SINDUSFARMA Working Group Regulatory Latam

SINDUSFARMA

Overview of ICH guidelines acceptance in Latin America

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INTRODUCTION

The ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) has been established in 1990 gradually evolving, to respond to the increasingly global face of drug development. ICH's mission is to achieve greater harmonization worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner.

In November 2016 the first Regulatory Agency in Latin America – ANVISA from Brazil – became member of ICH after more than 5 years of interactions. Mexico and Cuba became observers in June 2016 and November 2016 respectively, through their Regulatory Agencies, COFEPRIS (Mexican Health Authority) and CECMED (Cuban Health Authority). Additionally in November 2017, INVIMA (Colombia Health Authority) also became an observer at ICH.

ICH Guidelines were always considered a high standard reference in terms of technical requirements for Health Authorities in Latin America but their importance towards regulatory convergence have become more relevant with the introduction of ANVISA as member and COFEPRIS and CECMED as observers. In this scenario, Sindusfarma Regulatory Working Group – Latin America, formed by Multinational and Brazilian pharmaceutical industries performed an analysis of the current situation of ICH Guidelines acceptance in Latin America and this is presented in this document.

METHODOLOGY

There were selected 16 ICH Guidelines for evaluation:

1	Q1A (R2)	Stability Testing of New Drug Substances and Products
2	Q1B	Stability Testing: Photostability Testing of New Drug Substances and Products
3	Q1C	Stability Testing for New Dosage Forms
4	Q1D	Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
5	Q1E	Evaluation of Stability Data
6	Q1F	Stability Data Package for Registration Applications in Climatic Zones III and IV
7	Q7	Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
8	Q7 Q&A	Questions and Answers: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
9	E6 (R1)	Good Clinical Practice
10	E6 (R2)	Integrated Addendum to Good Clinical Practice (GCP)
11	E2A	Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
12	E2B (R3)	Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
13	E2B (R3)	IWG Implementation: Electronic Transmission of Individual Case Safety Reports
14	E2D	Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting
15	M4	CTD: The Common Technical Document
16	M1	MedDRA: Medical Dictionary for Regulatory Activities

The evaluation was done between the months of May and June of 2017 with the following markets: Argentina, Bolivia, Brazil, Central America (regulated markets), Chile, Colombia, Ecuador, Mexico, Paraguay, Peru, Uruguay and Venezuela.

For each one of the markets the following questions were done for each one of the above mentioned ICH Guidelines:

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

Q2. Is your local regulation aligned with this Guideline? (requirements are equivalent). Yes or No. If you responded "Partially", explain why.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

Based on responses provided by companies assessed, data compilation was done by the group in order to have a general view of ICH implementation scenario in Latin America.

SUMMARY

Q1A (R2) – Stability Testing of New Drug Substances and Products

Assessment Q1A (R2):

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

For those 17% who responded "Partially", the explanation is that ICH guideline is accepted, but still there are some local requirements that must be fulfilled (e.g. stability performed in zone IVb for Brazil).

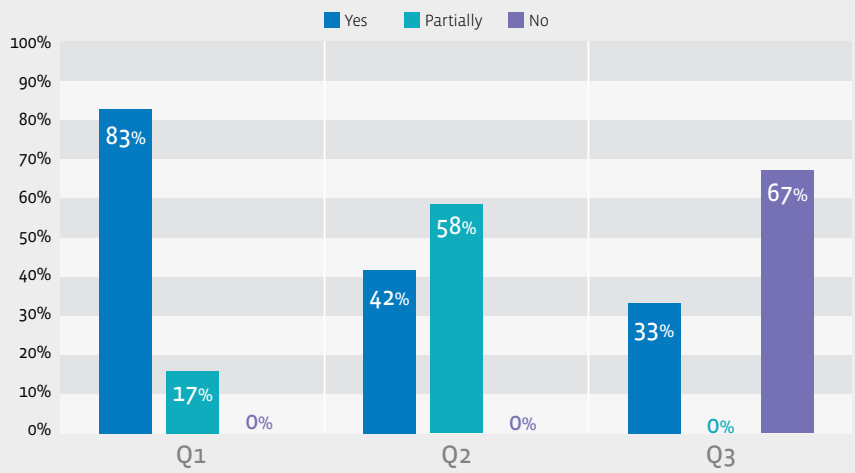
Q2. Is your local regulation aligned with this Guideline? (requirements are equivalent). Yes or No. If you responded "Partially", explain why.

For those 58% who responded "Partially", the explanation is that local guidelines usually follow essential aspects of the ICH guideline, but yet additional details are required (e.g. for Brazil biologic product's regulation has more details about in-use stability), or situations where stability studies based on ICH are accepted but local regulation still doesn't reflect ICH (e.g. Colombia).

