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Pharmaceuticals regulatory affairs

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The regulatory affairs is one of the key department in an organization and for those who are involved with the regulation of healthcare and related products, including medical devices, pharmaceuticals, biologics and nutritional products. It helps to

Regulatory Submission Team: Regulator submission team taking care of the preparation and submission of dossiers in different countries as per the national regional requirements and template.

Regulatory Compliance Team: Regulatory compliance team is responsible to see the regulatory compliance in the initial product evaluation, product development at research and development unit; plant regulatory compliance, impact analysis of changes (Variation), change control system, CAPP (Corrective action and preventive measure), cGxP (GDP, GLP, GMP) at manufacturing unit, post marketing surveillance/complain, vendor qualification as per regulatory compliance.

Regulatory Affairs department is governed by the in-built SOPs and system, which is based on the cGDP.

Regulatory affairs department ensures that the company adheres to regulatory requirements as per rules/regulations and laws imposed to protect public health

- Providing inputs regarding filing strategy of generic version of RLD product and Bio-equivalence criteria and requirements as per country specific requirements.

- Coordinating with different stake holders (plant, QA, QC, R&D, for documents) and compilation of high quality dossier of generic product (Module-2 to Module-5).

Since regulations are set and changed by the leading regulatory bodies such, as ICH, WHO, FDA and EMA etc., and consequently by local and regional regulatory bodies (SFDA, GCC, JFDA, NHRA, TFDA etc.) too, we are operating in, hence the compliance has been an unavoidable mandatory factor for adherence to laws, regulations in accordance with the guidelines. And failing to the compliance, results in delays, rejection of approval -- even refusal at initial submission sometimes. Not only this, violating of it may result to legal punishment, including from warning letter, federal penalties to the extent of locking the firm, as it has befallen few companies, we have come across.

So, a holistic approach is required to ensure that the proper steps are taken to meet global regulatory compliance from the beginning to ensure the origination of correct documents for regulatory filling and to set the system to increase the productivity with high quality and expedition, because if any step is skipped/missed, and thus right practices are NOT implemented correctly on/in time, then reverse effort to meet regulations and policies later, is likely to add cost dearly, and even may fail sometime to repair/meet.

Biography

Syed Abid Hassan is founder of Bismil Welfare Society. He has completed his D. Pharma from RLSY College, M.Sc. in Chemistry from VM University, MBA (in International Business) from EILM-India. He is pursuing his Ph.D. in Chemistry. He is Certified Lead Auditor for QMS (Quality Management System), by BSI (British Standard Institute) UK, and for ISO13485 (Medical Device) by IRCA (International Register of Certificated Auditor) UK. He has 17 years plus experi¬ence of QA/Regulatory and R&D. He is the member of RAPS (Regulatory Affairs Professional Society) – US, and CQI (Continuous Quality Improvement) UK. He has authored several publications in various journals of US and Germany. Has participated as Chairperson, Moderator, Panelist, Trainer or Speaker in several International Conferences in KSA, Egypt, UAE, Germany and USA. Presently he is working as Head of Regulatory Compliance and Team Leader of Variation Management Committee, in Jamjoom Pharmaceuticals Company – KSA

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