



Frequently Asked Questions: Online Bio-Pharmaceutical Courses

PfL will provide life science companies in Liverpool with a convenient, online method to gain a deeper understanding of governmental agencies' regulations and policies.

Q: Why Should I Take these Courses?

Your company must comply with regulations from FDA, EMEA and other regulatory bodies, as well as our own compliance guidelines, and assure that all employees are trained in these policies.

Through the ComplianceWire web-based learning platform from Kaplan EduNeering, you can ensure that your team gains a deeper understanding of FDA and EU compliance and enforcement guidelines. You can provide this training while eliminating the travel costs and time associated with classroom training.

Q: How Will Users Interact with the System?

Through this web-based system, users will access online courses any time, from any computer with an Internet connection. This enables users to learn at their own pace.

As they complete courses assigned to them, they will be able to view their own personal training history.

After users complete a course they can print a certificate of completion for their records.

Q: How do I enroll my team in the programme?

Simply contact your HR manager to enroll. You can then enroll your employees with the specific courses related to their job function.

Q: Will users be tested?

Yes, courses are designed with interim learning activities, or quizzes, that are based on the material presented in the course itself. Successfully completing, or passing, these activities allow users to proceed through a course.

Each course includes an end-of-course "Final Challenge," that is scored. If users score below the 80% minimum, users can immediately retake the Challenge.

Users can retake the Challenge as many times as necessary to pass.

Q: What Courses Are Included?

A. Nearly 100 courses are available, focusing on GMP issues and other regulatory guidelines from EU and US FDA, and include:

- Batch Records
- GMP Principles
- IT Validation
- Packaging
- Production
- Quality Assurance
- Quality Control



Sample screen from a course within ComplianceWire.

Q: Who can see the scores?

Scores are not maintained in the system. Only the manager will see actual scores, and only once immediately upon finishing each challenge. The term "qualified" is then recorded in the system, not the score itself.

Likewise, managers can see the course status and completed courses for their direct reports by accessing a special management report. They will also see the term "qualified" next to each course or work instructions users have completed.

Q: What if users are interrupted during my session?

If users are interrupted during the training session, the ComplianceWire system automatically 'bookmarks' their progress so they can return to the same location in which they left off.

Q: How do I get started?

Simply contact P/L Joanne Horgan on 0151 288 2100 or e-mail joanneh@pfl.org.uk.

Have Questions?

If you have any questions about this programme, please contact Joanne Horgan at joanneh@pfl.org.uk