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# FDA Establishment Inspections: Pharmaceutical, Biotechnology, Medical Device and Food Manufacturing Concise Reference

*Mindy J. Allport-Settle*

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## FDA Establishment Inspections

Pharmaceutical, Biotechnology, Medical Device  
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Mindy J. Allport-Settle

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By JinRNc This reference tool provides you everything you need to know about what the FDA does during their inspections. This can help your company prepare and focus your preparatory efforts based on what procedures the agency follows. This should be a must-have reference in any company.

Establishment Inspections, Chapter 5 of the FDA's Investigations Operations Manual, details every step FDA inspectors are required to follow when conducting a facility inspection. This text is a comprehensive reference for regulatory inspections and is useful as an introduction to the practical components of the FDA-regulated industries or as a refresher. While the specific regulations and requirements may differ widely between pharmaceutical, biotechnology, medical device, and food manufacturers, the inspection processes and procedures do not.

About the Author Mindy Allport-Settle has served as a key executive, board member, and consultant for some of the best companies in the pharmaceutical, medical device, and biotechnology industry. She has provided guidance in regulatory compliance, corporate structuring, restructuring and turnarounds, new drug submissions, research and development, product commercialization strategies, operational, project and contract management, and new business development. Her experience and dedication have resulted in international recognition as the developer of the only FDA-recognized and benchmarked quality systems training and development business methodology. Her education includes a Bachelor's degree from the University of North Carolina, an MBA in Global Management from the University of Phoenix, and completion of the corporate governance course series in audit committees, compensation committees, and board effectiveness at Harvard Business School.