BS Wutow GmbH
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CTA Regulatory Affairs Manager (m/w/d)

Your future employer is a successful life sciences company worlwide. With over 100,000 employees, this global group is specialized in the research and development, manufacturing and marketing of pharmaceutical products in the prescription market.

For this very international and high-quality oriented Client, we are looking for in Berlin:

CTA Regulatory Affairs Manager (m/w/d)

Ihr zukünftiger Verantwortungsbereich:

- Follow-up sending, submission and approval of CTA package with affiliate (GRA affiliates, or partners, as appropriate)
- Contribute to preparation of HA meeting, if any (e.g. consultation of HA for discussion on a protocol)
- Manages CTAs activities related SOPs (ie. Coordinates the creation, updates of the QDs)
- Identify any issues and propose resolution
- Provide support to Development Safety Update Report (DSUR) distribution preparation and assure the appropriate tracking of submissions for all entities
- Contribute to set up of new processes for new regulations implementation (e.g. New EU Clinical Trial Regulation, EU Clinical Data Disclosure)
- Build expertise in databases use (e.g. VEEVA Registrations Tracking), use communication tools (e.g. sharepoint I-connect to communicate within Corporate and affiliates)
- VEEVA RIM Expert User GRA: o Coordinate all user activities regarding the tracking of regulatory events in relation with clinical trials & all global and local disclosure activities
- Act as GRA window person for interactions with the Solution Leader, Solution Specialists, the other

Expert Users. o Quality Control (QC) VEEVA RT information content: Improve data quality
- Establish and maintain effective interfaces & communication with the VEEVA-RT user community/any other internal function to support achievement of GRA productivity goals
- Metrics: Provide the VEEVA-RT user community with meaningful metrics on various VEEVA-RT related topics

Das zeichnet Sie aus:

- Minimum of 3-5 years in the pharmaceutical industry. Demonstrated experiences in international regulatory affairs or in clinical development
- Problem-Solving Skills: Applies critical thinking to consider ways to solve a problem. Make rational judgments from available information and analysis. Understand the factors that adversely impact the preparation of CTAs, worldwide and propose mitigation solutions accordingly
- Project Management Skills: Responsible for the success of the CTAs preparation, submission and life cycle management, and operational aspects of ongoing clinical trials to ensure meeting all required timelines as well as adherence of quality and performance expectations. Ability to work with multifunctional and multicultural teams
- Strong leadership Skills: Take responsibility for decisions and accept accountability for results. Set a clear and persuasive direction, while communicating timelines and project goals with clarity. Act in a proactive, positive, and responsive manner to customer needs. Build good working strong relationships and act as a role model and change agent for the CTA coordination team. Form strong stakeholder management
- Risk Management: Ability to anticipate and mitigate risks/issues related to the CTA E2E process. Connect and anticipate the evolution of the internal and external environment and adapt processes as appropriate.
- Strong command of the English language, both spoken and written. Ability to communicate effectively and efficiently with other functional departments
- Education: Physician, Pharmacist or Life Sciences Degree Comprehensive knowledge and operational expertise in clinical trials regulation

Es erwartet Sie:
Gerne stehen wir Ihnen unter Angabe der folgenden Referenznummer für Rückfragen zur Verfügung.

Referenz-Nummer: 20263A29687

Ihr Kontakt:

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Wutow
Finding Competence