How Device-Makers Can Leverage FDA Data To Uncover The Agency's Current Thinking On Compliance

US FDA is an ever-evolving organization, from recent changes to facility inspections under its so-called "Program Alignment" initiative, to plans to harmonize the agency's Quality System Regulation with international quality systems standard ISO 13485 – just to name two big-ticket reforms.

As a result, device-makers are often in the dark when it comes to FDA's compliance and enforcement priorities. But by leveraging online information from the agency on inspectional observations, warning letters, product recalls and other vital data, companies can gain essential insight into where FDA is focusing its compliance eye, says Ricki Chase, a compliance practice director for Lachman Consultant Services, Inc. ("Lachman Consultants"), and a former FDA investigations branch director.

"History tends to be a good predictor of the future. Taking a look at multiple sources of information that are publicly available and understanding the link between those data is a sound way to understand the current thinking of the agency and where it may continue [compliance] efforts or change course," said Chase, who joined Lachman Consultants in 2016 after spending 16 years at FDA, where she was also an investigator, medical device specialist and supervisory investigator.

The "increasing amount and types of [FDA] data available to the medical device community allows for increased shared knowledge and experiences," she said. "The data can be leveraged to predict potential problems, prevent costly errors, and to understand where trends in devices may lead to more regulatory and compliance oversight."

But, Chase warned, device firms should be aware that with the increase of FDA data in the public domain comes a greater responsibility on the part of industry.

"No longer can manufacturers claim they didn't know or were unaware" of a particular quality system or product problem, she said. "Device-makers must make a concerted effort to use the [data provided online] for continuous quality improvement. The responsibility for compliance remains on the manufacturer now more than ever."

Step 1: Uncover Inspectional Observations

Chase urges manufacturers to first gather data on inspectional observations. This information can be found on FDA's website at www.fda.gov/ICECI/Inspections/ucm250720.htm.

At the bottom of that page, visitors can view a summary of fiscal year data or download it as an Excel file. Firms can find summaries dating back to 2006.

The Excel spreadsheet gives companies the ability to search "by commodity to look at all of the inspectional observation citations issued for [a specific] fiscal year, a description of those and the frequency," Chase explained.

For example, a review of fiscal year 2017 inspectional observation data shows that the observation most often cited was for failure to establish, or adequately establish, procedures for corrective and preventive action; this observation was noted 400 times on FDA-483 inspection forms that year.

Chase acknowledged that CAPA often tops the list because FDA investigators always review a firm's CAPA system during abbreviated level 1 QSIT (Quality System Inspection Technique) inspection, which makes up the bulk of the audits the agency conducts. Still, she agrees that, notwithstanding the FDA's focus and industry awareness, CAPA continues to pose great challenges for firms.

Rounding out the top five inspectional observations in 2017 was inadequate procedures for complaint handing (269 citations), inadequate procedures for purchasing controls (138), inadequate process validation (137), and inadequate procedures for nonconforming product (127).

"And, although not a cGMP requirement, a lack of written Medical Device Reporting – or MDR – procedures were as prevalent as inadequate procedures for nonconforming product, with 127 citations," Chase noted.

"So, the question is, are these just numbers or do they really mean something?" she said. "When looking at these numbers alone, they may not tell you much, so the key is to give the numbers some context by looking at additional data sources."

Step 2: Review Warning Letters

The next data to look at, Chase advises, are violations outlined in FDA warning letters. And the best way to do that is to read the missives, found online at www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm. The agency updates the page every Tuesday.

An informal review of warning letters "reveals that while an MDR observation may be less frequently cited [on FDA-483s] than the other leading five GMP observations, it routinely results in an official action," Chase said.

"The Medical Device Reporting rules are viewed as a critical way for FDA to know and understand what is happening with devices post-market," she added. Therefore, "failure of a firm to report – or to report in a timely manner – an MDR event is considered a serious violation potentially linked to harmful product remaining on the market or an early signal of a potential need for a product recall."

And, while a failure to have adequate CAPA procedures is most frequently cited on FDA-483s, warning letters reveal that inadequate process validation – and the even less frequently cited design control processes and procedures – are often top violations.

"CAPA may get you a 483 observation, but failure to perform process validation and design control, and failure to report MDRs, are the things that will earn you that unwanted warning letter," Chase concluded, pointing out that "process validation is often a sticky wicket for device-makers."

Step 3: Detect Common Recall Causes

Product recalls – found in FDA Enforcement Reports at www.fda.gov/safety/recalls/enforcementreports/default.htm – offer another rich source of information.

"The report can be sorted by commodity, so you can focus on device product recalls," Chase said.

The data found there shows that, in FY 2017, there were 64 high-risk class I medical device recall events, and 3,067 class II recalls. In FY 2018, manufacturers initiated 117 class Is and 2,985 class IIs.

"While those numbers are perhaps interesting to consider, the reason behind the recalls is the true information of value," Chase said. "A review of class I recalls for fiscal years 2017 and 2018 indicates that the majority of them were initiated due to device failure and problems with design."

