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Actalent rapidly deployed six skilled software QA testers to support critical verification and validation (V&V) testing in support of 510(k) approval for a new blood automation device.

The Client

The client is a large medical technology company that develops and provides products, services and insights for blood- and cell-based therapies and research purposes.

The Challenge

While preparing to submit the latest version of their blood automation device for 510(k) approval, the client discovered they had originally only validated it on non-production equivalent hardware — a problem they had never faced in the past. They would need to redo software test cases on the correct equipment; however, they lacked the internal resources and time to complete the retesting of the product in the timeframe they needed to do it within.

The shortage of manpower threatened to not only delay the approval process and product launch — a costly setback for the company — but it could also postpone the delivery of a device that could streamline essential blood work for lab technicians nationwide.

The client knew they needed a partner who could act quickly, provide skilled software QA testers and ensure regulatory requirements were met without burdening their internal teams.

The Actalent Solution

The goal was clear: to complete all manual test cases required for verification and validation (V&V) software testing to ensure the client's product could move forward through the 510(k)-approval process without delay.

We presented the client with two tailored solutions to address their urgent need for software QA testing: a Services solution where Actalent would oversee both the people and the work, and a staffing solution where we would identify, interview and select qualified talent while the client retained management of the work.

Recognizing the importance of direct oversight, the client chose our talent solution to bring in the interim resources they needed, allowing them to maintain control while benefiting from our rapid talent acquisition capabilities.

We committed to hiring a team of six on-site software QA testers within just one week of project approval, handling all screening, vetting and interviewing so the client could focus on their core priorities.

The Results

Our solution was designed to solve an urgent regulatory and operational challenge for the client by rapidly deploying a skilled QA team to conduct critical retesting of their device. This approach gave the client control, ensured project continuity and delivered the expertise needed to keep their product launch on track — all within a short timeframe.

Leveraging our local and Strategic Recruiting Center (SRC) recruiting teams, we sourced, vetted and deployed a team of six manual software QA testers to start work immediately. Through close project management — including weekly check-ins and performance reviews with the client's manager — the team was able to deliver results that exceeded expectations.

Our team was able to help reduce the project timeline by six months, which had a direct impact on time-to-market and delivered cost savings for the client. Ultimately, our team successfully enabled the client to hit their deadline for 510(k) approval and move forward with subsequent phases of the product launch and other projects, making it possible for them to release a quality blood automation device for commercial use in the U.S.

