Pfizer Inc.**
Biotherapeutics, Pharmaceutical Research and Development

Senior Scientist / Drug Product Team Lead, May 2022 – December 2023
Scientist / Drug Product Team Lead, October 2019 – May 2022

Drug Product Team Lead for a Late-Stage AAV Gene Therapy Asset

- Led a highly matrixed cross-functional Global Drug Product CMC Team in formulation, process development, tech transfer, validation, launch readiness, regulatory strategy, and complex problem solving in collaboration with multiple internal and external stakeholders, including internal manufacturing sites, CDMOs, regulatory, supply chain, clinical, safety, quality, and product launch teams to ensure critical project milestones were achieved
- Led the drug product team through multiple process improvements, phase 3 IND/IMPD approvals, several CTA amendment approvals, tech transfer and manufacture of 8 clinical supply batches, process validation for 2 dosage forms with 6 successful validation batches, and start of commercial drug product production with 4 market-ready batches made in 2023
- Managed a team of 5+ scientists on a smaller technical R&D team to perform necessary formulation and process development work, provide manufacturing support, and establish the control strategy
- Authored and reviewed CMC leaflets of the BLA and MAA with planned submission in 2024
- Represented CMC team on labeling and artwork teams, including authoring of relevant USPI and SmPC sections

Additional CMC Experience and Leadership

- Prior Drug Product Team Lead for another late-stage AAV-based gene therapy asset which successfully submitted a BLA and MAA this year
- Contributing or lead author of CMC drug product content for commercial license applications (BLAs/MAAs) of 4 drug products, resulting in one approval, one currently in FDA and EMA review, and one planned submission in 2024
- Authored and responded to queries for many clinical trial applications (INDs/IMPDs) with a track record of more than 15 successful approvals including initial submissions and amendments
- Attended meetings with health authorities including FDA and EMA to negotiate CMC strategy
- Led the process design and implementation of a new gene therapy platform process at a CMO for patient-specific labeling and packaging, enabling on-demand generation of multi-vial treatment packs for weight-based dosing of gene therapy products
- Key contributor to the establishment of a new gene therapy drug product manufacturing site and implementation of an innovative manufacturing process with a modular single-use process stream and a novel container closure and filling system for improved ultra-low temperature robustness
- Experienced in batch record creation, deviation impact assessment, root-cause analysis, and implementation of CAPAs
- Experienced in combination product development and design control, especially multi-component vaccines, closed system transfer devices for hazardous drugs, pre-filled syringes, and auto-injectors
- Experienced in drug product dosage form design, verification of instructions for use, in-use compatibility, stability, and related regulatory considerations

Senior Associate Scientist, October 2016 – October 2019

- Began project leadership experience with an early clinical stage oncolytic virus-based immunotherapy product which was manufactured at a new CMO in Germany. Fostered a positive relationship with the new CMO and led successful tech transfer and manufacture of 2 clinical supply batches
- Served as Empower chromatography data system administrator and led implementation of standardized integration methods and custom fields to streamline data processing and improve quality
- Performed complex troubleshooting and led initiatives to solve problems with assays or instrumentation
- Trained new employees on areas of technical expertise and compliance issues relevant to lab setting
- Authored multiple drug product CMC leaflets for several INDs/IMPDs

Associate Scientist, April 2013 – October 2016

- Simultaneously served as a key contributor to several complex projects, meeting all pertinent milestones
- Generated protocols, performed developmental studies to identify new product formulations and develop new manufacturing processes, analyzed data, and prepared technical reports and presentations presented both internally and externally
- Conducted document review, organization and quality control of data to draw relevant conclusions

January 2011 – December 2012: **University of Missouri**
Dr. Thomas Quinn Laboratory

Research Assistant

- Conducted NIH grant-funded research involving the use of modified bacteriophage capsids as vectors for targeted delivery of various nuclear isotopes for cancer imaging and treatment.

PUBLICATIONS AND PROCEEDINGS

Bhattacharya, D., **Wiley, C**., Latal, A., Krishna, V. *Antigen-Adjuvant Formulations – Key Considerations.* Book Chapter in Practical Aspects of Vaccine Development. 207-224. 2022.

Latal, A., **Wiley, C**., Scharf, M., & Devine, D. *Effects of Visible and Ultraviolet Light at AAV-based Gene Therapies: Considerations for Manufacturing, Handling, Storage, and Dosing.* Presentation at Pfizer Bioprocessing Sumit, (Virtual), August 2020.

Langford, A., Horwitz, T., Adu-Gyamfi, E., **Wiley, C**., Holding, E., Zimmerman, D., Alphonse-Ignatius, A., & Ohtake, S. *Physical Properties Governing the Resuspendability of Aluminum Adjuvant Containing Vaccines*. Journal of Pharmaceutical Sciences. 109 (4): 1460-1466. 2020.

Wiley, C., Czaicki, B., Singh, S., Starkey, J., & Radhakrishnan, V. *Polysorbate-80 Adsorption to Silicone Oil During Long Term Storage of Monoclonal Antibody Formulations in Prefilled Syringes*. Poster session presented at the American Association of Pharmaceutical Scientists (AAPS) annual meeting, Denver, CO. 2017.

Wiley, C., Goswami, S., Kolhe, P., McCluskie, M., & Davis, H. *Adsorption Dynamics of Antigen and CpG to Aluminum Hydroxide in a Vaccine Formulation*. Poster session presented at the American Association of Pharmaceutical Scientists (AAPS) annual meeting, San Diego, CA. 2014.

AWARDS AND ACCOLADES

Pfizer Global Supply Bold Move Award (2023): Accelerated Aseptic Technology Readiness for the Stage 2 Manufacturing Facility

Pfizer Global Supply Quarterly Award (2019): Aseptic Technologies Filling Kits Investigation

Biotherapeutics Pharm. Sci. Team Impact Award (2018): CMC leadership in the creation of the Allogene New Co. through complexity management, strategic agility and timely decision making

Biotherapeutics Pharm. Sci. Team Impact Award (2018): Development of Drug Product Formulation and Process for AAV Gene Therapies

Global Clinical Supply Patient Focus Award (2017): Clearing the Hurdles – B197 Trumenba (Penta)

Pfizer Global Supply Mission Award (2017): NextGen-HER2 Antibody Drug Conjugate Drug Substance Tech Transfer to B250

AFFILIATIONS

American Association of Pharmaceutical Scientists (2014 to present)