EUROPEAN MEDICINES AGENCY
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Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000
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28 July 2025

Submission of comments on Submission of comments on ICH Q1 Guideline on stability testing of drug substances and drug products (EMA/CHMP/ICH/130561/2025)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.
When completed, this form should be sent to the European Medicines Agency electronically, in Excel format (not PDF), to the following address:
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All the cells with an asterisk (*) should be filled in prior to completing the columns "Comment and rationale" and/or "Proposed changes / recommendation".
For more details on how to use this template please refer to the tab "Manual for commenter".

Name of organisation or individual*	Line from* (line Nr or 0 for general comment)	Line to* (line Nr or 0 for general comment)	Section number	Comment and rationale (to go to next line within the same cell use Alt + Enter)	Proposed changes / recommendation (if applicable - to be used if you want to propose specific text changes)
International Society for Stem Cell Research	140	328	2 - 3.2	We agree that accelerated or stress conditions may not yield relevant information, especially given that degradation pathways for cell therapies at room temperature differ significantly from those of cryopreserved products. However, the guidance still recommends conducting accelerated stability studies.	We recommend including specific examples to clarify how such studies may be appropriately applied.
International Society for Stem Cell Research	0	0		Guidance for centralized manufacturing models and materials stored prior to patient administration are well elucidated, however they do not consider diverse or decentralized manufacturing models or instances where the product is not cyropreserved post production and prior to administration to the patient.	We recommend the guidance incorporate considerations for diverse manufacturing models, particularly decentralized manufacturing, where the drug product is administered to patients immediately post-production, without prior storage.
International Society for Stem Cell Research	0	0		We note that the guidelines do not currently include recommendations on stability testing requirements for pluripotent stem cell (PSC) banks.	We recommend the inclusion of guidance on Pluripotent Stem Cell (iPSC and hESC) bank stability testing requirements.
International Society for Stem Cell Research	0	0		We note that the guidance does not include stability testing for platform technologies.	We recommend the inclusion of possible approaches to stability testing requirements for platform technologies.
International Society for Stem Cell Research	9	28	1.2	While the scope of the guidelines is extensive, it does not specifically include Tissue Engineered Products (TEP). This is a rapidly growing area of research and translation.	We recommend including reference to Tissue Engineered Products (TEP).
International Society for Stem Cell Research	27	28	1.2	It is unclear if ATMP combined products are included in the "combination of a drug product with a medical device".	Please confirm if ATMP combined products are included in the term "combination of a drug product with a medical device."