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

Three countries indicated potential change in local guidelines to reflect ICH: Brazil (Health Authority has a 5 years implementation plan to align local regulation to ICH guidelines), Colombia (Draft regulation to adopt/adapt ICH requirements for stability released by 2Q 2017 for Industry comments) and Peru (Draft regulation for pharmaceutical product's stability released by 3Q 2017 for Industry comments). Mexico Health Authority joined ICH in 2017 as observer and it is expected to become a member in the future. If this happens, there is opportunity local regulation could change.

Q1A (R2) – STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS



Q1B – Stability Testing: Photostability Testing of New Drug Substances and Products

Assessment Q1B:

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

100% informed that photostability testing performed according to ICH is accepted in their countries, although some do not have requirement to file such data.

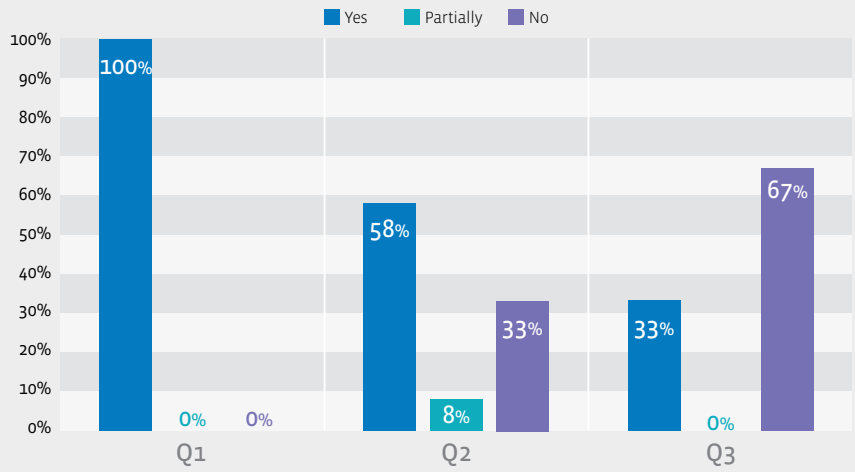
Q2. Is your local regulation aligned with this Guideline? (requirements are equivalent). Yes or No. If you responded "Partially", explain why.

33% does not have requirement for filing photostability data. 8% who responded "Partially" have local regulation not totally aligned with ICH, although photostability data is required.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

Three countries indicated potential change in local guidelines to reflect ICH: Brazil (Health Authority has a 5 years implementation plan to align local regulation to ICH guidelines), Colombia (Draft regulation to adopt/adapt ICH requirements for stability released by 2Q 2017 for Industry comments) and Peru (Draft regulation for pharmaceutical product's stability released by 3Q 2017 for Industry comments). Mexico Health Authority joined ICH in 2017 as observer and is expected to become a member in the future. If this happens, there is opportunity local regulation could change.

Q1B – STABILITY TESTING: PHOTOSTABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS



Q1C – Stability Testing for New Dosage Forms

Assessment Q1C:

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

8% who responded "No" informed that there is a specific guideline that defines the requirements for stability of New Dosage Forms (different time points and quality parameters).

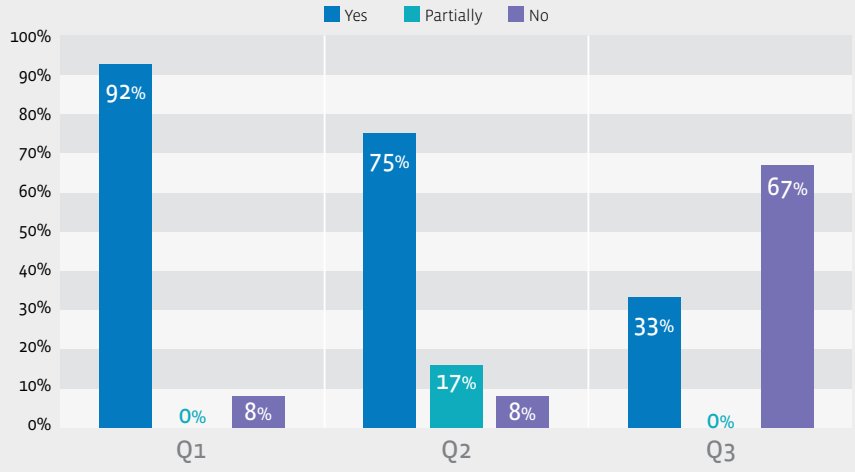
Q2. Is your local regulation aligned with this Guideline? (requirements are equivalent). Yes or No. If you responded "Partially", explain why.

