

# Efficient Resolution of Deviations for a Leading Manufacturer of Infusion Accessories

Case Study

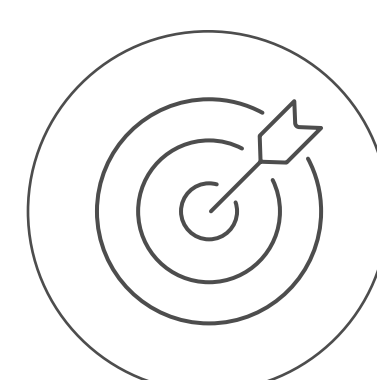


## Overview

In a thrilling race against time, the Johner Institute achieved an impressive feat: within just one month, we overcame a challenge for a leading manufacturer of infusion accessories that many had deemed impossible.

Through close collaboration and regular coordination between the Johner Institute and the client, effective solutions were quickly identified and implemented. The use of a master template for labeling and IFUs, as well as the creation of updated regulatory overviews and GSPR documentation, contributed significantly to the rapid resolution of the nonconformities.

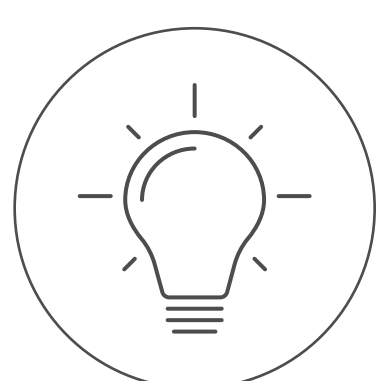
- ✓ All major discrepancies were resolved in a timely manner
- ✓ Excellent feedback on the quality of the clinical evaluation and the professional preparation of the documents



## Challenge

Our client faced the daunting task of resolving various critical nonconformities.

This ranged from updating documents and conducting clinical evaluations to ensuring compliance with standards in risk management.



## Solution

We approached this task with a tailored, intensive consulting and implementation strategy.

Our team focused on quickly adapting labeling and instructions for use, as well as updating critical evaluation dossiers, supported by a smart strategy that set priorities and established specific working groups to develop targeted solutions.

A multi-step approach was chosen to efficiently address the non-conformities. First, a thorough analysis of the main non-conformities was conducted to establish priorities. Subsequently, working groups were formed to focus on specific areas (e.g., labeling, risk management, clinical evaluation) in order to make the required adjustments quickly and effectively.

### AN OVERVIEW OF THE SOLUTION

- ✓ Analysis of the main deviations
- ✓ Formation of working groups for specific areas
- ✓ Required adjustments to simultaneously resolve the deviations

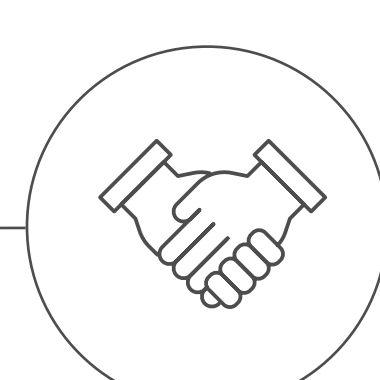


## Result

Not only were all major deviations resolved in a timely manner, but the project also received outstanding feedback on the quality of the clinical evaluation and the professional preparation of the documents.

Such success would not have been possible without the exceptional dedication of our team and the fruitful collaboration with our client. A big thank you to everyone who made this triumph possible!

This experience not only reinforces our ability to deliver excellent results even under pressure, but also lays the foundation for continuous improvements in our client's quality and compliance processes. We are proud to further solidify our role as a reliable partner in the field of medical device consulting.



Would you like to work with us?

CONTACT