Introduction and Best Practices on Pharmacovigilance and eCTD

18th September, 2017
09:00 to 17:00
Orchid & Olive Room, Level C, One World Hotel

Organised by PhAMA in collaboration with EXTEDO GmbH

NPRA had announced in the MADRAC Bulletin December 2016 that they are heading towards conducting Pharmacovigilance (PV) Inspection in Malaysia. PV Inspection is conducted on product registration holders to determine compliance with regulatory PV obligations. The Malaysian PV Guidelines will be updated with requirements for the PV System Master File and PV Inspection. Actual implementation of PV Inspection in Malaysia will be carried out in stages, and targeted to begin in 2018.

It is hence very timely for Product Registration Holders to attend this seminar for an Introduction to Pharmacovigilance and to learn about Best Practices on it. This will provide a better understanding on Pharmacovigilance requirements including on PV System Master File and PV Inspection and a higher level of readiness for the implementation of PV Inspection in Malaysia in 2018.

In addition to the presentations by Extedo, a specially invited speaker from NPRA will also be giving updates on NPRA's requirements on PV System Master File and PV Inspection.

Extedo will also share their expertise on Introduction and Best Practices on eCTD at this event.

About EXTEDO:

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). They focus on optimizing their clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 700 maintained customers across 60 countries to deliver Effortless Compliance™.

Speakers from Extedo: Dr. Silke Nolkemper, Dr. Andrea Striebel, Mr. Stefan Horneborg

PROGRAM

08:00 – 09:00 am Registration (Welcome coffee/tea at Orchid & Olive Foyer)

09:00 – 11:00am <u>Introduction and Best Practice of eCTD</u>

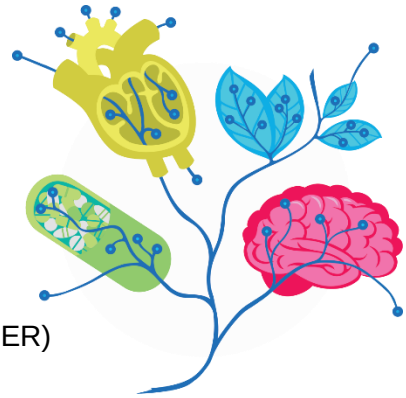
- General structure of an eCTD: Files and folders, Meta data, XML-backbone, Envelope
- Bookmarks and Hyperlinks
- Lifecycle in eCTD
- Regional differences of eCTD submissions
- Validation and Best Practice

(In between Coffee break at Orchid & Olive Foyer)

11.00am <u>Introduction and Best Practice of Pharmacovigilance</u>

- Introduction of Pharmacovigilance
    - General principles
    - Definitions
    - Involved parties
    - PV around the globe

- Pharmacovigilance activities
    - ADR processing and reporting
        - Live Demo
    - Periodic Benefit-Risk Evaluation Report (PBRER)
    - Risk management and signal detection
        - Risk management plan



1:00 – 2.30pm Lunch at Cinnamon Coffee House (Level C)

2.30 – 3.30pm

- Pharmacovigilance system
    - Pharmacovigilance System Master File

- Pharmacovigilance audits and inspections
    - PV inspection planning

3.30 – 4.30pm <u>Updates on NPRA's requirements on PV System Master File and PV Inspection</u>
by Special Invited Speaker: Puan Noor'ain Bt Shamsuddin, Senior Principal Assistant Director, Pharmacovigilance Section Centre for Post Registration of Products & Cosmetic Control, NPRA

4.30 – 5.00pm Q & A

(In between Coffee break at Orchid & Olive Foyer)