Focusing on Core Regulatory Knowledge

BEST PRACTICES FOR TRANSITIONING TO FULL-SCALE PRODUCTION

In our previous Knowledge Brief, we shared the "system" element of the learning and compliance infrastructure.

In this brief, we focus on the Regulations element. Even in the pre-commercial stage, companies must embrace critical regulations related to regulatory submission process as well as GxP regulations.

UL has observed two "regulatory-focused" best practices within companies transitioning from pre-commercial through post-commercial. These best practices have reduced risks associated with regulatory inspections, and also reduced the risks associated with nonconformities. Rather than perceive regulations as the "cost of doing business," companies have employed these regulatory learning best practices to promote a culture of quality:

- Continuous Learning: Commercializing clients map out a regulatory learning matrix that includes "continuous" regulatory education to specific job functions;
- First-Hand Regulatory Conversations: Beyond reviewing 483s and Warning Letters, many of our QA/RA executives make it a point to communicate directly with officials and also listen to these officials speak at association events. Associations or events that invite FDA officials to speak to the industry include: RAPS, ISPE, PDA, AdvaMed, FDANews, MedCon, PharmaLink, and others.

Benefits of Continuous Regulatory Learning Programs

There are several business benefits to building a sustainable regulatory learning program:

- Enables the QA/RA team to target key regulation updates to key teams, such as R&D, commercial, clinical and operations;
- Strengthens the ability of the company to communicate with agencies related to product submissions, reimbursement, manufacturing and more;
- Enables the commercializing company to build "anytime" audit readiness programs that span R&D, Clinical, Quality and Operations teams;
- Provides a Regulatory Knowledge Base that can be referenced as needed and serve as ongoing orientation for new hires.

The Regulations that Matter to Commercializing Companies

When we talk to commercializing companies, the QA/RA team has already mapped out a regulatory strategy that includes "core" regulations, which we have listed below. In addition, UL analyzed our 300+ Life Sciences eLearning courses and extracted the regulations noted in our most popular courses, which are used by companies of all sizes.

We also considered the key regulations cited in warning letters and 483s from US FDA.

For this Knowledge Brief, we have focused on the pharmaceutical segment of our business, and concentrated just on core US and EU topics. We are performing a similar analysis for the medical device industry and will present this in a future brief.

Commercializing companies must build a holistic regulatory learning strategy that extends beyond submissions and GxP topics. While not listed below, HR, Environmental Health and Safety, and Corporate Compliance topics must also be considered, including hazard communication (EH&S), workplace harassment (HR) and conflicts of interest (Corporate Compliance).

Many commercializing companies, as a best practice, segment the subparts of 21 CFR Part 211 so that specific job functions can learn about topics such as process validation or equipment cleaning, for example. In our next two briefs, we will share best practices on aligning regulatory "competencies" with other key core and technical competencies, and we will also share how commercializing companies cost-effectively build learning content to address this knowledge.

"Core" Regulations for the BioPharmaceutical Commercializing Company: