Marilyn M. Julien

CONTACT

+1 – 215–648–1208 Ext. 722

MJulien@thebrackengroup.com

LinkedIn Profile

www.thebrackengroup.com

EDUCATION

Bachelor of Arts
Chemistry, Rutgers University

PROFESSIONAL SUMMARY

Director for Global Regulatory CMC (chemistry, manufacturing, and controls). Equally competent with small and large molecule regulatory requirements. Expert experience with CMC development activities for investigational products (Phase 1 to Phase 3). Post-approval drug life-cycle management experience including annual reports and change control management including supplements to applications. Assertive, accomplishment-oriented personality combined with great interpersonal skills. Detail-oriented individual with strong oral and written skills. Fluently bilingual in English/French; proficient in Spanish. Active member of industry professional associations.

PROFESSIONAL EXPERIENCE

2022 – Present

The Bracken Group
Senior Consultant

2021 – 2022

Beigene
Director CMC Regulatory Affairs

- Responsible for developing, leading, and implementing Global Regulatory CMC strategies for early development biologics products.
- Responsible for implementing Module 3 templates for INDs/IMPDs/CTAs.
- Managed interactions with FDA and other global regulatory authorities for assigned project(s) to ensure acceptance, rapid review, and approval of clinical trial applications.
- Responsible for the authoring of the CMC-related information in briefing documents to support investigational dossiers.
- Evaluated proposed manufacturing changes for global impact to ongoing and future filings and provide strategic regulatory guidance for optimal implementation of changes.
- Active participant on cross-functional project teams, global regulatory and CMC sub-teams.
- Maintained knowledge of global Regulatory CMC landscape, assess applicability/impact on BeiGene early development products.
- Responsible for the drafting, review and approval of Module 3 documents.
- Responsible for the career development of 3 direct reports.

2021 – 2021

Kedrion Biopharma
Associate Director, Global Regulatory Affairs (Remote)

- Responsible for the coordination and compilation of IND amendments for plasma-derived drugs
- Guided Kedrion through a comparability protocol for the technology transfer of their plasma-derived bulk drug substance from initial strategy through FDA approval. This submission was Kedrion's only first-pass approval of a comparability protocol.
- Tapped to serve as a "Change Agent" to bring Kedrion to the NEXT level.
- Supported and guided junior level Regulatory CMC manager.
- Served as Regulatory CMC representative on project teams.
- Reviewed and approved change controls for development and commercial products.

2019 – 2020

Bayer Healthcare
Vice Preside Associate Director, Global Regulatory CMC - Small Molecules

- Responsible for strategy and drafting of IND/IMPD/CTA submissions and amendments.
- Managed and trained junior level Regulatory CMC managers.
- Served as Regulatory CMC representative on project teams for development products and line extensions for commercial products.
- Compiled sNDA and EU variations for commercial products.
- Reviewed and approved change controls for development and commercial products.

BRACKEN

2009 – 2018

Celgene Corporation

Associate Director, Global Regulatory

- Independently managed the entire biologics portfolio as Celgene's first (and for seven years, only) Regulatory CMC manager for biologics products (mAb, ADC, fusion proteins, and gene therapy).
- Successfully led Celgene through its first biologics IND from the preparation of the Pre-IND (Type B) meeting package through Requests for Information and receipt of Study May Proceed letter.
- Coordinated and compiled IND amendments for Celgene's gene therapy drug (CAR-T cells modified using a lentiviral vector).
- Guided Celgene through two comparability amendments for its mid- and late-stage large molecule development products.
- Represented Regulatory CMC on due diligence visits for new development compound assets.
- Partnered with core business units (Development Operations, Marketing, Program Management, QA, Medical Affairs, Nonclinical Development, Clinical Development, Manufacturing) to drive product development and regulatory strategy.
- Served as the Celgene representative on the cross-company team responsible for the PhRMA response to FDA's draft guidelines on biosimilars.
- Oversaw and trained junior level Regulatory CMC managers.
- Served as Regulatory CMC lead on cross-functional project teams for small and large molecule development products.
- Responsible for strategy and drafting of small and large molecule IND/IMPD/CTA submissions and amendments.
- Member of Regulatory CMC team selected to draft NDA templates for small molecule products.
- Compiled sNDA and EU variations for small molecule commercial products.
- Member of the REBLOZYL® (luspatercept) BLA Team.

2009 – 2018

Imclone Systems, INC.

