

Embracing recent strategies in global regulatory affairs

Paschal Iwuh
GlaxoSmithKline, Nigeria

The main function of Regulatory Affairs in the Pharmaceutical industries is to ensure products sent out to the public are 'right the first time'. There is a zero tolerance to this. This means that regulatory affairs units of various companies must present and submit information regarding new products to the government regulatory agencies long before the product is approved and marketed to the public. In a dynamic world, this poses some challenges to the regulatory affairs units in these companies. Therefore, new strategies must be adopted to address these challenges.

There are five factors that may be keys to recent strategies in Global Regulatory Affairs. These are New Product Types, Acquisition/In-Licensing, New Regulatory Requirements, Acceleration to time to market and Emerging Markets.

In order to meet all these challenges that face the regulatory affairs department, companies must cope with the need for additional resources as well as meet the need for expert knowledge and local experience to face the demands of new regulatory environments and requirements.

For example, there is an increasing trend towards outsourcing, which leads to cost-effective and lean processes. Having additional resources at hand for a certain period of time and sourcing specific expertise and local knowledge when needed keeps the regulatory departments agile and flexible. The important thing to such an outsourcing strategy is the selection of the right partner at the right time. Therefore, selection criteria for outsourcing partners very much depend on the nature of the tasks to be transferred but also on the structure and organization of the pharmaceutical companies concerned.

Biography

Paschal Iwuh is a trained engineer, with over 13 years in the biotechnology and pharmaceutical industries. He has held technical and leadership positions in major biotech, bio-pharmaceutical and consulting companies. Currently, he is the Site Validation Manager of GlaxoSmithKline (GSK), Agbara, Nigeria. Due to his passion for innovation and creativity, he is co-founded of The African Network (TAN). TAN fosters entrepreneurship amongst people of African descent. He became the President and CEO of TAN in 2008. As CEO, Paschal is the leader of the organization and responsible for its global operations, more specifically in Africa and USA. Paschal has a Ph.D. in Business Organization & Management from Capella University, Minneapolis, MN; a Master of Science degree in Chemical Engineering from the Technical University of Budapest, Hungary; a Bachelor of Science degree in Petroleum Engineering (first in his class) from the University of Ibadan, Nigeria and a Business Administration Certificate (with Distinction) from University of California, Berkeley.

iwuh@yahoo.com