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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 taking care of the preparation and submission of dossiers in different countries as per the national regional requirements and template. 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.

Biography

Mr. Abid is Certified Lead Auditor for ISO13485 (Medical Device) from BSI & IRCA, UK. He has 16 years plus experience of QA/Regulatory and R&D pharma Industries. At present he is working as following in Jamjoom Pharmaceuticals Company in KSA as Head Regulatory Compliance & Team Leader Variation Management Committee. Mr. Abid is the member of RAPS (Regulatory Affairs Professional Society) – US. He is fee launcer consultant. He is an International Speaker, Moderator, Panelist and Trainer as well.

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