17% who responded "Partially" states that ICH Guidelines are accepted but the requirements are not included in the local regulation. 8% who responded "No" states that data must rely on general local stability guidelines.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

Three countries indicated potential change in local guidelines to reflect ICH: Brazil (Health Authority has a 5 years implementation plan to align local regulation to ICH guidelines), Colombia (Draft regulation to adopt/adapt ICH requirements for stability released by 2Q 2017 for Industry comments) and Peru (Draft regulation for pharmaceutical product's stability released by 3Q 2017 for Industry comments). Mexico Health Authority joined ICH in 2017 as observer and is expected to become a member in the future. If this happens, there is opportunity local regulation could change.

Q1C – STABILITY TESTING FOR NEW DOSAGE FORMS



Q1D – Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products

Assessment – Q1D:

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

25% who responded "Partially" informed that the concept of Bracketing and Matrixing can be used to technically justify the study design. In the case of Brazil, it is applicable only when the composition of the different strengths are proportional.

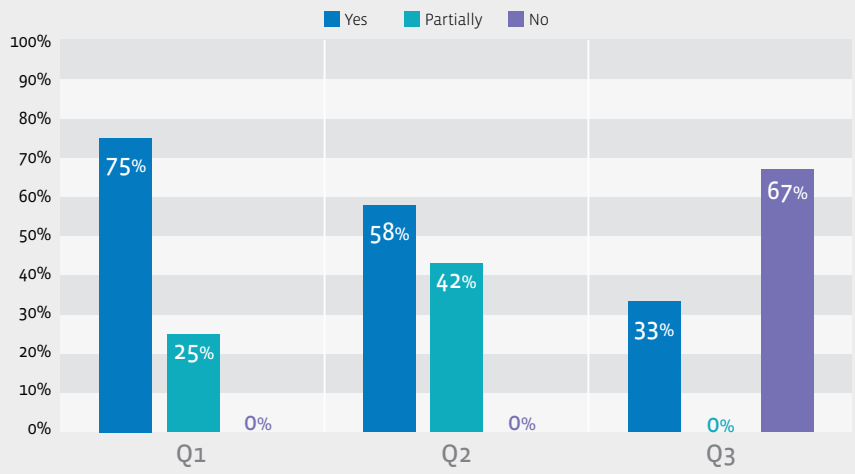
Q2. Is your local regulation aligned with this Guideline? (requirements are equivalent). Yes or No. If you responded "Partially", explain why.

42% who responded "Partially" states that local regulations don´t detail the requirements for Bracketing and Matrixing Designs. So, if it is required, the ICH guideline is accepted.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

Three countries indicated potential change in local guidelines to reflect ICH: Brazil (Health Authority has a 5 years implementation plan to align local regulation to ICH guidelines), Colombia (Draft regulation to adopt/adapt ICH requirements for stability released by 2Q 2017 for Industry comments) and Peru (Draft regulation for pharmaceutical product's stability released by 3Q 2017 for Industry comments). Mexico Health Authority joined ICH in 2017 as observer and is expected to become a member in the future. If this happens, there is opportunity local regulation could change.

Q1D – BRACKETING AND MATRIXING DESIGNS FOR STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS



Q1E – Evaluation of Stability Data

Assessment – Q1E:

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

8% who responded "Partially" informed that extrapolation is not considered. For shelf-life confirmation and extension it is required long term stabilities. The retest period for drug substances requires carry out tests that are indicative of the shelf-life.

Q2. Is your local regulation aligned with this Guideline? (requirements are equivalent). Yes or No. If you responded "Partially", explain why.

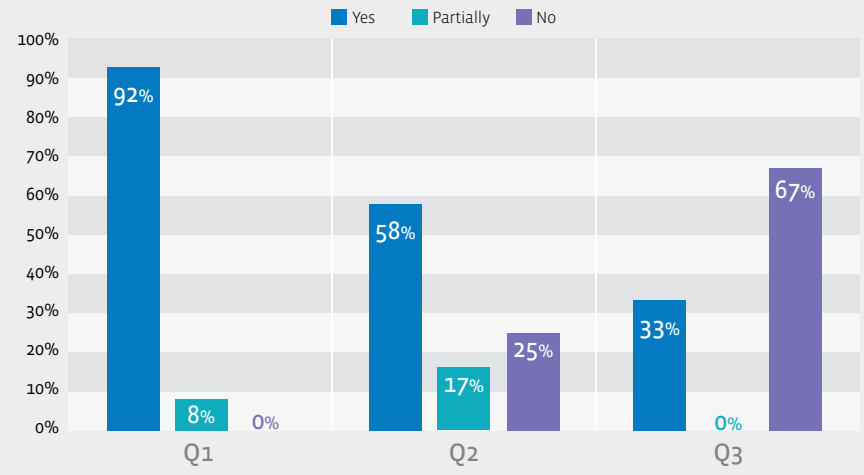
17% who responded "Partially" states that local regulations are not totally aligned with criteria described at this guideline. 25% who responded "No" states that local regulations doesn't detail how the evaluation of stability data is performed.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

Three countries indicated potential change in local guidelines to reflect ICH: Brazil (Health Authority has a 5 years implementation plan to align local regulation to ICH guidelines), Colombia (Draft regulation to adopt/adapt ICH requirements for stability released by 2Q 2017 for Industry comments) and Peru (Draft regulation for pharmaceutical product's stability released by 3Q 2017 for Industry comments).

