ICH M10 GUIDELINE ADOPTION BY ANVISA

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Coordination of Therapeutic Equivalence

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Internal Governance for ICH

- Ordinance (Portaria) 1.520/2019
- Service Orientation 75/2019
Internal Governance for ICH

Ordinance 1.520/2019 -> Ordinance with Anvisa´s regulatory performance model for harmonizing and internalizing themes developed within the scope of ICH.

- Governance structure;
- Requirements for representatives participation;
- Responsibilities;
- Flow for harmonization and internalization of ICH themes -

detailing of activities will be in specific Service Orientation (OS).
Internal Governance for ICH

OS 75/2019 -> Service Orientation on the flow to harmonization and internalization of themes developed within the scope of ICH.

After adoption on ICH -> Anvisa Internalization of ICH Guideline

• **Step 1:** Identification of the national legal basis related to the theme.
Brazilian Legislation on Bioanalysis

- RDC 27/2012 - Minimum requirements for the validation of bioanalytical methods used in studies for the purposes of medicine marketing authorization and post approval changes.
After adoption on ICH -> Anvisa Internalization of ICH Guideline

• **Step 2**: Internalization of ICH Guideline totally or partially.

• **Step 3**: Appropriate regulatory instrument for internalization.
Anvisa Regulatory Instruments

Service Orientation and Ordinance are instruments of internal scope
Resolution of Collegiate Board (RDC)
RDC is the act expressing collegiate decision to issue rules on matters within the agency's scope with provision for sanction in case of non-compliance.

Normative Instruction
Normative instruction is the act that expresses a normative decision of the collegiate board for the purpose of detailing rules and procedures of external scope, established in RDC.
After adoption on ICH -> Anvisa Internalization of ICH Guideline

• **Step 4:** Assessment of the need for a new consultation with external agents.

• **Step 5:** Deadline for internalization, including deadline for document translation.

• **Step 6:** Need to change or revoke a normative act.
Brazilian Legislation on Bioanalysis

• RE 895/2003 -> Guide for elaborate technical report of relative bioavailability/bioequivalence study -> tables and attachments

• RE 1170/2006 -> Guide for medicines relative bioavailability/bioequivalence evidences -> no impact

• RDC 27/2012 -> Minimum requirements for the validation of bioanalytical methods used in studies for the purposes of medicine marketing authorization and post approval changes -> almost all
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9. Glossary
After adoption on ICH -> Anvisa Internalization of ICH Guideline

• **Step 7:** The internalization plan must be submitted to DICOL’s decision (fully approve, approve with reservations or request diligences from the organizational unit to carry out complementations).

• **Step 8:** After approval of the internalization plan, the ANVISA ICH coordinator must inform ICH secretariat of the way and deadlines defined by DICOL for internalization.
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- **Step 9:** Elaboration of regulatory instrument (OS 56/2018).
  - Elaborate regulatory instrument;
  - Public consultation (analyze the contributions received and promote the relevant adjustments);
  - Legal analysis;
  - DICOL deliberation (approve, make adjustments, filing);
  - Publish the final regulatory instrument in the DOU.
Conclusion

Approval of ICH harmonised guideline of Bioanalytical method validation and study sample analysis --> November, 2021

After adoption by ICH, long way till its internalization in Anvisa.
Thank you!

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