**Associate Director, Regulatory Affairs, CMC**

Remote (US)

time type

Full time

job requisition id:  **R17518**

BeiGene continues to grow at a rapid pace with challenging and exciting opportunities for experienced professionals. When considering candidates, we look for scientific and business professionals who are highly motivated, collaborative, and most importantly, share our passionate interest in fighting cancer.

Position Summary:

The Associate Director, Regulatory Affairs CMC, is responsible for developing, leading, and implementing global regulatory CMC strategies to secure and maintain market access for assigned product(s) in line with business objectives, and in coordination with key internal stakeholders.  This position will lead and manage regulatory CMC aspects of BeiGene’s biological products through all phases of development, post-approval, and life-cycle of the product depending on assigned products.  Primary responsibilities will be in creating CMC regulatory strategies for development programs in preparation and maintenance of regulatory applications.

Essential Functions of the Job:

* Serve as the regulatory CMC representative on project teams.  Provides CMC regulatory support and guidance for assigned projects and interfaces with R&D, Project Management, Manufacturing, Quality, and Regulatory colleagues, as well as third party laboratories, global collaborations partners and contract manufacturers.
* Manage interactions with FDA and other global regulatory authorities for assigned project(s) to ensure acceptance, rapid review and approval of marketing applications, supplements/variations, clinical trial applications and other submissions which present CMC information.
* Develop and implement effective regulatory CMC strategies for global submissions knowing the life cycle of drug product from R&D through commercialization and interpret and apply local regulations and guidance to the life cycle of a drug product.
* Manage/prepare CMC document packages for regulatory submissions in support of development programs. This includes initial submission of INDs, CTAs and amendments to Health Authorities (HAs), and preparation of responses to questions from HAs balancing HA requirements and corporate objectives.
* Manage timelines in cooperation with Project Management on assigned projects.
* Review technical reports and CMC sections of IND, CTA, BLA, MAA, and other global submissions to support clinical trials and marketing applications, and their amendments in conformance with regulatory requirements, strategies and commitments.
* Work with regulatory CROs to identify regional/country-specific CMC requirements to support global applications.
* Evaluate proposed manufacturing changes for global impact to ongoing and existing filings, and provide strategic regulatory guidance for optimal implementation of changes.
* Actively participate as a member of global regulatory teams and CMC subteams.
* Support and manage regulatory aspects of CMC Operations including authoring, reviewing and and/or approving SOP’s, CAPA’s, etc.
* Maintain knowledge of global competitive landscape, regulatory environment, regulations and CMC guidance, providing interpretation to internal stakeholders and initiating process improvements as appropriate.

Qualifications:

* Minimum 10 years of experience in a global CMC regulatory affairs position with expertise in biologics and deep experience in product lifecycle management from Phase 1 through commercial and post-approval.
* Expertise in commercial product lifecycle as well as Phase 1-3.
* Prior success in filing marketing applications, supplements, and variations for biologic products within timelines is required, global submission experience desired.
* A good understanding or IND, CTA, BLA and MAA processes.
* Strong knowledge of US and international GMP quality regulations, current industry practices, and experience with interpretation and application to development projects and marketed product regulatory issues.
* Demonstrated experience in effective collaboration with multiple stakeholders both internally and externally including FDA and other Health Authorities.
* Demonstrated ability to coach, train and mentor teams.
* Strong negotiating skills and ability to think creatively and develop creative solutions.
* Ability to prioritize and handle multiple projects simultaneously.

Education Required: 10 years + BS/BA Biochemistry, Biology, or Pharmaceutical Science; Or Advanced degree with 7+ years preferred.

Computer Skills: Strong PC literacy required; MSOffice skills (Outlook, Word, Excel, PowerPoint)

Travel for Work: Must be willing to travel approximately 10-20%

Competencies:

Ethics - Treats people with respect; Inspires the trust of others; Works with integrity and ethically in accordance with BeiGene’s Code of Business Conduct and Ethics, policies and procedures.
Planning/Organizing - Prioritizes and plans work activities; Uses time efficiently; Completes administrative tasks correctly and on time; Follows instructions and responds to management direction.

Communication - Listens and gets clarification; Responds well to questions; Speaks clearly and persuasively in positive or negative situations; Writes clearly and informatively; Able to read and interpret written information.

Teamwork - Balances team and individual responsibilities; Gives and welcomes feedback; Contributes to building a positive team spirit; Puts success of team above own interests; Supports everyone's efforts to succeed; Contributes to building a positive team spirit; Shares expertise with others.

