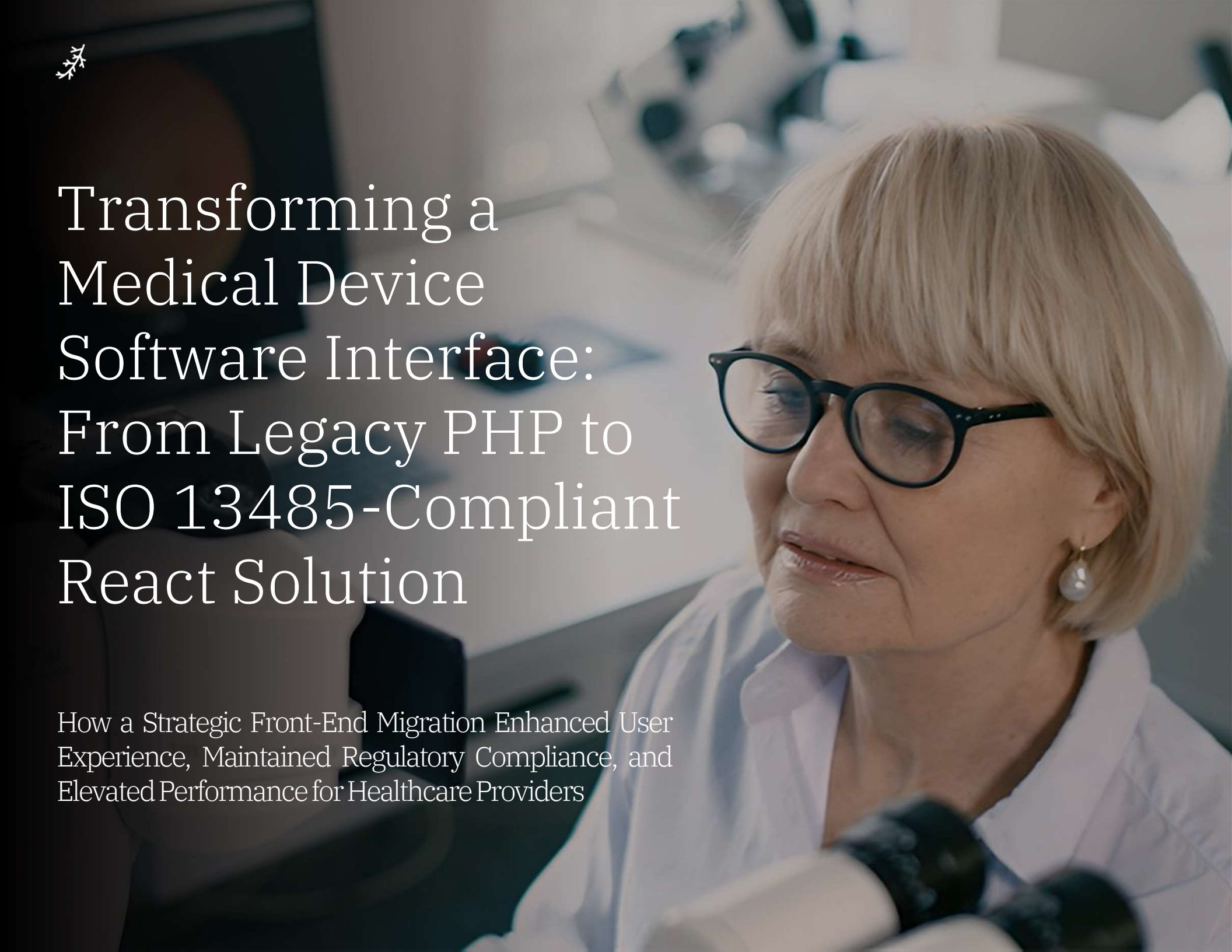


Transforming a Medical Device Software Interface: From Legacy PHP to ISO 13485-Compliant React Solution

How a Strategic Front-End Migration Enhanced User Experience, Maintained Regulatory Compliance, and Elevated Performance for Healthcare Providers

Overview

A medical device company approached us to **modernize their software interface by migrating their legacy PHP-based front-end to a React framework**. This shift was aimed at enhancing performance, user experience, and maintainability for their clinical software application, which is used by healthcare providers to interact with and analyze patient data.

Being ISO 13485-compliant, the project demanded adherence to strict quality and regulatory standards, ensuring the software met both usability and safety requirements for a regulated medical environment.

