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Regulatory affairs for healthcare products

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Regulatory Affairs has always been considered as a Drug registration department in Indian Pharmaceutical industry. When Drug Registration and Marketing approvals are essential day to day activities of a regulatory professional, there is lot more aspects bound to it beyond product registration. In a true scenario, Regulatory Affairs is a horizontal that cut across the Pharmaceutical Value chain right from Drug discovery, Drug Development, Manufacturing, Sales and Marketing and Post Marketing. In all of these phases there are number of compliance parameters to be met in order to pass the stringent regulatory scrutiny. Regulatory Compliance plays an integral role in Regulatory Affairs. It is a common belief that, when the product complies with its specification then quality is achieved. Testing the final product cannot assure the quality unless and otherwise it is built into the product itself. The concept of Quality by Design (QbD) helps in building the right product with a thorough understanding of the product and process by which it is developed. QbD applies equally to the software used in the Pharmaceutical Industry. Understanding and interpreting these regulations has always been a challenge in Pharma because Regulations like US FDA or UKMHRA would only provide the guidance document on its interested topics, the how aspect is left to the Pharmaceutical Company. Complying with these regulations is purely based on a company's internal policies and Procedures. Despite these regulations exist for so many years now, even today there are so many non- conformances and FDA 483s. What is the challenge? Why compliance is always considered as a painful exercise? What role does a Regulatory Affairs professional play in this entire process?

Wait and watch my session for the answers.

Biography

Amudha Krishnamoorthy is a Life Sciences Quality and Regulatory Consultant having 15 years of Experience. She has served in Departments like Manufacturing, Quality Assurance and Regulatory Affairs in her Pharmaceutical Industry career and currently working as a Regulatory Consultant in IT Company. Her expertise includes GxP Compliance, Software Compliance and Regulatory Submissions. She is also a certified mentor for Life Sciences imparting domain knowledge to the IT folks.

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A country perspective in exploring the links between hospital pharmacies and pharmaceutical industry: A case study application

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The pharmaceutical industry is one of the firms where the search for quality is very close to compliance. Yet a major paradigm change is occurring in this industry and an increase of returns and recalls has been seen. Hence, in this paper the authors combine the findings of previous literature reviews with a case study approach. Findings from previous literature reviews emerged from the links explored between pharmaceutical drugs quality, reverse logistics and sustainability. With the application of a case study on a global manufacturing corporation in the area of generic drug products one more step is introduced: understanding the type of returns companies receive, in particular from hospital pharmacies. The role of hospital pharmaceutical returns as a potential major contributor in resolving the noncompliance challenges will be compared and contrasted from a country perspective. With this approach authors are creating a link between two different parties: the application of a quality by design (QbD) risk management approach with the reduction of variability and risk of noncompliance.

Biography

Ana Margarida Santos Bravo is a Ph.D candidate at the age of 33 years from ISCTE, Lisbon University Institute, in Lisbon Portugal. She is a Researcher in Pharmaceutical Supply Chains. In addition, she is responsible for the Regulatory Affairs and Technology Transfer of injectable drug products to the US market in a global Pharmaceutical Organization. She has published several papers in reputed conferences and journals.

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