Senior Manager, Regulatory Affairs CMC

- Responsible for the coordination, compilation, writing and review of the CMC portion of INDs, CTAs, IMPDs and Investigator Brochures and their maintenance via amendments/annual reports to regulatory authorities. Developed regulatory development strategies.
- Served as Regulatory Affairs CMC representative to the Project Core Teams for two biologics oncology development products providing regulatory strategy for submissions.
- Reviewed, edited, and prepared documents and correspondence for IND, CTA, NDS, sNDS, BLA and sBLA submissions (including annual reports).
- Communicated with health authorities to discuss regulatory submissions strategies.
- Reviewed and approved change requests.
- Worked with QA, QC, development and manufacturing, as necessary, to ensure accuracy of CMC information to be incorporated into submissions.
- Participated on technology transfer teams for drug substance and drug product manufacturing.
- Maintained working knowledge of US, Canadian and European regulatory guidelines and kept abreast of regulatory guideline changes by regularly reviewing relevant internet sites and documents.
- Served as ImClone's Regulatory Affairs CMC liaison between ImClone Systems Inc. and its contract manufacturers.
- Provided regulatory guidance to ImClone's Raw Materials Team.

Kyowa Pharmaceutical, INC (KPI)

Manager, Regulatory Affairs

- Responsible for the coordination, compilation, writing. submission and maintenance of the CMC sections of INDs, CTAs, Investigator Brochures, DMFs and NDAs to FDA and other global regulatory authorities, and their maintenance via amendments/annual reports.
- Responsible for the coordination, compilation, and writing of the CMC section of an NDA.
- Received Kyowa Pharmaceutical, Inc. Excellence Award (2006) for significant contributions made toward resolving CMC issues, authoring and completing the Regulatory review of the CMC section of the NDA.
- Worked directly with non-clinical, clinical and CMC development, project management, and quality assurance functions to create systems that assure integrity and quality of submissions.
- Participated in drug development initiatives decision-making.
- Responsible for the coordination, planning, and compilation of the CMC section of the Pre-NDA Meeting.
- Trained Japanese CMC team members on the electronic Common Technical Document (e-CTD) Modules 1 through 3, and US industry standards.
- Worked with research and development during new-product start-ups and product development.
- Participated in the compilation of the Patient Information for the NDA
- Member of the Rapid Response Team designed to facilitate the rapid and timely response to health authority questions on KPI's first US NDA.
- Member of the Advisory Committee team for the approval of the NDA.
- Submitted and maintained DMFs to global regulatory authorities.
- Reviewed and approved change requests.
- Interact with regulatory authority personnel to expedite approval of pending applications and resolution of on-going regulatory authority/company issues
- Maintained current knowledge of global regulatory standards. Provided expertise and guidance interpretation of regulatory authority guidelines and internal policies to assure adequate and complete submissions.
- Contributed to the establishment of regulatory strategies for new products and processes.
- Coordinated and maintained reporting schedules for applications.
- Drafted and reviewed corporate and departmental SOPs and Work Instructions.

ADDITIONAL RELEVANT EXPERIENCE

Schering-Plough Research Institute

Associate Manager, Worldwide Regulatory Affairs – CMC
Regulatory Associate, Worldwide Regulatory Affairs – CMC

- Responsible for the handling of CMC regulatory activities for assigned development and post-approval products. Developed regulatory development strategies.
- Communicated with local and global project team members concerning supportive information for submissions.
- Communicated with FDA regarding pre-submission strategies/pathways, testing requirements, clarification, and follow-up on submissions under review.
- Communicated with appropriate FDA personnel concerning the coordination, preparation and conduct of formal meetings and teleconferences to facilitate drug development (IND) and FDA approval of NDA and sNDA submissions.
- Reviewed, edited, and prepared documents and correspondence for DMF, IND, NDA and sNDA submissions (including annual reports).
- Reviewed and approved change requests.
- Fulfilled registration/re-registration requests for international products.
- Worked with QA, QC, development, and manufacturing, as necessary, to ensure accuracy of CMC information to be incorporated into submissions.
- Participated on technology transfer teams for drug product and drug substance manufacturing.
- Maintained working knowledge of US and European regulatory guidelines and kept abreast of regulatory guideline changes by regularly reviewing relevant internet sites and documents.
- Managed the technical relationships between Schering-Plough and its partners.

Scientist, Analytical Development - Product Quality Review

Associate Manager, Worldwide Regulatory Affairs – CMC
Regulatory Associate, Worldwide Regulatory Affairs – CMC

- Assessed accuracy and sensitivity of analytical methods.
- Developed and validated chromatographically specific methods for drug substances and various dosage forms by designing experiments addressing key analytical parameters.
- Interpreted and evaluated scientific data to be submitted as part of the NDA update program and for method transfer to QC.
- Wrote detailed reports describing validation experiments performed on drug substances and drug products of various dosage forms.

Scientist, Technical Documentation

- Charged with the 100% review of the analytical data, stability reports, laboratory notebooks and chromatograms for the PROVENTIL® NDA submission.
- Identified a problem with the entry of information into the Turbo Chrom data acquisition system that resulted in incorrect calculations. Notified management and the computer team of the analytical research department of these errors, which subsequently resulted in the retraining of the entire Analytical Development laboratory staff. This greatly contributed to the department's fine showing during the Pre-approval Inspection.