Genentech
A Member of the Roche Group

Date: 10/21/19

Process and Compliance Lead

Job ID: 201909-127792

Job Function
Quality Compliance & Audit

Location
Basel
Basel-City
Switzerland

Schedule
Full time

Job type
Regular

Company/Division
Pharmaceuticals

Job Level

The Position

At Roche, we believe it's urgent to deliver medical solutions right now – even as we develop innovations for the future. We are passionate about transforming patients' lives and we are ambitious in both decision and action. And we believe that good business means a better world. That is why we come to work every single day. We commit ourselves to scientific rigour, unassailable ethics, and access to medical innovations for all. We do this today to build a better tomorrow.

As a senior member of the team, you will be joining a transforming team driving transformation into the business. With the introduction of content reuse and automation (CR&A), you are willing to challenge the status quo to shape the future of medical writing at Roche. You embrace customer-centricity to prepare, introduce and embed the new way to create content that forms the regulatory submissions transforming patients' lives. We would like to diversify our skills in the team, so we welcome individuals with agile mindset, who may be IT savvy, has knowledge of structured content management, or have knowledge of LEAN methodology to join our team.

The jobholder will collaborate closely with senior stakeholders across the business, including senior members from other functions that contribute to the delivery of content, Global Process Owners and Business Process Owners, the QPPV and members of working groups and governance bodies. This is an influential role in sustainment of capabilities, continuous improvement and ongoing process innovation in the regulatory content management arena at Roche.

Primary Responsibilities and Accountabilities:

- Lead design, development, maintenance, support, and continuous improvement of PDRD processes/capabilities, ensuring that they deliver high quality and timely regulatory documentation in line with evolving regulatory authority and internal

stakeholder requirements.
- Working in close partnership with subject matter experts (SMEs) in PDRD and broader organisation, accountable Global Process Owners and Business Process Owners. Serving as the principal SME for the assigned area(s) of process as required.
- Maintaining awareness of external trends and anticipating future requirements or opportunities.
- Identifying, sharing, and promoting good practice and innovation, both with regard to the assigned process(es) and the utilisation of process improvement methodologies: Providing guidance to ensure process continuity, consistency and alignment.
- Potentially serving as a Global Process Owner and/or Business Process Owner for one or more assigned process(es).
- Building and strengthening relationships within Roche (e.g. within PDR, with PDS sub-functions, other PD Functions, REDs, GPS, Affiliates and working groups) and with Roche partners
- Collaboration and close interface with internal policy governance bodies/stakeholders (e.g., EU QPPV, Drug Safety Committee, GCP and GVP Council, quality network etc.) in adapting PDRD processes in line with evolving Regulatory Authority requirements and business needs.
- Providing input/leadership into activities designed to promote continuous improvement, and gather broad organisational input to potential process improvements and ideas or opportunities for further innovation.
- Providing input/leadership to project prioritisation and capacity management activities.
- Ensuring critical process requirements are defined as an input to the development of associated tools and technologies, in partnership with internal and external informatics and IT system roles and providers, where relevant.
- Responsible for providing relevant input to the communication, training, implementation, follow-up and feedback, relating to assigned processes.
- Promoting a culture of continuous process improvement, innovation and a solution-orientated mind set.
- Networking with internal and external groups to understanding their needs and ideas; identifying and anticipating solutions and working collaboratively to find solutions
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Education/Qualifications:

- BSc or equivalent in relevant scientific discipline
- Relevant experience in GVP and/or GCP-related role (typically 5+ years of experience)

Experience, Skills, Knowledge

- Good knowledge of regulatory documents to develop and maintain licenses and a broad understanding of pharmaceutical drug development
- Good knowledge of regulatory GVP and GCP requirements and guidelines specific to the regulatory documents published by the major global Health Authorities (e.g. FDA, EMA, MHRA, etc.)
- Strong interpersonal and communication skills in a global environment
- Experience of influencing broad groups of stakeholders, adopting a range of influencing styles and/or communication techniques, and negotiating at various levels/matrix environment to achieve expected outcomesAbility to operate effectively in, and lead as needed, multi-functional matrix teams
- Excellent written and verbal communication skills (must be fluent in English) and the ability to present and critically discuss data in relation to its significance and impact on the processes in both internal and external discussions.

- Planning, Co-ordination and Organisation: possesses excellent organisational and project planning skills
- Excellent attention to detail and commitment to deliver high quality
- Prior experience in project management and/or process improvement is desirable
- Ability to meet tight deadlines and to work concurrently on several projects

Locations: We are hiring several people. This role can be based either in Basel, Welwyn, South San Francisco or Mississauga

Applications: Ideally, please specify at the beginning of your cover letter your preferred location

Roche embraces diversity and equal opportunity in a serious way. We are committed to building teams that represents a range of backgrounds, perspectives, and skills. The more inclusive we are, the better our work will be.

If you still have questions then please check our FAQs and videos on careers.roche.ch/faq.

Roche is an equal opportunity employer.

Who We Are

A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 40 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. Genentech has multiple therapies on the market for cancer & other serious illnesses. Please take this opportunity to learn about Genentech where we believe that our employees are our most important asset & are dedicated to remaining a great place to work.

Genentech is an equal opportunity employer & prohibits unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital & veteran status. For more information about equal employment opportunity, visit our Genentech Careers page.