Change Control Administrator

Pfizer is the world's premier biopharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for people. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

JOB INFORMATION

- To allow Pfizer to legally study, manufacture, market and supply medicines by obtaining, managing and maintaining product Marketing Authorisations in line with business goals and legal requirements.
- Under the guidance and supervision of line management, to conduct associated regulatory activities for the Belux markets and to contribute to the implementation and leading of national/regional/global projects within regulatory, as well as cross-functionally and cross-divisionally and building of expertise within the Regulatory Department, Global Regulatory Affairs-International and Global Product Development, striving for continuous improvement of regulatory processes.
- Actively contribute or lead projects to support internal and external stakeholders. Take initiative for timely and proper completion in order to meet regulatory requirements, internal standards and procedures and ensure full compliance, working under minimal supervision.

JOB RESPONSIBILITIES

- Ensure the accurate and timely maintenance of product information systems and databases, in line with local and global SOPs and procedures and with all applicable regulatory and legal rules and regulations, for the PBG (Pfizer Biopharmaceutical Group) portfolio.
- Support the delivery of change control processes linked to regulatory databases/systems and ensure timely notifications to stakeholders.
- Provide expertise to the team in operational processes and regulatory databases and systems, contribute to the implementation of projects and processes, contribute to building of processes and database/systems within the team and in global teams and projects.
- Add value to the business and ensure full compliance for the GRA-I Regulatory Affairs team by providing logistic and administrative support to the Belux PGB Regulatory Affairs Team under supervision of the Head of Regulatory Affairs and/or the Team Leader, by contributing to the preparation, follow-up, processing, implementation and electronic archiving of all regulatory submissions and activities, in order to meet regulatory requirements, internal standards and procedures and optimize the achievement of the global objectives.
- Collaborate with GRRS (Global Registration and Renewal Support) and manage all requests for export certifications and declarations from non-EU markets by providing timely and accurately required ancillary documents. Apply for Certificates of a Pharmaceutical Products (CPPs) at the Belgian and Dutch Health Authorities, and provide these to the requesting country responsible, as required.

Regulatory submissions and approvals – databases and systems:

- Provide administrative support as applicable for local regulatory submissions in collaboration with the Regulatory Affairs Team Leader, Executives and Associates. Support the process, coordinate and contribute to the preparation and assembly of documentation and dossiers for the assigned marketing authorization applications and maintenance activities where needed. Prepare "ready for submission" dossiers independently, as appropriate and in agreement with the concerned Regulatory strategist.
- Screen incoming correspondence from the Agency or other external and internal stakeholders and take appropriate action, and/or liaise with the concerned Regulatory colleague to ensure proper action is taken.
- Finalize approved inserts and create market versions of inserts and upload them on the appropriate internal systems for consultation by the internal stakeholders
- Ensure complete, correct, and timely notification of labeling, CMC and other approvals by the Belgian and/or Luxemburg/and or Dutch Health Authorities to the local and/or global internal stakeholders.
- Ensure that all local and global systems, tracking tools and databases are continuously and accurately updated with regulatory information, in line with Pfizer local, regional and global procedures and with legal /regulatory requirements. Develop processes for and coordinate routine and ad hoc QC checking of regulatory databases and systems and build expertise through management of operational processes and regulatory databases/systems.
- In compliance with applicable local and corporate SOPs and best practices, manage and complete all regulatory systems in collaboration with Regulatory Affairs colleagues, by checking events, key license details and labelling.
- Act as super-user and system owner for defined regulatory databases/systems, and manage business activities for assigned regulatory system development projects on behalf of the Belux Regulatory team. Provide expertise to local and global teams in operational processes and regulatory databases and systems, and contribute to or take the lead in projects and workgroups on developing, building, implementing and optimizing processes and database/systems.
- Liaise pro-actively with global and regional groups and/or project leads to ensure that the PCO Belux needs are adequately represented when new initiatives impacting regulatory operations and/or databases are being developed and rolled-out for the region, or when needs for enhancement of existing systems is identified.

