CriticalPoint
a trchealthcare brand

503B Curriculum

5 courses with 7 hours of CE

CriticalPoint curriculum for 503B is designed to provide a foundation for 503B practice. It is offered to ensure users acquire a comprehensive understanding of how and why 503B practice evolved. It also summarizes each of the FDA draft and final guidances so learners know where to seek guidance for 503B practice.

History Leading Up to 503B (1 hour law CE)
JA4008164-0000-24-3034-H03-P
JA4008164-0000-24-3034-H03-T

- Correlate the history of compounding mishaps with the evolution of compounding standards of practice and sterile compounding regulations.
- Discuss the current compounding regulations, including continuing ambiguities and controversies.
- Identify the keys to success of a 503B practice.
- Explain the difference between 503A and 503B entities.

What Are CGMPs? (21 CFR Part 211) (2 hours law CE)
JA4008164-0000-24-3032-H03-P
JA4008164-0000-24-3032-H03-T

- Explain the history, evolution, and significance of FDA 21 CFR 211 (known as the Current Good Manufacturing Practices, the CGMPs).
- Articulate the differences in how CGMPs are applied to 503A and 503B entities.
- Identify the keys to success of a 503B practice.

Review of FDA 503B Draft and Final Guidance (2 hours law CE)
JA4008164-0000-24-3033-H03-P
JA4008164-0000-24-3033-H03-T

- Discuss the FDA 503B Draft Interim and Final Guidance documents.
- Differentiate the elements of 21 CFR 211 that are applied to a 503B as compared to traditional pharmaceutical manufacturers.
- Describe what would be expected of a 503B outsourcer during an FDA inspection.

Insanitary Conditions (1 hour law CE)
JA4008164-0000-24-3031-H03-P
JA4008164-0000-24-3031-H03-T

- Identify the nuances between 503A and 503B expectations.
- List examples of insanitary conditions as defined by the FDA.
- Discuss possible remediation actions for insanitary conditions common in 503B outsourcing facilities.

Understanding FDA Forms and Other Relevant Documents (1 hour law CE)
JA4008164-0000-24-3035-H03-P
JA4008164-0000-24-3035-H03-T

- List the forms used by the FDA and the activities typically associated with those forms.
- Define the FDA inspectional classifications and interpret the information found on the Inspection Classification Database.
- Identify FDA Form 483 observations that are indicative of significant operational deficiencies.

ACPE credit is valid through December 31, 2026

Credit for Pharmacists and Pharmacy Technicians

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