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Globalization of pharmaceutical industry– Need of the hour

Sunny Chopra

Fresenius Kabi Oncology Ltd., India

Abstract

The threat of disease, access to medicine for the poor and rising health care costs has created a debate to develop globally acceptable regulatory guidelines and subsequently medicines. The regulatory landscape has continued to evolve in response to product safety, regulatory compliance, new technologies, improved understanding of disease states, stakeholder and customer needs and global imperatives, with new and increasing regulations and regulatory guidance. The challenging landscape is largely a result of the success of the biopharmaceutical industry in delivering medical therapies for many disease states, safety catastrophes from use of products post-approval and product quality compliance issues. These have sharpened regulatory authorities focus on product benefit/risk profiles and related stakeholders views on cost effectiveness and patient access. The demand for globally acceptable products heightens the importance for harmonization of regulatory requirements to lend efficiency and cost effectiveness to the process of product development, manufacturing and expediency to global access. In addition, biopharmaceutical companies have continued to expand their frontiers to attain a global reach, with presence in many regions and countries, and therefore exposed to myriad, and sometimes diverse, regulatory requirements and operating standards. The challenges of globalization in a heterogeneous world with an evolving regulatory landscape and expectations of multiple stakeholders have increased the complexity, unpredictability and intensity of the biopharmaceutical product development and registration process. Need of the hour is to harmonize the regulatory requirements round the globe which would not only reduce the time involved but would also ensure that every human being, regardless of his geographic location has access to quality medicines.

Biography

Sunny Chopra has around 9 years of research experience in the field of Drug development. He is currently serving as Sr. Research Scientist at Fresenius Kabi Oncology Ltd. He has completed his Ph.D. in Pharmaceutics from Jamia Hamdard (Delhi, India) while working on a Govt. of India funded project. Prior to this, he has worked as Research Scientist at Ranbaxy Research Labs. He has many research as well as review papers along with numerous patents to his credit. He has been awarded with young scientist award (Runners up) from Pharmahelpline society and was also the member of winning team at Novartis India Biocamp.