Mexico Health Authority joined ICH in 2017 as observer and is expected to become a member in the future. If this happens, there is opportunity local regulation could change.

Q1E – EVALUATION OF STABILITY DATA



Q1F – Stability Data Package for Registration Applications in Climatic Zones III and IV

Assessment – Q1F:

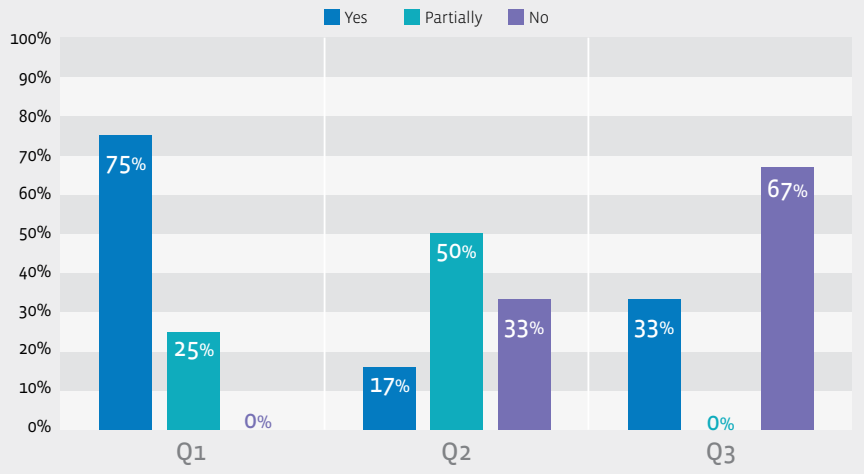
Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

25% who responded "Partially" informed that additional requirements are needed as per local regulations, such as packaging impermeability, specific storage conditions for excursion evaluation, differences in tests required by dosage form, stability documentation content, etc. Important to note that some countries in the region are placed in Zone II, however it is acceptable to present data in more stringent conditions (Zone II or IV).

Q2. Is your local regulation aligned with this Guideline? (requirements are equivalent). Yes or No. If you responded "Partially", explain why.

33% who responded "No" are countries that are placed in Zone II and regulations require stability studies to consider this zone, nevertheless in practice Zone IV (A/B) studies can be presented since they are more stringent conditions. 50% of countries that responded "Partially" informed that their local regulations are aligned with this guideline, however there are slight differences such as the number of lots for stability commitments, excursion evaluation with different settings, no differentiation of studies designs depending on pharmaceutical forms.

Q1F – STABILITY DATA PACKAGE FOR REGISTRATION APPLICATIONS IN CLIMATIC ZONES III AND IV



Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

Three countries indicated potential change in local guidelines to reflect ICH: Brazil (Health Authority has a 5 years implementation plan to align local regulation to ICH guidelines), Colombia (Draft regulation to adopt/adapt ICH requirements for stability released by 2Q 2017 for Industry comments) and Peru (Draft regulation for pharmaceutical product's stability released by 3Q 2017 for Industry comments). Mexico Health Authority joined ICH in 2017 as observer and is expected to become a member in the future. If this happens, there is opportunity local regulation could change.

Q7 – Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
Q7 Q&As – Questions and Answers: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

Assessment Q7 and Q7 Q&As:

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

17% that responded "Partially" informed that local regulation is aligned with WHO Guidance and also different GMP requirements when comparing the guideline with local regulations.

