



3V Introduction to the Science and Biosafety of Cell and Gene Therapy Clinical Trials

September 26 and October 3, 2025 | 11:00 am – 3:00 pm CDT
Virtual Professional Development Course



Instructors:

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Overview

The use of recombinant and synthetic nucleic acid molecules in clinical trials is growing at an explosive pace. This course is intended to introduce biosafety professionals to the science and biosafety of gene-based investigational products in clinical trials including gene-based vaccines, gene modified cellular products, gene therapy and gene editing. This course will provide an overview of molecular biology, virology and viral vectors. Participants will discuss risk assessments and best practices for dealing with risks associated with diverse types of biological hazards.

What You'll Learn

- **Scientific Foundations of Gene-Based Clinical Trials** – understanding **molecular biology, virology, and viral vectors** relevant to gene-based investigational products
- **Biosafety Considerations for Emerging Biotechnologies** – learn how to identify and manage risks related to **recombinant and synthetic nucleic acid molecules**
- **Risk Assessment and Best Practices** – emphasis on conducting **biosafety risk assessments** and applying **best practices** for handling diverse biological hazards in clinical trial settings

Objectives:

- Restate the basic molecular biology and microbiological principles behind gene-based vaccines, gene modified cellular therapies and gene therapies
- Summarize how to conduct a risk assessment for gene-based vaccines, gene modified cellular therapies and gene therapies
- Identify viral vectorology (properties, uses, and risks associated with commonly utilized viral vectors)

Suggested Background: None

Who Should Attend: All Safety Professionals, Laboratory Workers, New Biosafety Professionals, Research Administrators, Clinical Professionals

Course Logistics: Course is two 4-hour sessions. Attendees will need to log on 15 minutes prior to the start time. There will be a 15-minute break each session during the course. To receive credit and a certificate, attendees must attend the session and complete or access all course modules. The course materials are for **registered participants only**.

Course Fees: ***ABSA Member: \$500 Non-member: \$670** * To receive the ABSA member rate, participants must be current ABSA members during the training year. Fees include course handouts, access to the ABSA International training site, and 8 hours of expert-led interactive instruction.

Credits: This course has been approved for **1.0 CM points** toward RBP/CBSP recertification. *ABSA International is approved as a provider of continuing education programs in clinical laboratory sciences by the ASCLS P.A.C.E.® Program. This course is approved for **7.5 P.A.C.E.® contact hours**. Course access links are unique and for individual use only. **Sharing is prohibited**. Duplicate logins or unregistered attendees will be removed from the webinar without a refund.

Questions: Contact: Kari DeServi, MEd, Director of Education, ABSA Office, 866.425.1385 (toll free) Email: education@absa.org

Registration Form

3V Introduction to the Science and Biosafety of Cell and Gene Therapy Clinical Trials

*Name (First, Middle Initial, Last): _____

*Organization: _____

*Address: _____

*City, State: Country: Zip/Postal Code: _____

*Telephone: _____

*E-mail: _____

(Please provide your preferred email address, which you frequently access)

***Required information**

Payment:

_____ ABSA Members \$500.00 USD

_____ Nonmembers \$670.00 USD

To receive the ABSA member rate, participants must be current ABSA members during the training year.

_____ Visa _____ MasterCard _____ American Express

Card Number: _____

Expiration Date: _____ CVV: _____

Name on card: _____

To receive the ABSA member rate, participants must be current ABSA members during the training year. Confirmed, paid participants will receive course details a few days prior. Substitutions allowed with notice by 8/29/2025. Cancellations incur a 15% fee. Between 8/29/2025 and 9/5/2025, 50% refunds apply. No refunds after 9/5/2025.

Each participant will receive a unique, non-transferable link to access the course. These links are intended for individual use only. If multiple entries under the same name appear on the Zoom attendee list, or if unregistered names are detected, all such entries will be removed without refund. Sharing or unauthorized use of webinar links is strictly prohibited.

Register by phone:

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or On-line:

<http://www.absa.org/>