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Insider Insights:

The FDA Group

CWWeekly's semi-monthly company profile feature, Insider Insights, interviews executives of companies and organizations in the clinical trials space. Writer Ronald Rosenberg sat down with Nicholas Capman, president and CEO of The FDA Group.

Q How did The FDA Group—comprised of former regulatory agency personnel—get started? What did you see that was missing in the consulting and regulatory space and how has the company evolved?

A The company spun out of NNE Pharmaplan (Novo Nordisk Engineering), the fourth largest pharmaceutical engineering firm in the world, in 2007. We started with just a few former FDA investigators and have grown to 115 people, including 41 former FDA investigators, officials and reviewers.

What was missing in the consulting and regulatory space when we started was the ability to find a company that had a deep team of former FDA people. The FDA Group specializes in FDA compliance consulting, regulatory services and executive recruitment. Although many consulting firms and companies have former FDA people, what we provide is a place where companies can find just the right person they need.

This company has evolved in several ways, having been able to fine tune our staff to accomplish two things: we have experts in each FDA discipline and staff with the right background who can deliver exceptional service.

We started in compliance consulting and expanded into regulatory services. This year we launched an executive recruitment service, which we are very excited about.

Q What are some of the significant shortcomings of sponsors and CROs in working with the FDA that your organization routinely deals with on a consulting basis?

A Some clients think they can talk their way out of a perceived bad situation and that inspectors care whether it was too difficult to get patients to do this or that. Well, regulators don't care: if you didn't do it—and you were supposed to—then you didn't do it.

Another shortcoming is not performing frequent audits and follow-ups to ensure that observations do not recur, plus not updating SOPs. There also is a lack of understanding roles and responsibilities.

We've seen a client's personnel not able to answer an auditor's questions in a clear and convincing manner—a situation that can be avoided by identifying the appropriate person proactively when planning for an inspection and coaching the person in good interview techniques.

Headquarters: Westboro, Mass.
Year founded: 2007
Description: A consulting and regulatory services firm, which recently added executive recruitment capabilities, it includes former FDA employees as consultants. The primary audience for its compliance and regulatory consulting are pharmaceutical, biotechnology, medical device and diagnostics companies, as well as those in the food industry. Its services include strategies to identify FDA compliance gaps and risk-based corrective action to pass FDA inspections. It handles regulatory submissions to ensure FDA filings have the highest level of detail and quality, and offers validation and qualification services.
Offices: Westboro, with consultants in 27 states, Canada and India
Officers: Nicholas Capman, president and CEO
Tim Lamm, vice president
Blake Capman, director
Employees: 115
Clients: small and mid-sized pharma, biotech and medical device companies, food and cosmetics companies
Web site: www.thefdagroup.com

Also, requested documents and records are not delivered in a timely manner. This can be avoided by anticipating the documents that may be requested (laboratory notebooks, deviation investigations and reports) and retrieving them during a simulated/mock inspection.

Other issues include:

- not being able to deal effectively with an auditor's work habits/ personalities
- a client's laboratories or warehouse production facilities are overcrowded, disorganized or lacking good housekeeping practices
- not anticipating FDA requests and interests based on regulations and regulatory guidance
- failure to seek outside expertise in such important areas as inspections, and a reliance on limited or minimal internal resources as FDA inspections can be a "make or break it" in the approval process and are critical for sponsors.

Insider Insights

Q FDA Good Clinical Practice (GCP) inspections are increasing, especially overseas. What are some of the misconceptions about audits and issues (i.e., the critical role of the study coordinator) among your clients in how best to prepare for them?

A Clinical investigators in other countries are not directly accountable to the FDA unless they have signed a Form FDA 1572 [a compliance form required of all PIs before they can begin a study in the U.S. or for those conducting studies abroad for sponsors that will seek regulatory approval in the U.S.].

That's why it is important for sponsors to make it very clear to clinical investigators that their participation and cooperation during the inspection, and acceptance of the inspection process, is very important. It should be part of the original contract with the investigator before the trial starts.

At the same time, the communication channels between the U.S. and other regulatory agencies—especially in Europe and Asia—mean that very little escapes attention in either direction these days. For example, if there is a product registered in one of these regions it can be assumed the other regulatory authority may be aware of the issues and concerns regarding that product.

Also, standards of management and care can vary between the U.S. and other countries. The types of records and their retention overseas can be different than what is common here. The same concerns can occur in the U.S. between major centers and less prominent centers.

Finally, non-U.S. trials may be critical to U.S. registration, if those studies are part of the U.S. application. People think U.S. studies are only for U.S. registration and non-U.S. studies are solely for foreign registration. However, it really depends on how the application is structured.

Q With recent FDA changes in risk-based monitoring, what do drug makers expect from your work on their risk assessments and risk mitigating strategies?

A The concept of risk-based monitoring can be easily misinterpreted. Sponsors should realize the FDA did not say: "We want to make everything easier for you." It said, "There are instances when this risk strategy may make more sense, may yield a better result and may give better control than traditional means of monitoring."

"Alternative monitoring methods can be useful and valid in certain situations, and not very reasonable in others, so care is needed in determining where to apply them."

Nicholas Capman, president and CEO, The FDA Group

Pharmaceutical companies ask us to help them assess the situation by providing independent, unbiased reviewers of their plans, protocols, communications, data, etc., and to help identify those areas in which alternative monitoring methods can be used to an advantage, not as an escape. They ask us to work with the clinical, data management and statistics people to provide a clear analysis of a situation and help them use existing tools to determine areas to focus on different types of monitoring.

Drug makers also ask us to provide independent quality assurance services to assess the plans and outcomes of these strategies. We also are asked to provide independent quality assurance services to assess the plans and outcomes of these strategies.

Now, these alternative monitoring methods can be useful and valid in certain situations, and not very reasonable in others, so care is needed in determining where to apply them. Sponsors should remember they still must meet the requirements of the established regulations, as these methods often are particularly helpful in large trials.

Q The FDA recently modified its original plans to monitor social media traffic, which had been heavily criticized, and instead is focusing on monitoring and measuring the reach of its messages in real time, assessing the impact of its messages and monitoring mass media content. How do you view this new strategy, designed to draw data from multiple social media channels?

A The agency is to be commended for attempting to get a handle on this current phenomenon and its response to those concerns with revised ideas on dealing with social media issues.

However, there is likely to be continued conversation around this topic, as sponsors apply ideas to their situations and realize there is likely to be significant ongoing responsibility and resource implications around them. Oversight of all media channels, with all sponsors, manufacturers, etc., is an ambitious task, given the speed with which new technologies emerge and become popular in our culture.

Perhaps the biggest challenge to this draft guidance is getting sponsors and their representatives to recognize that the "hot new idea" they have for one of these channels is actually under this guidance and to see that they establish the oversight and controls needed.

Typically, people coming up with these new ideas and concepts are not the ones looking into the specific requirements and seeing the limits or concerns. We can help by pointing out where and why it fits under the guidance (if it does) and help to create the needed oversight process.