ICH Implementation at Anvisa

WCBP 2018
Washington, DC – 31/01/2018

Mônica Bernardes Floreano

Post-Approval’s Office for Sinthetics Drug Products
Anvisa as a Regulatory Member from ICH

Tear I Guidelines – Immediate Implementation
Q1; Q7; E6

Tear II Guidelines – 5 years
November 2021 - E2A; E2B; E2D; M4; M1

Tear III Guidelines – Medium to long term
Adopt other ICH Guidelines in a near future

Concluded and in progress activities
- Creation of a WG Responsible for the Implementation of the Tier II Guidelines → concluded Jan/2017;
- Mapping the resolutions that will need to be revised → concluded
- Establishment of a specific flow for implementation of ICH Guidelines → Regarding Regulatory Flow, activity in progress
- Translation (and validation) of ICH Tier II Guidelines, in progress
- Discussions with the Productive Sector:
  Biannual meetings with Industry to give a feedback about the implementation and assess stakeholder implementation difficulties, in progress
- Acquisition and Parameterization of Technological Tool → (E2B - ICSR) and M1 (MedDRA) implementation, in progress

Not the main focus, but initial discussions about the implementation of tier III guidelines have started. Efforts are concentrated on Tier II guidelines and active EWG

Osaka meeting (Nov/2016) → Anvisa accepted as a Regulatory Member

• **Benchmarking:**
  Conducting Visits / Conference Calls and surveys with other Regulatory Agencies that implemented CTD and eCTD → learn about their experience, main challenges an IT tools in use;

• **Pilot Project for Submission in CTD Format**
  Translated Guideline including Module 1 Definition → March/April 2018;
  Meeting with industry to present the pilot (paper + external media in CTD format) → March/April 2018

• **Evaluation of the results**
  Assess main challenges and opportunities obtained from the Pilot experience
  Define a transition period based on industry capacity and challenges (CTD format not mandatory to mandatory)

• **Acquisition of the IT Solution for the implementation of eCTD (M8)**
  Adopt e-CDT to enable the maximum benefits of CTD format
  Internal phase (elaborate the purchase documentation – 2018/2019) and external phase (request for tenders launch and conclusion)

• **Implementation of the IT Solution along e-CTD Submission Guideline;**
  Pilot project to be expected by 2022
Thank you!

ich.anvisa@anvisa.gov.br

Agência Nacional de Vigilância Sanitária - Anvisa
SIA Trecho 5 - Área especial 57 - Lote 200
CEP: 71205-050
Brasília - DF

www.anvisa.gov.br
www.twitter.com/anvisa_oficial
Anvisa Atende: 0800-642-9782
ouvidoria@anvisa.gov.br