Business Challenge

Project Objectives

Upgrade the User Interface (UI): Improve usability and streamline workflows to enhance clinician efficiency.
Enhance System Performance: Enable faster load times and smoother interactions.
Ensure Compliance: Maintain ISO 13485 and other regulatory standards to safeguard patient data and ensure software quality.

The Recruitment Challenge

The project's complexity required us to carefully assess and source the right talent. It was essential to **find professionals not only skilled in PHP and React but also experienced with ISO 13485 compliance and medical software development**. The ideal candidates needed to understand both technical challenges and regulatory constraints that demand meticulous documentation, risk assessment, and thorough testing.

Transformation

Key Roles and Required Skills

Front-End Developer (React): Required deep expertise in React and a strong understanding of migrating legacy systems.

Quality Assurance Engineer: Knowledge of ISO 13485 compliance for software development was critical to ensure that testing met regulatory standards.

Project Manager with ISO 13485 Experience: Needed to oversee the entire process, coordinate documentation for regulatory review, and manage timelines.

UI/UX Designer with Healthcare Experience: Tasked with optimizing user interfaces for medical professionals, ensuring accessibility and usability.

Transformation

Our Approach

Requirement Analysis and Discovery Phase

- We began by meeting extensively with the client's product management and compliance teams to understand their pain points and priorities for the new front end. During these meetings, we documented not only technical needs but also regulatory requirements, usability challenges, and end-user expectations.
- **This discovery phase allowed us to translate the client's broad goals into a clear, actionable roadmap, aligning with ISO 13485 standards.**

Targeted Candidate Search and Selection

- We crafted **detailed job descriptions emphasizing not only technical expertise in PHP and React but also specific experience with ISO 13485-compliant** software development. We used a rigorous screening process to identify candidates with both technical and regulatory experience.
- Through our networks and targeted outreach, we connected with candidates experienced in healthcare and life sciences software who understood the nuances of compliance-driven development. **Our ability to screen for these unique attributes ensured we found candidates who could handle the dual demands of technical migration and regulatory adherence**.

Transformation

Our Approach

Building a Collaborative Development Team

- We formed a cross-functional team consisting of developers, quality assurance engineers, a project manager, and a UI/UX designer. **Each team member brought both technical skills and experience with ISO 13485 requirements**.
- To ensure the team stayed aligned with compliance standards, the project manager conducted regular check-ins and collaborated with the client's regulatory team to ensure all documentation met ISO standards.

Transformation

Our Approach

Executing the Migration

- **Code Migration:** The developers rewrote the front-end codebase in React, maintaining a strong focus on scalability, readability, and maintainability. Throughout this process, they documented each step in alignment with ISO 13485 standards to create a traceable path from the legacy PHP system to the new React-based front end.
- **Quality Assurance:** The QA engineers conducted extensive testing, including unit tests, integration tests, and user acceptance tests, to verify that all features functioned correctly. The tests were documented to meet regulatory requirements, ensuring that the software could be validated and audited as needed.
- **Usability Testing and Feedback:** The UI/UX designer collaborated closely with end-users (healthcare professionals) to refine the interface, conducting usability testing to ensure that the new design was intuitive and efficient for clinicians.

Compliance Documentation and Handoff

At the project's conclusion, we provided the client with a complete set of documentation, from design specs to testing logs, which met ISO 13485 standards.

This documentation was essential for regulatory reviews and audits, confirming that the software adhered to compliance standards for medical devices.

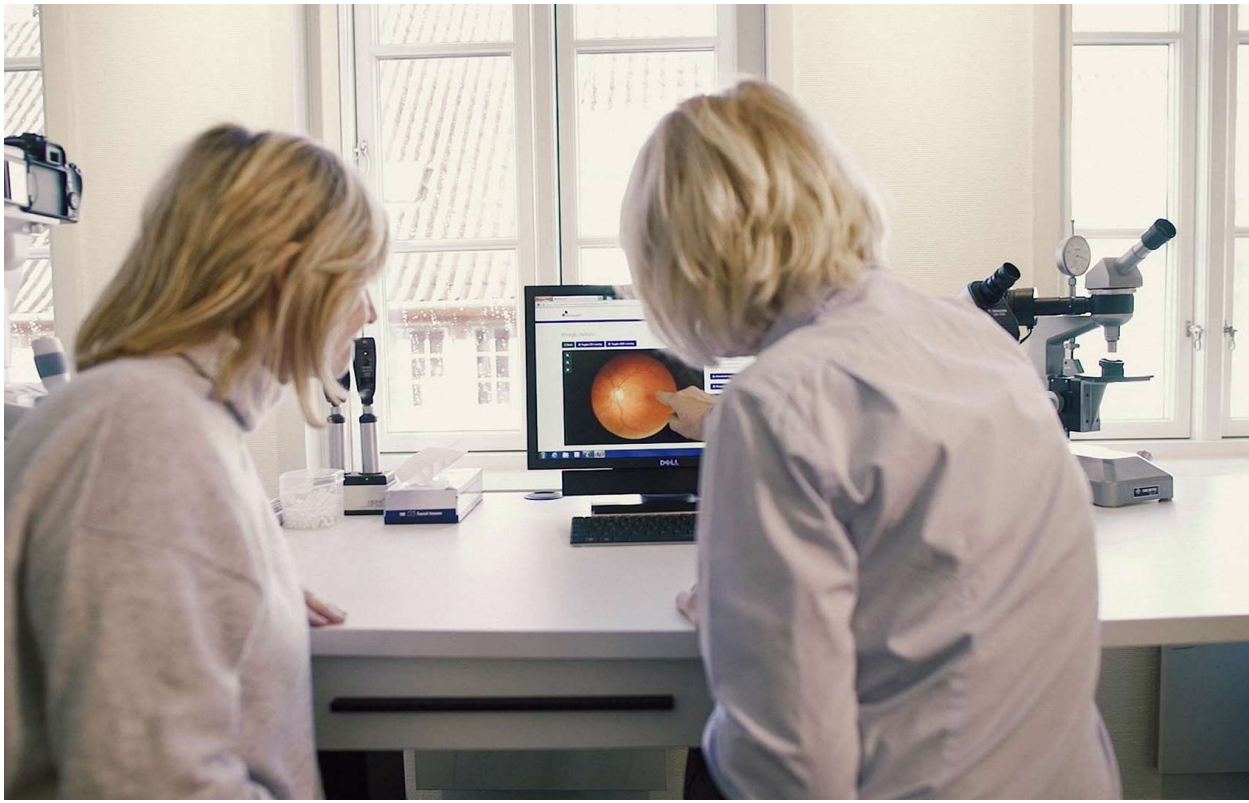
“Poly Consulting makes finding the right consultant effortless. Their consultants come in ready to work, needing minimal onboarding to make a meaningful impact. They’re not just qualified; they’re carefully matched to fit our unique culture and objectives, making them feel like a natural extension of our team from day one. Poly truly understands how to provide professionals who can integrate and deliver quickly.”

Teddy Birch Petersen
Chief Executive Officer
RetinaLyze Systems

Results

The new React-based front end provided a modern, user-friendly interface, with improved speed and enhanced usability for healthcare providers. The project met all regulatory requirements, allowing the client to maintain their ISO 13485 compliance.

The enhanced software solution improved clinician satisfaction, decreased system downtime, and provided a scalable foundation for future feature development.



Results

Highlighting Our Success in Candidate Selection and Client Understanding

Our ability to find the right candidates was central to the project's success. By deeply understanding the technical, regulatory, and user requirements, we were able to:

Identify Professionals with Dual Skills: We sourced individuals with a unique mix of React expertise and healthcare compliance knowledge.

Translate Client Needs into Technical Requirements: Through ongoing communication with the client, we ensured that our team had a detailed understanding of compliance and user experience standards, which were essential to achieving ISO 13485 certification.

Deliver a Compliant, High-Quality Solution: Our detailed approach to requirements gathering, documentation, and adherence to ISO standards provided a solid framework for the project's completion.

By finding the ideal candidates and accurately interpreting client needs, we facilitated a seamless front-end migration that met both technical and regulatory expectations, ultimately enabling the client to deliver a superior product to their healthcare customers.

Retinalyze Systems A/S

Based in Hellerup, Denmark, Retinalyze System A/S provides solutions to help eye-care professionals perform screenings for signs of pathology in a safe and efficient manner.

The automated algorithm (AI) module detects signs of eye diseases by analyzing fundus images and OCT-scans. RetinaLyze solutions can be used as a clinical decision support system (CDSS) or as a screening tool in conjunction with the telemedicine module.

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