NetDimensions

LIFE SCIENCES SOLUTIONS

TALENT MANAGEMENT FOR LIFE SCIENCES

Are You Compliance Ready?

Life sciences organizations such as pharmaceutical and biotechnology companies, medical device manufacturers, and food manufacturers must adhere to the demanding compliance requirements of the regulatory bodies in the various countries where they operate. They need to ask themselves:

- How prepared are we for a compliance audit?
- Are employee certifications and training records up-to-date, secure and easily retrievable?
- Is our Learning Management System (LMS) compliance ready?
- Do we have processes in place to support a validated LMS?
- Do we have the training content needed to maintain strict quality standards?
- How can we boost employee productivity and engagement?

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NetDimensions Solutions

21 CFR Part 11

NetDimensions Learning supports auditing, e-signatures, versioning control, and reporting capabilities to meet 21 CFR Part 11 and EU GMP Annex 11 compliance requirements for electronic records.

NetDimensions Learning has been validated for US FDA Title 21 CFR Part 11 and EU GMP Annex 11 compliance requirements in client implementations worldwide. The NetDimensions validation is practical, defensible, and in keeping with the most stringent computer system validations in regulated industries.

Electronic Training Records

Training records must be inspection-ready, whether they are stored as paper-based or electronic records. When preparing for an inspection, a significant amount of time will be spent checking that records are current and agree with applicable Standard Operating Procedures.

NetDimensions Learning has secure system controls to prevent unauthorized access and maintain data integrity and data accuracy at all times. NetDimensions' electronic records are updated in real time for proactive compliance reporting. They are also quick and easy to access and report on, thus allowing your organization to be inspection-ready more effectively and efficiently.

Validation Services

A validated learning environment can be a costly effort which requires a great deal of time and resources. NetDimensions provides ready to use consulting service packages for NetDimensions Learning that enable the product to be validated in client environments worldwide for intended use along 21 CFR Part 11, 21 CFR Part 211 and 21 CFR Part 820, as well as EU GMP Annex 11 and EU GMP Part 1 requirements.

Life Sciences Content

NetDimensions offers a full library of 'off the shelf' content to help employees stay compliant with FDA and GxP regulations. We can also create custom content and learning portals to address your specific needs, all integrated into our platform from a single source vendor.

Compliance Analytics

Best-in-class organizations take a proactive approach to compliance. NetDimensions has been at the forefront of proactive compliance management with:

- Competency-based compliance reporting to highlight current compliance levels and ongoing compliance risks, including the ability to drill-down to specific departments, teams, and individual employees

- A 'compliance analytics' module in NetDimensions Learning that includes a set of out of the box reports that are specific to people and training compliance
- NetDimensions Analytics, a state-of-the-art talent analytics application with dashboards, visualizations, self-service reporting, scheduling and predictive analysis of learning, talent, compliance, HR and operational data

SOP Assessments

NetDimensions Exams is a secure, high-stakes exam engine for testing the understanding of Standard Operating Procedures (SOPs) rather than just checking off boxes to confirm receipt of compliance-sensitive documents.

NetDimensions Exams moves compliance beyond a check box to actual knowledge assessments with a variety of exam formats, powerful workflows and unparalleled security.

