

 WHITE PAPER

4 Questions to ask about Your 21 CFR Part 11 Validation

Compliance impacts your organisation at three levels: employee, IT systems and records. The pressure is on to demonstrate how you control and record compliance training and procedures – through audits, system validations and e-signatures.

Non-compliance with the Food and Drug Administration (FDA) that mandates the authenticity of electronic records and signatures – including training records – has significant consequences.

That's not all. If your organisation operates in the life sciences field, then your learning management system (LMS) is a crucial part of the quality assurance process as well as a key element when it comes to maintaining your license to operate. This is because:

- Compliance training must be documented, tracked and recorded
- Changes to standard operating procedures (SOPs) need to be updated in the LMS and everyone will need to complete related new training
- Training records need to be accurate, up-to-date and inspection ready

As organisations digitalise their documentation and training, compliance with 21 CFR Part 11 has become increasingly critical.

The FDA, for example, requires an organisation's LMS to be validated for intended use. Even if your organisation is not directly governed by the FDA, you'll still need an approved system that's compliant with a regulator's control requirements in relation to audit trails, e-signatures, and record keeping.

At SumTotal we understand the challenges that relate to compliance validation in today's digital world. From managing complex compliance activities, to alleviating the administrative burden related to record keeping and reporting.

When it comes to minimising risk to your business, here are four questions you should be asking about CFR Part 11 Validation:

1. Are you using electronic records to save time and money?

With a LMS system, training records are always up-to-date and compliant with enterprise data reporting requirements. There's no time wasted gathering evidence to demonstrate training records are accurate – the completion and expiration of certifications, accreditations, and more, are tracked in real-time across the entire employee base.

2. How do you track and keep accurate records of individuals and their training plans?

Are individual electronic training records stored and easily accessible to all appropriate persons? Can line managers see the compliance status of their staff in real-time, and assign and track specific training for their people? Does your LMS instantly record when an individual signs onto a training class – and is completion automatically recorded? Can learners instantly review their personalised compliance training plan? And are they automatically prompted when they need to renew an existing certification?

3. How do you track and record training activity and adherence to SOPs?

Do you have a clear reportable view of the organisation's compliance to regulations? Are training records inspection ready? How much time do you need to prepare for an FDA inspection? Are the appropriate resources in place to manage performance of work and assessment activities, including internal quality audits?

4. Do you use a Quality Management system?

Is it connected to your LMS? In today's digital world, employees and managers need to e-sign documents to confirm they understand an SOP in relation to compliance with every good laboratory practice (GLP), good clinical practice (GCP) or good manufacturing practice (GMP) requirement. Furthermore, operatives – and those delivering training - must have an appropriate design, installation, operational or production qualification. These e-records will need to be trustworthy, reliable, and held and maintained appropriately.

Demonstrate and stay compliant with SumTotal

SOP Training records are always reviewed during a regulatory inspection or audit for 21CFR Part 11 compliance. Regulatory bodies, like the FDA, will request that your LMS is validated for intended use.

And that's where SumTotal can help:

- From managing workforce training and data reporting needs, to managing adherence to regulatory compliance requirements, we offer all the built-in advanced reporting and continuing education management tools you'll need to keep pace with an evolving regulatory landscape.
- We offer on-premise, SaaS or dedicated hosting options – meaning you select the delivery solution that's the best fit for your requirements; plus, you determine when any upgrade happens and stay in control of your validation risk.
- Unlike other providers, our use of domains enables us to run a highly regulated business (that requires validation) and a 'normal' business in one software instance; which means you won't be forced to run multiple LMS' in parallel.
- You'll find that our compliance reporting is real-time and instant – unlike other LMS providers whose reporting processes need to be run overnight.
- Our platform is detailed to a highly granular level:
 - Good manufacturing/clinical/laboratory practices
 - Course versions/completions/exam completions
 - Records can be used to verify compliance requirements, develop employee skills/talent, make key operational decisions

Our credentials


- With over 20 years' experience working with industries that are highly regulated, we understand the requirements imposed on licensed to operate businesses – and how to enable appropriate validation control and reporting.
- SumTotal's technology has been evaluated and selected by seven of the world's top 12 pharmaceutical and life sciences companies, including AbbVie Inc, Pfizer Inc and Toshiba Medical Systems Corporation.



About SumTotal

SumTotal Systems, LLC, a Skillsoft Company, is the only HR software provider to deliver Talent Expansion® solutions that help organisations discover, develop and unleash the hidden potential within their workforce and entire business ecosystem. SumTotal goes beyond traditional talent management and HCM applications, offering contextual and pervasive HR solutions that actually help improve employee performance in real time.

More than 3,500 organisations, including some of Fortune's "Best Places to Work," rely on SumTotal's award winning solutions to empower their employees. For more information, visit www.sumtotalsystems.com.

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