Consultation: Release of Draft (Step 2) ICH Guideline: Q13: Continuous Manufacturing of Drug Substances and Drug Products

October 28, 2021

Our file number: 21-114345-131

The above referenced draft guideline was released by the International Council for Harmonisation (ICH) Assembly for consultation and is being posted on the ICH website for information and comment in accordance with Step 2 of the ICH process.

Please note that draft guidelines are only available in English until finalised by the ICH. It is also important to note that amendments to draft documents may occur as a result of regulatory consultations and subsequent deliberations within the ICH.

All comments forwarded to Health Canada will be transmitted to the ICH as is, with the disclaimer that they are provided for information and do not necessarily represent the views of Health Canada, except as specifically indicated in separate comments.

As appropriate, your organization may alternatively wish to provide comments to your affiliate association in the United States, Europe or Japan for their input directly to ICH.

Please use the ICH template for public consultations to send in your comments. Comments provided to Health Canada should be submitted by **December 27, 2021** in order to allow sufficient time for their assessment and subsequent transmission to the ICH.

Comments should be directed to:

Health Canada - ICH Coordinator
E-mail: ich@hc-sc.gc.ca

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