Time for an FDA-Program tune up

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The FDA has moved to a new all-electronic system. If your firm has not yet registered under the new system, start planning to do it this spring.

The winter weather is now receding, signaling the start of one of the busiest times of the year for taking care of administrative maintenance activities. This makes it a great time to take care of the annual required maintenance on a firm's FDA compliance program. Here are some helpful tips for keeping the firm's compliance program running smoothly.

FDA Registration

In June of 2009 the FDA eliminated their traditional paper-based registration system and went to a new, all-electronic system. If you have not yet registered under this new system now is the time to make plans to do so. If a firm currently has a 2009 registration it has until December 31, 2010 to register. If the current registration year shown on the FDA's website is 2008, or earlier, then your company is not properly registered and you need to take care of this immediately. To check the status of your firms' current FDA registration, go to: http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm and type in the company's name.

While the FDA's electronic registration process is not difficult, it does have a steep learning curve, and can eat up a lot of time navigating through the process. We have filed hundreds of these registrations for customers, so if you are looking for some assistance please give us a call.

One thing to keep in mind, the FDA only has so many resources dedicated to this activity, and they tend to be busy the last couple of months of the year. Our experience is that the whole process slows down considerably at the end of the year as companies who have waited until the last few months all try to access the system at the same time. There is no penalty for getting this done earlier in the year and our advice is plan ahead, and avoid dealing with the end-of-year delays and frustrations.

cGMP refresher training

The FDA expects all firms to perform an annual cGMP refresher training with their employees. If it has been a while since you conducted this training, with the spring just ahead, now is a good time to do it. It is also the perfect time because you can finish before summer vacations start. The vacation season typically makes it a lot harder to gather all the needed employees together, and

more likely to miss some key individuals. That could result in the need to schedule additional sessions.

This is training a company can do for itself. However, we can also offer cost-effective web-based options. Another training consideration is remedial SOP training. If you have changed any of the operating procedures since the last time the firm documented training with its employees now is the time to train all affected employees in the revised procedure requirements. If it has been three or four years since employees were trained in any of the procedures that govern their tasks, now is a good time to think about sitting down with them and reviewing the applicable procedures, to make sure they have not developed any bad habits during that time period.

One of the perennial top ten FDA citations issued to medical gas companies involves employees not following their own procedure requirements, and the best way to avoid this is to make sure the workforce is re-trained periodically. When performing refresher and remedial training make sure to remember the FDA Inspector's cardinal rule – "If it is not written down it is merely a rumor."

We recommend the following:

Make sure to adequately document all training.

Record who was trained and the date.

Record the training subject.

Document the session agenda especially the topics.

Also, keep a copy of the training materials tucked away, just in case an FDA inspector asks to see them.

Police the work space

Another FDA citation we often see is employees using out-of-date procedures or forms. We recommend that you make a tour of your work spaces at least annually. During this tour look for expired copies of forms, old copies of procedures, out-of-date SOP manuals, out-of-date medical gas fill technical data, or any other supplemental information that is no longer applicable.

It is a natural tendency for people to hold onto materials they have acquired over time. However, if these items are or could be used to guide or document filling operations the FDA expects that these out-of-date and expired forms and procedures will be culled and destroyed.

When doing your tour make sure to look in drawers and under, in, and around stacked papers and manuals. It is uncanny how expired and out-of-date materials often tend to just pop to the surface when FDA investigators are visiting, so don't be afraid to dig around a little. Some digging now can save you a major embarrassment down the road.

Drug label review

Another good spring maintenance item is to review drug labels and make sure they conform to

current FDA and CGA requirements. Over the last year we have reviewed hundreds of drug labels for compliance. For us it was a real eye opener how many company's labels failed to meet all the current requirements.

One of the most common omissions is not putting a statement on a refrigerated liquid label not to modify or change connections. Now is the time to get a copy of the latest CGA labeling requirements contained in publication C-7 Guide to the Preparation of Precautionary Labeling and Marking of Compressed Gas Containers, and review the firm's labels against those requirements.

Remember, if you do update your labels the old label stock needs to be destroyed. Many companies phase in new labels so they can use up the old stock. This is acceptable as long as the old labels do not have a clear violation of FDA requirements, such as not having the "Rx Only" legend on them. If you need to order labels we recommend performing a label review to make sure they meet all requirements. If you need some help, give us a call.

Another point is to check is the status of drug label reconciliation process. Periodically, companies need to reconcile their label activity by comparing how many labels have been purchased, how many have been issued for application to cylinders, how many were destroyed, how many were returned to inventory, and how many are still in inventory. Determine the number in inventory and physically count how many are actually in stock. Then compare that figure to how many you actually have Investigate and explain any discrepancies, and then document it.

Annual program review

Firms are required to annually perform a program evaluation or review under 211.180 (e). The FDA expects that a firm will review key records associated with its manufacturing processes to determine the need for changes in product specifications or manufacturing processes.

Specifically, the FDA requires that a representative number of batch records and all supporting documentation, as well as customer complaints, internal non-conforming investigations, and records of returned or salvaged drugs "shall be reviewed." The results of these reviews must be communicated to the firm's management, along with any recommendations for improvements. To satisfy this requirement the company needs to have a procedure on performing an annual review, and how and to whom the results are communicated.

Secondly, document how the annual review and any results/recommendations were conducted.

Record retention

Medical gas firms are only required to keep FDA-regulated records for a finite period of time. We strongly recommend that a firm expunge any records whose time has "expired."

This is as for your protection. The reason is that if FDA shows up and the firm still has old records on hand, the inspectors are permitted to review them if they choose – even if those old records are technically "expired."

Typically, most inspectors will not bother with records that are three to seven years old, but if FDA wants to look at old records hanging around, an owner cannot legally refuse. If you do not apply an expiration date to cylinders, then you must maintain records that span the last three years – plus the current year.

That means if any records dating to 2006 and older meet the shredder you should apply an expiration date. It also means you need to keep records for one year past the expiration date. If you have not taken care of shredding expired FDA records already, now is the time to take care of this little maintenance chore.

With some simple maintenance you can keep your FDA compliance program running smoothly and avoid some of the most common FDA citations for violations of 21 CFR. If you have any questions about anything in this article, or FDA compliance in general, please feel free to give us a call or drop us an email.