In regulated industries such as pharmaceuticals, medical device manufacturing, and life sciences, a Learning Management System (LMS) is critical to an organization’s operational success. The LMS may be deployed for a variety of reasons including career development, sales training, operational training, safety training, partner/supplier training, and customer education. A comprehensive learning solution in these areas can certainly help an organization drive better business results.
However, in FDA regulated industries, compliance is the area that most often comes under scrutiny. Lack of compliance can lead to negative business results such as FDA Form 483 citations. In fact, inadequate training and/or the inability to capture, store and report on training data has resulted in several high profile fines, expensive litigation and plant shutdowns — resulting in hundreds of millions of dollars in losses.

An LMS must not only manage the volumes of data generated by training efforts to help ensure compliance and avoid negative 483 reports, it must also provide a secure, comprehensive system that supports audit processes (including records storage and electronic signatures), and GxP (i.e., ‘Good Practice’ regulations and guidelines), including FDA 21 CFR Part 11. Moreover, especially within the life sciences/pharmaceuticals industries, the LMS must prove that it can do what it says it can do. SAP SuccessFactors can help.

SAP SuccessFactors has implemented functionality to meet 21 CFR Part 11 requirements as a standard feature of the application.
SAP SuccessFactors LMS - Validated SaaS
With more than 10 years’ experience supporting regulated industries with strict validation requirements, SAP SuccessFactors now provides an optional, Validated SaaS environment for Learning Management System customers. There are two primary components provided within SAP SuccessFactors LMS - Validated SaaS:

- Premium Multi-Tenant SaaS with Annual Updates
  - Updates are done once per year, and customers have six months to review and prepare for the upgrade.1
  - Patches are only applied if required for stability. Plus, customer specific extensions and connector changes are only applied on customer defined deployment schedules.

- Validated Environment, with IQ Reports and Validation Toolkit
  - IQ Reports provide documented evidence that updates are installed in accordance with SAP SuccessFactors and the customer’s specifications, with a resultant IQ audit report.
  - A Validation Toolkit provides learning software requirements, sample test cases and OQ templates to assist with the completion of the OQ validation process.

Now we offer a Validated Learning app for iPad and iPhone. This offers the same great benefits as the regular SAP SuccessFactors Learning app. By downloading the app from the SAP Marketplace, validated customers can access Learning through the validated app and can still access other talent management modules through the regular SAP SuccessFactors app from the Apple Store. All mobile learning features up to the August release will be in the validated app, with a once yearly update.

The bottom line? SAP SuccessFactors LMS - Validated SaaS provides customers with all the benefits of SaaS based LMS, and helps them reduce risk and meet their toughest validated requirements.