

# AGA Medical Speeds Time to Close Product Change Orders by 83%



## Customer

AGA Medical

## Revenue

USD ~ \$150M

## Location

USA

Employees: 400 Worldwide

## Industry

Medical Devices

## Solutions

- Implementation Service
- Agile Product Collaboration
- Agile Quality Management
- Agile Product Portfolio Management

## Summary

AGA Medical designs and manufactures minimally-invasive devices for correction of heart and vascular defects.

## Client Objectives

- Executing Change Quickly/Efficiently Prohibited by Paper-based System
- Averaged 12 product change orders (COs) completed per month, 26 days from submit to closed
- Controlling Paper (Rev) Used on Floor – Labor Intensive, Risky
- Change Impacts - Limited Visibility of Critical Information
- Change History For Process & Complete Product Tree
- Active Deviations to Current Approved Build
- Non-conformance Incidents and Yield Problems
- Corrective Action / Preventive Actions
- Approved Manufacturers

## Feedback

*“The FDA and Notified Body Auditors were astounded by what we were able to achieve with Agile PLM. They had never seen a company able to move from paper to electronic with such success. Agile PLM has helped us do some amazing things in a very short amount of time.”*

Wendy Schweigert  
Quality Assurance Manager

## Results

- Implemented Agile PLM in only 4 months
- Accelerated product development by 76% more change orders a month, 83% faster
- Grew from 12 CO’s a month, 26 days long; to 50 CO’s a month, 4.5 days long
- 20-40% reduction in effort and time for processes supported by Agile
- Received high praise from FDA and auditors for significantly reducing their on-site audit time
- Engineer adoption 100%; fast, simple
- 100% electronic procedure used by all employees