

Thursday 14th December 2017

Pharmacovigilance for Herbal Medicines: Update for 2018

Venue: London Mathematical Society, De Morgan House, 57-58 Russell Square, London, WC1B 4HS

There have been many changes to pharmacovigilance requirements in the past 5 years with the introduction of new legislation, and there have been many challenges in the practical implementation into everyday pharmacovigilance activities.

This seminar aims to update industry on the pharmacovigilance requirements moving forward into 2018, and focus on key pharmacovigilance areas impacting those companies with Marketing Authorisations and Traditional Herbal Registrations for herbal medicines. It will also cover what to expect should a pharmacovigilance inspection take place in a company.



Registration: 10:00- 10:30

Agenda

10:30-
10:45

Welcome & Introduction

Ann Godsell

Director, AGRegulatory Ltd.

Ann Godsell has over 30 years experience in regulatory affairs of medicines, including herbal medicines. She has worked in areas of pharmacovigilance including implementing new processes and procedures, managing submissions, handling safety issues and supporting Health Authority inspections.

10:45-
11:30

Pharmacovigilance requirements for Herbal Periodic Safety Updates (PSURs)

Christoph Buss

Senior Manager Regulatory Affairs Pharma

Diapharm GmbH & Co. KG

Christoph Buss joined Diapharm GmbH & Co. KG in 2012 after postdoc studies at the University of Applied Science, Münster and is currently Pharmacovigilance Manager and QPPV.

11:30-
12:05

The role of the Qualified Person Pharmacovigilance

Cheryl Reid

Regulatory Affairs Manager and QPPV
IVC Brunel Healthcare Ltd.

Cheryl Reid has over 30 years industrial experience, and since 1996 has been involved in Regulatory Affairs. She is now responsible for regulatory requirements in different markets for pharmaceuticals, traditional herbal medicines, medical devices, borderline products and food supplements.

12:05-
13:05

Lunch Break

13:05-
13:45

Pharmacovigilance for herbal products –MHRA Assessors perspective

Leigh Henderson

Unit Manager, Benefit Risk Group
Medicines & Healthcare products Regulatory Agency (MHRA)

Leigh Henderson has worked for the MHRA for 19 years, involved with the pharmacovigilance of herbal medicines since 1999. As a manager in the Benefit Risk Management Group she is responsible for monitoring the safety of broad range of medicines and introducing risk minimisation measures in response to new safety issues across a broad range of medicines in multiple therapeutic areas and includes herbal medicines.

13:45-14:15

Outsourcing? What can be provided & can it be menu driven

Lorraine Bedford

Director and QPPV, QP Services UK Ltd.

Lorraine Bedford has over 20 years experience in the pharmaceutical industry, and currently is the QPPV for multiple UK companies, and with oversight of all pharmacovigilance activities contracted to QP-Services including ADR reporting, literature searches, routine signal detection including PSURs, training and maintenance of the PSMF and XEVMPD.

14:15- 15:00

Pharmacovigilance inspections – what to expect

Jo Harper

Expert GPvP Inspector
Medicines & Healthcare products
Regulatory Agency (MHRA)

Jo Harper is a MHRA Expert Inspector in Pharmacovigilance. With over 8 years of inspection experience, she led the MHRA inspectors and EU PV Inspector's Working Group contribution to the development of the Implementing Regulation and was rapporteur for GVP Module II (PSMF) in support of the 2012 pharmacovigilance legislation changes.

15:00-15:30

Panel Discussion

All Speakers

15:30

Close

Cost:

Members £75.00 + VAT = **£90.00**

Non-members £150.00 + VAT = **£180.00**

Payment must be included with booking form. A VAT receipt will be sent on receipt of booking form. Applications will open to non-BHMA members after 01 November 2017.

Please book place(s) for the meeting on Thursday 14th December 2017

METHOD OF PAYMENT (please tick one box)

Cheque or International Draft: "British Herbal Medicine Association" in £ sterling drawn on a UK bank.

Bank Transfer: BHMA account at Lloyds TSB Bank PLC, 4 Castle Street, CHRISTCHURCH, BH23 1DU, UK

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