**Reviewer Comments and Suggestions**

**Title: WHO Approach towards the development of a global regulatory framework for cell and gene therapy products**

**(document WHO/BS/2022.2424)**

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| Written comments proposing modifications to this Guideline MUST be received by **9 September 2022.**Comments should be submitted electronically to the Responsible Officer: Dr. Richard Isbrucker at: isbruckerr@who.int |
| Reviewer(s)(Name, Organization, and contact details): |  |

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| Line No. | Original Text | Comment | Suggested Amendment | Internal Use Only |
| **General / Overall comments on the document:** |
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| **1. Introduction** |
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| **2. Purpose** |
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| **3. Terminology** |
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| **4. Classification of HCTs and ATMPs** |
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| **5. Regulatory expectations for HCTs and ATMPs** |
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| **6. A risk-based approach for the regulatory oversight of HCTs and ATMPs** |
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| **7. Considerations in th edevelopment of a regulatory framework** |
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| **8. Collaboration and strengthening regulatory capacities for the oversight of HCTs and ATMPs** |
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| **9. Conclusion and next steps** |
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| **Acknowledgements, References, Appendix 1** |
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| **Table 1** |
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| **Figure 1** |
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