

3rd International Conference and Exhibition on Pharmacovigilance & Clinical Trials

October 27-29, 2014 Hyderabad International Convention Centre, India



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New European pharmacovigilance legislation; Current status and issues - The generics perspective

In July 2012, the new European Pharmacovigilance legislation started to come into effect. Final implementation is not expected until 2016. There are now just over two years experience with the implementation of the new legislation, and it is certainly no bed of roses. The aim of this session will be to review the status of the implementation of the new legislation and to look at some of these issues and concerns regarding the implementation. This will be from the perspective of the generics sector.

Biography

John Barber is currently the QPPV for Dr. Reddy's Laboratories, UK, a role he has been in since April 2010. Prior to that, he was Global Clinical Pharmacovigilance Manager for Glenmark Pharmaceuticals, during which he initiated the development of the company's Pharmacovigilance quality management system for its clinical development programme. He was previously employed by Alliance Pharmaceuticals, a specialist UK pharmaceutical company, where he was latterly Director of Scientific Affairs. In this role, he was responsible for Pharmacovigilance, medical information and clinical development. He also has experience as an information analyst with ICI Pharmaceuticals, Roche and Glaxo Wellcome. He is currently the Immediate Past President of the UK Pharmaceutical Information and Pharmacovigilance Association (PIPA) and is a lead on Pharmacovigilance issues for the British Generics Manufacturers Association (BGMA). By education, he is a pharmacologist, attaining a BSc (Hons) from the University of Liverpool.

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