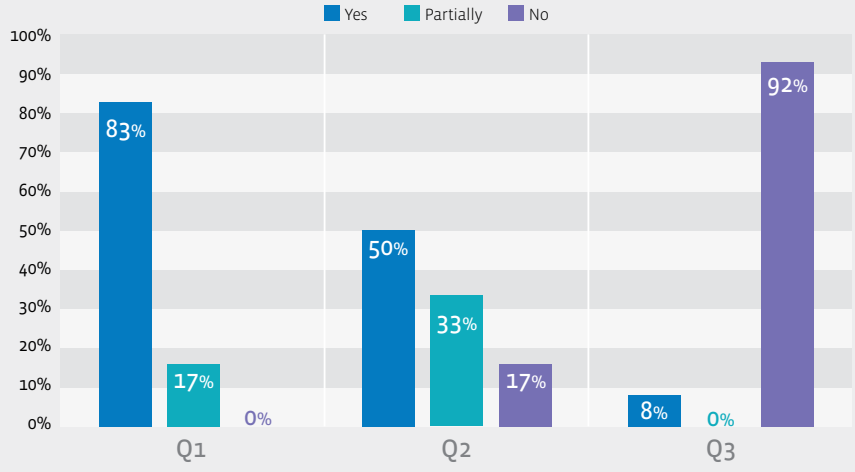
Q2. Is your local regulation aligned with this Guideline? (requirements are equivalent). Yes or No. If you responded "Partially", explain why.

33% that responded "Partially" informed that local regulation have some different requirements compared to this guideline. 17% that responded "No" has no specific determination of such requirements in local regulations.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

One country indicated potential change in local guidelines to reflect ICH: Brazil (Health Authority has a 5 years implementation plan to align local regulation to ICH guidelines).

Q7 AND Q7 Q&As – GOOD MANUFACTURING PRACTICE GUIDE FOR ACTIVE PHARMACEUTICAL INGREDIENTS



E6 (R1) – Good Clinical Practice

Assessment E6 (R1):

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

92% informed that Good Clinical Practice Guideline is accepted in their countries. 8% who responded "Partially" have local regulation not totally aligned with ICH.

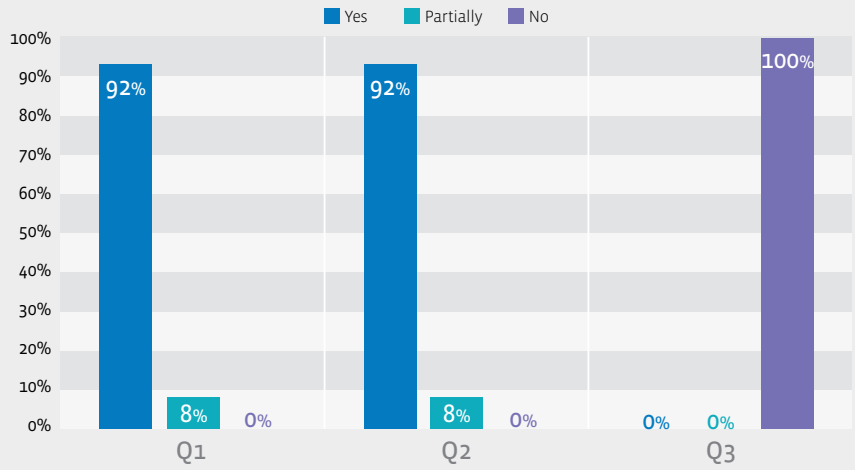
Q2. Is your local regulation aligned with this Guideline? (Requirements are equivalent). Yes or No. If you responded "Partially", explain why.

92% is aligned with this Guideline. 8% who responded "Partially" have local regulation not totally aligned with ICH.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

We haven´t identified any activity from the Health Authorities in the countries that are not aligned to this guideline to review their current regulation.

E6 (R1) – GOOD CLINICAL PRACTICE



E6 (R2): Integrated Addendum to Good Clinical Practice (GCP)

Assessment E6 (R2):

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

92% informed that Integrated Addendum to Good Clinical Practice (GCP) is accepted in their countries. 8% who responded "Partially" have local regulation not totally aligned with ICH.

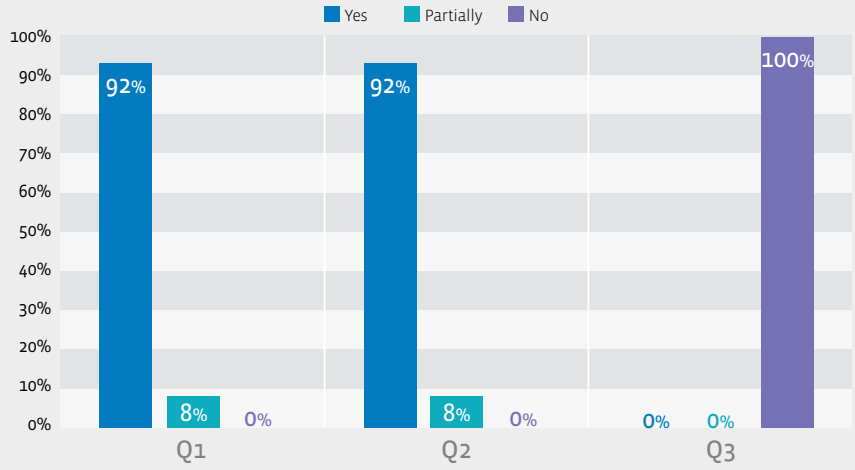
Q2. Is your local regulation aligned with this Guideline? (Requirements are equivalent). Yes or No. If you responded "Partially", explain why.

