THINKING BEYOND QbD: ACCELERATING RISK SMART DEVELOPMENT & TECHNOLOGY TRANSFER

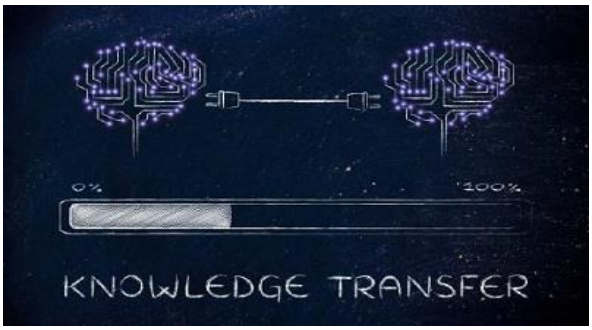
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Abstract

A risk smart **QbD-based methodology** driven by improved Informatics, goes beyond tactical & reactive development and streamlining standards-based Technology Transfer by capturing mechanistic understanding to support the probabilistic modeling approach from early ideation through research, development, optimization and scale-up as well as integrating standards (ISA-88 and ISA-95) and structuring data in a fully searchable format. Moreover, the **recognition of lean QbD risk assessment** through process knowledge is a product lifecycle issue as opposed to a once and done aspect of development is a good first step. That recognition shall catalyze organizational development whose ultimate goal is a broad organizational understanding and competence in QbD concepts and tools, focusing on top-down approach of technology transfer beyond Product Development to include Operations, Engineering, QA, Regulatory Affairs and even Finance.

A DIbD (Data-integrating-based-design) supported QbD strategy that expands Research, Development and Manufacturing enables seamless information from across the organization to support continuous product and process improvement. It offers significant opportunities to accelerates products to market, reduces compliance costs and improves product quality by reducing the number of experiment cycles, speeding individual cycles and facilitating technology transfer between cycles. Consistency and standards driven through informatics enable rapid technology transfer between scientists and systems, while Cloud based software deployments enable remote organizations to collaborate in the QbD process.

Image



Recent Publications

1. Accelrys (2011) informatics driven quality by design for drug development :1-11.
2. OQSIE at Generis' American Bio Manufacturing Summit (2018) "QbD, A Risk Management Strategy for Competitive Advantage." May 23-24th in San Diego, CA
3. Sandhu R., Gujral B., and McNicoll A. (2018) Pharmaceutical manufacturing: The Role of Mechanistic Understanding in QbD.
4. Lenich B and Greenwald B. (2017) Pharmaceutical manufacturing: Tech Transfer: Let's Take It from the Top.
5. Bronfeld, J.,"Strategy Driven Informatics." Keynote address at the Symyx Symposium 2010, May 4-6, 2010, Barcelona, Spain.



Biography

Kishor K Chakraborty is a professional (M Pharm. PhD, MBA) having more than 30 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), Riyadhpharma and currently has been serving as Head – R&D in Julphar Saudi (A leading pharmaceutical company in GCC). He has published & delivered over 20 manuscripts and lectures respectively.

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