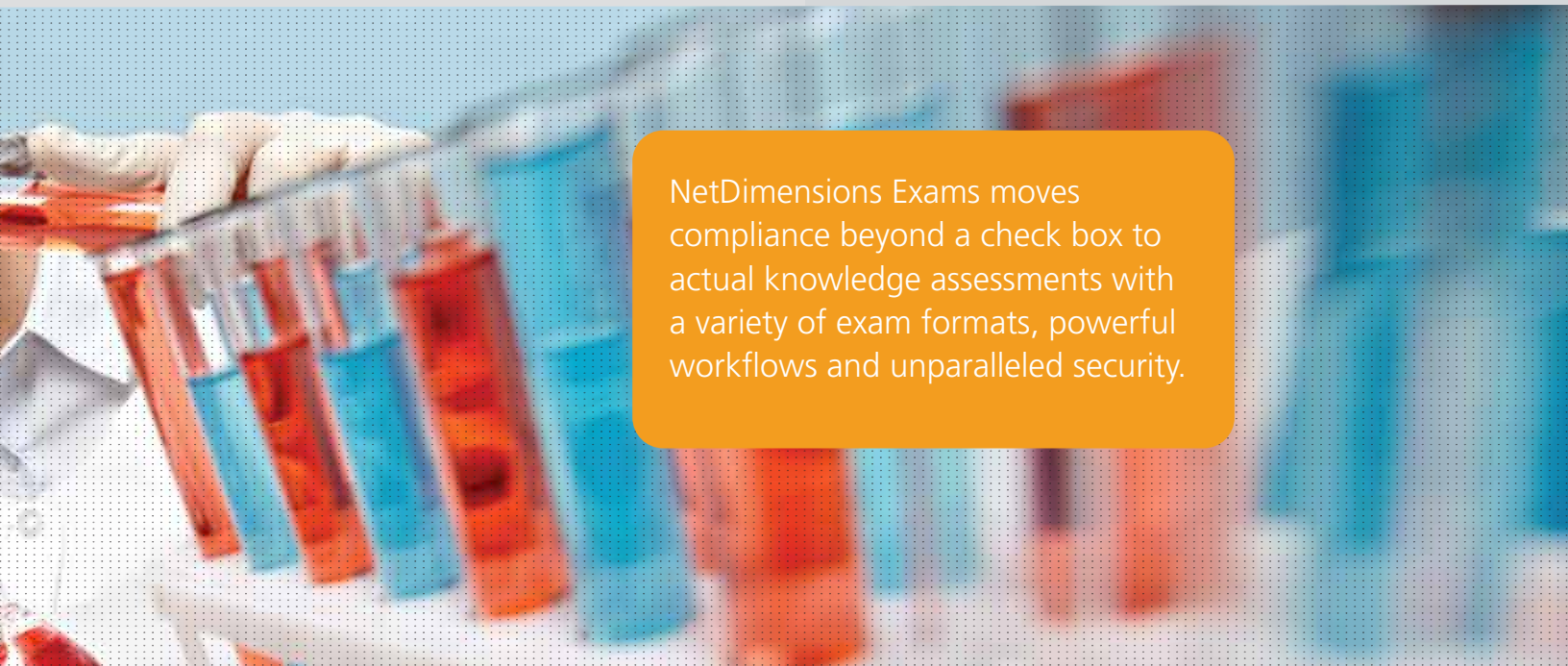
NetDimensions provides all of the necessary API's to link to a client's document management repository and provide a full audit trail, including electronic signatures, of exactly who has done what, when and where in relation to all training activity around these documents.

Consequences of Non-Compliance

The U.S. Food and Drug Administration (FDA) documents observations and deficiencies on Form 483. Each observation is a case of non-compliance or regulation violation. Companies must reply in 15 days and address these non-compliance issues individually with a plan for corrective or preventive action.

Organizations cannot afford the high costs related to non-compliance. Companies at risk may face:

- Substantial financial fines and legal action
- Stoppage of operations and closure of inspected site
- Tarnished reputation that hurts their standing in the marketplace
- Loss of license to conduct business
- Delay in product go-to-market plans



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NetDimensions Solutions (continued)

Secure SaaS

Multi-tenant SaaS models can provide challenges in highly regulated environments where software validation is a requirement.

NetDimensions Secure SaaS combines all of the benefits of SaaS with unique advantages that are specific to highly regulated environments, such as:

- Control over updates to support validation timeframes
- Best-in-class authentication, security, and data privacy
- Customizations to meet business needs and improve the user experience
- ISO 27001 certification

Life Sciences Industry Clients

NetDimensions delivers talent management solutions and eLearning content solutions to life sciences organizations worldwide, including:

- 3Shape
- Eisai Pharmaceutical
- Elekta
- Fresenius Medical Care
- GenScript
- Omron Corporation

The NetDimensions Approach

NetDimensions is widely recognized for delivering a high level of client satisfaction. We understand that we are only successful if our clients are successful. Every interaction, from our conduct during the sales process, to our consulting and implementation services, to our account management and ongoing customer support, to our client advocacy programs, is wholly client-centric. This means that we don't believe in a "one-size-fits-all" solution.

Our Global Services team understands the challenges and compliance issues of the life sciences industry. We are committed to work with you to understand your objectives, help you address the particular needs of your organization in the most effective way, and invest in making you successful.

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