

Points to consider when managing regulatory submissions in Asia Pacific countries

Linda Yang

KleanGen, LLC., USA

Abstract

Asia Pacific region is the fastest growing pharmaceutical market in the world, providing significant opportunities for drug development and marketing. At the same time, the Asia-Pacific region is one of the most vibrant areas in the world and presents a major challenge: a complex and continually evolving regulatory environment. This complicated regulatory landscape can be a barrier to success for non local companies that don't have the experience or resources that are essential to overcome the obstacles in countries such as Japan, South Korea, Hong Kong, Taiwan, and Southeast Asian countries.

The environment surrounding the regulation of pharmaceutical products has shown steady improvement, had significant changes in the last few years and expects more changes over the last five years. Some of the major challenges are still remaining, which include understanding the local requirements, communicating effectively with the authorities, managing the time to receive the approvals, and providing solutions for the unexpected problems. Equally important, the challenges are different for each country. The Asia-Pacific region cannot be treated as a single market, but must be approached with an abundance of local knowledge. Success is contingent upon understanding the regulatory as well as medical and social characterizations of each country.

With the right combination of local knowledge, perseverance, and flexibility, companies can overcome most of the challenges and take advantage of the opportunities to expand their products in this dynamic part of the world.

Biography

Linda Yang was until recently Associate Director, Regulatory. Currently as an independent regulation consultant and teaches regulatory affairs for UCB, 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.