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Chair: David Abraham (QRS-Associates)

ATMP Group:

Chair: Dr Sabine Hauck dequra pharma consult hauck

Cannabis Group:

Chair: Lance Smallshaw (UCB Biopharma)

Subject: Stakeholder Comments on Draft Annex 22 to the EU GMP Guidelines

Dear Sir or Madam,

On behalf of the ECA Foundation and the ECA Academy, we would like to thank you for the opportunity to provide comments on the draft Annex 22 to the EU GMP Guidelines.

In the attached Excel file, we have focused on what we consider to be the most essential aspects that, in our view, should be revised before the final version of Annex 22 is published. Our comments are based on the practical experiences of our Working Groups and experts active in GMP and pharmaceutical quality assurance.

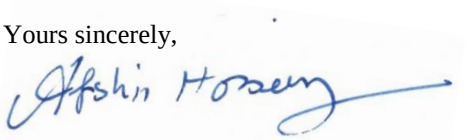
In addition, we would like to respectfully raise one further consideration. From the experience with all previous Annexes, it usually takes many years until a revision is published, and again revisions are subject to public consultation. In the fast-moving field of Artificial Intelligence, this timeline is far too long. Within just a few months, AI systems undergo rapid and sometimes disruptive developments which may have significant positive as well as negative impacts on pharmaceutical quality assurance.

A broad exclusion or limitation of certain AI systems, as currently foreseen, may hinder timely implementation of innovative solutions that could improve pharmaceutical quality. To address this, we would like to suggest considering a mechanism to complement Annex 22 through Q&As, either partially or fully. This would allow more agile updates and provide the flexibility required for such a dynamic and evolving field.

The ECA Foundation and its Working Groups would be pleased to support this process by drafting and submitting proposals for Q&As for your consideration.

We thank you again for the opportunity to comment on this important draft and remain at your disposal for any further clarification or dialogue.

Yours sincerely,



Dr Afshin Hosseiny
Chairman
ECA Foundation