

Biogen Specific Teaching Material

ICH – International Council for Harmonisation





Questions & Answers

1. What is the ICH's mission?



1. The ICH aims to achieve greater harmonisation worldwide for ensuring the safety, efficacy and high-quality of medicines developed, registered and maintained in Europe.
- 

2. What does the ICH develop?



2. The ICH develops standardized, commendable guidelines for the evaluation of the quality, efficacy and safety of medicines.



3. What is the standardized format for the submission of approval documents called?




3. The standardized format for the submission of approval documents called the Common Technical Document (CTD).



4. What is the Common Technical Document (CTD)?


4. The CTD is the harmonised, standardized electronic format for submitting scientific documents for regulatory review and approval, which enables the implementation of good review practices, is called the



5. What is MedDRA?



5. The MedDRA is a clinically-validated international medical dictionary used by regulatory authorities and the regulated biopharmaceutical industry.



6. What types of scientific guidelines is the ICH designed to produce and develop for Europe?



6. The ICH serves to produce scientific guidelines for the safety, quality, efficacy, and other disciplines, in pharmaceuticals for human use.




7. Swissmedic are standing regulatory members of the ICH.
(true or false?)



7. True. There are two Swiss members on the board of the ICH.



8. The number of founding members at the ICH are always the same. (true or false?)



8. That's correct. By definition, a founding member can only ever be the same. The number of additional members (and observers) can change, however.



9. Which four categories comprise the harmonication of ICH?



9. ICH harmonisation activities fall into four (4) categories of procedures: formal ICH, Q&A, revision, and maintenance.



Thank you for your attention!

D-SCHULE – Your Language School



D-SCHULE
Domenika Hüsler
info@d-schule.ch
+41 79 730 52 35