



Use Case

Pharmaceutical Industry: Ensure Audit Readiness



Business Challenge:

Meet audit, quality, and compliance requirements with ease

When a pharmaceutical company is audited by a government regulatory body, it is required to produce an audit trail of successfully completed employee training in a timely manner. As noncompliance may result in fines, litigation, and other issues that may have a material effect on business, it is in the company's best interests to swiftly and thoroughly comply with auditors — the faster the company can resolve an audit request, the more it reduces exposure to negative consequences. In the United States, pharmaceutical companies must comply with **21 CFR Part 11** regulations, including electronic signatures and audit trails, and other countries have **similar regulations**. Without an enterprise learning management system (LMS) that features a built-in auditing solution, an audited company is unable to provide signature data and electronic record changes that satisfy regulatory requirements.

Solution:

Partner with a pharma-experienced LMS provider

By partnering with an LMS provider that has demonstrated expertise in the highly regulated pharmaceutical industry, pharmaceutical companies will be better equipped for an audit. SumTotal's LMS helps pharmaceutical companies meet regulatory requirements via three key areas: electronic signatures, tracking changes to electronic records, and the ability to provide data on demand. Electronic signatures show changes to user details, learning activity, and training records on the roster, while tracking changes to electronic records allows visibility into every instance of a record being touched (i.e., who did it, when, and why). Moreover, SumTotal's auditing module allows for real-time

analytics on electronic signatures and electronic records in a format recognized by regulatory bodies.

Business Value:

Be audit-ready

Audit preparation is part of everyday business for pharmaceutical companies — and with this in mind, SumTotal automates recordkeeping in a secure and validated system. With the confidence that content created and electronic records generated within the SumTotal LMS will meet regulatory requirements, organizational leaders in the highly regulated pharmaceutical industry can feel secure that partnering with SumTotal helps them mitigate the risks associated with noncompliance. SumTotal's solution provides the insight needed to make proactive decisions regarding LMS platform activity and future training, and also ensures all employees have access to the latest required training that will help them stay compliant and prevent incidents.

Learn more about SumTotal integrations and services at:

www.sumtotalsystems.com/customers/industries/healthcare

Benefits:

- ◆ **Maintain** a clear audit trail
- ◆ **Identify** gaps in training
- ◆ **Stay** up to date on certifications and continuing education

