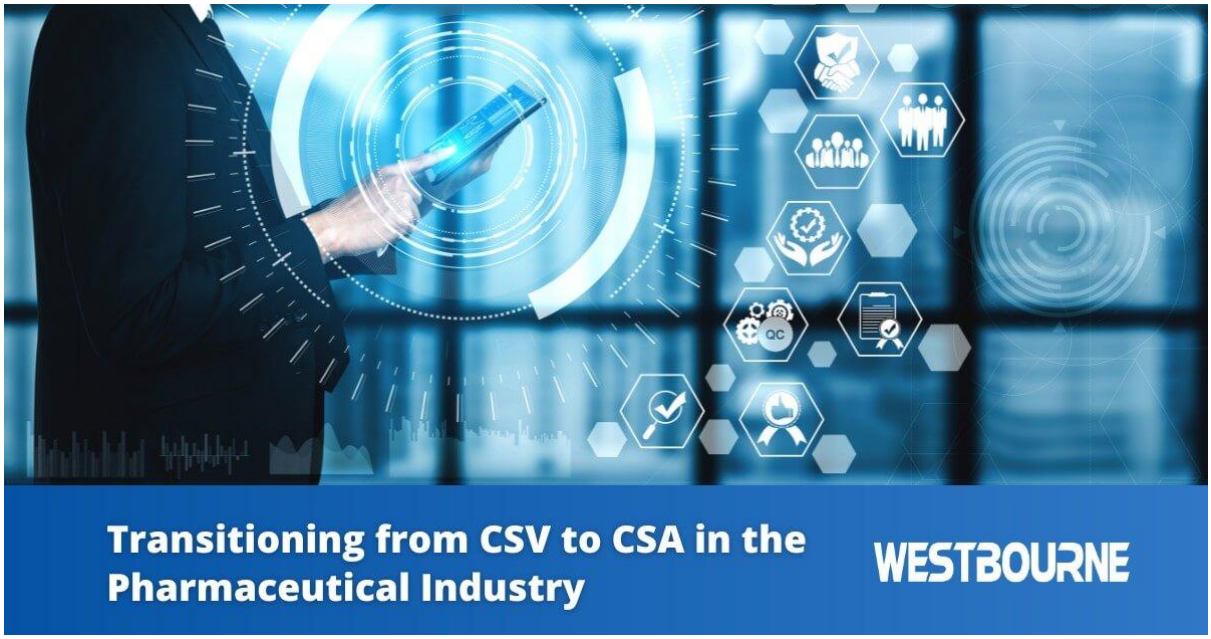
Transitioning from CSV to CSA in the Pharmaceutical Industry



The transition from Computer System Validation (CSV) to Computer Software Assurance (CSA) represents a shift in approach to validating software and other computer systems used as part of production or quality systems in the pharmaceutical industry. CSA focuses on critical thinking, risk management, and assurance activities rather than the more traditional, checklist-based approach of CSV.

While the traditional CSV approach has its place in certain situations, it can also cause delays in the agile implementation of new technologies. This can have knock-on effects for pharmaceutical companies, including staying competitive and compliant in a rapidly changing marketplace.

Software development processes and modern ways to manage IT and operational infrastructure have moved on considerably. There is also a recognition that validation should no longer be about documentation and processes. Instead, validation needs to be about the safety of patients.

The methodologies used to validate computer systems in the pharmaceutical industry need to be modernised. That means transitioning from CSV to CSA.

What is CSA and How Did We Get Here – A Quick Recap

The FDA has been developing CSA for several years now. It published draft guidance in September 2022. This means it is not fully finalised, but CSA is the clear direction of travel and the FDA-recommended approach when validating computer systems used as part of production or quality systems in the pharmaceutical industry.

Furthermore, the EU's GMP Guide Annex 11 “Computerised Systems” is aligned with the main principles of CSA.

CSA involves moving away from a prescriptive, document-heavy, tick-box approach when validating computer systems.

CSA replaces this traditional approach with one that is based on risk and critical thinking, where the method of validation is based on the intended use of the computer system and the risks it poses to patient safety, product quality, and system integrity.

The Benefits of CSA

It is not hard to find lists of CSA benefits on the internet, but we are going to talk about our own direct experience of using a CSA approach to validate software for one of our clients.

At Westbourne IT, we have extensive experience providing validation support to companies in the pharmaceutical industry. So, we have direct experience with the considerable amount of time that is required to complete a validation project using the traditional CSV approach. In fact, in some projects, the resources required to validate the software can be almost as high as the resources required for development!

Using CSA methodologies, you can move away from the traditional validation-in-a-box approach that is so resource and time-intensive. In its place is a process that involves conducting a risk-based analysis on each change, function, and feature, with the risk analysis results then used to create a framework for testing.

This saves a considerable amount of time, and it does so, crucially, without adding any risks. That last point is important to stress as it’s essential to avoid doing anything during a validation project that adds any level of risk or compromises data integrity.

In summary, our CSA approach to software validation ensured a much more efficient use of time and resources in a real-world project for a pharmaceutical company. Furthermore, our client was able to see clear evidence of the value of CSA.

Making the Transition from CSV to CSA

From our experience of working with companies as they transition from CSV to CSA, we recommend five essential steps.

Step 1: Understand CSA

A key starting point is to ensure that all relevant stakeholders, especially those in QA and IT, understand the core principles of CSA. This includes its focus on critical thinking and risk-based decision-making over prescriptive testing.

Going back to the real-world CSA example mentioned earlier, developing a clear understanding of CSA was an essential part of ensuring project success. We spent a lot of time explaining at different levels of the organisation the validation approach we would take. This built confidence in the process and an understanding of CSA principles.

Step 2: Mindset and Culture

Many companies in the pharmaceutical industry have a compliance focus, where there is a tightly defined series of steps that need to be worked through to meet the requirements of regulators.

Transitioning to CSA involves moving away from this compliance focus to instead focus on quality. This is where critical thinking becomes an essential component.

Step 3: Partner with Validation Experts

It is beneficial to partner with validation experts that have real-world experience in using CSA methodologies to validate software and other computer systems in pharmaceutical organisations. By working with the right partners, you will save time and money while ensuring best practices are adopted from the beginning.

Step 4: Provide Training

CSA will be a new concept to many people on your team with quality, compliance, and validation responsibilities. Therefore, providing training will help your transition to CSA.

Step 5: Establish a Pilot Programme

From our experience, establishing a pilot programme is an effective approach when starting your transition from CSV to CSA. CSA doesn't completely replace CSV, so it's not a case of disposing of one system in favour of another. Instead, CSA is a modern approach to validation in the pharmaceutical sector, so starting with a small and well-defined pilot project makes sense.

Support at Westbourne IT

Our team at Westbourne IT has been working with validation in the pharmaceutical sector for several years now. We can help at all stages of your transition to CSA and on any validation project that is upcoming. This includes everything from providing expert consultancy services to full-scale project management and support. Get in touch with us today to find out more.