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

Regulatory inspection findings at the GMP/GCP interface

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The Clinical Trial Directive 2001/20/EC set out to harmonise the conduct of clinical trials across Europe. This came into effect on the 1st May 2004. Now, nearly ten years on, this presentation will provide an update on its effects including regulatory inspection findings. In particular, this talk will focus on the role of the qualified person in clinical pharmacology-type studies. Amongst other responsibilities, QPs would certify the compliance of a batch in accordance to good manufacturing practices, but what exactly is a GMP activity in phase 1? Commision Directive 2005/28/EC lays down the principles and detailed guidelines for Good Clinical Practice (GCP) as regards to investigational medicinal products (IMPs) for human use, as well as the requirements for authorization of the manufacturing or importation of such products. What constitutues a GCP activity in phase 1? In clinical pharmacology units, the use of IMPs must comply with the guidelines for both GCP and GMP. How do pharmacists/QPs ensure that they are in compliance with the standards? This presentation will compare GCP and GMP inspections together with common findings. It also explores what is deemed GMP and GCP activities for phase 1 clinical trials in different ICH regions.

Biography

Dave Sharma is a pharmacist and a qualified person with extensive experience in quality assurance and supply chain management. Having worked in both big pharma and small biotech companies, he has sponsored many GxP projects in specialist environments. He has significant exposure to phase 1 environments and has participated in numerous audits from both a GCP and GMP perspective.

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