Manage requests from emerging markets for certificates of a Pharmaceutical Product (CPP) and ancillary documents:

- Receive and handle requests and prepare regulatory submissions for application of CPPs. Follow-up receipt of Health Authority approval and negotiate where needed. Build up a network with the Health Authority members and provide input on the process in the concerned workgroup at the Trade Association.
- Manage process for apostils, notarization and legalization of documents by Embassies.
- Manage requests for ancillary documents and negotiate on content and format with requesting country and the Global Support Team to comply with local approvals, and ensure sign off by appropriate function within the Benelux team.

Artwork responsibilities:

- Coordinate artwork initiation, changes and follow-up for all packaging components for new and marketed products through the appropriate Global Artwork management systems and interact with the above-country hub for Artwork Implementation as required
- Discuss and define artwork needs in coordination with the Regulatory team members, and ensure the above-country hub for Artwork Implementation and/or plant are aware of the legal timelines for implementation and the local needs and requirements
- Pro-actively prepare Artwork Requests and Editor Copies as required, according to Pfizer procedures in coordination with the concerned Regulatory Affairs colleague(s), Logistics, and the manufacturing plants, and ensure appropriate QC has been performed.
- Maintain regular contacts with the above-country hub for Artwork Implementation and inform Regulatory colleagues on any potential impact on label text, artwork and/or product availability.
- In conjunction with the Regulatory Affairs Head, Team Leaders, Executives and/or Associates, ensure the artworks are in compliance with current local legislation and Pfizer local/international policies on packaging
- Coordinate requests from regulatory team members for submissions artworks (mock-ups) as needed to ensure timely and complete regulatory submission
- Maintain the internal network on artwork development and approval
- Participate and implement the strategic decision related to the packaging development for new and marketed products in cooperation with Regulatory Affairs, the concerned BU and the local Logistics department, as well as Medical and Market Access/Health & Valu, if applicable
- Ensure that the local artwork database is continuously and accurately updated to be available for the local Affiliate Quality group and Regulatory team, and that local and global tracking systems are accurately and timely updated.
- Ensure that Country Requirements sheets for artwork centres are kept up to date in the global system
- Actively participate to EU Support SME Meeting (ALIM) bi-monthly
- Actively participate to Community of Practise monthly meeting

General administrative work:

- Provide support and back-up to executive assistant for administrative tasks as needed, including financial activities/systems, contracts, logistics, organizing meetings and traveling, uploading expenses, keeping minutes of meetings.
- Maintain and update organisation charts and product responsibility lists as needed, and inform stakeholders as appropriate, including submission to the global repository
- Ensure logistics for onboarding of new colleagues or contractors and act as delegate in the GIDM system for upload and renewal of contractors
- Ensure update of the RA team sharepoint

QUALIFICATIONS / SKILLS
Technical Skill Requirements

- Computer literacy: good knowledge on use of MS Word, Excel, PowerPoint, Outlook. Experience in using electronic document management systems and other electronic/digital tools.
- Languages: Fluent in written and spoken Dutch, French and English; notions of German are an asset
- Ability to communicate effectively verbally and in writing.
- Accurate, organised and problem solving, able to meet concurring deadlines
- Basic Project Management Skills
- Compliance minded

Minimum level of education:

- Bachelor degree in Management/(Medical) Secretarial Assistant, Life Sciences or equivalent, with relevant experience in Regulatory Affairs.

Functional / Professional Competencies Specific to the job:

- Autonomous but with a strong team spirit,
- Service-minded, keen sense of initiative, accountable
- Strong administrative orientation
- Strong organizational skills, multiple projects flexibility; very good time management
- Accurate and detail oriented, precise in oral and written communication
- Very good resistance to stress and a high workload.

Experience:

- Preferably 5 years of experience in the field of administration, secretarial work or office management, with previous experience and proven track record in a Regulatory Affairs environment (for Human Medicinal Products)

Pfizer is an equal opportunity employer and complies with all applicable equal employment opportunity legislation in each jurisdiction in which it operates.

APPLY HERE!