Global Nominated Signatory Leader

Cambridge, UK

Competitive Salary and Benefits

https://astrazeneca.wd3.myworkdayjobs.com/Careers/job/UK---Cambridge/Global-Nominated-Signatory-Leader_R-121549-1

At AstraZeneca, we work together across global boundaries to make an impact and find answers to challenges. We do this with the upmost integrity even in the most difficult situations because we are committed to doing the right thing!
This role is responsible for the following; apply medical governance within the designated therapeutic area and drive excellence through focus on medical quality and standards, guiding marketing and medical activities to be undertaken in a compliant and ethical manner. Provide training for medical teams and nominated signatories according to business need. Advising on, reviewing and approving materials and events crafted and produced by Global Brand teams with respect to Company standards including the Global Policies on Ethical Interactions and providing information on our products as well as the regulatory requirements and applicable external codes including the IFPMA code

Accountabilities/Responsibilities:
Act as the AstraZeneca authority and leader on medical quality and standards for the allocated therapy area. This includes promotional claims acceptability (including avoiding off-label claims); interactions with healthcare professionals; cross border digital activities, medical ethical acceptability and other matters within the scope of the IFPMA Code of Pharmaceutical Marketing Practices.

- Lead the AZ approach and tone for medical standards within the designated therapy area. Ensure that the importance is recognised and coordinated into everyday business while avoiding unnecessary inhibitions to creativity and actively supporting innovation through deep understanding of the regulations.
- Support for Global, Regional & Marketing company Medical colleagues through training that drives high medical standards
- Supervise the application of relevant Global Medical policies and SOPs within the allocated therapy area
- Guide Marketing Company Nominated Signatories and others worldwide on medical standards for the allocated brands and therapy area activities
- Work with commercial, compliance, audit and legal functions to develop and implement company policy interpretation and mentorship on difficult and controversial compliance and ethics topics relevant to the therapeutic area
- Pro-actively and reactively work with the Marketing Company Nominated Signatories providing help and guidance on difficult approval issues relating to their allocated therapeutic areas.
- Support the Global Nominated Signatory Practice Director in knowledge sharing between Global, Regional and Marketing Company medical compliance functions, and other stakeholders, with respect to optimising brand messages and claims within the codes, regulatory and ethical constraints.

Biopharmaceutical Business Unit (BBU) & Oncology Business Unit (OBU) promotional activity, compliance and standards.

- Review and approve for distribution promotional and medical materials including brand strategy documents and promotional claims prepared by Global Brand teams within the allocated Therapeutic Area for compliance with AstraZeneca Global Policies and Standards, applicable codes, regulatory requirements and ethical acceptability.
- Act as a final signatory for items and activities that do not undergo local approval including above country digital activities and global press releases.

Global Therapeutic Area medical standards leadership

- Sets standards for promotional claims and non-promotional product information sharing; ensuring AstraZeneca's promotion and communications adhere to regulations and support appropriate use of our medicines in patients as well as driving business goals.
- Advise global brand teams on development activities including brand strategy, target product profiles and target product claims with respect to medical standards including draft positioning and claims provability. Strive to optimise innovation while interpreting the ethical and regulatory requirements.
- Provide training according to business need for Global, Regional & Marketing Company Medical teams to drive quality & high standards
- Drive continuous quality improvement of Global Brand team outputs by providing consultation and feedback to Brand Teams during concept creation and throughout design and development process whilst ensuring consistency of approval decision-making. Lead projects/activities relating to standards, covering brand claims supportability, avoiding off-label claims, distinguishing advertising from non-promotional communications, accuracy of promotional and non-promotional medical and product materials. Co-ordinate dissemination of claims updates following challenges to global product claims & support local teams with challenges to competitor labels
- Identify future compliance and quality risks from commercial and promotional innovation within the Therapeutic Area and collaborate with the Medical Quality & Standards Practice Director in creating effective and practical medical quality policies and standards to ensure continued commercial success in a compliant and ethical manner.
- Providing support for marketing company nominated signatories by answering medicines promotions queries and sharing code cases as well as reviewing new product launch messages developed by global that support the promotional activities of brands planned for launch

Minimum Requirements – Education and Experience, Functional & Business knowledge, Specialist Skills

- Advanced bioscience or pharmacy/medical qualification with experience of the pharmaceutical industry including medical affairs and compliance
- Good scientific understanding of the allocated therapeutic area, previous oncology or virology experience is highly preferred.
- Sound knowledge of international medical compliance legislation, codes of practice and their practical application
- Knowledge and experience of corporate governance are desirable
- Knowledge and understanding of the pharmaceutical industry 'political' environment and of AstraZeneca as an important and leading player
- Experience of successful cross functional and worldwide influencing

Skills and Capabilities

- High ethical standards. An understanding of ethical decision-making processes and an ability to discuss ethical and regulatory issues with credibility and authority.

