Annex 1 Draft Revision and Stakeholder Comment Period

Mar 16, 2020 7:00 am EDT

Annex 1 was first published in 1971, to ensure sterility of medicinal products placed on the market for the benefits of patients.

Although it has undergone periodic targeted updates, this is the first time it has undergone a complete review. Seemingly the current Annex 1 has not kept pace with current regulatory and technological advancements and so this thorough review was necessary. According to the European Commission “this revision is intended to add clarity, introduce the principles of Quality Risk Management to allow for the inclusion of new technologies and innovative processes and to change the structure to a more logical flow.”

Key changes noted are:

- Introduction of new sections
- Introduction of QRM Principles
- Restructured to give more logical flow
- Added detail to a number of the previous sections to provide further clarity

IVT Network has been given an opportunity to represent you — the relevant stakeholders, in the second consultation. Further, IVT has agreed to receive all the comments of this second consultation from our members, to compile and return to the European Commission.

For more detail and explanation on the specific changes to Annex 1 and the expected impact on manufacture of sterile products please read our blog and watch for pending articles coming up in the March Journal of GXP Compliance.

In the meantime, you may download the Annex 1 revision documents and prepare your comments.

To better understand some historical data and the proposed changes that are included in the draft revision for comment listen to this insightful conversation with Dr. Tim Sandle: