Michael Page www.michaelpage.co.jp

CMC RA Manager at Top Global Pharma

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Job Information

Recruiter
Michael Page

Job ID
1561057

Industry
Pharmaceutical

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
10 million yen ~ 15 million yen

Refreshed
October 8th, 2025 15:31

General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

Join a global pharmaceutical leader as a Regulatory Affairs CMC Manager in Japan. This role offers the opportunity to shape regulatory strategies, lead health authority interactions, and contribute to the development and lifecycle management of cutting-edge therapies.

Client Details

- A global pharmaceutical company with a diverse portfolio including small molecules, biologics, vaccines, and cell & gene therapies
- Offers exposure to the full product lifecycle, from early development to post-approval
- Encourages innovation and supports professional growth in a psychologically safe environment
- Strong presence in Japan with direct engagement with PMDA and MHLW
- Active in global regulatory policy and industry associations
- Committed to cross-functional collaboration across R&D, Manufacturing & Supply, and Regulatory Affairs
- Provides opportunities to contribute to global regulatory science and policy initiatives

Description

- Develop and implement innovative Japan regulatory CMC strategies for development and marketed products

- Lead regulatory interactions with PMDA/MHLW, including quality consultations and strategic negotiations
- Manage CMC change controls and regulatory impact assessments for post-marketed products
- Prepare and review high-quality regulatory CMC dossiers in collaboration with global and local teams
- Contribute to global regulatory strategy documents, ensuring alignment with Japan-specific requirements
- Support regulatory inspections (PAI) as a local GMP sub-team lead when required
- Monitor and interpret local and global regulatory guidelines and trends
- Participate in internal and external regulatory policy initiatives and industry associations
- Promote continuous improvement in dossier preparation processes
- Mentor and support team development where applicable

Job Offer

- Opportunity to lead regulatory strategy for innovative therapies
- Hybrid working style
- Exposure to a wide range of modalities and global regulatory frameworks
- Career development in a globally recognised pharmaceutical company
- Competitive compensation and benefits package

Page Group Japan is acting as an Employment Agency in relation to this vacancy.

Required Skills

- Bachelor's degree in a science or health-related field (advanced degree preferred)
- Minimum 3 years of direct Regulatory CMC experience (5+ years preferred)
- Experience in pharmaceutical CMC functions (e.g., QC, manufacturing) desirable
- Strong knowledge of Japan and global regulatory guidelines and dossier requirements
- Proven ability to manage strategic regulatory issues and engage with health authorities
- High fluency in English and Japanese (non-native level speakers will not be selected)
- Experience with regulatory authorities is a plus

Company Description

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