

CriticalPoint's 503B eLearning Curriculum

CriticalPoint eLearning 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 to 503B (1 hour law CE)

JA0006454-0000-21-3344-H03-P/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)

JA0006454-0000-21-3345-H03-P/T

- Explain the history, evolution, and significance of FDA 21 CFR 211 (known as 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)

JA0006454-0000-21-3346-H03-P/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 big pharma.
- Describe what would be expected of a 503B outsourcer during an FDA inspection.

ACPE-Approved Continuing Education is valid from April 2021 through July 2022

Credit for Pharmacists and Pharmacy Technicians



In support of improving patient care, Therapeutic Research Center is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Statement of Participation/Course Completion

Credit will be awarded to participants who take the course, successfully complete the quiz with at least an 80%, submit a course evaluation, and have provided an accurate NABP e-Profile ID and DOB. Participants who have successfully completed this course AND have provided accurate NABP e-Profile information, including month and day of birth, will have their CE credits submitted to CPE Monitor.



503B eLearning Curriculum

It is the participant's responsibility to verify credit is accurately posted to CPE Monitor. Participants who have questions about their credits or do not see their credits on CPE Monitor 20 days after their participation should contact CriticalPoint. Requests received after day 30 may not receive credit. Official statements of credit are only available from CPE Monitor.

CriticalPoint/TRC Healthcare Faculty, Editors, & Staff

Sarah Andresen

Director of Marketing & Communications

Tammie Armeni, RPh, PharmD

Editor, Senior Director of Continuing Education & Content Management

Trish Cipoletti

Quality Control Manager

Melanie Dorey, RPhT, QP503A

Compounding Learning and Product Specialist

Eric Kastango, MBA, BPharm, FASHP

President, Kastango Consulting Group

Patricia Kienle, RPh, MPA, BCSCP, FASHP

Director of Accreditation & Medication Safety for Cardinal Health

Mary Nazzal, PharmD, BCSCP

Associate Director of Field Operation, Kastango Consulting Group

Abby Roth, CMQ/CO, QP503A qualified

Senior Director of Business Operations

Adam West, RCCP-SCF, NSF-49 accreditation

Environmental Monitoring and Training Specialist

Colene West

Continuing Education Content & Regulatory Affairs Supervisor

Disclosures

The faculty, reviewers, and editors of this activity and its publisher Therapeutic Research Center (TRC) have no relevant financial interests related to the products or services covered by this activity with the exception of Ms. Kienle, who is employed by Cardinal Health. All relevant financial relationships (when present) have been mitigated. TRC focuses on delivering completely objective, unbiased drug information and advice for the benefit of subscribers.

Users of this activity are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical or legal judgments. Information and internet links in this activity are current as of the date of publication.

Software/Hardware Requirements

This activity can be viewed on any device with an internet connection using one of the following browsers:

- Google Chrome, most-recent stable version: Google Chrome applies updates automatically. TRC makes every effort to test and support the most-recent version. No configuration recommendations.
- Mozilla Firefox, most-recent stable version: TRC makes every effort to test and support the most recent version. No configuration recommendations.
- Microsoft Internet Explorer version 11: Apply all Microsoft updates. Outdated versions of Internet Explorer may result in issues with the connection and eLearning.
- Apple Safari versions 5.x, 6.x and 7.x on Mac OS X: No configuration recommendations.



503B eLearning Curriculum

NOTE: For all browsers, you must have JavaScript and cookies enabled. To view PDFs, you will need a PDF-capable browser or standalone PDF viewer.

Your Privacy

In order to provide you with continuing education, Therapeutic Research obtains information such as your name, address, email address, phone number, payment information, etc. We treat this information as confidential and use it to provide you with the best service possible. Therapeutic Research has NEVER released any of this information to any outside organization for such organization's own commercial or marketing use and has a policy against doing so. We do not engage in renting out, selling, or trading names of subscribers or any information about any subscriber.

To provide you with valuable services, we will occasionally employ third parties to meet your needs. In such cases, only the information needed to meet your need will be shared with the outside organization. Therapeutic Research only employs third parties that have similarly protective privacy policies. We do not allow any other organization to send you unsolicited emails about any products or services. We might send you information about your subscription, your continuing education credits, or our own drug information services. We do not gather data or track your web usage of any websites other than our own. For further information see our Privacy Policy, or submit a request at <http://info.therapeuticresearch.com/privacyofficer>.