Adaptability – Able to adapt to changes in the work environment; Manages competing demands; Changes approach or method to best fit the situation; Able to deal with frequent change, delays, or unexpected events.

Technical Skills - Assesses own strengths and development areas; Pursues training and opportunities for growth; Strives to continuously build knowledge and skills; Shares expertise with others.

Dependability - Follows instructions and responds to management direction; Takes responsibility for own actions; Keeps commitments; Commits to long hours of work when necessary to reach goals; Completes tasks on time or notifies appropriate person with an alternate plan.
Quality - Demonstrates accuracy and thoroughness; Looks for ways to improve and promote quality; Applies feedback to improve performance; Monitors own work to ensure quality.

Analytical - Synthesizes complex or diverse information; Collects and researches data; Uses intuition and experience to complement data.

Problem Solving - Identifies and resolves problems in a timely manner; Gathers and analyzes information skillfully.

Project Management - Communicates changes and progress; Completes projects on time and within budget.

Salary Range: $139,000.00 - $189,000.00 annually

BeiGene is committed to fair and equitable compensation practices. Actual compensation packages are determined by several factors that are unique to each candidate, including but not limited to job-related skills, depth of experience, certifications, relevant education or training, and specific work location. Packages may vary by location due to differences in the cost of labor. The recruiter can share more about the specific salary range for a preferred location during the hiring process.  Please note that the listed range reflects the base salary or hourly range only. Non-Commercial roles are eligible to participate in the annual bonus plan, and Commercial roles are eligible to participate in an incentive compensation plan. All Company employees have the opportunity to own shares of BeiGene Ltd. stock because all employees are eligible for discretionary equity awards and to voluntarily participate in the Employee Stock Purchase Plan. The Company has a comprehensive benefits package that includes Medical, Dental, Vision, 401(k), FSA/HSA, Life Insurance, Paid Time Off, and Wellness.

We are proud to be an equal opportunity employer and we value diversity. BeiGene does not discriminate on the basis of race, religion, color, sex, gender identity, sexual orientation, age, disability, national origin, veteran status or any other basis covered by appropriate law. All employment is decided on the basis of qualifications, merit, and business need.

**Director, Regulatory Affairs, CMC**

* **R14497**

* We value our talented employees and support their professional development. If you see a position that interests you we encourage you to apply!

**Position Summary:**

The Director, Regulatory Affairs CMC, is responsible for developing, leading, and implementing global regulatory CMC strategies to secure and maintain market access for assigned product(s) in line with business objectives, and in coordination with key internal stakeholders.  This position will lead and manage regulatory CMC aspects of BeiGene’s biological products through all phases of development, post-approval, and life-cycle of the product depending on assigned products.  Primary responsibilities will be in creating CMC regulatory strategies for development programs in preparation and maintenance of regulatory applications.

**Essential Functions of the Job:**

* + Serve as the regulatory CMC representative on project teams.  Provides CMC regulatory support and guidance for assigned projects and interfaces with R&D, Project Management, Manufacturing, Quality, and Regulatory colleagues, as well as third party laboratories, global collaborations partners and contract manufacturers.
	+ Manage interactions with FDA and other global regulatory authorities for assigned project(s) to ensure acceptance, rapid review and approval of marketing applications, supplements/variations, clinical trial applications and other submissions which present CMC information.
	+ Develop and implement effective regulatory CMC strategies for global submissions knowing the life cycle of drug product from R&D through commercialization and interpret and apply local regulations and guidance to the life cycle of a drug product.
	+ Manage/prepare CMC document packages for regulatory submissions in support of development programs. This includes initial submission of INDs, CTAs and amendments to Health Authorities (HAs), and preparation of responses to questions from HAs balancing HA requirements and corporate objectives.
	+ Manage timelines in cooperation with Project Management on assigned projects.
	+ Review technical reports and CMC sections of IND, CTA, BLA, MAA, and other global submissions to support clinical trials and marketing applications, and their amendments in conformance with regulatory requirements, strategies and commitments.
	+ Work with regulatory CROs to identify regional/country-specific CMC requirements to support global applications.
	+ Evaluate proposed manufacturing changes for global impact to ongoing and existing filings, and provide strategic regulatory guidance for optimal implementation of changes.
	+ Actively participate as a member of global regulatory teams and CMC subteams.
	+ Support and manage regulatory aspects of CMC Operations including authoring, reviewing and and/or approving SOP’s, CAPA’s, etc.
	+ Maintain knowledge of global competitive landscape, regulatory environment, regulations and CMC guidance, providing interpretation to internal stakeholders and initiating process improvements as appropriate.

