Food and Drug Administration Areas of Focus for Regulated Life Sciences Industries

Empowering Trust®

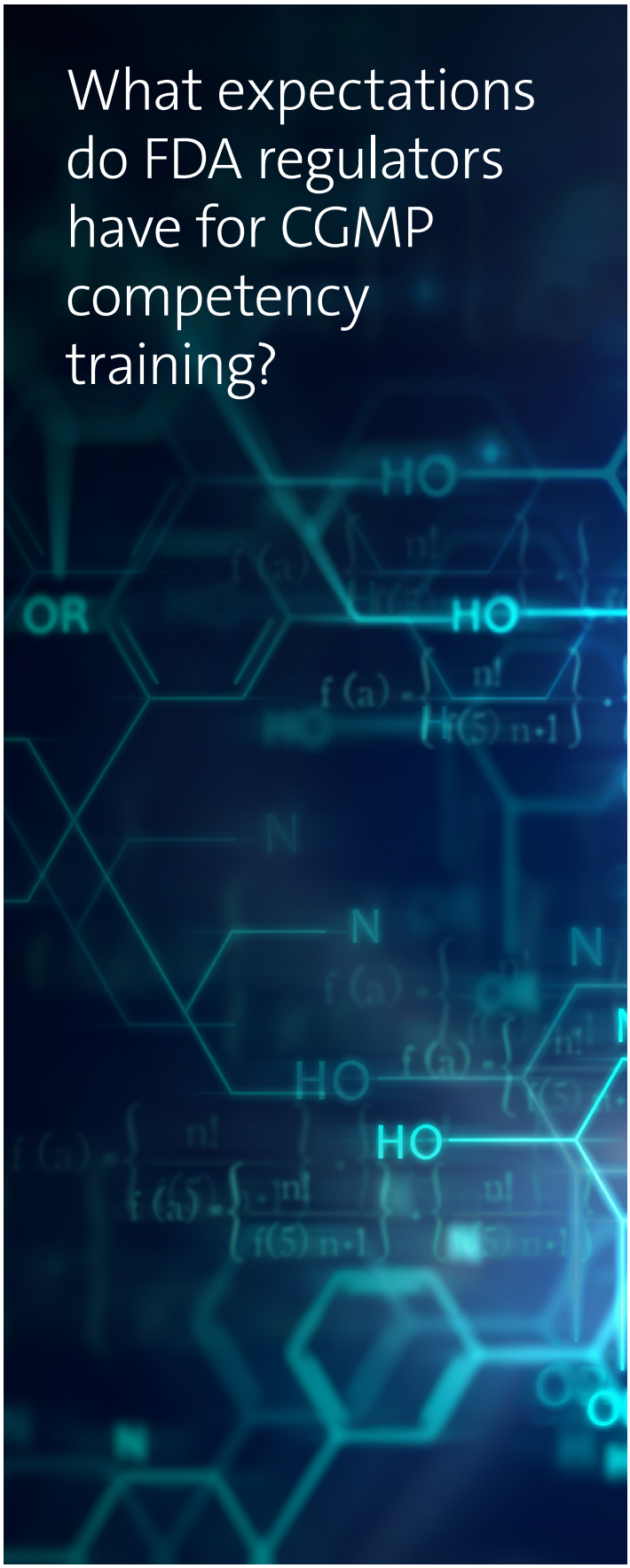
Cooperative Research and Development Agreement (CRADA) Relationships With the Food and Drug Administration (FDA) Offer Unique Insight Into Training Expectations for Current Good Manufacturing Practice (CGMP) Regulations

Introduction

The Food and Drug Administration's (FDA) priorities constantly evolve to meet and exceed the demands of an ever-evolving industry. With these changes and stricter requirements, the FDA's expectations have become increasingly complex.

To keep up with new industry developments, the FDA engages in Cooperative Research and Development Agreements (CRADAs) with testing agencies to co-develop and deliver critical regulatory and compliance training to FDA investigators worldwide. These agreements allow for unique insight into what the FDA may be prioritizing going forward, based on the development of regulatory training curricula for its investigators.

What expectations do FDA regulators have for CGMP competency training?