92% is aligned with this Guideline. 8% who responded "Partially" have local regulation not totally aligned with ICH.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

We haven´t identified any activity from the Health Authorities in the countries that are not aligned to this guideline to review their current regulation.

E6 (R2) – INTEGRATED ADDENDUM TO GOOD CLINICAL PRACTICE (GCP)



E2A – Clinical Safety Data Management: Definitions and Standards for Expedited Reporting

Assessment E2A:

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

83% informed that Clinical Safety Data Management: Definitions and Standards for Expedited Reporting is accepted in their countries. 8% who responded "Partially" have local regulation not totally aligned with ICH. 8% who responded "No" informed that regulation will be reviewed according with ICH.

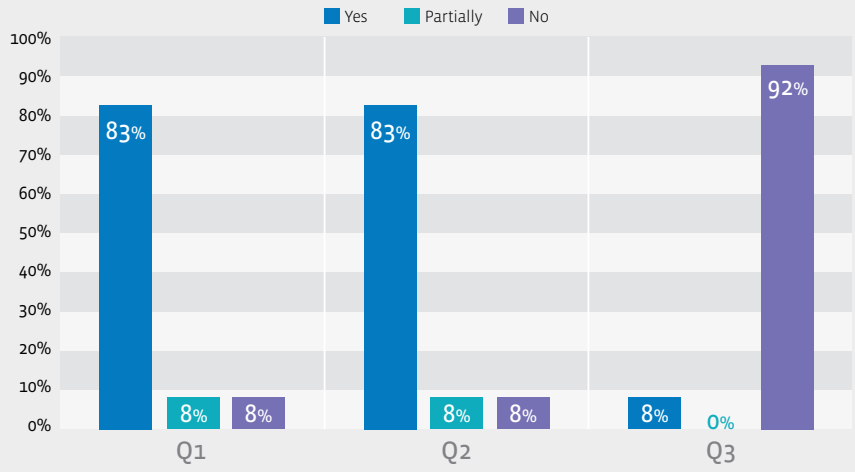
Q2. Is your local regulation aligned with this Guideline? (Requirements are equivalent). Yes or No. If you responded "Partially", explain why.

83% is aligned with this Guideline. 8% who responded "Partially" have local regulation not totally aligned with ICH. 8% who responded "No" informed that regulation will be reviewed according with ICH.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

One country indicated potential change in local guidelines to reflect ICH: Brazil (Health Authority has a 5 years implementation plan to align local regulation to ICH guidelines).

E2A – CLINICAL SAFETY DATA MANAGEMENT: DEFINITIONS AND STANDARDS FOR EXPEDITED REPORTING



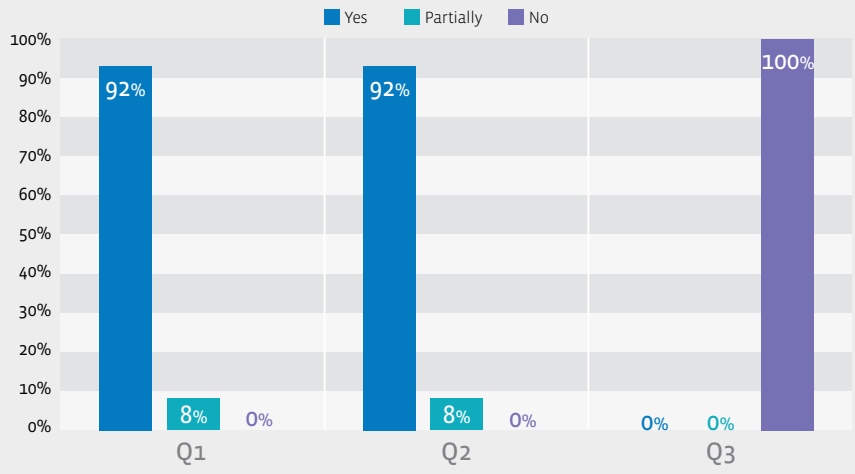
E2B(R3) – Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
E2B(R3) IWG – Implementation: Eletronic Transmission of Individual Case Safety Reports

Assessment E2B (R3) & E2B (R3) IWG:

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

92% informed that Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports Guideline is accepted in their countries. 8% who responded "Partially" have local regulation not totally aligned with ICH.

E2B (R3) & E2B(R3) IWG – CLINICAL SAFETY DATA MANAGEMENT: DATA ELEMENTS FOR TRANSMISSION OF INDIVIDUAL CASE SAFETY REPORTS



Q2. Is your local regulation aligned with this Guideline? (Requirements are equivalent). Yes or No. If you responded "Partially", explain why.

