What is CSV?

CSV stands for Computer System Validation.

FDA is currently evaluating its approach to CSV, and the consensus is that they will issue new guidance in 2020. The shift aims to reduce the burden on pharmaceutical and medical device companies for validating systems that do not directly impact patient safety or product quality, allowing companies to focus efforts on things like product innovation.

In reality, CSV for pharmaceutical and medical device companies must meet the obligations of regulatory compliance and business needs. Striking the right balance between the two ensures not only compliance but also realized business value.

Customer Value:

RAO customers understand the need to "right size" their CSV projects to meet both objectives efficiently and with high-quality standards. We are excited to see many of our customers moving from "test everything just to be safe" to testing the functions that really matter to meet regulatory compliance.

How Can RAO Help:

RAO has supported CSV planning, documentation and implementation for many new, replacement and upgrade technologies which include:

- ✓ Quality Systems
- ✓ Document Management Systems
- ✓ DMR Reporting Systems
- ✓ Registration Management Systems

Whether you're exploring software-as-a-service (SaaS), configured or customized technology, let RAO help you conduct your next CSV project. We will guide you through the process to have a **well-planned, risk-based strategy with a fully compliant, more efficient, lower cost** approach.

RAO can also help with **change management** and **training** to ensure the successful implementation and sustainability of your systems.

RAO has been doing this work for more than 20 years. Let us do the heavy lifting, while you focus on other things.