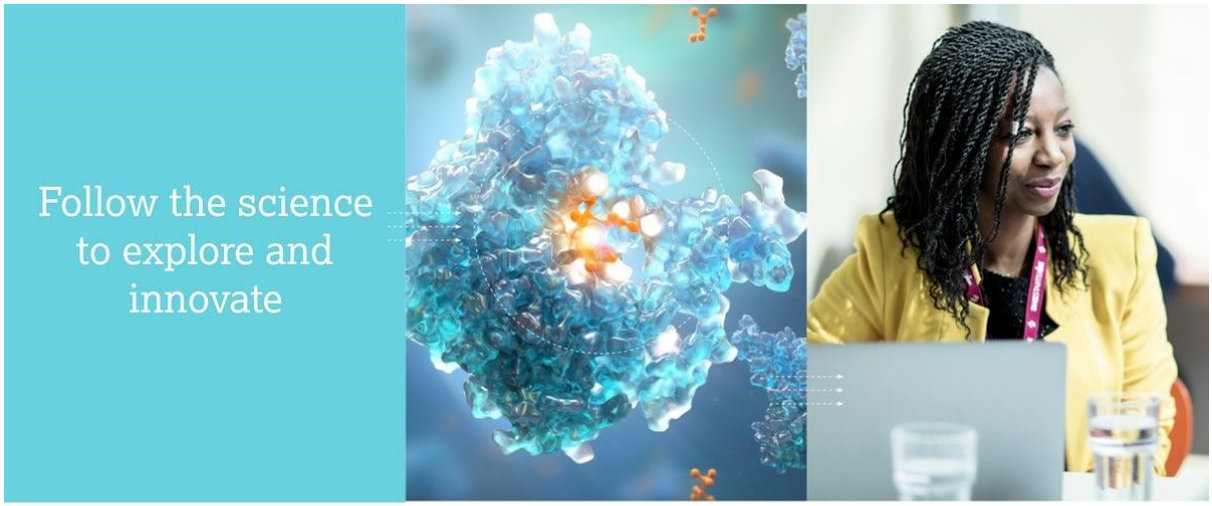
- Innovative and creative approach to sophisticated problem solving and confidence to make decisions when there is no certain right or wrong answer.
- Manages Multiple Customer Needs: individual represents the needs of multiple customers in AZ decision making and planning.
- Uses Deep Insight to Impact Broadly: individual is still thinking broadly, but also sees opportunities and develops solutions that impact beyond their role/function.
- Builds Transparency for Others to Make Decisions: individual crafts the climate for others to act decisively by clarifying roles and responsibilities and limits of decision-making.
- Anticipates and/or Removes Obstacles for Others: individual anticipates and removes obstacles so that teams/workgroups can deliver results and succeed.
- Creates Shared Purpose Across Boundaries: individual works across boundaries to establish common purpose and goals to deliver value to the business.
- Develops Others for the Long-Term: individual invests in the long-term development of others by agreeing challenging and relevant development opportunities to prepare them for future roles.
- Applies Long-Term Customer Insight: individual engages customers over time and is focused on future needs and challenges.
- Anticipates the Future: individual has a future oriented, long-term view due to the depth and breadth of insight. They develop plans that have impact across AZ and are based on what is likely to happen.
- Demonstrates Courage to Support Decisions: individual demonstrates courage in addressing the underlying issues that prevent effective decision-making.
- Addresses Blockers to Effective Collaboration: individual identifies and courageously addresses issues that may inhibit effective collaboration.
- Builds Organisational Capability: individual proactively facilitates cross-functional assignments/opportunities in and outside of their own area to develop broad capability for AZ.
- Effectively challenges the business and positions compliance appropriately to influence decisions: Adopts a solution-oriented approach and focuses on business enablement i.e. achievement of business goals whilst mitigating risks
- Ethics and compliance efficiency: Supports transition to a value based culture and uses feedback and external benchmarking to ensure continuous improvement of practices
- Leading compliance risk: Anticipates future risks and works to innovate by sharing practices with colleagues

We are an equal opportunity employer and value diversity at our company. We do not discriminate on the basis of race, religion, colour, national origin, sex, gender, gender expression, sexual orientation, age, marital status, veteran status, or disability status. We will ensure that individuals with disabilities are provided reasonable accommodation to participate in the job application or interview process, to perform essential job functions, and to receive other benefits and privileges of employment. Please contact us to request accommodation.

So, what's next?
Are you already imagining yourself joining us? Good, because we can't wait to hear from you!

Additional information
Our Company Values & Behaviors underpin everything we do so please take a moment to familiarize yourself with them. You may also want to check out our new R&D Video showing how we turn Science into Medicines.

More information about our sites:
Cambridge, UK
Gothenburg, Sweden
Gaithersburg, US



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