Annex 1 Webinar

Annex 1: Interpretation and Implementation of the latest revision

Insight from Industry Experts - Understanding and applying aspects of Annex 1 revision

Thursday 11th March 2021 Time: 14:00 – 15:30 (Irish Standard Time)

13:40 – 14:00	**Registration** & **Log in**	All Attendees
14:00 – 14:05	**Moderator:** Welcome & Introduction from PDA	Alan Kelly, Project Engineer, PM Group
14:05 – 14:25	**PUPSIT** – Consideration of the risk-based approach and potential challenges when implementing PUPSIT and how to overcome them to ensure compliance is achieved. **Contamination Control Strategy** (CCS) – Discussion of the intended approach to the CCS and how it links-in with other key GMP strategies	Andrew Hopkins, AbbVie, Ex-MHRA Regulator and previous member of Annex 1 working group
14:25 – 14:45	**Process simulations** – On outline of the key changes and how they can be implemented. **Impacts to Biological DS manufacture / Low Bioburden** – a walkthrough of how some of the Annex 1 principles are applied in the manufacture of low bioburden products and how compliance should be demonstrated.	Greg McGurk, Regeneron, Ex-HPRA Regulator and previous member of Annex 1 working group
14:45 – 15:05	**HPRA Regulatory Status –** A status update from the previous consultation and status update regarding Annex 1 revision.	Paul Sexton, HPRA Regulator
15:05 – 15:20	**Q&A Session** – Alan Kelly, Andrew Hopkins, Greg McGurk, Paul Sexton	
15:20 – 15:25	**Fireside Chat** – Q&A discussion on how pharmaceutical equipment suppliers can help enable end users comply to Annex 1 revision.	Alan Kelly, Project Engineer, PM Group Alf Gregg, Commercial Director SteriTech Process Solutions
15:25 – 15:30	**Closing remarks** -	Alan Kelly, Project Engineer, PM Group

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PDA members: 90 euros, non-members: 150 euros (plus booking fee)