



# Product Corrective Action Letter Localization

## INTRODUCTION

When a manufacturer receives a “warning letter” (FDA Form 483) of non-conformity due to specified reasons, the firm is required to respond within 15 days with Product Corrective Action letter (PCA letter) which includes a detailed plan of action, including all documentation being fully translated for any local regulatory authorities. Failure to comply with the warning letter’s tight deadline can lead to restrictions on selling of the firm’s products in a given market.

An American biomedical device manufacturer found that their Language Service Provider’s (LSP) response and turnaround times occasionally skirted the project deadlines and so was understandably concerned about the potential losses that could be incurred in the event of a missed FDA Form 483 deadline. With this in mind, the company contracted CSOFT.

## THE CHALLENGE

Given the 15-day response timetable, full translation of documents would optimally be accomplished within three days in order to ensure the client’s own internal review processes could be fully and thoroughly carried out. Otherwise, there were significant risks of their products being ordered to stop shipment.

## SOLUTION

CSOFT created a “Green Light Team” specially trained to provide translations within the required three-day timeframe, whenever such an event would occur (50+ times per year). PCA documents included, but were not limited to “Dear Doctor” and “Dear Patient” letters. To ensure that PCA translations are handled within the client’s timeframe and with the highest quality, CSOFT’s life sciences team designed a detailed process protocol that included:



- Detailed workflow diagrams
- Timeline and productivity charts
- Risk mitigation plans
- Measurable high translation quality (technically and contextually)
- On-time delivery, even on weekends and holidays
- Communications methodology and frequencies
- Team members with roles and responsibilities clearly and precisely defined
- Invoicing and payment protocols
- Other detailed instructions

## CONCLUSION

The savings for our client came immediately in form of saved time and money, and improved service. They were able to prevent costly stop-ship orders on their products and continue uninterrupted distribution worldwide. This enhanced their service level to their internal and external customers and saved them over \$250,000 in resource and administrative fees annually. As a result, they awarded CSOFT the “Quality Supplier” designation and continue to partner with us for their localization needs.

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