Peter Jones, J Develop Drugs 2013, 2:4
http://dx.doi.org/10.4172/2329-6631.S1.004

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Summit on
GMP, GCP & Quality Control
November 12-14, 2013 DoubleTree by Hilton Hotel Chicago-North Shore, IL, USA

The application of quality by design principles to analytical methods

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Following the implementation of ICH Q8, Q9 and Q10 for drug product development and manufacture, a number of major pharmaceutical companies developed an interest in extending Quality by Design to analytical methods. The analytical target profile (ATP) concept was developed by industry as a mechanism for enabling method flexibility, with the vision that any methods complying with the ATP could be interchanged without regulatory approval. However, the implications of the ATP on method performance requirements were not fully developed/understood/articulated. Examples of the implications of ATP requirements for chromatographic method development and subsequent routine use will be given and the pros and cons of developing analytical methods, within a Quality by Design framework, will be discussed. Discussion of the regulatory acceptability of the ATP concept in its entirety (leading to method flexibility) and whether analytical Quality by Design should be placed in the regulatory environment or whether industry's needs are best served via ICH Q2, will take place.

Biography

Peter Jones holds a Ph.D. from the University of Wales. He is a member of the Royal Society of Chemistry and is a chartered chemist. He had experience at Wyeth Laboratories and Rorer Healthcare, prior to joining Pfizer. He was previously head of analytical control, which provided analytical support to the clinical trials supply chain. From 2010 to 2012, he was director of Global Analytical Quality by Design Method Development and was accountable for changing the business process for the development of analytical methods, in accordance with QbD principles. Since May 2012, he has been an independent pharmaceutical consultant.

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