



zenosis[®]
by Intellego



Taking regulatory and compliance training to **new horizons**

A 'turn-key' solution

Zenosis is an Internet-based, regulatory and compliance learning-on-demand provider. Zenosis is available as a remote or integrated solution for life science organisations with contrasting sizes of user base. This almost instantly deployable solution is a continually updated resource providing vital knowledge that will enable your staff to comply with regulatory requirements and increase productivity. This is offered at a cost substantially less than that of conventional training methods, resulting in increased return on investment. Our solution is rigorous, able to record and manage training records and provide comprehensive training for staff of different skill levels and disciplines within your organisation. It incorporates the following essential components:

- **Instructionally Designed e-Learning courses** that ensure that the learning objectives of the organisation are fully met.
- **'Always-up-to-date'** – unlimited version upgrades of the e-learning courses with e-mail alerts to the users to inform them of regulatory changes when they occur – there is no obsolescence.
- A growing **international curriculum** that is supported and endorsed by the appropriate industry experts, regulators and leaders in their fields.
- **A robust, 21 CFR Part 11 validated electronic training records system.** This is vital as the data may have to stand up to scrutiny in a court of law and therefore must have an extremely high level of assurance.
- **Ergonomically designed,** intuitive and flexible interface and navigational design that empowers users of all technical skill levels.
- **A highly secure infrastructure,** including encrypted password access, back-up systems, powerful firewalls and disaster recovery services.
- **A robust support service,** with analysts available online.
- **An administration and reporting interface** that enables line managers to ensure that change management is facilitated and the system itself is being used efficiently within the organisation.

A validated, scalable and flexible system

The Zenosis solution can be provided in three forms, or three phased delivery methods for larger organisations. The important point is that this is a truly scalable solution, adaptable to your needs as your organisation grows. We cater for global companies that range dramatically in size, scope and discipline.



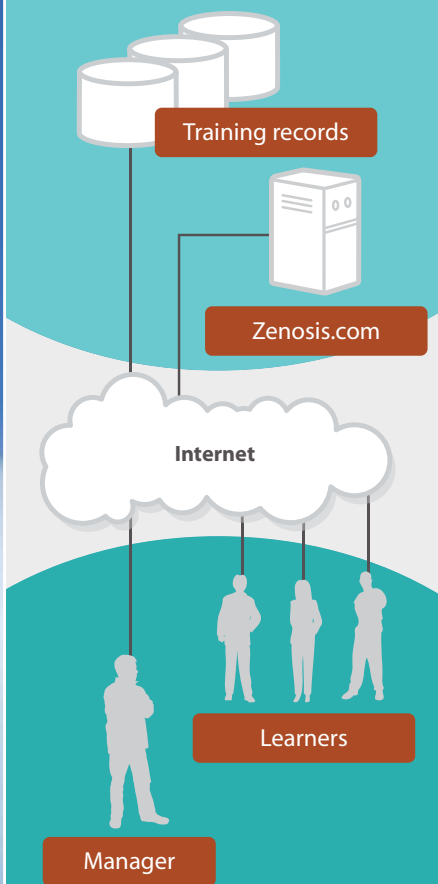
The Zenosis solution provides full Learning Management System (LMS) capability as standard. Training records for personnel involved in cGxP activities are a predicate rule requirement and, as such, all companies working in the pharmaceutical area have a regulatory obligation to maintain these records. Zenosis' system is 21 CFR Part 11 and Annex 11 validated.

The system has reporting functionality as standard. This allows managers to monitor the usage of the system by learners and check up on their status: for example to determine if they have completed a module assessment and, if so, whether they passed or failed, or to see how often the modules are used in order to help determine their value to the organisation.

Managers can even be allowed to see employees' assessment results on a question-by-question basis in order to help identify areas for development and provide support. This latter item is configurable should it not be required.

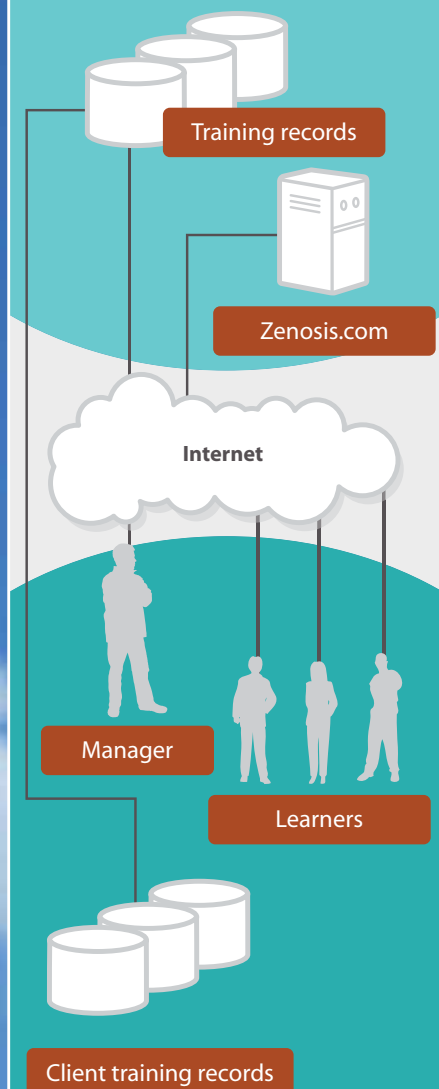
All assessments and pass certificates are held electronically on Zenosis' servers and can be printed or downloaded by clients.

