# Definitions of terms in the context of the implementation of ICH Guidelines

| *Term* | Definition | Comments |
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| ***Not (yet) implemented*** | The process for the implementation of an ICH Guideline has not yet started. | a) No guideline exists or b) national/ regional guideline deviating from ICH Guideline or national/regional guideline exists but the process for replacement or amendments for alignment with the ICH Guideline has not started yet. |
| ***In the process of implementation*** | The process for the implementation of the ICH Guideline has started and has reached a specified milestone. The process is monitored by the regulatory agency and the progress is reported to the ICH MC/Assembly on a regular basis. | The process can have different starting points: a) no national/regional guideline exists; the ICH Guideline defines new requirements and b) a national/regional guideline is in the process of development or c) a national/regional guideline exists and is replaced by or is amended to be in line with the ICH Guideline. Generic processes for a) non-electronic and b) electronic guidelines will be defined outlining the milestones that should be followed. |
| ***Implemented*** | The process of implementation is completed. This step is identical to step 5 of the ICH process. | This term refers to the self-declaration of the regulator regarding the conclusion of the implementation process. Usually, the regulator publishes the final guideline. |
| ***Adequately implemented*** | All relevant elements, concepts and principles of the ICH Guideline are followed. This is done preferably by referring to/implementing the original ICH Guideline text and/or translating the original guideline text. This may include in justified cases | Minimal elements, concepts and principles will be defined and included in the survey to assess the degree of implementation. Additional information to the ICH guideline should only be included in order to provide clarity and facilitate implementation by |

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| | implementation of the guideline in a way that may incorporate additional information beyond those defined in the ICH Guideline in circumstances when the Guideline is too high-level and does not provide sufficient guidance. | industry, but should not increase regulatory burden.<br><br>Deviations or additional information to help clarify concepts should be communicated (with the justification) to the ICH Management Committee for transparency and possibly assessment. |
| ***Not adequately implemented*** | The ICH Guideline has been implemented in a modified way that a) incorporates additional requirements beyond those defined in the ICH Guideline without objective justification in cases where clear guidance is provided, or b) does not include all relevant elements, concepts and principles of the ICH guideline and does not provide any objective justification for omitting some requirements in the guideline or c) requires application of the guideline for a smaller range of products than outlined in the ICH Guideline. | Lack of adequate implementation means that the ICH guideline has not been adequately implemented following an assessment of the regulatory or administrative measure that incorporates the ICH Guideline into the regulatory framework.<br><br>There may be varying degrees of inadequate implementation and this assessment can only be done on a case-by-case basis. Examples could be taken from the Industry Survey to illustrate this range. It should be noted that according to the Assembly RoP (v. 4.0), deviation from the guideline, in exceptional cases, may be accepted if objectively justified. |
| ***Adherence**** | In its practice, the regulatory authority consistently adheres to (applies) all identified relevant elements, concepts and principles of the ICH Guideline over time. | Once an ICH Guideline has been (adequately) implemented by a regulatory authority, experience is gathered on how the regulator applies the guideline in practice. Adherence leads to a stable regulatory environment and to increased sustainability. Adherence may be assessed in regular intervals. |

* Adherence at this point in time is defined as application of the ICH Guideline by the regulator's view. At a later stage, consideration will be given to the aspect of adherence to the guideline requirements by industry's view.

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| ***Lack of adherence*** | Even if the guideline has been adequately implemented, it is not being applied and adhered to in practice. | The regulatory authority does not in practice require industry to adhere to the guideline or does not follow the guideline when assessing the applications; e.g. is in its practice adding requirements beyond what is provided in the (implemented) ICH guideline. |
| ***Confirmed implementation/ adherence*** | Both the implementation of and adherence to the ICH Guideline have been assessed by an independent third party and have been found to be adequate by the Assembly/the MC (see above). | The assessment should be done in two-steps: first assessment of a) adequate implementation and then b) adherence to the ICH Guideline.<br>The implementation should not be considered confirmed even in case of adherence if there is no adequate implementation of the ICH Guideline (i.e. where the regulatory authority in practice accepts submissions that comply with the requirements in the ICH Guideline despite not having adequately implemented it). |
| ***Not applicable*** | The implementation of a specific ICH guideline is not applicable in a country/region. An appropriate justification is provided. | Example: A country may not have its own Pharmacopeia but references internationally recognized Pharmacopoeias. Hence, the ICH Q4B Guideline is not applicable (and does not need to be implemented). |