Head Regulatory Writing

Job ID
REQ-10025068
Oct 07, 2024
Japan

About the Role

Major Accountabilities

- Business and operational management of local RW.
- Manage quality, timeliness, efficiency and high scientific standards for written documents produced by the local RW; Clinical Study Reports (CSR), Common Technical Document submission documents (clinical overviews, summaries of clinical efficacy and safety), other documents for health authorities (e.g., Briefing Books, answers to questions, PMS and re-examination related documents).
- Act as documentation consultant to other line functions in GDD-J and more widely.
- Lead development of document templates, documentation-related processes and strategies by close interaction with global counterpart.
- Participate in priority setting, workload distribution and resource planning to ensure adequate assignment of writing resource to projects.
- Coordinate outsourcing of RMW activities by acting as liaison between internal vendor management and internal customers
- Contribute to the development of the RW organization through interactions within management team and across functional areas.
- Recruit talent, manage performance (set objectives, review performance and plan compensation).
- Identify training needs to foster high level of performance within RWS. Coach/mentor and/or train less experienced writers.
- Maintain audit, SOP and training compliance.
- Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures.
- 100% timely delivery of all training requirements including compliance.

Key Performance Indicators

- Delivery of high quality clinical and safety documents in time and in compliance with internal and external standards, according to RWS metrics.
- Completion of an adequate volume of work (taking into account complexity) per year in accordance with the Key Performance Indicators.

Job Dimensions

Number of associates:

- Can act as operational and functional manager (head) for Regulatory Writing
- Indirect: matrix management of cross-functional teams.

Financial responsibility:

- Internal costs in RW and external costs for project related activities in documentation area

Impact on the organization:

- Timely preparation of high quality clinical documents supporting pharma/oncology registrations.
- Contributor to cross-functional process improvement.

Ideal Background

Education:

- Minimum university life science degree or equivalent is required. Advanced degree or equivalent education/degree in life sciences/healthcare is desirable.

Languages:

- Fluent Japanese/English (oral and written).

Experience / Professional Requirement:

- ≥ 8 years medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus expert knowledge of medical writing processes.
- Expert knowledge of global regulatory environment and process (key regulatory bodies, key documents, approval processes).
- Expert knowledge, extensive experience, and demonstrated record of accomplishment in Japan local registering of drugs.
- Excellent communication skills (written, verbal, presentations)
- Expert knowledge of biostatistics principles.
- Proven ability to prioritize and manage multiple demands and projects.
- Demonstrated ability to define and solve complex problems (“Problem-solver”)
- Broad knowledge and future oriented perspective
- Proven ability to drive and manage organizational and team performance across cultures.
- Proven track record in matrix environment
- Repeat experience in managing global, cross-functional teams or complex Japan projects.
- Demonstrated ability to motivate and coach people.

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We believe the answers are found when curious, courageous and collaborative people like you are brought together in an inspiring environment. Where you’re given opportunities to explore the power of digital and data. Where you’re empowered to risk failure by taking smart risks, and where you’re surrounded by people who share your determination to tackle the world’s toughest medical challenges.

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Role Requirements

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Business Unit
Innovative Medicines
Location
Japan
Site
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Company / Legal Entity
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Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Job ID
REQ-10025068

Head Regulatory Writing

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