

## Case Study: Leading Medical Device Company Achieves Major Efficiency Boost by Utilizing SPK's SolidWorks CSV Expertise

A publicly traded medical device manufacturer with 33,000 employees and several international locations approached SPK and Associates for assistance in streamlining their validation processes. The validation process took months, but the customer wanted complete validation within a few weeks, saving significant engineering hours and reducing potential product release delays.

### Challenges

The customer realized the importance of CSV. However, no one on their team was willing to take it on. Many on the team viewed CSV as a distraction from other, more meaningful and fulfilling work. The in-house IT team couldn't take on CSV because they lacked the depth of Solidworks knowledge necessary, as well as an engineering background. Still, the FDA requires CSV. If ever audited, they would receive a warning letter and be required to perform CSV after the fact, leading to delays in product release. The company likewise wanted other advantages of CSV, including effective change control and continuous improvement. However, due to the man hours associated with CSV, the company felt there was no real return on the investment.

### Solution

SPK and Associates delivered all FDA-required CSV documentation in a month, compared to several months the customer spent trying to do it on their own. We achieved this by leveraging templates we've developed over decades of experience. Our experience working with SolidWorks, and specialization in medical device-focused engineering, empowers us to take templates and customize them for individual customer needs. We continue to work closely with this customer, holding their CSV so when they need to re-CSV, we can make quick changes rather than starting all over again.

### Results

- Client's SolidWorks CSV was completed in less than a month.
- Customer upgraded from a four-year-old version of SolidWorks to the most current version.
- Customer planned for migration and consolidation of multiple SolidWorks and SolidWorks PDM vaults distributed across the entire organization.
- The customer can now easily update SolidWorks twice annually to stay current with updated versions and patches.
- Access to SolidWorks PDM is controlled, with verifiable training requirements met. Engineers can install SolidWorks within an hour of requesting it.
- Changes to SolidWorks PDM are controlled. Changes improving business productivity happen in a controlled fashion.
- Customer can now rely upon SolidWorks as a validated environment, allowing them to easily to connect other systems to SolidWorks PDM.