

15 Oxford consultants help achieve an observation-free site review.



INDUSTRY

Medical Device

SERVICES

Inspection Readiness

Auditing & Assessment

Documentation

SKILLS

FDA Compliance

Quality Management Systems (QMS)

Mock Inspection

Case Study

FDA Inspection Prep for Hearing Aid Maker

The Challenge

A global market leader in the hearing aid and diagnostics industry received a notification in August that the FDA would be inspecting their manufacturing sites in Denmark for the very first time in November of that same year. Our client requested a team of consultants to visit their facilities and assist with an FDA Inspection Readiness project.

We previously engaged with this client when they hired an Oxford FDA auditor to assist with inspection readiness audits and mock inspections at other locations.

The Solution

Management estimated that they would require 15 consultants to work both on-site and remotely on short 4-8 week assignments to prepare for the inspection. Within a period of 2 weeks, we found qualified, available consultants from multiple countries across Europe and arranged for their travel and accommodations.

Our consultants had to quickly familiarize themselves with the product line and adjust to the local working culture immediately. Their main task was to implement FDA compliance standards into all of the company's quality documentation, technical files, systems, and processes.

Oxford's FDA expert performed a mock inspection at two sites and led the inspection readiness project. The other 14 consultants then focused on several potential weak points, which included software validation, review of SOPs, CFR 820 compliance, ISO 14971/Risk Management Files, CAPAs, deviations and complaints handling, and Human Factors Engineering.

The Result

When the FDA inspection took place, our client received no 483s or major observations. This was a considerable achievement that would not have been possible without the help of the 15 consultants we had placed at very short notice.

This successful project strengthened our relationship with our client and enhanced our reputation within the tightly knit medical devices community.

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