

E-Learning in Pharmaceutical Companies: Flexible, Efficient and GMP-Compliant

Whitepaper

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1. Introduction

Digitalization is fundamentally transforming employee training in the pharmaceutical industry. Today, companies face the challenge of training employees efficiently while complying with regulatory requirements such as the EU GMP Guidelines, the AMWHV, and Annex 11. Digital learning platforms offer new possibilities for this—from automated documentation to audit-compliant performance tracking.

In the following, we introduce **OSIANTO**, a modern e-learning solution for regulated environments. It helps pharmaceutical manufacturers and service providers design efficient training processes, meet compliance requirements, and comprehensively document training outcomes.

2. Legal Requirements as Drivers of Digital Learning

In accordance with Chapters 1 and 4 of the EU GMP Guidelines and the German Ordinance on the Manufacture of Medicinal Products and Active Substances (AMWHV), pharmaceutical companies must have sufficiently qualified personnel and must document their training “*in a verifiable manner, both initially and on an ongoing basis*” (Section 4(1) AMWHV). Annex 11 further requires the validation of all computer-based systems with a complete audit trail.

3. Modern Work Styles and Learning Behaviors

Changing Work Environments After COVID-19: The trend toward working from home and remote work has taken hold. Employees are increasingly using digital communication platforms such as Microsoft Teams and Slack for meetings and project work.

Learning management systems (LMS) complement these tools to handle even the sometimes substantial training requirements in a smart and cost-effective manner.

Efficiency and scalability: Digital training significantly reduces travel costs and downtime. Once created, learning modules can be replicated indefinitely and deployed worldwide—while maintaining consistent quality and compliance.

Learner Expectations: Today's employees expect flexible learning opportunities that they can access anytime, anywhere. **OSIANTO** enables personalized learning paces, on-demand review, and the seamless integration of short learning units into the daily work routine (micro-learning).

4. OSIANTO at a Glance

OSIANTO was developed jointly by pharmaceutical experts, IT specialists, and media educators. The platform offers:

- **Modular architecture:** Built on modern web technologies (Django, PostgreSQL) **OSIANTO** scales from departmental to enterprise-wide implementations.
- **Intuitive workflows:** Automatic import of master data (e.g., from SAP/HR), targeted course assignments, and automated reminder emails.
- **Interactive learning content:** Quizzes, videos, interactive graphics, and document sharing (PDFs, SOPs, links to government agency websites).
- **Audit-ready reports:** **OSIANTO** generates customizable reports that transparently detail all training sessions, participation rates, and test results.

5. Legal and Regulatory Framework

To meet complex compliance requirements, **OSIANTO** adheres to the following standards:

- EU GMP Guidelines & AMWHV: Ongoing training requirement (Section 4(1) AMWHV), documented performance monitoring, validation of computerized systems (Annex 11).
- Data protection (GDPR/BDSG): **OSIANTO** implements role- and permission-based concepts, encrypted data transmission (TLS), data minimization, and data erasure policies in accordance with Art. 5 GDPR.
- GAMP 5: Validation approach and risk-based software qualification (IQ/OQ/PQ) with complete protocols and audit trails.

6. Usage Scenarios

Feature	Benefits for Users
Automated Onboarding	New employees are automatically assigned to the relevant courses and notified via email.
Document Training (“Reading Training”)	Quick and straightforward training on internal company documents (SOPs, instructions, etc.)
Blended Learning Scenarios	Combined in-person and online modules for flexible training designs.
Microlearning	Short learning units (5–10 minutes) increase motivation and learning efficiency.

7. OSIANTO at a Glance

Feature	Benefits for Users
Learning Analytics	Dashboard with KPI metrics: completion rates, average completion time, performance trends.
Multichannel Access	OSIANTO is browser-based and optimized for mobile devices—learn on a laptop, tablet, or smartphone.
Certificate Management	Automatic generation and distribution of certificates of participation upon passing the knowledge test.
Multilingual Support	Content can be delivered in multiple languages—ideal for globally distributed teams.

8. Validation and Quality Assurance

OSIANTO undergoes regular audits by internal quality management departments and external certification bodies. Each new release version is qualified in accordance with GAMP 5 (IQ/OQ/PQ). User companies receive complete qualification documentation upon request and can supplement it with their own test reports as needed.

9. Implementation and Best Practices Approach

- **Needs Analysis:** Identification of company-specific training requirements and regulatory guidelines.
- **Design & Content Creation:** Selection of appropriate instructional modules; production of videos, interactive exercises, and quizzes.
- **Technical Integration:** Integration with HR systems (e.g., SAP), lab software, or ERP systems. Deployment on a dedicated server or in the company's own data center.
- **Pilot Phase & Training:** Test run with selected departments; conducting webinars and hands-on workshops—both on-site and remotely.
- **Rollout & Monitoring:** Phased go-live, continuous performance monitoring using learning analytics and surveys.
- **Continuous Optimization:** Regular working group meetings with key users, incorporation of change requests, and updates in response to regulatory changes.

10. Conclusion

With **OSIANTO**, pharmaceutical companies have access to a highly flexible, scalable, and legally compliant e-learning platform. It meets all requirements of EU-GMP, AMWHV, Annex 11, and data protection regulations. Thanks to its integration with common communication platforms and modular components, training projects can be efficiently managed and fully documented—a decisive advantage during audits and inspections.

11. Product & Company Highlights

Compliant e-learning courses: Comprehensive support for AMWHV, EU-GMP guidelines, and Annex 11 requirements through integrated performance tracking and complete documentation.

Versatile e-learning formats: Chapter-based training, videos, document reviews with read receipts, and interactive quizzes (single- and multiple-choice).

Automated communication workflows: Configurable reminder emails, push notifications, and weekly reports ensure proactive participant support.

Comprehensive event management: Plan and document in-person seminars, field sales meetings, and medical training sessions directly in **OSIANTO**.

Made in Germany & GDPR-compliant: Hosted in German data centers, with German support and full compliance with European data protection regulations.

Regular audits & validation: GAMP5-compliant qualification (IQ/OQ/PQ), last external audit in February 2025, risk-based software development.

Fast content creation: Import PowerPoint, Word, and PDF files to quickly create new training content.

Scalable deployment: Modular design enables use in departments, companies, and global corporations.

High customer satisfaction: Positive testimonials from pharmaceutical companies and service providers attest to increased efficiency and user-friendly operation.

12. Contact & Demo

For more information, a live demo, or technical advice, please visit:

<https://www.osianto.de/?lang=en>

Or contact us:

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