

# Abiomed implements TrackWise Digital Within 30 days



## Business Overview

Abiomed (NASDAQ: ABMD) is a pioneer and global leader in healthcare technology and innovation, with a mission of recovering hearts and saving lives. From the world's first total replacement heart to the world's smallest heart pump, Abiomed is dedicated to finding ways to bring the most advanced and beneficial technology to patients and physicians.



## Business Challenge

Abiomed engaged Sparta Systems looking for an EQMS solution that would be easy to configure, implement and use. One of their main criteria was that the solution needed to be delivered within a true cloud environment. They also wanted a solution that could be validated and maintained in accordance with internal Standard Operating Procedures (SOP's), corporate policies and external standards and regulations.

## Solution and Implementation

After performing vendor evaluations, Abiomed confirmed that the TrackWise Digital solution was the superior choice. Abiomed implemented Sparta Systems' TrackWise Digital cloud EQMS solution. The solution not only offered the scalability of the cloud but also an intuitive design and an executable validation package out of the box. The TrackWise Digital Quality Management Suite manages Abiomed's processes in accordance with FDA and ISO regulations from initiation through further investigation, root cause analysis and final quality approval. In addition, the Quality Management System is fully compliant with 21 CFR Part 11 including full audit trail and electronic signature functionality.

## Result

After purchase, Abiomed was able to implement and validate the solution in 30 days. The executable validation package delivered with the TrackWise Digital solution was a critical component of this rapid implementation time. Abiomed was able to quickly gain greater visibility into their corrective action, preventive actions and audit findings from discovery to investigation, root cause analysis, action planning, execution and verification of effectiveness.

*"They understood what we were looking for right away and were able to implement and validate our CAPA application within 30 days. We are pleased that we found them, especially since we were able to use all the functionality we needed all within the Salesforce App Cloud."* - **Suzan O'Leary, Project Manager, Abiomed, Inc.**

## Company Overview:

*Name: Abiomed*

*Industry: Medical Device*

*Revenue: \$330 Million*

*Distribution: Global*

*Headquarters: Danvers, MA*

*Founded: 1981*

*Solution: TrackWise Digital*