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Implementation of changes aligned to regulatory framework

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Despite having specific role of a manufacturing unit of any Pharmaceutical company with its regulatory function, still there is a close connection between the functions and for smooth operation both the functions should act simultaneously to meet the diversified requirement of various regulatory authorities in a timely manner irrespective of region or country. The most challenging situation for the manufacturing or technical operations unit is to incorporate relevant changes planned or unplanned or to incorporate frequent update done by different pharmacopoeial bodies or even by suppliers. Challenge may not be serious for the first time dossier submission as there are scopes to include everything then; however, it might have impact specially for interim variation submission due to process change or improvement, alternate source development for any API or excipients or packaging material, batch scale up or machine change or change of analytical method or specification followed by questions to be handled on relevant stability studies for the change already implemented or the requirement of BE studies if required. For all the cases, Tech Ops function has to be aligned with the stipulated changes and to make sure documentation and its quality required for updating the respective dossier. Submission of a dossier for the first time is completely different than to the maintenance work related to handle deficiency queries subsequently asked by different regulatory bodies or Health authority for the already submitted dossier, since different body needs different requirement. Moreover, time line is a crucial barrier for filing up variation and it depends on specific country or regional regulatory set up, lack of which severe market shortage can happen. This paper presents a critical analysis of steps required for preparing dossier in CTD template, on time necessary document support to be provided by manufacturing unit to generate different modules and harmonization of critical changes to align with regulatory requirements e.g. for US market, EU or rest of the world.

Biography

Mohammad Iqbal Hossain has completed MSc in Chemistry from the University of Chittagong followed by an MBA degree in Marketing from another University. He has more than 10 years of practical experience in Pharma analytical field and working with Sandoz from the very beginning of his career to till date. He successfully led a project 'Quality Transformation Program' to make fine tuning Sandoz's quality issues specially Data Integrity & lab in- control to improve. He is a Senior Executive & Team Leader for Analytical Method Development, Validation of Analytical Procedures & Tech Transfer issues. He is responsible for dealing registration activities for Sandoz Bangladesh Tech Ops.

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