// **The new Annex 1:** Essential Workshop for Pharmaceutical Manufacturers. ///

BAUSCH+STRÖBEL

The revised Annex 1 is forcing pharmaceutical plant operators to re-evaluate even well-established processes, introducing a host of new challenges and leaving many questions unanswered. Fortunately, there are already practical solutions available: Annex 1 workshops tailor these solutions to each individual facility, ensuring it meets audit requirements.

Sterile medical manufacturing technology is advancing at a rapid rate. The updated version of Annex 1 is designed to keep in step with these developments, supporting efforts towards GMP compliance (see box). However, many producers are now facing uncertainty about whether their systems meet the latest guidelines. The auditing process is already underway, and non-compliance could result in costly production downtime, expensive retrofitting, or even the closure of entire production sites.

Workshops on Industry Best Practices in Production

Lisa Pasemann reports, „In our Annex 1 workshops, we‘ve already helped more than three dozen customers bring their systems and processes into line with the new guidelines.“ As a Technical Trainer and Aseptic Support Consultant at Bausch+Ströbel, she advises manufacturers, drawing on her extensive knowledge of industry best practices. These workshops are an integral part of the GMP compliance consulting process,

+ analyzing all components and procedures – from setup and cleaning to monitoring, maintenance, and repair – to ensure all requirements of the directive are met.
+ offering practical solutions by recommending improvements in processes, quality management, and technical adjustments.
+ ensuring planning security and enabling manufacturers to prepare effectively for future audits.

Annex 1: What It Regulates and What's New

The Annex to „Good Manufacturing Practice“ (GMP) sets out the latest requirements for the production of sterile medicinal products. The updated version of Annex 1 harmonizes production guidelines beyond the EU and standardizes their interpretation during audits. It now reflects the latest technological advancements, with a focus on the following areas:

+ Cleanroom classification and monitoring
+ RABS/isolators
+ Aseptic Process Simulation (Media Fill)
+ Handling of equipment that comes into direct or indirect contact with the product.

The directive also requires manufacturers to implement and continuously develop a Contamination Control Strategy. Quality Management must document and evaluate every measure taken to prevent contamination, not only within the production chain but also at suppliers and other external sources.

Lisa Pasemann evaluates systems in Annex 1 workshops and provides expert guidance to help manufacturers comply with the new guidelines.

Innovative Risk Analysis: Where to Begin?

The Annex 1 Workshop utilizes an innovative risk analysis tool (RA Tool) developed by the German automotive industry a few years ago. This advanced version of the "Failure Mode and Effects Analysis" (FMEA) prioritizes countermeasures rather than assessing the probability of risks occurring or being identified, with all steps clearly presented in a table. "This tool almost makes risk analysis fun," laughs Pasemann. The tool monitors the workshop process, identifying risks and areas where production needs to be realigned.

1. The RA Tool begins by assessing the hygienic design of all components, equipment, and processes.
2. Next, the tool evaluates the current status of the facility.
3. Experienced engineers, designers and programmers work with the manufacturer's specialists to develop new system solutions.
4. New SOPs are proposed, outlining all handling processes in detail.
5. Workshop solutions are assessed, and necessary actions are prioritized.
6. The identified improvements are either implemented directly or assessed in a feasibility study, complete with a detailed schedule and budget.
7. Finally, the RA Tool allows manufacturers to track progress and seamlessly update management reports at any time.

From years of experience, Pasemann knows that “the workshop must be tailored to each system to meet its specific requirements.” She adds, “Naturally, we always aim to minimize system downtime and often find alternatives to retrofitting.” Even after the workshop, she ensures ongoing communication with manufacturers, closely monitoring emerging solutions across the industry.

„We've already carried out the workshop on three facilities, enabling us specifically address all technological and process requirements.“

A participant in the Annex 1 Workshop

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Questions? Let's talk!

If you would like more information about this topic please feel free to contact us.

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