FDA CRADA UL

The FDA and its CRADA partners have developed life sciences e-learning courses used by businesses and governmental bodies worldwide as well as learning management systems (LMS) to manage federal, state and local investigator training and tracking. To help satisfy regulatory compliance requirements, investigators and customers can also access the same FDA e-learning courseware, LMS delivery and data-tracking capabilities.

Looking ahead, the FDA appears to be focusing on specifications for human behavior and competency, in addition to their product manufacturing and inspection scrutiny.

To meet these increasingly rigorous requirements, UL experts recommend that life sciences professionals master the following essential competencies prior to FDA inspections.

Timely training

The FDA expects to see documented confirmation that an employee's training and expertise is up-to-speed and current for their role and satisfies the position's requirements.

Assessment

Is the employee qualified for their role and what relevant expertise do they have? What type of testing/evaluation have they completed to measure competency? What are their strengths and weaknesses? How are learning gaps being addressed?

Qualification

Critical competency areas should be reviewed and measured regularly through continuous learning curricula created specifically for each role.

Periodic re-qualification is essential and can be achieved through quarterly refresher training, as recommended by the FDA. This training content should focus on Good Manufacturing Practice (GMP) weaknesses rather than repeating previous professional development learnings.

Continuous Training

Regulators in life sciences industries expect learning to be ongoing. E-Learning courses tailored specifically to the medical device and pharmaceutical industries can retrain employees on the essential importance of a sound, quality system and culture throughout their organization. Examples include:

- **Medical Device Quality –** Learn to identify the seven primary subsystems and objectives of medical device quality system regulation and see how a robust culture of quality can support the effective execution of quality systems.

- **Pharmaceutical Quality System –** Learn to identify the elements and objectives of the Q10 Pharmaceutical Quality System (PQS) and see how a robust culture of quality can support the effective execution of quality systems.

Looking Forward

The FDA's top five GMP inspection targets

Through their direct relationships with the FDA, companies have identified the following themes to help project what the FDA will be prioritizing in 2021 and beyond.

1 **Data Integrity (DI)**
One in three warning letters are related to DI issues. The FDA has identified data that is not secure or controlled as well as data that has been inadvertently or deliberately falsified. Facility inspections outside the U.S. have increased 70% over the past five years.

2 **Quality Management Systems**
A quality management system (QMS) is a collection of business processes that focuses on consistently meeting customer requirements while enhancing their satisfaction. A QMS is aligned with an organization's purpose and strategic direction, and — from clinical stages to product realization — spans the entire product life cycle. The FDA's focus on inspection has significantly increased.

3 **Sterile Manufacturing**
Product contamination and unsterile worksites are a chronic challenge which haunt many life sciences organizations. Aseptic processing is stubbornly complex to control successfully, so frequent training and retraining in this critical area is essential.

4 **Risk Management**
Risk management has expanded beyond the medical device industry into pharmaceuticals and healthcare. The FDA has consistently identified poor error investigations and deviations from procedures, resulting in a greater likelihood of unchecked errors.

5 **FDA Inspection Readiness**
Surprisingly, comprehensive preparation for an inspection is often presumed to be satisfactory, only for a team to discover a critical process or document is not in place. Is your current team adequately prepared for a scheduled or surprise inspection by the FDA in the next few weeks — or days? Are quality systems and documentation updated, well maintained and compliant with 21 CFR, Part 820? How do you manage an inspection overall, and how do you judiciously prepare staff for this critical event?

UL's best-in-class e-learning supports the FDA's CGMP practices

UL, the global safety science leader, is a proud partner in many life sciences training courses that feature modern learning techniques to boost employees' learning at all levels and help achieve competency.

Our goal is to provide your organization with the tools necessary to help employees achieve the qualifications, compliance and competency that they need to perform their jobs.

The ever-evolving nature of the medical device, pharmaceutical and healthcare industries demands a commitment to promoting continuous learning, using various digital devices, day and night, to reach all corners of the world.

Emboldening your personnel with an array of high-quality learning tools and opportunities inspires them to continuously improve their qualifications.

Our highly qualified subject matter experts and instructional designers specialize in employee development curricula which help to satisfy FDA requirements, achieve regulatory compliance and measure individual or organizational performance.

To learn more about how to achieve enterprisewide compliance, quality and performance goals with ComplianceWire® LMS, visit UL.com/compliancewire or call +1.609.627.5300 to speak with one of our LMS product specialists.

UL.com

0821