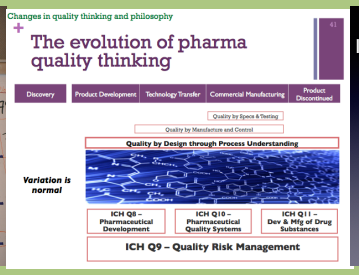
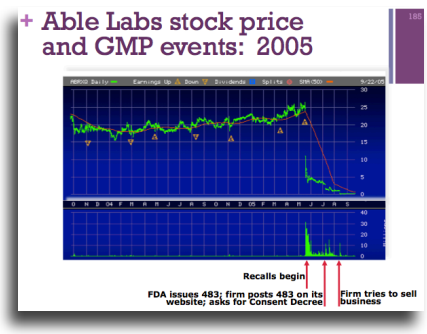
Management Responsibilities in a GMP Environment



An in-house course from *LearningPlus*

Requirements and expectations of senior management who are working in a pharma/biopharma organization



Description

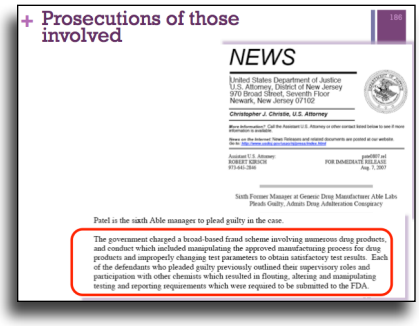
U.S. Supreme Court cases, laws, regulations, guidelines, and Warning Letters have shaped the expectations that regulatory agencies have of the senior management of a pharmaceutical firm.

This workshop examines the key requirements and expectations along with principles of good manufacturing practice (GMP). Participants discuss ways that they support GMP and quality performance along with how they could demonstrate their involvement with GMPs during a regulatory inspection.

Examples of recent FDA Warning Letters relating to management and the functioning of the quality unit are discussed. Through case studies, participants see the relationship between business goals, stock prices, and noncompliance.

Audience

Senior and executive leadership team members.



Course goal

Understand the basis for the regulation of the pharma/biopharma industry and the specific requirements related to good manufacturing practice and quality systems.

Objectives

- Identify the requirements and expectations that drug regulatory agencies have of senior management.
- Discuss the general progression of noncompliance from inspections to regulatory action.
- Identify seven essentials of all GMP systems.
- Discuss the use of quality metrics by regulators and industry.
- Identify what can happen in the event of noncompliance with GMPs.
- Describe the role of GMP compliance in a virtual organization that utilizes third parties.

Length

Three hours.

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