



Global Nominated Signatory Leader  
Location: Cambridge (UK) or Gaithersburg (USA)

At AstraZeneca we win through science, it's at the heart of our every success. That science is only possible when we all work together – we'll always make sure you're clear about how your role is connected to our wider mission to really show what science can do.

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 designed 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.

### **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 AstraZeneca approach and tone for medical standards within the designated therapy area. Ensure that the importance is recognised and integrated 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 guidance 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 Medical Standards 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.
- Work with and manage relationships with the outsourced vendor so that internal colleagues see you as one seamless team.
- 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.
- Identify future compliance and quality risks from commercial and promotional innovation within the Therapeutic Area and collaborate with the Global Medical Standards Practice Director in creating effective and practical medical quality policies and standards to ensure continued commercial success in a compliant and ethical manner.
- 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.

### **Required Skills and Experience**

- 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.
- Sound knowledge of international medical compliance legislation, codes of practice and their practical application.
- Knowledge and experience of corporate governance.
- 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.
- Strong independence and credibility.
- Excellent communication and presentation skills.
- Strong strategic thinking ability.
- Strong analytical skills and ability to ascertain the relevant issues from large masses of information.

Applications open: 20th September 2018

Applications close: 18th October 2018

<https://job-search.astrazeneca.com/job/gaithersburg/global-nominated-signatory-leader/7684/8991391>

AstraZeneca is an equal opportunity employer. AstraZeneca will consider all qualified applicants for employment without discrimination on grounds of disability, sex or sexual orientation, pregnancy or maternity leave status, race or national or ethnic origin, age, religion or belief, gender identity or re-assignment, marital or civil partnership status, protected veteran status (if applicable) or any other characteristic protected by law.

Apply now to join us and help turn ideas into life changing medicines!