Monika Jadhav et al., J Pharma Care Health Sys 2015, 2:5
http://dx.doi.org/10.4172/2376-0419.C1.008

OMICS International
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Pharmaceutical Summit and Expo

October 08-10, 2015 New Delhi, India

Implementation of quality by design approach to analytical method development and validation

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A QbD and lifecycle management approach to analytical method development and qualification results in a better understanding and fewer failures of analytical methods due to more robust methods which produce consistent, reliable, quality data throughout the lifecycle. This, in turn, leads to less method transfer failures and method "incidents" when used in the routine environment. As the MNC's are now applying Quality by Design (QbD) to process development, it is now being recognized that this is also the way forward to improve and standardize approach to analytical procedures. The recent focus within the pharmaceutical industry and associated regulatory bodies on QbD approaches to analytical method development are a positive sign that both the industry and regulators are acknowledging the importance of understanding the contribution of measurement uncertainty to drug processes and products. The benefits of applying QbD principles to analytical methods include identifying and minimizing sources of variability that may lead to poor method robustness and ensuring that the method meets its intended performance requirements throughout the product and method lifecycle. The ultimate goal is to highlight that QbD concepts and terminology can be applied to analytical methods and to suggest how adoption of a QbD approach might be used to develop more robust analytical methods and effective control systems. At the same time, these efforts aim to support more advanced regulatory approaches to change management.

Biography

Monika Jadhav has completed MPharm from Pune University and has a teaching experience of 2.5 years as Assistant Professor. She is currently working at Shri D D Vispute College of Pharmacy & Research Center, Navi Mumbai. She has published 05 research articles from which 03 are international publications. And she is also one of the Reviewer Board Members of *International Journal of Pharmaceutical Chemistry and Analysis, Innovative Publication.*

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