

4th International Summit on

GMP, GCP & Quality Control

October 26-28, 2015 Hyderabad, India

Question based review for generic drug for regulatory compliance in US

A Swetha Kumary, Shashi Kumar Yadav, P Haritha and A Sambasiva Rao
Sri Indu Institute of Pharmacy, India

The US Food and Drug Administration Office of Generic Drugs has developed a Question-based Review (QbR) for the Chemistry, Manufacturing, and Controls (CMC) evaluation of an Abbreviated New Drug Application (ANDA). This new QbR system incorporates quality by design and implements risk-based assessment. It recommends that ANDAs be submitted using the Common Technical Document and include the Quality Overall Summary (QOS) that addresses all the QbR questions. QbR contains the important scientific and regulatory review questions that focus on critical pharmaceutical attributes for ensuring drug product quality. It contains questions regarding drug substance and 37 questions about the drug product. The study features about Question based Review and corresponding review template for the registration applications. The specificity incorporated into the standardized format of the QbR ensures that critical areas remain the central focus in every review. The main benefits of this QbR system are to: (1) assure product quality through design and performance-based specifications, (2) facilitate continuous improvement and reduce CMC supplements through risk assessment, (3) enhance the quality of reviews through standardized review questions, and (4) reduce CMC review time when applicants submit a QOS that addresses the QbR questions. The clear format of the QbR template has provided a framework that has increased review consistency. QbR questions have increased the quality of CMC reviews by shifting the focus of review to areas that are most likely to affect product quality for a particular drug product.

swetha.azmera@gmail.com

Notes: