CTD Adopting in Emerging Countries: ANVISA Perspectives

june 2018

Anvisa/Brasília

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Agência Nacional de Vigilância Sanitária

Anvisa as ICH Regulatory Member

ICH
harmonisation for better health

- Main Forum for harmonization of technical requirements;
- Composed by regulators and pharmaceutical industry;
- It was reformed in 2012 which allowed ANVISA approched the Forum;
- In December 2015 Anvisa officially becomes an Observer in ICH;
- In November 2016, at the Osaka meeting, ANVISA becomes a Regulatory Member of ICH

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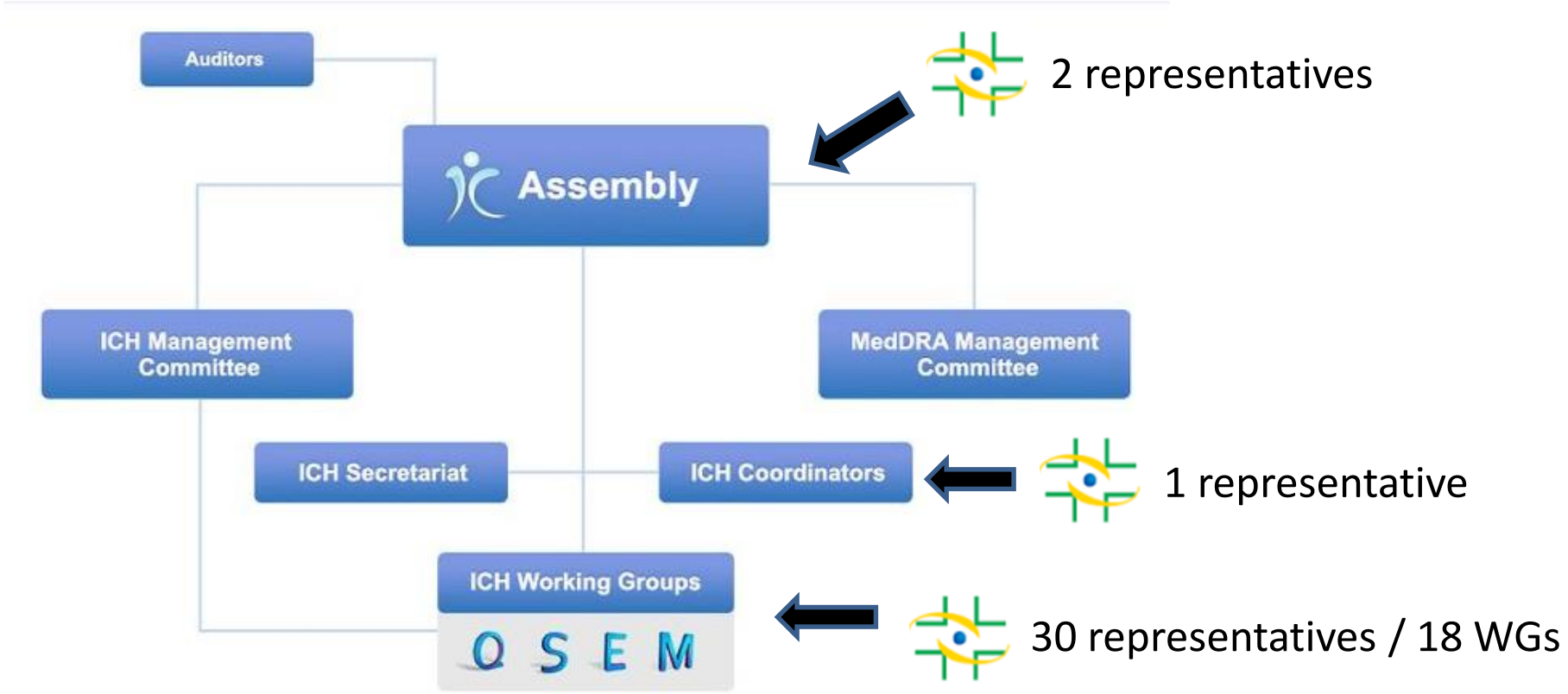
Organisation of ICH



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Members

Founding Regulatory Members:
FDA, United States
EC, Europe
MHLW/PMDA, Japan

Regulatory Members:
ANVISA, Brasil
CFDA, China
HAS, Singapore
MFDS, Korea

Standing Regulatory Members:
Health Canda, Canada
Swissmedic, Swiss

Founding Industry Members:
EFPIA
JPMA
PhRMA

Industry Members:
BIO
IGBA
WSMI

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Observers

Standing Observers :

IFPMA
WHO

Legislative or Administrative Authorities

CDSCO, Índia
CECMED, Cuba
COFEPRIS, México
INVIMA, Colômbia
SAPRAH, África do Sul
NATIONAL CENTER, Kazakhstan
ROSZDRAVNADZR, Russia
TFDA, Taipei
TGA, Austrália

http://www.ich.org/about/membership.html

Regional Harmonization Initiatives (RHIs)

APEC
ASEAN
EAC
GHC
PANDRH
SADC

International Pharmaceutical Industry Organisation

APIC

International Organisation Regulated or Affected by ICH Guideline(s)

Bill& Melinda Gates Foundation
CIOMS
EDQM
IPEC
PIC/S
USP

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ICH involves: 86 Representatives of Members/Observers
(at Assembly/ICH MC/MedDRA MC)

ICH comprises

- 23 WG– 1 dormant (M4)
- 525 Experts in WGs
- ANVISA has 30 representatives in 18 WG
- http://www.ich.org/products/guidelines.html - WGs Activities status

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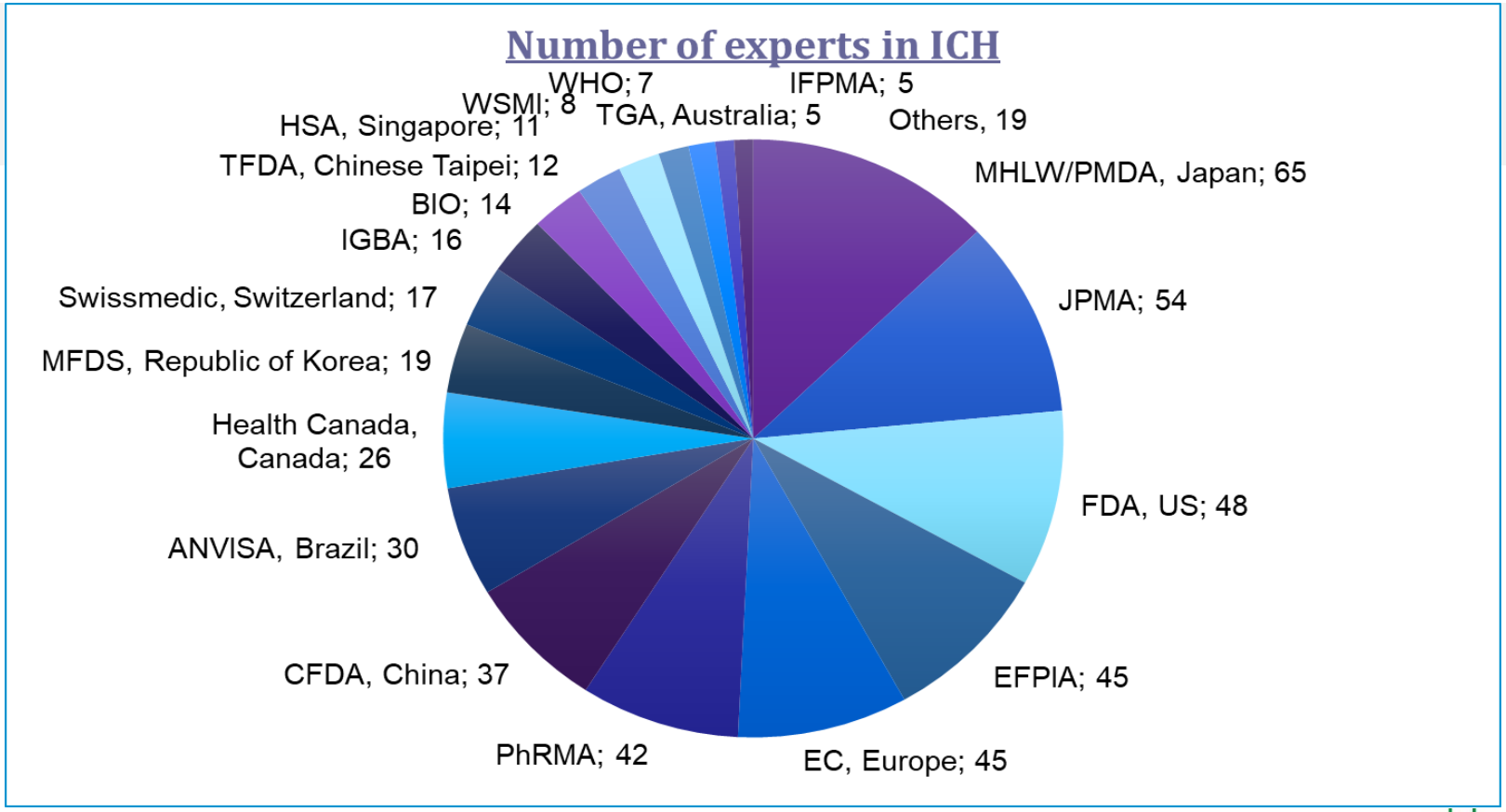

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Tier 1 – Immediate implementation
. Q1: Stability;
. Q7: Good Manufacturing Practice; e
. E6: Good Clinical Practice.

Tier 2 – 5 years to implementation – until november, 2021
. **E2A: Clinical Safety Data management: Definitions and Standards for Expediting Reporting;**
. E2B: **: Clinical Safety Data management: Data Elements for Transmission of Individual Cas Safety Reports;**
. E2D: Post-Approval Safety Data Management: Definitions and Standards for Expediting Reporting;
. M4: Common technical Document;
. M1: MedDRA Terminology (Medical Dictionary for Regulatory Actvities.

Tier 3 – Medium to Long Term
Adopt the remain guidelines. Total over the sixty Guidelines.

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ANVISA Working Group – Implementation of the Level 2 Guidelines (E2A, E2B, E2D, M4, M1)

1. Portaria nº 2.309/ANVISA – establishes a Comission for the elaboration and follow-up of the implementation plan of the level 2 ICH Guidelines. (representatives from all ANVISA Boards and relevants technical areas);
2. Verification of existing implementations, pending and challenges;
3. Designing, planning and identify the needs to purchase the technological solutions to enable the implementation of the Guidelines;
4. Step wise approach for adaptations;
5. **Preparation of the Work Plan specifying action items and timelines;**
6. Validation by Collegiate Board of Directors– DICOL/ANVISA.

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M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Informal Working Group – General Drugs Office - GGMED

1. WG has representatives from all technical areas involved/affected;
2. Mapping:
   A) Define GGMED scope tier 2 Guidelines (E2A, E2B e M4)
   B) Check existing implementations;
   C) The legislations that will have to be reviewed;
   D) The main Challenges;
   E) IT needs;
   F) Benchmarking
3. **Elaboration of a working plan for implementation of the Guidelines E2A, E2B e M4;**

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M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

General Activities of the Implementation Plan:

1. Benchmarking; ✓

M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Benchmarking

Goal:

Obtain information about the experiences and challenges in the implementation of the CTD and eCTD, and learn about the technological tools used.

Completed activities in 2017:

Technical visits to TGA/Austrália, Health Canada/Canadá e Swissmedic/Switzerland;
Survey/questionnaire sent to some RAs (FDA, Cuba, Swissmedic) about the challenges on CTD/e-CTD implementation.
Meetings with suppliers of IT.

Evaluation:

During the transition period between NO FORMAT CTD to CTD FORMAT is very important that the stakeholders have the necessary knowledge of the M4 Guideline. ANVISA plans to assit in this transition include to make avalilable Protocols Guide, Q&A as well educational meetings.

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M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Benchmarking – cont.

Evaluations:

The CTD format brings a lot of benefits to both (regulator and industry) and a clear communication is essential;

The acquisition of the IT solution is not a quick and simple process. We need follow the bidding procedures (tender) and after the completion of the acquisition process we need a period around 3,5 years for development, deployment and tests.

A transition period is strongly recommended before mandatory adoption of the eCTD;

M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Atividades Gerais do Plano de Implementação

1. Benchmarking; ✓
2. Assessment of stakeholders implementation difficulties;

M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Assessment of stakeholders implementation difficulties

Goal:

Obtain stakeholder information about the needs, challenges, investments necessary to implement the CTD and eCTD format. The Agency will use this information to plan the necessary transition time (voluntary adoption of the CTD and eCTD format) and ways to assist industry to achieve total adoption of the CTD and eCTD format.

Activities planned for 2017/2018:

Stakeholders Trainnings: 1st held in November 2017 in SP in partnership with Interfarma and 2nd held in March 2018 at ANVISA headquarters in partnership with Sindusfarma

Publication of the Public Notice with the Questionnaire (expected to be made available 60 days after publication of the ANVISA CTD GUIDE)

Evaluation of the Public Notice and definition of the next steps (End of 2018)

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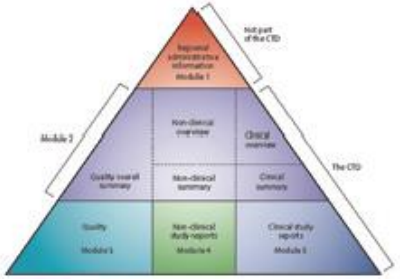
M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Implementation Plan – general activities:

1. Benchmarking; ✓
2. Assessment of stakeholders implementation difficulties;
3. Publication of the Protocol Guide in CTD Format;

M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Publication of the Protocol Guide in CTD Format



Goal:

Make the protocol in CTD format non-mandatory

Activities planned for 2017/2018:

Consult GEDOC (Protocol Sector) about the procedures of electronic protocol and scanning (2017);
Definition of CTD Module 1 (March 2018);
Translation of the M4 guides in partnership with APEX and Associations (March 2018);
Preparation of the ANVISA CTD Guide comprising Guides M4, M4Q, M4S, M4E and module 1 (April 2018)
Meeting with the productive sector to present the draft guide (March 2018);

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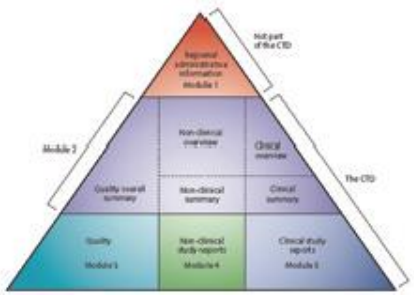
M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Publication of the Protocol Guide in CTD Format



Activities planned for 2017/2018:

Sharing of CTD Format Submission Guide for Contribution (April 2018);
Sharing of CTD Format Submission Guide with all affected areas of ANVISA (April 2018);
Publication of the CTD Format Submission Guide with instructions for paper protocol (legal document) + Electronic media (expected in June 2018)
Elaboration of Questions and Answers document considering the doubts and contributions received (expected by June 2018)

M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Implementation Plan – general activities:

1. Benchmarking; ✓
2. Assessment of stakeholders implementation difficulties;
3. Publication of the Protocol Guide in CTD Format;
4. Definition of transition rule for drugs already registered;

M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Definition of transition rule for drugs already registered;

Goal:

Definition of the transition rule for approved drug products that intend to addopt the CTD format.

Activities in 2017 and 2018:

Post market areas have established strategies for approved drug products (february 2018);
The transition rules will be published together the CTD Submissiont Guide (June 2018).

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M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

CTD Technical Requirements – Diagnostic Report x Registration Rules;

Goal:

Identify the existing gaps between the CTD technical requirements X ANVISA Registration requirements to support future revisions.

Activities planned for 2018:

Distribution of activities between technical areas (March 2018);

Completed gap analysis for all regulatory categories (June 2018);

A report will be made available to all affected areas (Agust 2018) for consideration during revision of legislation.

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M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Implementation Plan – general activities:

1. Benchmarking; ✓
2. Assessment of stakeholders implementation difficulties;
3. Publication of the Protocol Guide in CTD Format;
4. Definition of transition rule for drugs already registered;
5. Acquisition of the Technological Solution for eCTD implementation

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M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Acquisition of the Technological Solution for eCTD implementation

Goal:

Acquire the IT Solution for eCTD implementation to facilitate the assessment of applications, lifecycle and if possible include automation of database systems and process flow.

Planned Activities:

Elaboration of the documents for tender - internal phase (2018/2019);

Publication of the tender results and sign of the contract - external phase (2019).

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M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Implementation Plan – general activities:

1. Benchmarking; ✓
2. Assessment of stakeholders implementation difficulties;
3. Publication of the Protocol Guide in CTD Format;
4. Definition of transition rule for drugs already registered;
5. Acquisition of the Technological Solution for eCTD implementation
6. Implementation of the Technological Solution

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M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Implementation of the Technological Solution;

Goal:

Ensure the correct implementation of the Technological Solution for eCTD.

Planned Activities for 2019 - 2022:

Several steps are defined in the work plan considering all stages of installation, definition of validation criteria, internal flows, submission guides, etc.
An eCTD Pilot Project is planned for 2022.

M4 Implementation - Common Technical Documents for the Registration of Medicinal Products for Human Use

Implementation Plan – general activities:

1. Benchmarking; ✓
2. Assessment of stakeholders implementation difficulties;
3. Publication of the Protocol Guide in CTD Format;
4. Definition of transition rule for drugs already registered;
5. Acquisition of the Technological Solution for eCTD implementation
6. Implementation of the Technological Solution
7. Publicação do Guia de Submissão eCTD

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Final Considerations

- The adoption of the CTD format will initially be non-mandatory;
- Anvisa intends to maintain an open and constant dialogue with the stakeholders to ensure an effective adhesion to the new format with constant training sessions and discussions;
- Anvisa intends to adopt the eCTD to ensure maximum benefit from adopting the CTD format;
- The date of mandatory adoption shall be defined taking into account the needs of all stakeholders.

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