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Quality by design- Regulatory considerations for pharmaceutical analytical methods

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QbD is a systematic process of building desirable quality in the end product by careful evaluation of all the attributes that go into characterizing quality, from the inception of a product to its end use, thus ensuring at any time that it meets patient needs. This initiative was introduced by the FDA in 2002 and is being promoted within the pharmaceutical industry with the aims of increasing regulatory flexibility and creating an easier path for the manufacturers to introduce process and product improvements. Recent pharmaceutical regulatory documents have stressed the critical importance of applying quality by design (QbD) principles for in-depth process understanding to ensure that product quality is built in by design. The concept of QbD can be extended to analytical methods. This article outlines the application of QbD concepts to the development of analytical methods, the methods are then carefully assessed in a structured manner for risks, and are challenged to determine the robustness and ruggedness criteria are satisfied. As a result of these studies, the method performance can be understood and improved if necessary and a control strategy can be defined to manage risk and ensure the method performs as desired when validated and deployed including high-performance liquid chromatography etc, for chemical identification, stability indicating methods and trace analysis for genotoxic impurities etc.

Biography

M V Narendra Kumar Talluri joined as a Faculty in 2009 at NIPER-H. Previous positions held by him include Scientific Manager at Biocon. He has a broad pharmaceutical experience in analytical activities in drug discovery, development etc. He received PhD from IICT, Hyderabad. He has published ~50 articles (invited articles/talks, presentations/book chapters). He successfully supervised 25 MS students for their research work and is presently guiding PhDs. He has been in the Editorial Advisory Board of *Journal of Pharmaceutical Science-Clinical Practice* and serves as a reviewer for *international journals*. The Indian Drug Manufacturer's Association conferred prestigious "Young Pharmaceutical Analyst Award 2011" for his outstanding research contribution in the field of Pharmaceutical Analysis.

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