



# Pharmaceutical Compliance and Enforcement Answer Book 2016

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## Pharmaceutical Compliance and Enforcement Answer Book 2016

PLI's *Pharmaceutical Compliance and Enforcement Answer Book 2016* provides a comprehensive overview of the regulatory issues faced by the different participants in the pharmaceutical industry.

In an easy Q&A format, *Pharmaceutical Compliance and Enforcement Answer Book 2016* describes:

- The FDA's authority and potential actions to regulate prescription drugs and biologics both before and after approval by the agency
- A facility's rights and compliance obligations during an inspection by the agency
- How to best evaluate a company's potential of being in violation and what to do to mitigate those risks
- What advertising and promotion of prescription drugs is permitted
- How product liability issues overlap with FDA enforcement initiatives
- When criminal prosecution is used as part of the regulatory enforcement effort

Filled with practical suggestions, *Pharmaceutical Compliance and Enforcement Answer Book 2016* provides the attorney and his or her clients with a roadmap to effective compliance with FDA pharmaceutical regulations.

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