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EU Annex 1 – Revision 2 Draft Update Brief

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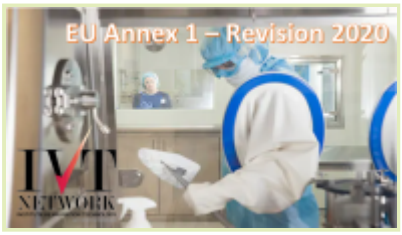

The long-awaited revision to the EU Annex 1 draft documents has caused much excitement in the world of regulated industry. In drafting the revision, the EC worked closely with the World Health Organization and PIC/S to maintain existing global standards and will now enter a 3-month period of collecting comments from stakeholders and industry leaders.

The current version of the European Union's (EU) Annex 1 to the GMPs, was issued in 2008 and applies to the manufacture of sterile medicines. A draft revision to the EU GMPs Annex 1 – Manufacture of Sterile Products (revision 1) came onto the scene in 2017 ,and that revision to Annex 1 was designed to become a structured guidance using state-of-the-art principles, e.g., quality risk management and current expectations in aseptic processing.

Some of the changes in the new draft guidance include updates or reframed text around:

- **Premises:** Barrier Technologies; Clean Room and Clean Air Device Qualification; Disinfection
- **Aseptic Utilities:** Water Systems; Steam Used as a Direct Sterilizing Agent; Gases and Vacuum Systems; Heating and Cooling and Hydraulic Systems; Personnel
- **Production and Specific Technologies:** Terminally Sterilized Products; Aseptic Preparation and Processing; Finishing of Sterile Products; Sterilization; Form-Fill-Seal; many more
- **Viable / Non-Viable:** Nov-viable Particles; Environmental and Personnel Monitoring – Viable Particles; Aseptic Process Simulation

In general, the scope of these documents has been changed to reflect that the Annex applies to Manufacture of Sterile Products, rather than the Manufacture of Sterile Medicinal Products, as evident in ***"Includes additional areas (other than sterile products) where the general principles of the annex can be applied".*** This can be considered insignificant but does provide a broader scope of applicability.

The importance of Quality Risk Management (QRM) is also emphasized in greater detail than in the 2017 version, stating: ***"This Annex provides general guidance that should be used for the manufacture of all sterile products using the principles of Quality Risk Management (QRM), to ensure that microbial, particulate and pyrogen contamination is prevented in the final product."***

Of course, we have only highlighted a few select items in this blog, however, over the coming weeks we will have several subject matter experts authoring articles and commentary on the draft EU Annex 1 2020. Please watch the JVT and GXP Journals, the IVT Blog and Podcast updates, and of course LinkedIn Groups for further information regarding the draft document/revision and the commentary period.

In the meantime, if you have comments or questions please do not hesitate to reach out to our Managing Editor at CustomerService@IVTNetwork.com

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