Rikul Patel, Pharmaceut Reg Affairs 2014, 3:3
http://dx.doi.org/10.4172/2167-7689.S1.016

OMICS Group Conferences
Accelerating Scientific Discovery

4th International Conference on
Pharmaceutical Regulatory Affairs
September 08-10, 2014 DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA

Regulatory requirements for API - CTD, CEP and active substance master file in EU

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This presentation is to provide guidance on the content, structure and submissions procedure for the pharmaceutical documentation of the quality of the drug substance for different types of dossiers (the CTD, the CEP and European ASMF). Since 1992, in Europe there are four different ways to submit the required quality information of an API for the purpose of marketing authorisation:

- Certificate of Suitability of the pharmacopoeial monograph (CEP)
- Full details of manufacture (according to CTD Module 3 Quality of Drug Substance)
- European Active Substance Master File (ASMF)
- Other supportive data in consideration of the qualification of impurities

Discussion will include requirements of quality information based on the following classification of an API:

- New active substance, used for the first time in a medicinal product either for human or veterinary use
- Existing active substance not described in the European Pharmacopoeia (Ph. Eur.) or the pharmacopoeia if an EU member state
- Existing active substances described in the Ph. Eur. Or in the pharmacopoeia of and EU member state

The discussion will include requirements for the Certificate of Suitability (CEP Procedure, Content of the CEP dossier, CEP for a substance for TSE risk assessmentect) along with information on how to compile an ASMF using the CTD Format (Data in Module 3 Quality 'Drug Substance', Compilation of an ASMFect). This information has been collected using various published guidelines in the EU which are based on the various directives of European Parliament and of the Council.

Biography

Rikul Patel is Regulatory Quality Compliance Executive at AMCo Ltd. He holds an MSc (Research) in Analytical Chemistry from University of Northumbria (UK), MSc in Organic Chemistry and BSc in Chemistry from S. P. University Gujarat (India). He was a post graduate research fellow at S. P. University. During his career development in pharmaceutical field he has worked with companies like Procter and Gamble and GSK, gaining experience in method development, process development, Quality Assurance, Regulatory and Quality and Compliance.

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