92% is aligned with this Guideline. 8% who responded "Partially" have local regulation not totally aligned with ICH.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

We haven´t identified any activity from the Health Authorities in the countries that are not aligned to this guideline to review their current regulation.

E2D – Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting

Assessment E2D:

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

83% informed that Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting Guideline is accepted in their countries. 8% who responded "Partially" have local regulation not totally aligned with ICH. 8% who responded "No" informed that regulation will be reviewed according with ICH.

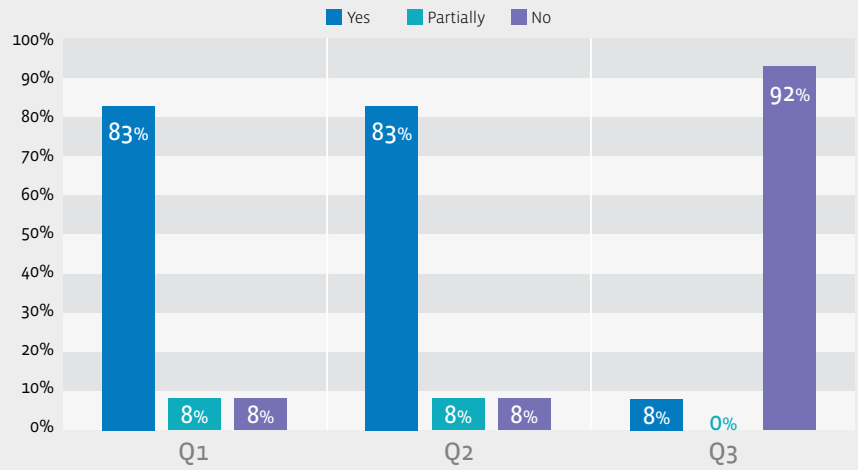
Q2. Is your local regulation aligned with this Guideline? (Requirements are equivalent). Yes or No. If you responded "Partially", explain why.

84% is aligned with this Guideline. 8% who responded "Partially" have local regulation not totally aligned with ICH. 8% who responded "No" informed that regulation will be reviewed according with ICH.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

One country indicated potential change in local guidelines to reflect ICH: Brazil (Health Authority has a 5 years implementation plan to align local regulation to ICH guidelines).

E2D – POST-APPROVAL SAFETY DATA MANAGEMENT: DEFINITIONS AND STANDARDS FOR EXPEDITED REPORTING



M4 – CTD: The Common Technical Document

Assessment M4:

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

58% that responded "Partially" informed that sections of the CTD are accepted; however other sections are not required. Also, local guidelines establish format for each submission, so countries extract the sections of the CTD to include in the local structure. There also differences about CTD acceptance across products' modalities (e.g. CTD is accepted for Biologics but not for Small Molecules).

Q2. Is your local regulation aligned with this Guideline? (Requirements are equivalent). Yes or No. If you responded "Partially", explain why.

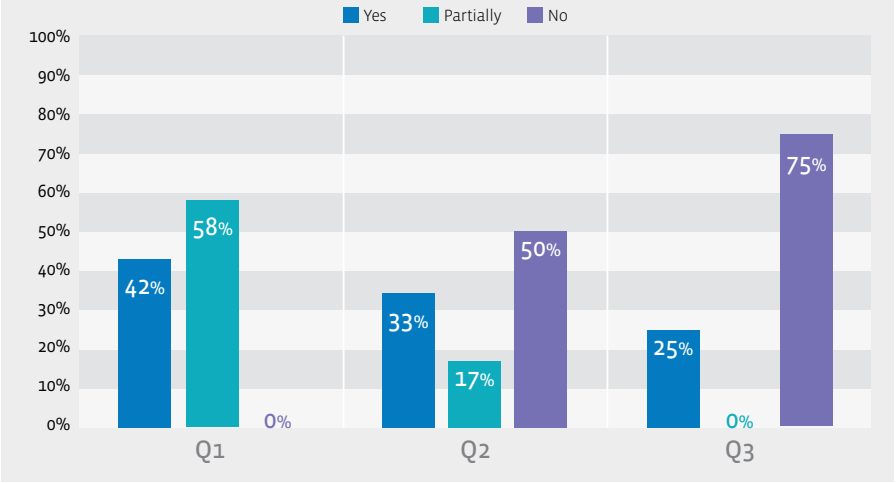
17% that responded "Partially" informed that CTD structure is according to local regulations, but

there are small differences, such as requirements for wet signatures, or additional contents or formats to be fulfilled. 50% that responded "No" informed that local regulations establish content and format differently that CTD, even though in some cases CTD format is acceptable.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

25% of pooled countries (Brazil, Mexico and Colombia) may have the opportunity to formally implement this guideline in the near future, considering they are now members or observers of ICH. This can be considered more certain and short-term for Brazil since there is already a plan in place for the implementation, differently than Mexico and Colombia, which Health Authorities have not disclosed any implementation plan yet.

