

GMP Training Systems, Inc.

Creators of the GMP Ready-to-Use Training System™

Creating a Culture of Quality and GMP Compliance

David C. Markovitz
President, GMP Training Systems, Inc.

Some companies have it.

Some don't.

Some people in some companies get it.

And some people don't.

THOSE WHO DON'T HAVE IT AND DON'T GET IT

You can read about those who don't have it by scanning the FDA website¹.

One - Go to FDA's website and click on Warning Letters. There you will find Warning Letters issued by FDA.

FDA's new Commissioner, Dr. Margaret Hamburg, in a speech delivered on August 6, 2009 said the following.

"The FDA must be vigilant, the FDA must be strategic, the FDA must be quick, and the FDA must be visible. We must get the word out that the FDA is on the job."

Commissioner Hamburg highlighted six initial steps designed to hone the effectiveness

and timeliness of the FDA's regulatory and enforcement system. These six steps are related to the Warning Letter process.²

Two - Go to FDA's Electronic Reading Room. It is managed by FDA's Office of Regulatory Affairs under compliance with the Freedom of Information Act.³ There you will find assorted FDA 483 Observation Reports, Establishment Inspection Reports, Recall documents, Court case records, and other documents of interest.

One generalization we can come to about the companies found in the "Don't Have It" column is that they do not have a Culture of Quality in their organization. They have not made GMP a Lifestyle. GMP is not part of the fabric of these organizations.

THOSE WHO HAVE IT AND GET IT

Let's look at the companies in the "Have it" column. These are companies who have been successful in Creating a Culture of Quality and have made GMP a Lifestyle in their organizations.

Here are some of the things about the people in these companies that we've observed.⁴

- Senior management takes responsibility for Quality and GMP compliance. It is not something delegated to the Quality unit or to the Regulatory Affairs group.
- Senior management views quality issues equal to production issues.
- Senior management balances business needs with quality requirements.
- GMP is viewed as Good Business Practice.
- Quality and GMP compliance is seen as the only acceptable way of doing business.
- Everyone in the organization recognizes that GMP risk is unacceptable.
- Everyone in the organization actively seeks to do the right thing all the time.
- Freedom of speech prevails throughout the organization. Everyone is encouraged to speak out if they see something wrong or amiss.
- Quality and GMP compliance is seen as an opportunity, not as an obligation, and is owned by everyone in that organization.
- People in the organization address tough issues and are not afraid to make uncomfortable decisions if they are the right thing to do.
- People in the organization proactively anticipate changing standards.
- People in the organization acknowledge other perspectives.
- You don't hear anyone saying "Good enough," "Close enough," or "We're pressed for time so let's take a shortcut."
- People effectively use a Corrective and Preventive Action system.
- People use statistical tools and techniques to prevent problems.
- Training is viewed as an investment, not a cost.
- People are trained in their job skills – and the training is well documented.
- People are trained on an ongoing basis in GMP and the regulations that apply to their jobs – and the training is well documented.
- The facility is clean, neat, and orderly.
- Visible signs of GMP compliance are present as a daily reminder of the importance of GMP compliance.

- Internal audits are performed and viewed as a process for identifying gaps in the operating systems and processes.
- Action is taken to make corrections or adjustments in response to internal audits.
- An effective orientation process is in place for new employees, both at the company level and at the department level.
- People use the words “we” and “our” more than they use the words “they” and “their”.
- A healthy level of stress exists, but rarely turns to distress.
- A system of checking and double checking is in place to guard against complacency.
- Managers are visible and ask open-ended questions. And then listen to the answers.
- People care about the work they do. People take ownership of their work.
- Performance metrics are clear, visible, and understood by everyone in the organization.
- People are recognized for their contributions and feel a sense of accomplishment at

the end of the shift, week, month, and year.

- There is a sense of pride throughout the organization.
- After an FDA inspection, if an FDA 483 Observation Report is submitted, it is clearly communicated to everyone in the organization.
- Plans to address any FDA 483 observations are clear and understood by everyone in the organization.
- The goals, aims, strategic plans, and focus are clear and understood by everyone in the organization.

Use the above items as a checklist for evaluating how your company is doing.

It is ALWAYS less expensive to invest in those activities that lead to a GMP Lifestyle than having to take corrective actions in response to an FDA 483 Observation Report or an FDA Warning Letter.

It takes diligence and consistency to build a solid foundation where Quality and GMP compliance become part of the fabric of an organization.

And it takes diligence and consistency to maintain that culture once it's achieved.

David Markovitz is the Founder and President of GMP Training Systems, Inc., (www.GMPTrainingSystems.com) a top tier provider of GMP training products and services. David can be reached at David@gmptrainingsystems.com and at 714-289-1233.

¹ FDA website www.fda.gov

² FDA Commissioner Sets Out Vision on Enforcement to Support Public Health
www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm176119.htm

³ ORA FOIA Reading Room

<http://www.fda.gov/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/default.htm>

⁴ Personal observations of David Markovitz from working with hundreds of companies in the FDA regulated industry over the past three decades.