

Sterile preparation under isolator: when the detergent contaminates us

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Introduction

During renovation work in our sterile drug preparation unit (SDPU), five consecutive cases of contamination by the bacterium *Ralstonia insidiosa* were detected during the daily monitoring of an aseptic preparation isolator (API).

The objective of this study is to retrospectively reconstruct the chronology of events, analyze the relevance and effectiveness of the measures implemented, and identify any potential limitations.

Materials and Methods

Our SDPU has four APIs. In accordance with the 2023 Good Preparation Practices (GPP), the microbiological monitoring plan for controlled-atmosphere areas of class A (isolator) and class C (environment) includes, per IPA and per production day: 2 glove samples and 2 settle plate (sedimentation) samples.

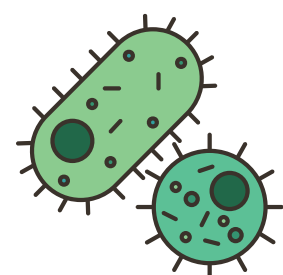
The cleaning and disinfection protocol for the API involves the sequential use of a detergent and a disinfectant, with two interventions per day.

As part of the investigation, a multidisciplinary team, bringing together professionals from the pharmacy department and the environmental microbiology laboratory, was mobilized to reconstruct the chronology of events and analyze the various factors that may have contributed to the contamination.



Results / Discussion

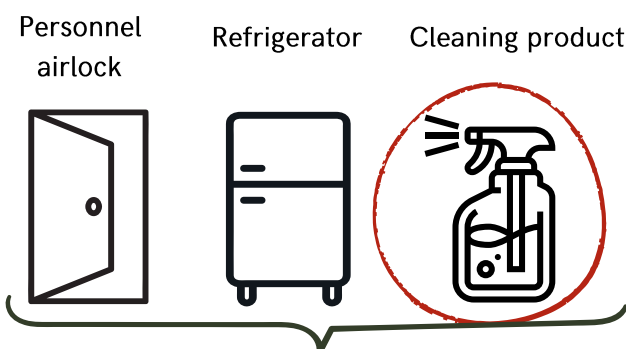
Detection



Ralstonia insidiosa was isolated from five consecutive microbiological samples, with one positive sample collected each day. The positive results consisted of two glove samples and three settle plate samples.

Investigation

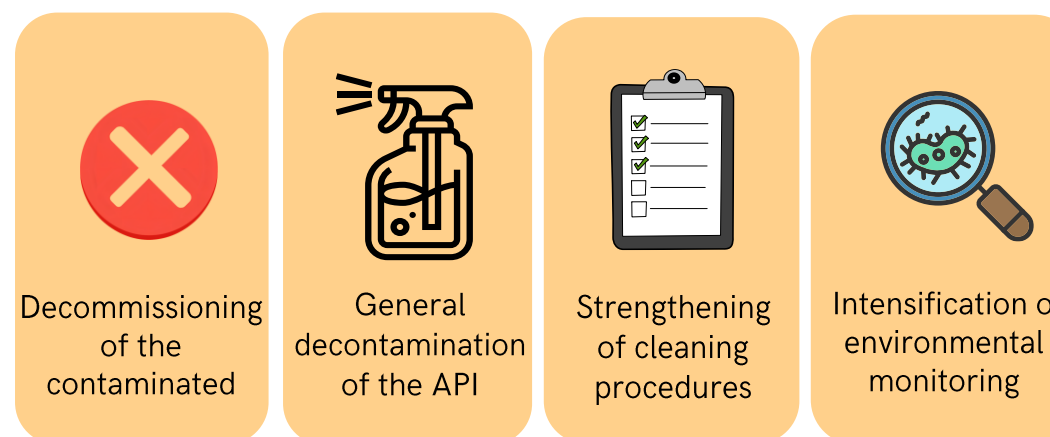
As *Ralstonia insidiosa* is a waterborne bacterium, several potential sources of contamination were considered, including the personnel airlock, the refrigerator, and the products used for cleaning and disinfection.



15 days of investigation

Action plan

IMMEDIATE



RETROSPECTIVELY

After 15 days of investigation, a specific batch of detergent was identified as the source of contamination. *Ralstonia insidiosa* was detected in both opened and unopened bottles.

Identified limitations

- Time required to identify the disinfectant as a potential source of contamination
- Absence of contingency planning in the event of product unavailability.

Conclusion

This incident confirms the need to implement appropriate action plans in the event of microbiological contamination of an API.

It also highlights the importance of not underestimating potential sources of contamination and of conducting thorough and comprehensive investigations.



The investigations conducted by the manufacturer following this event revealed contamination limited to a specific batch of detergent. This batch was withdrawn from the market seven weeks after the events began. Following this episode, the detergent is now marketed in a radio-sterilized form, in order to strengthen control over the risk of microbiological contamination