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ICH Q6 (R1) Specifications of Drug Substances and Drug Products: Annex 1 - ATMPs

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Why Revision of ICH Q6A and Q6B?

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- ICH Q6A and Q6B reached Step 4 sign-off in 1999
- Advances in manufacturing, analytics and modelling
- New and revised ICH guidelines (Q2, Q3C-D, Q5A, Q8-14)
- Novel therapeutic modalities
- Unclear how Q6A/B should be applied in light of new ICH Guidelines

→ Modernisation needed. Start of revision in Q2/2024

Key Objectives of Revision

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- Consistency: Align Q6A and Q6B and establish general principles for both chemicals and biologicals including new modalities
- Modernisation: Adopt risk-based principles of ICH Q8-Q11
- New Scope: Broaden the scope to new or now well-established modalities
- Addition of training materials with examples and case studies

Were the objectives attained?

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- Combining of chemicals and biologicals in a single Guideline Q6(R1)
- Including science- and risk-based principles and process and product understanding for setting specifications
- Employing traditional and/or enhanced approach
- Guidance on setting specificiations for new modalities such as ADCs, ATMPs, mABs, DDCs considered as medicinal product, etc.
- Discussion of prior knowledge, modelling, simulation and statistical evaluation included.

Structure of ICH Q6 (R1)

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Guideline consisting of

- Overarching general principles,
- Specific sections for biologics and chemicals,
- Product specific appendices covering e.g. oligonucleotides, peptides, ADCs, live biotherapeutic drugs, phage therapy products, etc.
- Annexes for ATMPs and Vaccines

ATMP Annex Considerations

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- ATMP Annex is not a self-standing part of the document; it covers only ATMP-specific aspects
- Should be read in conjunction with main guideline text on general principles and biologics
- Highlights unique characteristics of ATMPs relevant to consider for setting specifications, including challenges derived from starting materials, manufacturing process and analytical testing
- Addresses specifics regarding specifications and their justification as well as selection of reference standards/materials
- Provides specific discussion on potency testing strategy for the different ATMP modalities.

Current Status and Future Steps

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- ✓ First proposal for constituency review in March 2026.
- ✓ More than 3700 comments have been received from all stakeholders, including major, minor and editorial aspects.
- ✓ Discussions of main issues took place at the EWG-Meeting in Rio in June and continued afterwards to reach common understanding.
- ✓ 2nd short-term constituency review of selected sections that have been significantly revised.

- ✓ For the ATMP Annex about 230 comments have been received.
- ✓ Comments on ATMP Annex are addressed in online-discussions without 2nd round of review.

Current Status and Future Steps

- The current plan is to publish the Step 1/2 document for public consultation after the next F2F ICH-Meeting in Prague, i.e. in Q1/2027
- At that time, work on training materials and examples will start
- Comments received from public consultation will then be addressed to reach the final revised guideline by mid 2028

THANK YOU VERY MUCH

FOR YOUR ATTENTION