



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

Mindy J. Allport-Settle

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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.

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