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Drug regulatory affairs

Drug regulatory affairs cater by interpretation of Health Authority expectations for product development & accordingly dossier building for Regulatory Submission. Marketing Authorization granted by HA is the result of sufficient data generated to meet HA expectations considering quality, efficacy and safety aspects of drug product. This helps to market product as per target HA expectations and extends the product to international markets based on business strategy. Understanding of science behind product & developed product meeting minimum expectations of ICH standards, will ensure successful regulatory path for product registration. As we move from major markets, documentation requirements may go down as the international markets or emerging markets are more dependent on reference countries for first level evaluation. Industry is now aligning with ICH guidelines for product development which help to meet expectations of majority of the international markets or emerging markets. But it puts pressure on Pharma industry in the emerging markets to reconsider product develop strategy.

Biography

Vishal Mhatre is a career oriented Pharmacist with 23 years of experience in Pharma Industry and Domain Consultant with substantial expertise in Regulatory Project Management, Strategy Development and Operations. He has knowledge and understanding of applicable pharmaceuticals, biological/biotech rules & regulations covering different types of submission procedures during Product Lifecycle Management with 19+ years of experience in Regulatory Affairs covering regulatory strategy development for Global submission, preparation of regulatory submissions and product lifecycle management across the Globe. He has demonstrated project management skills managing multiple assignments in regulatory operations involved in competency development of regulatory team through developing extensive training program covering current regulations & HA expectations on product development. Also, he is responsible for regulatory business strategy development and process improvement activities in current role.

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