

Aseptic Process Simulation

Compliance to EU-GMP Annex 1, PIC/S and FDA requirements

Aseptic Process Simulation (APS or Media Fill) is a binding GMP requirement.

The purpose is to demonstrate that an entire aseptic pharmaceutical manufacturing process (including personnel, facilities, materials, and procedures) is producing sterile products and is robust against realistic disturbances and interventions.

Only with risk-based approaches and a comprehensive process simulation APS can be implemented in a modern, GMP-compliant manner!

This is a challenge where our GMP experts, with their extensive process experience, will provide you with comprehensive support!

Regularly APS risk assessment is part of the process risk analysis. If this task is done thoroughly, APS risks can easily be traced. To **serve compliance requirements** towards this risk assessment, an **APS plan and report** is expected together with a successful (contamination free) **execution of the APS.**

A sufficient scope (process steps, batch size, container/closure combinations) plays a key role in a production-equivalent scale with suitable worst-case scenarios for interventions (like interruptions, needle changes, manual transfers and exposure times, complex operations, critical openings or connections). **Our approach: Operational excellence** paired with **routine analyses and investigations** laid down traceable in **professional documentation.**



Our Competence

- An experienced Senior GMP Consultant who overarches pharmaceutical aseptic processing will guide you through the complexity of APS tasks, make you miss the common mistakes, provide you with suitable, compliant and specific documents, support you in organization and lead you through successful execution and finalization.

Our Services and Support

- APS concept
- APS master SOP
- Process risk analysis
- APS specific risk analysis
- APS protocol
- Training of employees in APS
- Managing operation/analysis
- APS report

Your Benefits

- Seamless, smooth and time efficient integration in your product life cycle
- No common start-up failures
- GMP-compliant documentation
- Hands on support (if necessary)
- Theoretical and practical Training by a pharmaceutical expert



Contact us now if you are planning the execution of an aseptic process simulation. Together more successful!

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