Violations Of 21 CFR Part 820 Quality System Regulation, Subparts D-F: Document Controls, Purchasing Controls, Identification and Traceability: ... (FDA Warning Letters Analysis) (Volume 10)

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Inspection teams often know that a deficiency at one company will often be found at others, so they tend to look for what teams have found in previous inspections. A numerical analysis of past inspections results in the discovery of inspection trends for future inspections. This analysis contains a collection of violations listed in the Warning Letters (WLs) issued by U.S. Food and Drug Administration (FDA) that are available to the public on FDA website, www.fda.gov, as of May 23, 2015. Specifically, the violations included in this analysis are extracted from Warning Letters issued since January 2005. The violations collected here are specifically for failures to meet the requirements described in U.S. Code of Federal Regulations (CFR) Title 21 Food and Drugs, Part 820 Quality System Regulation Subparts D-F, Document Controls, Purchasing Controls, Identification and Traceability. As of May 23, 2015, there were 513 warning letters issued describing violations of Code of Federal Regulations Title 21 - Food and Drugs Part 820 Quality System Regulation Subparts D-F, Document Controls, Purchasing Controls, Identification and Traceability. Within these warning letters, 706 violations are listed in this book. The analysis also includes summary of FDA Inspectional Observation issued on Form 483.

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