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Strategic management of global post approval regulatory activities

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Abstract

Biopharmaceutical companies have continued to expand their frontiers to attain a global reach, with presence in many regions and countries, and therefore exposed to many 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.

Activities traditionally focused on the post-approval period of the product life cycle, such as CMC changes and safety reporting, demanding a high degree of specialized knowledge for appropriate compliance from countries to countries. Thus, require companies to develop strategic approaches to manage the post-marketing activities and lifecycle optimization.

Biography

Linda Yang was until recently Associate Director, Regulatory. Currently as an independent regulation consultant and teaches regulatory affairs for UCBE, she provides directions for regulatory strategy/submissions, regulatory requirements for different development stages, product indications, and labeling. She has spent last 20 years working for pharmaceutical and biologics companies and is an expert in regulatory and quality compliance. She has played leadership role in functional areas such as quality compliance, clinical and regulatory strategy. She had experience in managing marketing registrations in US, EU, Asia, and Latin Americans countries.