STERILE PRODUCT COMPLIANCE RISK ASSESSMENT FOR ASEPTIC PROCESSING MANUFACTURING

ASSESSMENT METHOD DEVELOPED BY DR.GAPP

Axys-Network
Aseptic processing consulting

YOUR RISK

- Aseptic manufacturing processes of sterile products are highly vulnerable against microbial/ particulates contamination
- If you do not know the inherent contamination risks of your process, the sterility of your product may get compromised
- Potential risk factors are e.g. poor facility design, wrong company´s quality culture, human misbehaviors and errors or lacking process & product controls (list not comprehensive)
- Finally you have a high risk to deliver contaminated product to the market, and subsequently get heavily scrutinized by regulatory agencies and customers
- You will certainly loose your good reputation, and certainly run into financial losses.

Axys-Network helps and supports you with our experts to mitigate our risks and fix your issues

- Our service includes the execution of a proactive and independent assessment by outstanding experts in the field. And this should be done BEFORE you run into problems !
- Our Risk Assessment tool is a well established and functioning HAZOP Risk Assessment method (Hazard Operability Analysis), and has been proven worldwide in the industry successfully since 10 years
- It is an overall review of your production process and product quality, including Contamination Control Systems, QA & QC Systems, Media Fill Validation, Environmental Monitoring, Personnel Qualification, Training, Operator Behaviors and QA oversight, Aseptic working practices, sterilization methods, quality of utilities such as WFI, (note: list is not comprehensive)..
- Finally this in “deep dive” assessment (5 days) results to a simple number and risk- classification, which is called “TRF” (Total Risk Factor), telling simply the overall risk about your process/ product
- We will help you to prepare appropriate CAPAs and find resolutions for all of your problems, because we are the experts

THE SERVICE

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- Perform a proactive risk assessment BEFORE you run into non-compliance with product quality and audits, find and define appropriate CAPAS
- Is a beneficial tool for benchmarking between different facilities within your multi-site company
- The benefit of a 3rd party review by experts will certainly overcome organizational blindness and lower the risks for contamination and audit findings

WHY ASSESS

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- The Risk Assessment is a HAZOP (Hazard Operability) method, which is comprised of a comprehensive list of specific questions about each of your production units (currently more than technical 250 – 300 questions)
- Is deep dive assessment into your manufacturing process and controls to review product quality, and will no audit but a teamwork between partners
- Each technical question will be answered on a scale from 1 (excellent) to 5 (very poor or missing), or with 100 when this topic has an important impact
- Resulting form all answers the average is multiplied with the inherent risk emphasis factor for each production unit, finally leading to a TRF Total Risk Factor
- The lower this number and if in the “low risk/ green” range the process/ product will be acceptable regarding product quality and regulatory compliance
- Our service includes three tools : Sterile APIs, Finished Dosage Forms
- Tool is used worldwide since 10 years

THE METHODOLOGY

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Axys Network & Gapp

Sterile Product Compliance Risk Analysis

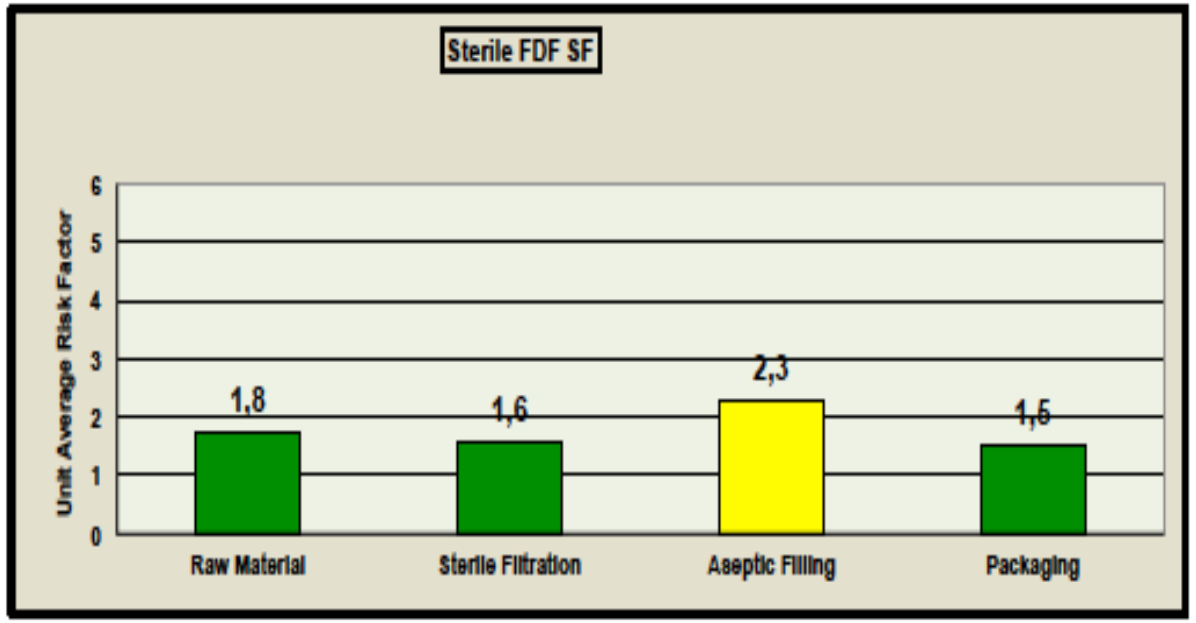
Sterile FDF SF

Edition: 2
Date: 01.05.2017

Production site:	Site XXX
Product:	Product YYY
Evaluation Date:	xxxxxx

Unit Average Risk Factors	
1,0 - 1,9	low
2,0 - 2,9	moderate
3,0 - 3,9	major
4,0 - 5,0	critical

Total Risk Factors	
10-19	low
20-29	moderate
30-39	major
40-50	critical



	Unit Average Risk Factor	Unit Risk Emphasis Factor	Unit Risk Factor
Raw Material	1,8	1	1,8
Sterile Filtration	1,6	3	4,8
Aseptic Filling	2,3	5	11,5
Packaging	1,5	3	4,5
Total Risk Factor			22,6

Unit Risk Factor =
Unit Average Risk Factor x Unit Risk Emphasis Factor

The plant shows a Total Risk Faktor of **22,6** Therefore the Risk for product non-sterility and regulatory non- compliance **moderate**

FINAL SUMMARY DIAGRAMM

- Deep dive assessment by independent, world-class experts within 5 days to prevent regulatory and product non-compliance
- Identifies –proactively- the majority of your gaps in your aseptic process
- Appropriate CAPAs and practical solutions are provided
- A simple number = TRF and a color represents your overall risk !
- Is a great and simple tool for everybody, including your senior management, to understand the overall compliance status of their facility

CUSTOMER BENEFITS

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AXYS-NETWORK SERVICES

- Risk assessment of your manufacturing aseptic lines
- In-House Training

Our experts to deploy the methodology :

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