Michael Page www.michaelpage.co.jp

CMC RA Manager at Top Global Pharma

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募集職種

人材紹介会社
マイケル・ペイジ・インターナショナル・ジャパン株式会社

求人ID
1561057

業種
医薬品

雇用形態
正社員

勤務地
東京都 23区

給与
1000万円 ~ 1500万円

更新日
2025年10月08日 15:31

応募必要条件

キャリアレベル
中途経験者レベル

英語レベル
ビジネス会話レベル

日本語レベル
ネイティブ

最終学歴
大学卒： 学士号

現在のビザ
日本での就労許可が必要です

募集要項

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.

スキル・資格

- 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

会社説明

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