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Challenges in analytical method development of biopharmaceuticals

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Biopharmaceuticals are the diverse groups of bio-therapeutics that offer supportive therapy to many critical conditions like cancer, auto-immune diseases, etc. Many of these biopharmaceuticals are macromolecules like proteins. Analytical methods developed for characterization of the proteins include HPLC based methods, Capillary Electrophoresis methods, Electrophoretic methods, ELISAs and Real time PCR methods. Lot many challenges are encountered during development of the analytical methods for biopharmaceuticals. Some of them are: Lack of availability of reference standards and impurity standards, extremely low levels of impurities in the test samples, sensitivity of analytical methods, lack of clear guidelines on acceptable assay variation, etc. Many of these challenges can be overcome by adapting several sample preparation techniques, sample enrichment techniques, improvement of assay range, etc. A robust analytical method requires validation as per ICH guidelines. Parameters included in analytical method validations are based on the category of the test. The most important parameters are specificity, linearity and range, precision, accuracy, limit of detection and quantitation.

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Quality by design in pharmaceutical quality control analysis: Tool for regulatory flexibility

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FDA has approved a few New Drug Applications (NDAs) with regulatory flexibility for Quality by Design (QbD) based analytical development approach. Quality by design is defined in ICH Q8 (R1) guidelines as 'a systematic approach to pharmaceutical development starting with pre-defined objectives with an emphasis on product and process understanding control'. Within the pharmaceutical industry there is increasing discussion about the principles of QbD analytical methods. For many years, analysts used to develop methods based on trial and error approach. With this traditional approach, many unexpected results are observed during the stage of validation in analytical methods including the disappearance of peaks or appearance of new peaks creating a need to go back from starting of the method development steps. This approach is very tedious and time consuming and it cannot give robust results. This can be avoided by applying quality by design approach. It allows the analytical method for movement within method operable Design Space (DS). This approach reduces the number of Out-Of-Specification (OOS) results due to the robustness of the method within the DS. It is a current trend among pharmaceutical industry to implement quality by design in analytical method development process as a part of risk management, pharmaceutical development, and pharmaceutical quality system (ICH Q8, 9, 10).

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