

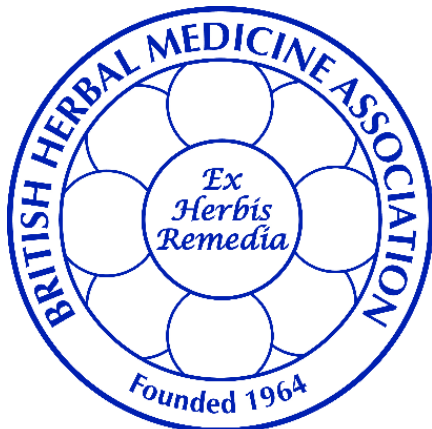
Wednesday 17th January 2018

Understanding eCTD submissions: the impact on your company

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

The inevitable progress of electronic dossiers becoming a mandatory requirement for regulatory submissions has been evolving in many Health Authorities in recent years. The common requirement for submissions in eCTD (electronic Common Technical Document) is now well established in the EU, and will impact herbal medicines with Marketing Authorisations and Traditional Herbal Medicines.

This seminar aims to explain the mystery of an eCTD, focusing on the technical requirements, and providing practical advice on how to build and publish submissions to the required standard expected. It will also consider the advantages and disadvantages in outsourcing such operations to an external provider.



Agenda

10:30-
10:40

Welcome & Introduction

Registration: 10:00 - 10:30

Ann Godsell

Director, AGRegulatory Ltd.

Ann Godsell has over 30 years experience in the regulatory affairs of medicines, including herbal medicines. She has worked in areas relating to electronic submissions including implementing new processes and procedures, managing submissions and working with internal and external publishing teams.

10:40-
11:25

eCTD and how to compile successfully

Stefan Leyers

Senior Regulatory Affairs Manager
Regulatory Affairs Pharma,
Diapharm GmbH & Co. KG

Stefan Leyers joined Diapharm GmbH & Co. KG in 2015. After completing postdoc studies, he has worked in regulatory positions in the pharmaceutical industry, and also has worked as a Scientific Assessor for the German Health Authority (BfArM).

11:25-
12:10

Considerations and challenges – can outsourcing be the solution?

Jasbir Chohan

CEO, Onix Life Sciences Ltd.

Jasbir Chohan, Founder and CEO of ONIX, has over 18 years experience leading to an extensive knowledge of eCTD Global Regulatory Operations Requirements. A regular key speaker at conferences, she specialises in supporting companies looking to develop or transition their regulatory operations to an eCTD compliant infrastructure, also providing an oversight for PDF publishing, eCTD compilation tasks and quality assurance compliance for electronic submission procedures and processes.

12:10-
13:30

Lunch Break

Display stands and demonstrations from Diapharm GmbH & Co. KG, Onix Life Sciences Ltd. and EXTEDO GmbH

13:30-
15:00

eCTD Best practice & live demonstration of eCTD manager software

Maren Müller

Product Manager
eCTD Manager, EXTEDO GmbH

Maren Müller has experience in internal and external consulting regarding various types of eSubmissions, software training, and has been a project manager for industry and agency projects. Recently she has taken her current role as Product Manager for eCTDmanager and eSUBmanager at EXTEDO GmbH.

15:00-15:20	Future developments – what is coming next and when?	Navila Rehman Senior Principal Consultant Onix Life Sciences Ltd. <i>Navila Rehman has worked within the pharmaceutical industry for over 18 years, with a background in Quality Management. She is experienced in all aspects of e-submission publishing and oversees the management of eCTD submissions to health authorities and life-cycle management. Her current role is Senior Principal Consultant at ONIX.</i>
15:20-15:50	Panel Discussion	All Speakers
15:50-16:00	Review & Close	Ann Godsell Director, AGRegulatory Ltd.

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 20 November 2017.**

Please book place(s) for the meeting on Wednesday 17th January 2018

METHOD OF PAYMENT (please tick one box)

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