Galenisys Business Case

Case Study – Root Cause Investigation & Remediation of Sterile Product Contamination

A leading manufacturer of sterile injectable products recently encountered an unexpected microbiological issue affecting one of its well-known pharmaceutical gels based on hyaluronidase. Upon detection of this deviation by their internal Quality Assurance team, the manufacturer promptly engaged Galenisys to investigate the root cause and propose corrective and preventive actions.

Following the signature of a mutual non-disclosure agreement, Galenisys submitted a proposal for an on-site assessment by two senior industrial microbiologists, each with extensive expertise in the manufacture and quality control of sterile medicinal products. The scope of this intervention covered all contamination prevention systems and procedures, including those related to raw materials, equipment, personnel, and environmental controls.

Once our proposal was rapidly approved, the Galenisys experts worked in close collaboration with the site team to conduct a comprehensive assessment. The contaminant had already been correctly identified by the client's QA function as *a species of Pseudomonadaceae*, which allowed our investigation to focus on potential sources and vectors throughout the facility, including utilities, equipment design, manufacturing steps, cleaning practices, and validation protocols.

Thanks to the transparency and professionalism of the site team, Galenisys was able to pinpoint key contributing factors, notably issues related to equipment design and inadequate cleaning and sanitization procedures. Our experts provided detailed written recommendations, including practical explanations to help operational and QA staff understand the specific conditions under which *Ps.spp.* can thrive.

Additional recommendations were made concerning the maintenance and management of the purified water system, with a focus on minimizing the risk of microbial proliferation.

Following our intervention, we were pleased to receive confirmation from the manufacturer that the proposed corrective measures had been implemented, and that the issue of contamination had been fully resolved.

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This case study highlights the effectiveness of two key formal documents within the Galenisys Quality Assurance framework, which are available to all clients:

1. **Galenisys Contamination Prevention & Control – Key Elements**
2. **Galenisys Contamination Prevention & Control – Programme**

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