MEETING REGULATORY REQUIREMENTS: RISING TO THE CHALLENGE WITH A TRUSTED EQUIPMENT PARTNER

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Drug developers and manufacturers face a number of challenges today, many of which are directly correlated with the increasingly stringent and complex regulatory demands and pressures being imposed on the industry. Pharmaceutical suppliers are tasked with responding to ever-evolving changes in regulatory requirements, which impact everything within an organization — from operations to the way trials are conducted and how drugs are disseminated, labeled, packaged and even consumed.

As the largest stocking dealer of used manufacturing equipment, with over 60 years of experience successfully operating as partners within the industry, Federal Equipment Company has the background and the bandwidth to provide facilities with an update based on our wide array of inventory.

CURRENT AND FUTURE REGULATORY CHALLENGES

There are a number of regulatory challenges facing manufacturers, though perhaps the most buzzed about within the industry include serialization and the promotion of continuous manufacturing. The FDA has mandated that all manufacturers conform to stringent but generally broad requirements for serialization. All companies must arrive at a solution, though how they actually do so is widely open-ended, and there is ample room for interpretation. This has given companies a chance to

innovate, with some manufacturers going above and beyond Track and Trace regulatory requirements, to the point where each drug product – down to the individual pill – is labeled. This is in keeping with the larger effort to increase accountability within the supply chain and prioritize patient safety.

The FDA has mandated serialization through the Drug Supply Chain Security Act (DSCA) and issued a guidance for identifying products. The DSCA had to be postponed a full year (from 2017 to 2018), as the industry was generally underprepared to conform to these product requirements within the allotted time.[1] One DSCA stipulation is the product identifier guidance, which goes into effect in November 2018 and stipulates that each prescription drug package and case must include a unique identity marker to allow members of the supply chain to easily classify drug packages throughout all phases.

The FDA has outlined that the traceable marker must include "the product's lot number, expiration date, national drug code (or NDC), and a serial number." Each serial number must be unique to each package or case, which must be able to be read by both humans and machines in order "to enable product tracing throughout the supply chain and enable all trading partners to better detect illegitimate products within the supply chain."[1]

Though not an official mandate, the FDA has also placed an emphasis on continuous manufacturing, advocating for the transition to this automated processing approach. In May 2017, Sau Lee, Deputy Director of the Office of Testing and Research for the Center for Drug Evaluation and Research, published a guidance on the regulatory agency's official website. In the piece, Lee discusses the appeal of a move to continuous manufacturing and how it will update the industry, making operations as a whole more cost-effective and efficient.[2] This push to upgrade facilities from batch to continuous processing has since been echoed, and it seems only a matter of time before this guidance becomes standard, and facilities that do not adapt to the impending trend are left behind.

It is likely that the move to continuous processing will occur, especially as it is seen as a way to ensure traceability. Lee points out, "Continuous manufacturing may allow for more flexible tracking and tracing, which would be an advantage in the event of a product failure. For example, in batch manufacturing, a specific quantity (or batch) of a drug is defined by the size of the equipment that produced it. In continuous manufacturing, a quantity (or batch) can be delineated by a time stamp, amount of drug produced or the amount of raw input material. These tracking methods permit the manufacturer to isolate a smaller amount of defective material in the event of a process failure, which leads to less waste and less chance of a shortage."[2]

This is followed by the observation that the transition to automation has already begun for chemical and petrochemical industries. A move to continuous manufacturing is perceived as the safer option and as a way to preserve equipment. Additionally, automation of operations will allow issues to be detected faster, before failure occurs.[2]

AN EMPHASIS ON EQUIPMENT: RELYING ON AN EQUIPMENT PARTNER

With such a seismic shift in operations comes a host of challenges. These include cost issues, potential issues with spacing and concerns about the obsolescence of current equipment and having to source an alternative. These regulatory measures are affecting operations significantly, and the majority of change is centered on equipment.

In order for a company to fully prepare for and conform to all DSCA measures, updated equipment is a must. Equipment needs are constantly changing in an evolving regulatory landscape. In the case of serialization, partnering with an organization such as Federal Equipment Company is an opportunity for a manufacturing organization looking to make a smooth transition during a time of regulatory upheaval.

This same logic applies to continuous manufacturing requirements. A firm looking to differentiate themselves from other manufacturing partners is likely to begin the transition to integrated and automated operations. Although this is an expensive – not to mention labor-intensive – process in the immediate term, the long-term benefits are considerable. The firms that make the transition to continuous processing or that "modernize" without having to be told to do so will command an advantage within the industry. This advantage includes capturing clientele looking for a trusted partner that can provide them with the highest level of quality manufacturing.

With literally thousands of machines in stock and the most extensive inventory in North America, Federal Equipment Company is the partner that manufacturing organizations can rely on, whether they are buying additional equipment for the facility or selling equipment that is no longer needed. We are equipped to guide pharma manufacturers through the process of acquiring new solid dose equipment through our subsidiary partner Techceuticals. Techceuticals provides equipment training and troubleshooting to ensure that operators are using equipment properly over the long term.

THE CHALLENGE OF SOURCING EQUIPMENT

Sourcing equipment provides its own set of challenges. For instance, will the equipment be a good fit within the facility? Is it the right machine? How can you ensure that a team is fully trained and able to operate the equipment? There are numerous issues raised when simply adding or removing a piece of machinery, let alone starting or expanding a facility. This is why you need an equipment provider you can trust.

A SOURCING STRATEGY: PROCURING USED EQUIPMENT AND RELYING ON REPUTABLE COMPANIES

In order to address these challenges, a manufacturing organization must do their research and determine what is needed from an equipment partner. There are many advantages to sourcing used equipment, such as cost and lead time. Lead time for a new machine, including selection, customization, factory acceptance test (FAT) and site acceptance test (SAT) can take months. A used machine can be sourced, shipped and installed immediately: a time-saving and contract-saving way to upgrade any plant.[3]

Federal Equipment Company partners with top original equipment manufacturers (OEMs) to bring customers peace of mind that the right machine is selected and can be installed and serviced post-purchase. Working with a reliable, trusted and experienced equipment partner can make a significant difference in meeting federally imposed regulations, most often on an abbreviated timeline and under a constrained budget.

WORKING WITH A RELIABLE, TRUSTED AND EXPERIENCED EQUIPMENT PARTNER CAN MAKE A SIGNIFICANT DIFFERENCE **IN MEETING FEDERALLY IMPOSED REGULATIONS, MOST OFTEN ON AN ABBREVIATED TIMELINE AND UNDER A CONSTRAINED BUDGET.**

Investing in equipment is taxing on all fronts, which is why the best strategic option is working with a trusted company like Federal Equipment Company that is as invested in your machinery as you are. P

REFERENCES

1. *FDA Issues Draft Guidance: Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy.* U.S. Food and Drug Administration. 30 Jun 2017. Web.

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3. Hicks, Matt. "Buying used equipment saves time and money." *Pharma's Almanac.* 6 Mar 2018. Web.

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Federal Equipment Company has on-hand inventory in more than 200 categories, enabling you to source reliable processing and packaging equipment that's housed in clean, climate-controlled warehouses. We obtain much of our inventory by providing asset management programs to large, multinational companies. This gives you a wide range of options to get the leading OEM-brand equipment you need from reputable sources installed and operating in your facility as fast as possible. No matter what your equipment needs are, make Federal Equipment your first call.

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