System one



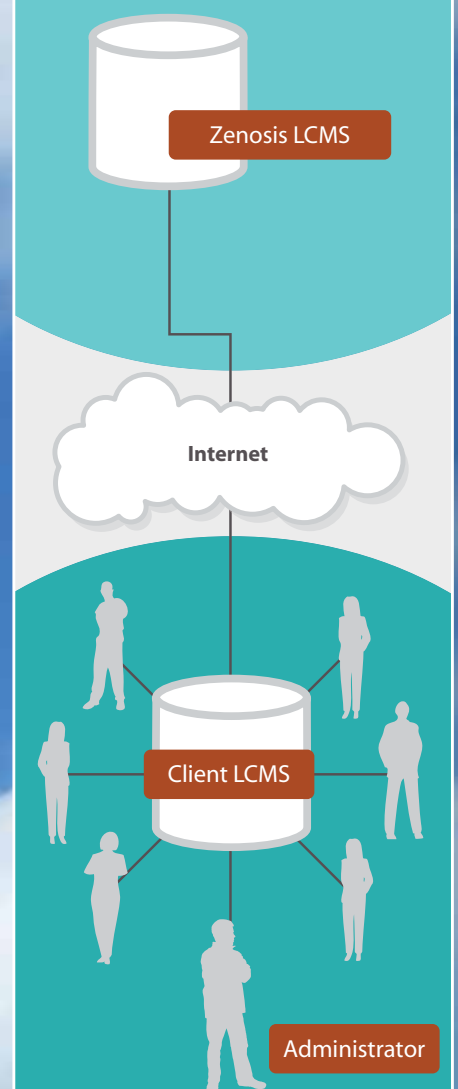
System One, or a total ASP solution, is very straight-forward, requires virtually no IT integration and is suitable for organisations with 1 to 100,000+ staff.

System two



System Two is still based upon the complete ASP solution of System One but with one addition. The training records are transferred to an e-records repository in the client organisation.

System three

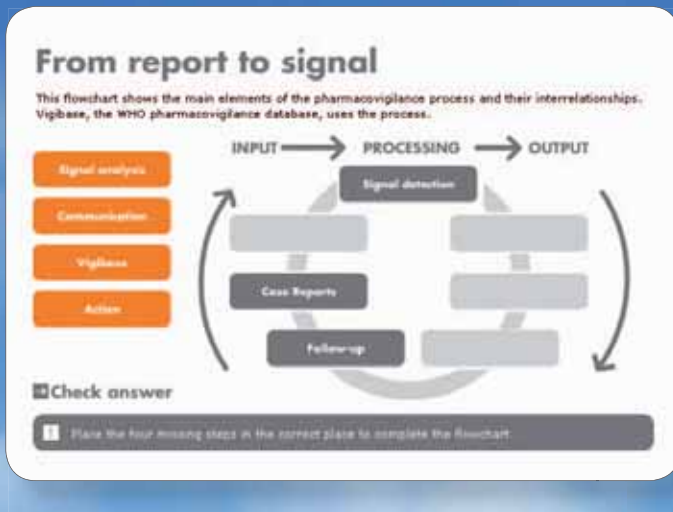


System Three is an extranet integration with a client's Sharable Content Object Reference Model (SCORM) compliant, locally installed, 21 CFR Part 11 validated LMS.

Comprehensive, quality-driven, contextual learning modules

Zenosis' range of modules will expand to cover all countries and functions where compliance with the requirements of regulatory authorities and international harmonisation is paramount.

Zenosis modules are created in suites designed to simplify module selection by a company or individual department. Each suite typically consists of one or more introductory modules plus a range of more advanced titles.