Meanwhile, "class II recalls are by far the most common classification of recall," she said. "Those are often related to a lack of interoperability of non-OEM [original equipment manufacturer] accessories with the device, failure to meet testing and manufacturing specifications, supplier concerns, and labeling issues."

Step 4: Mine FDA's Data Dashboard

FDA's handy Data Dashboard, found online at https://datadashboard.fda.gov/ora/cd/complianceactions.htm, is also a valuable resource that allows users to search for compliance data including information on facility inspections, compliance actions, recalls and import activities.

The dashboard "provides good high-level knowledge of industry, as well as very specific knowledge of any given firm," Chase said. "It is global and can be filtered to help you digest the data and look for trends you may be specifically interested in."

Observations noted on FDA-483 forms are also presented here; just click on a company FEI (FDA Establishment Identifier) number at the bottom of the page under "Compliance Actions Details." Up will pop a "Firm Profile," which offers an array of compliance data.

The dashboard is updated every six months.

What Does All Of That Data Mean?

So, collectively, what do the inspection outcomes, warning letter content, product recalls, injunctions and other compliance data tell device-makers about FDA's mindset when it comes to compliance and enforcement? "That there is a consistency in the failings of manufacturers to really understand and apply the concepts of corrective and preventive actions, management of complaints and the handling of suppliers," Chase concluded.

"But these failures are not those that tend to lead to an action

and/or a recall," she said. "Rather, CAPA and complaints are symptoms of inadequacies in processes and design."

The good news is that a company can overhaul its processes relatively easily. That's because "processes can be improved, and efficiencies created, and new technologies can lend themselves to less human intervention and more machine control – a benefit with proper qualification and validation techniques," Chase said.

The bad news? "Design can be much more complicated," she said.

"The use of [FDA's] 510(k)-clearance pathway allows device manufacturers to demonstrate design controls primarily during a post-market inspection, unlike a PMA device, which requires exceptional scrutiny," Chase explained. "By the time the device is in production, the opportunities for design change and significant remediation of design challenges has shrunk."

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Data gathered from FDA "demonstrates that design is related to warning letters and serious recalls," she said. Therefore, "the investment in quality by design is an area where returns can be greatest."

Chase pointed out that healthy design activities lead to a better understanding by a firm of its manufacturing processes and take place within a high-functioning quality system, which manages change from the point of design freeze.

"The benefits of a good design include significant monetary savings by reducing the time and manpower necessary to manage complaints and CAPA actions," she said. "Additionally, the cost of recalls and warning letters is impactful and has driven some businesses to bankruptcy. And data support that a good design provides an increase in return on investment."

A solid design plan can help reduce device failure and the potential of serious injury or death, in addition to preventing costly regulatory actions and budget drain by moving a company to a preventive stance rather than a reactive one.

"In fiscal year 2017, more than 500 adverse event reports were filed as linked to patient death," Chase said. "While in many instances the relationship between the patient death and the device is not conclusive, the cost of patient loss is in both reputation and value."

FDA's Manufacturer and User Facility Device Experience (MAUDE) database, found online at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm, is where the agency stores information on adverse events and is another excellent source of compliance data for device-makers.

"The ability to review adverse events and malfunctions related to a similar device you are designing or may already be manufacturing post-market allows for prediction of what could be otherwise unrealized failure modes, helping to bring robustness to both design and process," Chase said.

And the ability of manufacturers to uncover pre- and post-market signals related to devices that are similar to their own has been made even easier thanks to FDA's Total Product Life Cycle (TPLC) database, found at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm.

"In this database you can search by product code or common name, and failure modes are captured and linked to supporting reports," Chase said.

Look To CDRH Priorities, Too

In addition to the immense amount of data FDA has made publicly available, the agency's Center for Devices and Radiological Health (CDRH) is also freely sharing its strategic priorities, which offers a roadmap of sorts for where FDA is headed when it comes to compliance.

"The center's most current strategic priorities document discusses changes and improvements for 2018 through 2020," Chase said. "One of the most critical goals of the center is the establishment of the NEST program."

The National Evaluation System for health Technology, or NEST, "strives to create opportunities to collect real-world user experience data as a means by which to drive decisions on benefit-risk analysis," she said, noting that "NEST will also bring more timely exposure to post-market data signals" – a clear advantage for device-makers.

"And CDRH is continuing to push its Case for Quality initiative," Chase added. "The years-old Case for Quality creates a community of patients, payers, industry and government to reward manufacturers of high-quality devices with regulatory and market incentives. This is yet another reason why using [FDA's available compliance and enforcement tools and data] will help you make quality improvements going forward for your regulatory and market benefit."

The bottom line? "CDRH is increasingly partnering with all members of the medical device community," she said. "The opportunity to leverage the tools provided, and to participate in the development of new tools and programs, can provide a competitive advantage in bringing new products to market and improving the safety of those that are already being sold."

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