M4 – CTD: THE COMMON TECHNICAL DOCUMENT



M1 – MedDRA: Medical Dictionary for Regulatory Activities

Assessment M1:

Q1. Is this Guideline accepted by your Health Authority? In other words, if you provide documentation according to this Guideline in your submissions, will this be accepted? Yes or No. If you responded "Partially", explain why.

83% informed that MedDRA: Medical Dictionary for Regulatory Activities Guideline is accepted in their countries. 8% who responded "Partially" have local regulation not totally aligned with ICH. 8% who responded "No" informed that regulation will be reviewed according with ICH.

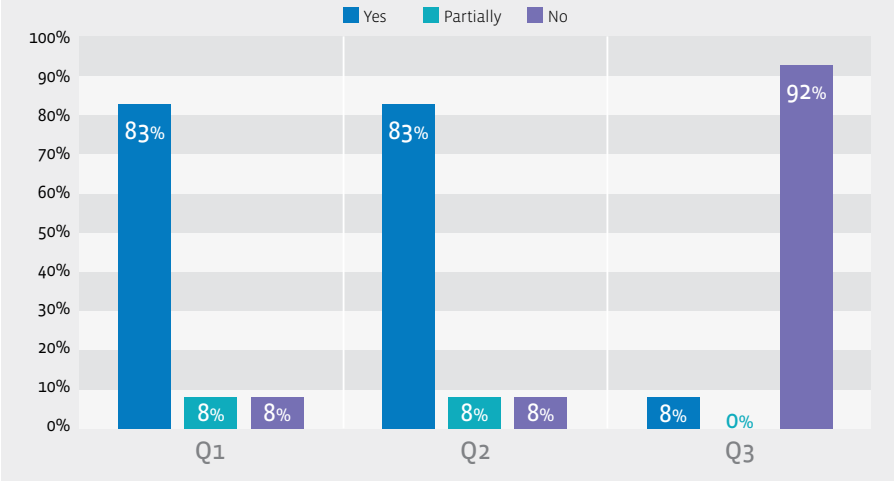
Q2. Is your local regulation aligned with this Guideline? (Requirements are equivalent). Yes or No. If you responded "Partially", explain why.

83% is aligned with this Guideline. 8% who responded "Partially" have local regulation not totally aligned with ICH. 8% who responded "No" informed that regulation will be reviewed according with ICH.

Q3. If not implemented or accepted, is there any plan for it? Yes or No. If yes, expected date for implementation or acceptance.

One country indicated potential change in local guidelines to reflect ICH: Brazil (Health Authority has a 5 years implementation plan to align local regulation to ICH guidelines).

M1 – MEDDRA: MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES



CONCLUSIONS AND RECOMMENDATIONS

This study had the intention to evaluate the acceptance of ICH Guidelines in Latin America region, and also identify opportunities for harmonization of requirements. The collected data is based on local regulations, but when regulations were not clear the information relied on the local knowledge and experience of interviewed companies. Information was also validated by several different professionals in the regulatory area (local and regional) from different pharmaceutical companies.

As showed by the collected data, there is still a lack of harmonized requirements among the Latin America countries, making the regulatory operations in this region very complex mainly for multinational companies. On the other hand, it is very positive the movement of some Health Authorities to became observers or members of ICH, clearly indicating the intention to seek global convergence.

The biggest impact is seen for ICH guidelines related to Quality and Control, while ICH Clinical Guidelines have more acceptance by local Health Authorities.

Of the evaluated Guidelines, stability guidelines are those with more opportunities for convergence, because there are still many local specific requirements not enclosed in ICH Guidelines, and it represents one of the major critical information to be planned and part of CMC dossiers worldwide.

Another area of opportunity that has been verified is related to M4 Guideline – Common Technical Dossier format, since each country has its own format and content for regulatory submissions. Even though some countries do accept submissions in CTD format, additional ancillary documents and local customizations are required by the Health Authorities, duplicating efforts for dossier preparation and therefore delaying local submissions and approvals.

All these aspects impairing requirements and dossier convergence are ultimately impacting new drug and technologies access to the patients and also the lifecycle management for the drugs already in the market in Latin America.

It is notable the intention from Health Authorities to look for regulatory convergence and some initiatives like reliance, reviewing of old regulations, countries seeking ICH membership are welcome, however there is still a big area of improvement towards convergence.

MASTHEAD / EXPEDIENTE

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