**Qualifications:**

* + Minimum 10 years of experience in a global CMC regulatory affairs position with expertise in biologics and deep experience in product lifecycle management from Phase 1 through commercial and post-approval.
	+ Expertise in commercial product lifecycle as well as Phase 1-3.
	+ Prior success in filing marketing applications, supplements, and variations for biologic products within timelines is required, global submission experience desired.
	+ A good understanding or IND, CTA, BLA and MAA processes.
	+ Strong knowledge of US and international GMP quality regulations, current industry practices, and experience with interpretation and application to development projects and marketed product regulatory issues.
	+ Demonstrated experience in effective collaboration with multiple stakeholders both internally and externally including FDA and other Health Authorities.
	+ Demonstrated ability to coach, train and mentor teams.
	+ Strong negotiating skills and ability to think creatively and develop creative solutions.
	+ Ability to prioritize and handle multiple projects simultaneously.

**Education Required:**10 years + BS/BA Biochemistry, Biology, or Pharmaceutical Science; Or Advanced degree with 7+ years preferred.

**Computer Skills:** Strong PC literacy required; MSOffice skills (Outlook, Word, Excel, PowerPoint)

**Travel for Work:**Must be willing to travel approximately 10-20%

**Competencies:**

**Ethics -** Treats people with respect; Inspires the trust of others; Works with integrity and ethically in accordance with BeiGene’s Code of Business Conduct and Ethics, policies and procedures.
**Planning/Organizing -** Prioritizes and plans work activities; Uses time efficiently; Completes administrative tasks correctly and on time; Follows instructions and responds to management direction.

**Communication -** Listens and gets clarification; Responds well to questions; Speaks clearly and persuasively in positive or negative situations; Writes clearly and informatively; Able to read and interpret written information.

**Teamwork -** Balances team and individual responsibilities; Gives and welcomes feedback; Contributes to building a positive team spirit; Puts success of team above own interests; Supports everyone's efforts to succeed; Contributes to building a positive team spirit; Shares expertise with others.

**Adaptability –** Able to adapt to changes in the work environment; Manages competing demands; Changes approach or method to best fit the situation; Able to deal with frequent change, delays, or unexpected events.

**Technical Skills -** Assesses own strengths and development areas; Pursues training and opportunities for growth; Strives to continuously build knowledge and skills; Shares expertise with others.

**Dependability -** Follows instructions and responds to management direction; Takes responsibility for own actions; Keeps commitments; Commits to long hours of work when necessary to reach goals; Completes tasks on time or notifies appropriate person with an alternate plan.
**Quality -** Demonstrates accuracy and thoroughness; Looks for ways to improve and promote quality; Applies feedback to improve performance; Monitors own work to ensure quality.

**Analytical -** Synthesizes complex or diverse information; Collects and researches data; Uses intuition and experience to complement data.

**Problem Solving -** Identifies and resolves problems in a timely manner; Gathers and analyzes information skillfully.

**Project Management -** Communicates changes and progress; Completes projects on time and within budget.

**Manager, Regulatory Affairs CMC**

**R16633**

* Apply

·                We value our talented employees and support their professional development. If you see a position that interests you we encourage you to apply!

**Position Summary:**

The Manager, Regulatory Affairs CMC, is responsible for developing and implementing global regulatory CMC strategies to secure and maintain market access for assigned product(s) in line with business objectives, and in coordination with key internal stakeholders. This position will manage regulatory CMC aspects of compounds (large molecules) through all phases of development, post-approval, and life cycle of the product depending on assigned products. Primary responsibilities will be in creating CMC regulatory strategies for development programs in preparation and maintenance of regulatory applications

