

Annex 1: Top Tips & Key Takeaways

1. The comments received on Annex 1 draft have been reviewed. There won't be a second consultation period for Annex 1 revision, but it may not be issued until 2020 as the European Commission has more pressing matters to address currently.
2. It is essential that companies do not wait for the final publication as there may only be a minimum grace period before regulatory observations will be received – it was suggested it could be as little as 3 months, but this is still to be agreed by the commission. It is essential that companies read the draft, carry out a detailed gap analysis and embrace the changes.
3. Regulators perspective – the revised Annex 1 should result in fewer deviations and a better supply chain integrity.
4. In Regulators opinion and due to strong expectations driven over the years from HPRA, Ireland has embraced the revised Annex 1 and is in an excellent position regarding the draft revision for most companies.
5. Contamination Control Strategy and QRM Linkages were the strongest themes presented during the Annex 1 updates. In the original document, there were only 21 mentions of QRM. Now 132 references to QRM throughout the draft.
6. Under 'Scope' in the new Annex revision, the additional areas mentioned (low bioburden areas) are 'suggestions' where it could be applied and not mandatory.
7. A Contamination Control Strategy aims to define the ethos of a site's approach to contamination control. How we define existing controls, how we intend to enhance them, the re-evaluation frequency and how we integrate QRM within and proving we have less dependence on end testing detection. Every area should be involved in the generation of the site Contamination Control Strategy
8. Companies need to move away from tick-box compliance and prove they are applying risk-based thinking under each PQS
9. If QRM is done well, it can be used as a tool to drive innovation and continuous improvement.
10. Need a mature QRM process if we are going to deal with all the risk management expectations in the new revision of Annex 1
11. The biggest challenge for Annex 1 implementation is the execution of risk management and incorporating risk culture into organisations - Indicator of maturity of a QRM program is the "people."
12. A stable Pharmaceutical Quality System (PQS) is fundamental to the success of a CCS. Make sure you have a clear path for your Quality Systems (deviations etc.) to feedback to the quality risk assessments to reassess the effectiveness of your contamination control site strategy
13. Are we translating our risk information and data into actual Knowledge Management? Are operators and analysts gaining the correct knowledge during the training of the "why" we do things in procedures to mitigate risk?
14. Knowing your risks is positive - Organisations should not be afraid to speak to regulators about their risks and how they are managing them.