CASE STUDY

Efficient JET System Validation

DSI Validation Services provided a turn-key process for completing a system validation for a medical device customer working in a GLP regulated environment.

The Challenge.

A medical device company, with little experience using DSI technology, required validation of their JET ECG system to successfully execute a study. This particular study involved monitoring ECG data from minipigs to develop a new implantable cardiac medical device. Although the company was familiar with GLP and 21 CFR Part 11 compliance, it did not have the time or in-house experience to successfully complete a system validation. As a result, they were faced with the challenge of meeting an aggressive timeline for a difficult task. The scientists understood that a successful validation of a JET system would take a minimum of six months with dedicated internal resources. Their study timeline was at risk.

The Solution.

The medical device company contacted DSI with an urgent request for validation services with a quick turn-around time. They were impressed with DSI's knowledge and experience in the industry as well as the proposed approach for validating their commercial-off-the-shelf (COTS) system. The DSI team worked closely with the client's stakeholders including system end users, IT department, quality assurance and the validation team. They walked through the entire process with the medical device team to gain alignment on the project needs, scope, timelines, budget, and system requiring validation. Using a standardized, industry-accepted approach, DSI successfully facilitated a system validation and met the client's aggressive timeline of four weeks from system purchase.

The Outcome.

The DSI Validation Services team implemented their proven validation processes using a disciplined project management plan with clear communications. The medical device company was pleased to achieve system validation on budget within 1 month as it saved them 5 months of time and internal resources.