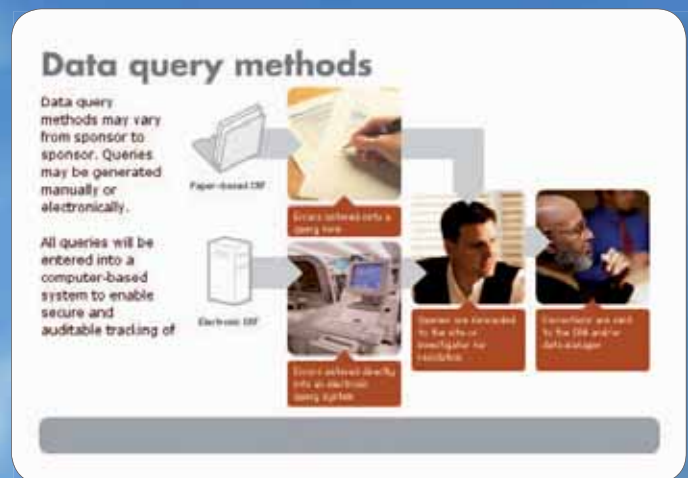


The following suites are either available or currently in production:

- EU regulatory submissions
- Clinical development and Good Clinical Practice (GCP)
- US regulatory submissions
- Medicinal product safety and pharmacovigilance
- Regulatory affairs in Japan
- Good Laboratory Practice (GLP)
- Chemistry, manufacturing and controls documents
- Good Manufacturing Practice (GMP)
- Marketing and promotion of medicinal products
- Validation of computerised systems for regulated environments
- Regulatory affairs outside the EU, USA and Japan



In addition to Zenosis' internal team of regulatory and compliance professionals each module has a dedicated Subject Matter Expert (SME). The SME works with Zenosis during the development of the module and after its release to ensure that its content is accurate and up-to-date. We believe that only those working actively in the area a module covers can provide the meaningful, real-world examples and detail we wish to include. Our experts work in the field with a variety of their own clients. They are among the world's best consultants in their fields and are contracted to Zenosis for at least five years.



Next steps:

Thousands of life science professionals are now using the Zenosis solution, but prior to becoming Zenosis clients they did a two week, no obligation trial/pilot. If you would like to arrange one of these trials or ask further questions about how we may be able to help you or your company, then please call 877 740 0931 (Toll Free) or drop us a line at sales@zenosis.com where one of our team will be delighted to help you.

Zenosis Modules

Function	Notes
Content accuracy	All content is reviewed by Subject Matter Experts, Zenosis' regulatory intelligence department and then cross checked by an independent peer reviewer to ensure accuracy.
Content up-to-date	All qualified by Subject Matter Experts and regulatory intelligence (currently updated within 30 days).
Links always up-to-date	Links always up-to-date pointing to current legislation, guidelines etc.
Print screen	Prints page viewed.
Glossary	Containing amongst other things all acronyms used in the modules.
Intuitive user interface	Intuitive design, consistent presentation and clear learner instruction.
Email update	Users automatically receive an email informing them of version update and changes to the module.
Objectives	Expert instruction assessed through clear objectives and meaningful goals.
Media	Real world scenarios, examples and case studies provide relevant experience and foundation for new knowledge.
Efficiency	Effective use of interactivity, text, images and animations enhance retention and transfer.
Self-paced	Learners determine own pace through instructionally designed educational objects.
Learner guidance	Learners are directed to relevant information and given appropriate feedback.
Additional resources	Additional links to the latest documentation, tools and resources support further research.
Version history	Each module contains a version history detailing key updates.
Free text search	The system provides a facility for the learner to search the text in a module for user defined phrases.
Visibility of changes	A user logging on to a new version of a module has the content which has been changed automatically highlighted. They are also informed which modules have updated since they last accessed the system.

Zenosis System & Platform

Function	Notes
Assessments recorded	Assessments are recorded and results can be viewed by individuals (Company or Group results can be viewed by authorized line-managers).
Assessment answer location	If there is an incorrect answer in the assessments a description of where the correct answer is found is provided to aid the learner.
Version control	The updated module automatically replaces the module version on which the user is currently registered and provides evidence that this has happened.
Book marking for module	User asked if they wish to start where they left off when the course is opened.
Completion certificate	Electronic and printable certificate of module pass and completion.
Automated online help	Forgotten password, FAQs, 'click here to contact support functionality' and an interactive tutorial.
Learner reporting	The system contains a reporting function which can be used to see their system utilization (time online, status, last accessed etc).
Manager assessments	Assessments are recorded and results can be viewed by individuals and authorized managers (if required).
Manager access & reporting	The system contains a reporting function which can be used by managers to access the test results, user list, time online and last accessed data for staff assigned to them.
Course feedback mechanism	Learners are able to provide feedback on the course as a whole and on subsections within the module from the module page.
User/version audit trail	An audit trail is created so it is possible to determine if a user has visited a module since its last update.
Full printing	The system supports formatting of the modules and screens for printing via a 'print' button which can be used for screens, parts or the whole module.
Transfer test results	Can export test results in a format for others to import.
Preview of module	Allowing users to access preview versions of the courses and to register on the wait list for upcoming courses, then communicate the release of new courses to learners on this wait list via email.
Extranet solution	Integrated solution with other LMS systems available (SCORM compliant) on a project-by-project basis for larger clients.
21 CFR part 11 compliant	System is validated and meets the requirements of 21 CFR part 11 and EU Annex 11.



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