

The US FDA in Perspective

“The FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.”

– US Food and Drug Administration

The US Food and Drug Administration’s mission is broad encompassing food, medicine, beauty products, and radiation-emitting devices. In short, the FDA protects the public health.

No one argues the need for that, but there are those who have concerns about how the public’s health is protected. For biotech, pharmaceutical and biopharmaceutical companies, FDA authority, in the form of guidelines and guidance documents, affects research and development, drives operations, defines clinical trials and checks marketing efforts.

In the world of drug and device development, the usual lines of tension fall along the FDA’s need to fulfill their mission, a company’s need to get to market and

make a profit and consumers’ right to safe and effective products. Today, big-pharma is in flux. Technologies are rapidly advancing. Big pharma is experiencing stricter enforcement, and funding options for small to mid-size companies are available but limited. The FDA is trying to address all of it with new programs, regulations and guidance documents that are not only setting US but also global standards. The result is a level of tension far beyond the normal lines.

In this regulatory environment, what are companies to do? What kind of game plan is necessary? These are the questions experts in the field answered to put the US FDA in a little better perspective. **i**

Never too Early to Plan



Russ King, managing partner, MethodSense

Plan your work and work your plan. In the case of the US Food and Drug Administration, there is not a truer saying. The catch is to start early, almost as soon as the decision is made to commercialize a discovery.

“Typically a company has a fabulous idea and a little bit of money coming in,” said Russ King, managing partner of

MethodSense, Inc. “The temptation is to pump every cent into the development of the product and not allocate funds to properly plan their regulatory strategy. That in our experience is a shortcut that will typically generate unnecessary costs in the long run.”

Russ’ experience is based on 23 years in life science companies working in medical devices, healthcare and professional services enterprises through which he’s acquired expertise in compliance operations, business development, customer support and strategic alliances.

MethodSense is also built on the experience of Rita King, managing partner of MethodSense. Rita spent 10 years working at UL (Underwriters Laboratories), a global product safety testing and certification organization, where she worked with US, European, Canadian and Japanese regulations across multiple product categories. She also has 22 years of experience as a professional auditor and as a regulatory affairs expert.

Through their combined experience, the Kings have identified the common pitfalls that companies, especially young ones, should avoid to set down a smoother, faster and potentially less expensive road through the FDA.

CREATE A REGULATORY MAP

“We speak with a lot of executives who are smart and scientists who are truly innovating, but they are frequently unfamiliar with life science business environments,” Russ said. “That lack of familiarity often creates surprises about all of the different regulatory and quality tasks that have to be completed and all of the



Rita King, managing partner, MethodSense

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That’s why Russ urges company executives, especially if they don’t have regulatory experience, to carve out the regulatory map early and in great detail. Advanced planning can have the advantage of highlighting options that save time and money.

Planning, Rita continued, can mean that “companies who thought they have to take a more stringent, costly path find out they don’t have to. For example, companies that thought they wanted to start with the US market may find out they have a better path in Europe. Planning up front and understanding the path that is right for you can actually help when you are setting milestones for investors. Planning can open up more doors for companies than they realize.”

DON'T SHORT-CUT COMPLIANCE

The King’s often are called into companies that have purchased quality checklists or pre-packaged quality templates as compliance solutions. “They think if they follow the checklist, they’ll be in compliance with the FDA or other regulatory bodies,” Russ said. “Checklists are very good. Make no mistake about it. One thing that checklists never do, they never account for who you are as a business or the demands on your business.”

“We often go into companies who purchase pre-packaged templates and find the quality system inappropriately structured for that company,” Rita added. “They end up forcing themselves immediately out of compliance because they have something on paper that they can’t follow. Templates can expedite compliance, but they can create regulatory problems without the right advisor to support you.”

The FDA is doing more to check-up on companies, whether through official interactions, website reviews or gathering information at professional conferences. High-dollar fines, publicly available warning letters and

closing operations are just some of the actions the FDA can take against companies who are non-compliant.

“We are seeing a lot of companies who thought the risk for FDA action on them was not that high and took some shortcuts,” Rita said. “They can find themselves in a very challenging position because the risk was higher than anticipated.”

DO DUE DILIGENCE ON VENDORS

Most companies today choose to outsource solutions to third party vendors and spend a lot of time negotiating prices. As they start the project, Rita commented, “they often find out they did not do sufficient due diligence on those vendors. Companies need to make certain they not only have the appropriate expertise, but they can also deliver services in a way that truly supports the company’s goals.”

Many companies, the Kings point out, don’t put quality agreements in place that adequately address responsibilities, reporting requirements, decision-making, documentation and approval. Planning can help companies identify the type of vendor needed and the relationship with the vendor that can help them the most.

“We spend a lot of time helping companies with these kinds of issues,” Rita said. “The ones who take the time to identify their expectations have a lot of success with vendors. Your due diligence will help bring up areas of weaknesses so you know where to invest time and dollars, and there are fewer surprises later.”

The Kings stress that there is incalculable value in a solid regulatory plan that can guide a company, help identify and mitigates risks and make the difficult path through the FDA and to market easier, less expensive and, ultimately, successful. **i**

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