Pharmaceutical & Medical Device Manufacturers

Meet FDA Training Requirements using Learning Management Technology!
Compliance, regulations and guidelines govern the research, development, manufacture and clinical trials process, as well as the marketing and sales of drugs, biologics and medical devices. In fact, the FDA not only requires that drug and device manufacturers train their employees, but they put the burden on firms to establish comprehensive procedures that specify how employees will be trained and how those training records will be kept.

During an FDA inspection, records will be reviewed to ensure that firms are following their procedures and that their programs are effective. This begs the following questions:

- How prepared would your company be for an audit?
- Are your training records up to date and audit ready?

“The time is always right to do what is right.”

– Martin Luther King
Pharmaceutical Requirements

The requirements for training for pharmaceutical or drug firms is contained in 21 CFR 211.25, which states the following:

(a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

(b) Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.

(c) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product.

Source: www.fda.gov
**Pharmaceutical Citations Commonly Identified by FDA Investigators Include...**

<table>
<thead>
<tr>
<th>Code</th>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 CFR 211.25(a)</td>
<td>Training--operations, GMPs, written procedures</td>
<td>Employees are not given training in [the particular operations they perform as part of their function] [current good manufacturing practices] [written procedures required by current good manufacturing practice regulations].</td>
</tr>
<tr>
<td>21 CFR 211.25(a)</td>
<td>Training , Education , Experience overall</td>
<td>Employees engaged in the [manufacture] [processing] [packing] [holding] of a drug product lack the [education] [training] [experience] required to perform their assigned functions.</td>
</tr>
<tr>
<td>21 CFR 211.25(a)</td>
<td>GMP Training Frequency</td>
<td>GMP training is not conducted [on a continuing basis] [with sufficient frequency] to assure that employees remain familiar with CGMP requirements applicable to them.</td>
</tr>
<tr>
<td>21 CFR 211.25(b)</td>
<td>Supervisor Training/Education/Experience</td>
<td>Individuals responsible for supervising the [manufacture] [processing] [packing] [holding] of a drug product lack the [education] [training] [experience] to perform their assigned functions in such a manner as to assure the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess.</td>
</tr>
<tr>
<td>21 CFR 211.25(c)</td>
<td>Inadequate number of personnel</td>
<td>The number of qualified personnel is inadequate to [perform] [supervise] the [manufacture] [processing] [packing] [holding] of each drug product.</td>
</tr>
</tbody>
</table>

Source: www.fda.gov
Medical Devices

The requirements for training for medical device manufacturing firms is contained in 21 CFR 820.25 (b), which states the following:

(a) General. Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.

(b) Training. Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.

   (1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.

   (2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

Source: www.fda.gov
Medical Device Citations Commonly Identified by FDA Investigators Include...

<table>
<thead>
<tr>
<th>21 CFR 820.25(b)</th>
<th>Training records</th>
<th>Personnel training is not documented.</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 CFR 820.25(b)</td>
<td>Training - Lack of or inadequate procedures</td>
<td>Procedures for training and identifying training needs have not been [adequately] established.</td>
</tr>
</tbody>
</table>

Source: www.fda.gov

A Few Words about Standard Operating Procedures...

FDA and quality auditors expect regulated companies to have standard operating procedures that define their training programs. When establishing your Standard Operating Procedures for documenting your training, don’t forget to include the following:

- The reason for training
- Who is conducting the training
- How the training is to be conducted (online, instructor-led, etc.)
- When the training will occur and how often
- Who will be attending the training (role-based programs)
- How training effectiveness will be measured
How Can You Develop an Effective Training Program?

Developing an effective compliance training program is no easy task, but adopting a “culture of learning” company-wide is a great first step. A comprehensive training program includes performing needs assessments, implementing training programs, evaluating training program effectiveness, and making sure all training records are accurate and up to date.

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**Training Program Considerations**

1. Adopt a “culture of learning”
2. Analyze your training requirements
3. Determine which personnel need to be trained on which tasks
4. Describe the body of knowledge that goes along with those tasks
5. Decide which type of training is appropriate
6. Conduct, Track and Document ongoing training
7. Maintain all of your training records
Tracking, Documenting, and Maintaining Training Programs/Records May Be Your Greatest Challenge!

Auditors will be looking for documented proof that you have a comprehensive and systematic training process. If this is required for a single department, you may be able to handle it on paper; but when this is required for your entire organization, it becomes quite challenging. The volume of tasks required to keep track of training can be tremendous.

Training variables that impact the complexity of your programs can include:

- Corporate training requirements such as orientation, safety, and quality systems
- Job-specific training requirements
- Number of employees, working multiple shifts at multiple locations
- Re-training and annual training requirements

Once these variables are identified, and training programs are developed per employee type, then training schedules must be established, employees need to be notified of their training requirements, reminders need to be sent, training needs to be conducted, attendance needs to be recorded, training records must then be maintained and audit ready. These tasks are complex, time consuming and can become very costly.
Reduce Risk – Be Audit Ready – Incorporate Training Technology!

The good news is, Learning Management System (LMS) Technology makes it easier than ever before for you to automate and manage your compliance training initiatives. Using software ensures that your training records are up-to-date and audit ready.

A LMS manages learner information including: assigning and tracking training, allowing access to eLearning and virtual learning, scheduling and assigning instructor-led training, controlling course enrollment, email notifications, and serves as a repository for documentation, course materials and historical training data.

A LMS can easily become an integral component of your compliance system. With an LMS you’ll experience clear, real-time visibility into your company’s compliance activities and you’ll be able to transform your labor intensive processes into a valuable area for business improvement, cost savings and above all – risk mitigation!

“New and expanding regulations, along with advances in technology, are transforming the compliance landscape.”

– David Wentworth, Senior Research Analyst
Brandon Hall Group
What are Some Additional Benefits of Implementing an LMS to Manage Compliance Training?

- Employees become more engaged with better visibility into their own personalized training curriculums.
- Transitioning live training to online training reduces your overall costs for delivery.
- LMSs featuring testing and assessment tools help to ensure that your training programs are understood, effective and well received.
- Consistent training is accessible across distributed workforces.
- Reports are easily run exactly when you need them and with the granularity you need across departments, business divisions, operating facilities, and more.
- Training content is easily managed - versions and access to content are traceable and auditable.

Well-managed training programs minimize the risk of noncompliance and ultimately helps to improve your product/service quality. Implementing a LMS helps you to easily meet your compliance training requirements.

Would you like to learn more about how implementing an LMS technology can benefit your company? Perhaps you’d like to see a live demonstration of our LMS platform? Feel free to contact us at 908-722-6622, via email sales@ePathLearning.com, or visit our website at www.ePathLearning.com.