Sharlin Learning Lesson

Topic: FDA and Regulated Companies are Mutually Dependent

Developed and Presented by
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Main Idea

• Your company and FDA are mutually dependent for success
Regulated Companies Depend on FDA

- Products must be safe and effective
- Need FDA approval before a product can be marketed in the U.S.

FDA Depends on Regulated Companies

- Reviewers...
  - Need high quality submissions for their own success
  - Must work efficiently to meet review deadlines
  - Want submissions that are organized, complete and consistent
How to Be More Effective With FDA

- FDA reviewers want to help you
- Ask good questions the right way
- Provide multiple choice answers to your questions
- Don’t expect reviewers to do your job

Conclusions:
FDA & Regulated Companies are Mutually Dependent

- Learn the needs of reviewers
- Reviewers have strict deadlines
- If you help reviewers, they’ll help you
- Create good questions that prove your knowledge

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Transcript

Slide 1

Theme

Welcome to Sharlin Learning, a less than 5 minute presentation of information you can immediately use. My name is Joshua Sharlin, president of Sharlin Learning & Consulting and I specialize in applying an FDA reviewer’s perspective to my support of companies in all aspects of their work with FDA.

Slide 2

This lesson describes an important idea I emphasize with all companies I work with. That is, how your company and FDA are mutually dependent for success.

Slide 3

Why are companies dependent on FDA? The goal of an FDA product review is to evaluate documents and data that demonstrate your product is safe and effective. This is a requirement before your product can be sold in the US.

Slide 4

What’s not well known, or understood, is that the reverse is also true. That is, FDA reviewers need high quality submissions from the companies they regulate to be successful at their government job. This principle makes sense once you understand the reviewers’ environment at FDA. Reviewers are under a lot of time pressure to complete their reviews by the deadlines determined by legislation. For a reviewer to work efficiently and maximize the speed of their work, they must have submission that are well organized, complete and contain consistent information.

Slide 5

So how can you use the fact that reviewers want high quality submissions to be more effective with FDA? First, recognize that reviewers are motivated by self-interest to help you improve your submission. When a submission has better content, reviewers can work faster.

Even though reviewers have incentive to answer your submission-related questions, you still have to ask good questions the right way. For example, don’t ask open ended questions such as “How should I analyze this data?” Instead, create detailed questions with multiple choice answers.

A good question might say “I have determined that there are three possible methods for analyzing this data”. Then you would describe each method. And finally you would ask a reviewer which
method they think is best. Remember, reviewers want to help you be successful, but they are not going to do your job.

Slide 6

So what conclusions can be reached about your mutual dependency with FDA? First, treat reviewers like a customer and learn about their needs. Be aware they have deadlines for all their work. If you help them by creating a great submission, they'll be motivated to provide useful advice. Finally, structure your questions to prove you've done your homework. Providing multiple choice answers is one way of proving your knowledge.

This is Joshua Sharlin, and thanks for participating in Sharlin Learning. In addition to consulting, every month I teach three, 60-minute audioconferences on FDA-related topics.

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