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Lessons Learned - Learning From Others' Mistakes

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As GMP trainers, we are always looking for "real world" training topics that will link GMP theory with practice. One great way to do this is to study other companies' compliance mistakes - in a training program. There are many sources of information for this type of program. The FDA website posts recall information, Warning Letters, and other regulatory actions taken against the industry. We can learn a lot from seeing where other companies had problems, comparing their situation with our own, and coming up with corrective and/or preventive actions to avoid making the same mistakes. So how do we do it?

1. Research online and find regulatory actions in a company similar to yours. (Note: It makes no sense to present problems at an aseptic facility if your site makes tablets. Try to get as close a match to dosage forms and processes as possible.)
2. Present some introductory information on the FDA's powers and types of regulatory actions. Then lead into the sample regulatory action you have selected for this program.
3. Pick 4-5 relevant examples of observations and review.
4. Have the attendees break into small groups; have each group take 1 observation and discuss the compliance status in your facility, and what you could do to strengthen compliance to avoid this type of observation. If the situation is not completely analogous, have the group brainstorm similar weak points and corresponding corrective actions.
5. Have each group share its findings and discuss.
6. End by discussing the importance of preventive action and studying lessons learned in order to improve GMP compliance.

October 2011 GMP Training and Education Association Biennial Training Conference in Florida presentation by Elaine Lehecka Pratt on *What Training Can Learn from FDA Consent Decrees* and a synopsis of the group exercise discussion from the conference will be posted on www.lpa-training.com after the conference.

Links to "Others' Mistakes"

For quick access to the mistakes mentioned in the previous article, see:

<http://www.fda.gov/Safety/Recalls/default.htm> for FDA recalls, market withdrawals and safety alerts

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm> for FDA Warning Letters

<http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm272028.htm> for 2011 FDA enforcement actions

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Innovative GMP and Regulatory Compliance Training for the Pharmaceutical Industry

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