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First to file (FTF) regulatory challenge to QbD adoption

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During finished pharmaceutical product (FPP), manufacturing process development following QbD (Quality by Design) and in the race to be first to file product registration, a balance is needed between effective management of limited budgets and resources and obtaining and implementing sufficient process knowledge & understanding in a way that demonstrates process stability and predictability. This balance is necessary in order to manufacture products safely, reliably, and economically. This is particularly challenging for generic companies that are mostly or completely virtual, since their prevalent bias is towards both cost minimization and rapid development. A requirement common to all strategies, at all types of generic organizations, is adequate documentation and justification of the ultimate process used for late-stage development (exhibit batch) and commercial launch, in order to demonstrate that quality by design (QbD) has been implemented. There is an inherent tension between the need to move as rapidly as possible (first to file), and the need to accumulate sufficient knowledge along the way that can be leveraged at each successive stage of development. This present study explored these competing priorities and attempted to address the conceptual uncoupling of expediency and QbD vis a vis proposes several strategies (i.e. Self- auditing, outsourcing, concurrent/overlapping e-submission & automated continuous conformity monitoring and cybernetics correction of the process deviations etc.) for how these seemingly contradictory needs may be accommodated in a single, integrated (matrixes) approach. Three critical aspects of this approach are quicker development of process understanding, a smarter strategy of experimentation (screening, characterization, and optimization) that collects the right data in the right amount at the right time and a process management system that faster integrates process control and process improvement. It is concluded, there is definitely link of high probable regulatory conformance satisfaction/ confidence level to likelihood of success in accelerating regulatory speed of approval of submission.

Biography

Kishor K Chakraborty is a professional (MPharm PhD) having more than 29 years of diverse global exposure in various research and development assignments with Lederle (a division of American Cyanamid company), Hindustan Antibiotics, Concept Pharma (a farmer subsidiary of Lupin Pharma), and currently has been serving as Head – R&D in Riyadh Pharma (A leading pharmaceutical company in GCC). He has published & delivered over 20 manuscripts and lectures respectively.

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