**Essential Functions of the Job:**

* + Serve as the regulatory CMC representative on project teams. Provides CMC regulatory support and guidance for assigned projects and interfaces with R&D, Project Management, Manufacturing, Quality, and Regulatory colleagues, as well as third party laboratories, global collaborations partners and contract manufacturers.
	+ Manage interactions with FDA and other global regulatory authorities for assigned project(s) to ensure acceptance, rapid review and approval of marketing applications, supplements/variations, clinical trial applications and other submissions which present CMC information.
	+ Develop and implement effective regulatory CMC strategies for global submissions knowing the life cycle of drug product from R&D through commercialization and can interpret and apply local regulations and guidance’s to the life cycle of a drug product.
	+ Manage/prepare CMC document packages for regulatory submissions in support of development programs. This includes initial submission of INDs, CTAs, and amendments to Health Authorities (HAs), and preparation of responses to questions from HAs balancing HA requirements and corporate objectives.
	+ Manage timelines in cooperation with Project Management on assigned projects.
	+ Review technical reports and CMC sections of IND, CTA, BLA, MAA, and other global submissions to support clinical trials and marketing applications, and their amendments in conformance with regulatory requirements, strategies, and commitments.
	+ Work with regulatory CROs to identify regional/country-specific CMC requirements to support global applications.
	+ Evaluate proposed manufacturing changes for global impact to ongoing and existing filings and provide strategic regulatory guidance for optimal implementation of changes.
	+ Actively participate as a member of global regulatory teams and CMC subteams.
	+ Support and manages regulatory aspects of CMC Operations including authoring, reviewing and and/or approving SOP’s, CAPA’s, etc. •
	+ Maintain knowledge of global competitive landscape, regulatory environment, regulations, and CMC guidance, providing interpretation to internal stakeholders and initiating process improvements as appropriate.
	+ Other duties as assigned.

**Core Competencies, Knowledge and Skill Requirements**

* + Expertise in development and commercial product lifecycle (Phase 1-3, Marketed products). •
	+ Prior success in filing marketing applications, supplements, and variations for biologic products within timelines is required, global submission experience desired.
	+ A good understanding or IND, CTA, BLA and MAA processes.
	+ Strong knowledge of US and international GMP quality regulations, current industry practices, and experience with interpretation and application to development projects and marketed product regulatory issues.
	+ Demonstrated experience in effective collaboration with multiple stakeholders both internally and externally including FDA and other Health Authorities.
	+ Demonstrated ability to coach, train and mentor teams.
	+ Strong negotiating skills and ability to think creatively and develop creative solutions.
	+ Ability to prioritize and handle multiple projects simultaneously.

**Communication & Interpersonal Skills** •

* + Excellent interpersonal, oral, and written communication skills as well as strong organizational skills with demonstrated ability to manage and adhere to timelines.
	+ Proven ability to build trust and respect within the organization.

**Significant Contacts**

* + Interacts with BeiGene employees and senior management.
	+ Interacts with external business partners and Regulatory Agencies.

**Qualifications:**

Bachelor of Science degree, in a related scientific discipline with 5 to 7+ years of experience. Masters with 4 to 5+ years of experience.

**Education Required:** Bachelor of Science degree, in a related scientific discipline with 5 to 7+ years of experience. Masters with 4 to 5+ years of experience.

**Computer Skills:** Strong PC literacy required; MS Office skills (Outlook, Word, Excel, PowerPoint), Veeva Data Management System

**Travel for Work:** Must be willing to travel approximately 10-25%

**Competencies:**

**Ethics -** Treats people with respect; Inspires the trust of others; Works with integrity and ethically in accordance with BeiGene’s Code of Business Conduct and Ethics, policies and procedures.
**Planning/Organizing -** Prioritizes and plans work activities; Uses time efficiently; Completes administrative tasks correctly and on time; Follows instructions and responds to management direction.

**Communication -** Listens and gets clarification; Responds well to questions; Speaks clearly and persuasively in positive or negative situations; Writes clearly and informatively; Able to read and interpret written information.

**Teamwork -** Balances team and individual responsibilities; Gives and welcomes feedback; Contributes to building a positive team spirit; Puts success of team above own interests; Supports everyone's efforts to succeed; Contributes to building a positive team spirit; Shares expertise with others.

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**Technical Skills -** Assesses own strengths and development areas; Pursues training and opportunities for growth; Strives to continuously build knowledge and skills; Shares expertise with others.

**Dependability -** Follows instructions and responds to management direction; Takes responsibility for own actions; Keeps commitments; Commits to long hours of work when necessary to reach goals; Completes tasks on time or notifies appropriate person with an alternate plan.
**Quality -** Demonstrates accuracy and thoroughness; Looks for ways to improve and promote quality; Applies feedback to improve performance; Monitors own work to ensure quality.

**Analytical -** Synthesizes complex or diverse information; Collects and researches data; Uses intuition and experience to complement data.

**Problem Solving -** Identifies and resolves problems in a timely manner; Gathers and analyzes information skillfully.

**Project Management -** Communicates changes and progress; Completes projects on time and within budget.

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We are proud to be an equal opportunity employer and we value diversity. BeiGene does not discriminate on the basis of race, religion, color, sex, gender identity, sexual orientation, age, disability, national origin, veteran status or any other basis covered by appropriate law. All employment is decided on the basis of qualifications, merit, and business need.