

CASE STUDY

CONTAMINATION ROOT CAUSE INVESTIGATION AND RISK REDUCTION

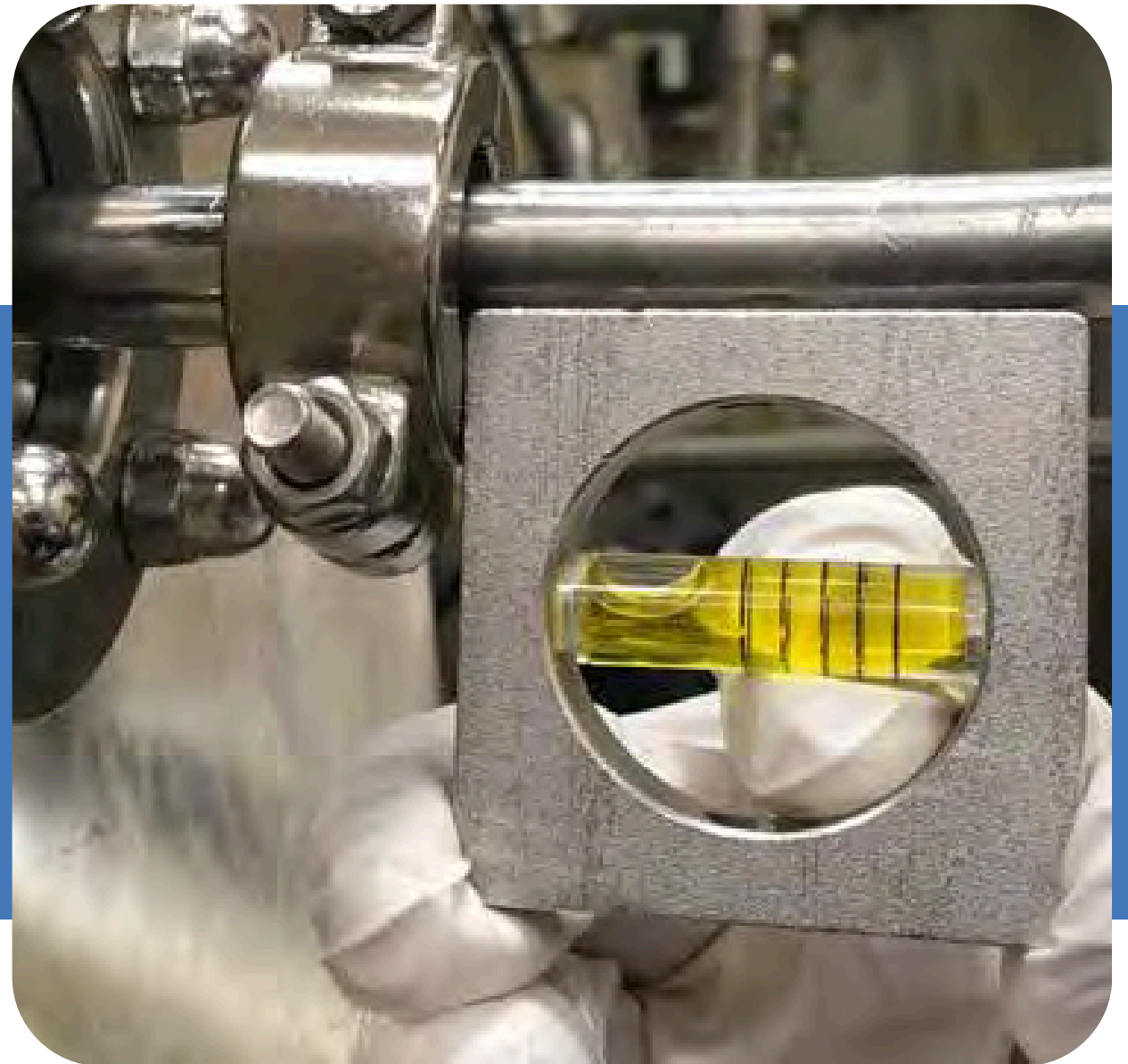


Image Details: Borescope view of outlet valve reveals ~50 mL retained fluid and high contamination risk.



Image Details: Handling for alignment dented the filter housing, increasing contamination risk at the ferrule.



Image Details: Loose or missing supports lead to slope issues, raising contamination risk

THE CHALLENGE

Frequent contamination affecting approximately 20% of batches per year causing significant impact to 40,000L of large scale Mab manufacturing capacity.

THE SCOPE

ABEC root cause investigation focusing on equipment, equipment design, and operating practice evaluating

- Line slope to promote drainage
- Functionality of existing supports/brackets to maintain slope
- Alignment of piping/equipment connections
- Sanitary gasket and clamp types and their application
- Design, fabrication, and/or quality gaps

THE RESULT

ABEC mobilized a cross-functional team of Engineers and Technicians to perform a Vessel & Equipment Inspection at the customer's facility.

Reports of 262 poor design, fabrication and equipment issues were recorded. ABEC provided the customer with:

- A matrix report referencing each issue to its associated detailed piping and instrument diagram (P&ID)
- Prioritized ranking of all issues by type, proximity to product contact, and level of risk
- Immediate follow-up site visits to repair over 100 of the identified issues
- A list of improvements in operating and maintenance practices to avoid future risk

Customers reported a dramatic reduction in contamination occurrences.



Maximizing Customer Productivity, Controlling Costs, and Reducing Risk

ABEC's service team is highly trained and experienced, working for customers to maximize productivity, control operating costs and mitigate risk. In every way, we strive to eliminate unscheduled shutdowns, while bearing in mind all factors associated with maintaining and improving bioprocess production operations and equipment. Our expertise and capability to address your specific requirements, in line with your schedule, make us the first choice for bioprocess services, no matter the location, the scale of the task, or the original manufacturer.

