

How to Overcome 5 Common Challenges in Computer System Validation (CSV)



The FDA Group **Presentation**

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Rashida Ray

A Brief Introduction

Rashida is a seasoned quality assurance and compliance professional with a robust background in computer system validation (CSV) and auditing in the pharmaceutical, medical device and biologics sectors. As an industry consultant serving as a Senior Validation Engineer, she offers a deep understanding of regulatory requirements and quality systems, underpinned by over a decade of experience in the industry.

In her current role at The FDA Group, she leverages her CSV expertise to evaluate computer systems for clients, ensuring they comply with all relevant regulations and standards. Her skills extend to conducting audits, managing quality systems, and providing guidance on regulatory compliance.

Agenda



Today, we're exploring challenges in 5 areas pertaining to CSV:

1. **Planning for CSV**
2. **Communication**
3. **Understanding regulations**
4. **User requirements specification**
5. **Cross-functional collaboration**



Common CSV Challenge #1



Planning – Failing to think through the entire process of implementing a new system

KEY CONSIDERATIONS & BEST PRACTICES:

- Create a process map** that outlines how the system will be used across different functional areas
- Understand **how data is acquired, stored, and used** within the system to ensure data integrity
- Don't discount the importance of understanding **the entire data lifecycle** within the system

Common CSV Challenge #2



Communication – Siloed departments and lack of regular meetings between them

KEY CONSIDERATIONS & BEST PRACTICES:

- Host cross-functional team meetings** to help to break down these silos, fostering better communication and collaboration
- Involve all relevant departments **from the beginning** of the process to ensure their needs are taken into account
- Plan **regular meetings** and **create open lines of communication** to ensure everyone is on the same page

Common CSV Challenge #3



Understanding applicable regulations

KEY CONSIDERATIONS & BEST PRACTICES:

- Regulations can **affect different departments in different ways**, so it's important to understand the specific implications **for each department**

- Organizations should ensure they have a **deep understanding of the regulations that apply to their system**. These often include:

21 CFR Part 11, Part 820, Data Integrity Guidances, Computer Software Assurance (CSA)

- Stay up-to-date** with regulatory changes and understanding how they impact your system

Common CSV Challenge #4



User requirements specification – Defining and establishing user requirements is a crucial step in CSV

KEY CONSIDERATIONS & BEST PRACTICES:

- Reach out to all relevant departments to **gather requirements** and **understand how the system will affect their processes**
- Use a User Requirements Specification document** to clearly define these requirements and ensure they are met by the system

Common CSV Challenge #5



Cross-functional collaboration

KEY CONSIDERATIONS & BEST PRACTICES:

- ❑ Establish a cross-functional team to oversee the implementation of the system
 - This team should include subject matter experts from each department
 - Learn from them how the system will be used and how it can be integrated into existing processes

Value of CSV Consultants



- 1. Fresh perspectives.** Identify blind spots and potential issues; challenge existing assumptions and status quo; Bring new ideas and innovative solutions
- 2. Best practices informed by experience.** Leverage a broad range of experiences across various systems; Provide industry benchmarks and standards; Help avoid common pitfalls and mistakes
- 3. Ability to navigate regulatory requirements.** Deep understanding of the latest regulations; Ensure system compliance, reducing risk of penalties; Provide regulatory training to enhance internal knowledge

Preparing to Work with a CSV Consultant



FOUR QUICK TIPS:

1. **Define your needs ahead of time.** Clearly define what you need from the consultant. This includes understanding your system, your regulatory requirements, and your specific challenges.
2. **Prepare your team.** Ensure your team is ready to work with the consultant. This includes setting expectations, defining roles and responsibilities, and fostering open communication.
3. **Provide access to information.** The consultant will need access to all relevant information about your system. This includes technical documentation, user requirements, and regulatory requirements.
4. **Be open to feedback.** Consultants will provide feedback and recommendations. Be open to this feedback and be ready to implement changes as needed.



A FEW FREQUENTLY ASKED QUESTIONS:

1. How does risk management play into the CSV process and how should risks be assessed and mitigated?
2. What considerations should be made when validating a cloud-based system versus an on-premise system?
3. Our software vendor claims their product is 'validated'. What does this mean and what additional validation might we need to do?
4. How do you typically handle validation of software that is frequently updated, like Microsoft Office applications used in our processes?
5. Do you have any tips or best practices for revalidating a system after significant changes or upgrades?



Thank You

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