Job Description

Job title: **Regulatory Affairs Manager – Food supplements**

Location: Holborn, London

Reports to: Director of Regulatory Affairs

Updated: November 2024

Overall Accountability:

- Supports the Director of Regulatory Affairs (DRA) on all matters relating to products in scope of PAGB
- Supports the development and delivery of PAGB's strategy for medicines, medical devices and food supplements
- Responsible for own day to day management and prioritisation, including taking initiative and finding solutions where required
- Attends meetings independently with relevant stakeholders and forges and maintains relationships with PAGB members, government organisations and other trade associations
- Supports broadly across the product portfolio in the regulatory department, learning and understanding the wider regulations for all categories in PAGB, whilst maintaining specialisation in Food Supplements
- Providing day to day member support relating to medicines, medical devices and food supplements
- Manages relevant PAGB working groups and subgroups
- Involvement in wider cross-functional PAGB projects including ad hoc projects as they arise

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Key Areas of Responsibility:

2. <u>Regulatory and Technical</u>

- Support both the development and roll out of agreed PAGB strategies
- Independently support the provision of regulatory advice, information and analysis on UK and international issues, current and forthcoming EU and UK regulations and guidelines affecting all products within scope of PAGB membership
- Specialise in key product area to become key point of contact for member companies in that area, whilst widening knowledge and providing support in other regulatory product categories within the PAGB portfolio
- Support the DRA in monitoring live issues and potential issues for the OTC sector and assist in the delivery of resulting PAGB work programmes
- Ensure the delivery of reports and updates for member companies to inform them of issues which impact their business
- Liaison with senior regulatory team members and stakeholders in companies
- Manage agreed PAGB working groups

- As required, provide technical input on behalf of PAGB on ingredient challenges and safety issues relating to all products in scope of PAGB membership
- Manage, monitor, analyse and respond to consultations and proposals on regulatory matters in appropriate area of specialisation to ensure that the views of PAGB members are promoted
- Provide advice to members relating to New Product Development initiatives, including but not limited to reclassification, product classification, compliance to regulations, borderline issues
- Provide technical input to codes and guidelines as they are reviewed
- Manage the development of position papers on relevant topics as required
- Liaise as appropriate with other trade associations, including European Self Care Industry association AESGP, attending relevant working group meetings as required
- Present PAGB views to regulatory bodies independently
- Responsibility for ad hoc projects as required
- Learn and gain an understanding in regulatory affairs arena via on-the-job projects and experiences, as well as mentorship
- Gain a general understanding and keep abreast of ongoing work and issues within the PAGB regulatory team in all the product areas
- Deputise for other members of the Regulatory affairs team as appropriate
- Monitor relevant regulatory inbox as per agreed schedule

3 Policy

- Support the DRA with development and implementation of PAGB policy positions on regulatory issues which impact members
- Draft and/or contribute to the development of consultation responses and submissions to Government and other stakeholders as required
- Support DRA with regulatory policy development. Help support and organise PAGB representation in discussions with relevant government departments, regulators, self-regulatory bodies and trade associations at UK and EU level as part of a stakeholder engagement programme. Deputise for DRA in these discussions as required
- Represent PAGB on AESGP's Committees
- Represent PAGB in discussions with other AESGP associations to collaborate on regulatory issues of common concern

4. Training

- Develop regulatory training modules as required
- Support the development of PAGB training events and seminars
- Conduct training modules as appropriate as appropriate

5. Media, Communications and External Relations

- Develop and maintain links with government and competent authorities such as the MHRA, FSA, DHSC, DEFRA
- Collation of data from members for submission to MHRA and other stakeholders
- Develop and maintain links with other trade associations (e.g. AESGP) including representing the PAGB at meetings with external stakeholders – both national and international

- Provide technical input into media statements, press releases and research papers
- Oversee the monitoring and reporting on regulatory and marketing issues and update members via mailings, presentations and PAGB publications e.g. Regulatory Intelligence, This Week and Spotlight

6. **General**

- Involvement in wider cross functional working groups and projects across PAGB
- Manage additional regulatory and scientific support including outside agencies
- Promote PAGB's services to existing members and to be an advocate of PAGB to potential new members
- Deputise for DRA in their absence
- Undertake any task that may be reasonably requested by the DRA or PAGB

Qualifications and Experience

- Educated to degree level in relevant science-based subject
- At least 4 years significant regulatory experience in the OTC / Food Supplement industry
- Good understanding of the regulatory and pharmaceutical environment. Having commercial and strategic awareness
- Experience in multiple OTC product categories
- Significant experience in regulatory affairs, preferably in the consumer health sector including understand impact of regulatory change on product portfolio and supply
- Regulatory knowledge of medical device certification preferable
- Project management
- Proven successful interaction with the Regulatory Authorities
- Experience of authoring, implementation and training of internal processes

Profile and Skills

- Able to motivate a team and support them through change
- Able to analyse complex data to determine the key facts and to be able to communicate these at the right level for the audience
- Problem solving skills, methodical, pragmatic, logical with technical aptitude
- Good organisation, planning, able to prioritise
- Can work under pressure to achieve deadlines
- Effective communication and report writing skills
- Proven negotiation skills
- Strong Word, Excel, Adobe and PowerPoint skills