Call for Volume 32 (2027) Special Issue Papers:

Safety Oversight for Novel Immunotherapies from Benchtop to Bedside

Deadline for Manuscript Submission: November 1, 2026

Guest Editors:

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Notable advances have been made in treatment modalities in recent years resulting in significant growth in promising treatments for patients. Two treatments that are being successfully used for cancer include antibody drug conjugates and (ADC) and chimeric antigen receptor (CAR) - T cells (CAR-T). ADCs consist of a cytotoxic drug that is chemically linked to a monoclonal antibody (mAb) which targets and kills cancer cells. CAR-T therapy uses genetically modified T cells either from the patient or a donor which are expanded in a laboratory setting and infused into the patient. A number of other promising treatments are also under development and include modalities such as radio-pharmaceuticals, bi-specific antibodies, and CRISPR - gene editing to name just a few. This special issue will focus on examining the risks posed when conducting work with these therapeutic agents and proposed mitigation efforts. As work conducted in different settings may involve different risks, manuscripts may be focused specifically on one of the following settings:

- research and development
- pilot scale
- GMP manufacturing
- pharmacy, and
- clinic

Manuscript contributions from each biomedical setting are invited on a variety of topics, including, but not limited to:

- assessing and mitigating biosafety and toxicology risks with new biomodalities and relevant standards
- role of industrial hygiene in environmental monitoring during scale-up processes
- novel elements considered in an IBC review
- safety in pre-clinical animal model testing programs and Animal Care and Use Committee review
- risk assessment and mitigation for working with new biomodalities
- addressing replication competent virus and/or transduction of off-target cells in the manufacturing process
- integration of biosafety in a GMP setting

- controls for large-scale viral vector development and manufacturing
- working with central nervous system materials and mitigating risks related to prion-like proteins
- conducting risk assessments for working on benchtop vs BSC
- New Approach Methodologies (NAMs) that offer the tools to assess safety, efficacy, and pharmacology of drugs and therapeutics. Some examples may include: in vitro humanbased systems, organoids, "in silico," artificial intelligence use or computer-based modeling, as well as other innovative platforms that can collectively evaluate immunogenicity.
- response to release of biomodalities cells from primary containment in a manufacturing setting
- occupational health and medical surveillance programs for individuals working with biomodalities
- communicating and countering biomodalities biosafety risks in the pharmacy or clinic
- biosafety considerations for biomodalities in preclinical studies

Submissions will undergo a double-blinded, expert peer-review process in the Special Issue on Safety Oversight for Novel Immunotherapies from Benchtop to Bedside. The deadline for submissions to the special issue is November 1, 2026. Accepted articles may be published online ahead of the print release.

Please refer to the <u>Instructions for Authors</u> before submitting your manuscript for consideration. Please select "Special Issue on Safety Oversight for Novel Immunotherapies from Benchtop to Bedside" as the type when submitting your manuscript.

If you have any questions or pre-submission queries, please contact Barbara Johnson at barbara johnson@verizon.net.

About the Journal: *Applied Biosafety (APB)* is a peer-reviewed, scientific journal committed to promoting global biosafety awareness and best practices to prevent occupational exposures and adverse environmental impacts related to biohazardous releases. APB provides a forum for exchanging sound biosafety and biosecurity initiatives by publishing original articles, review articles, letters to the editors, commentaries, and brief reviews. APB informs scientists, safety professionals, policymakers, engineers, architects, and governmental organizations. The journal is committed to publishing on topics significant in well-resourced countries as well as information relevant to underserved regions, engaging, and cultivating the development of biosafety professionals globally. *Applied Biosafety* is under the editorial leadership of Coeditors-in-Chief Karen B. Byers, MS, RBP(ABSA), CBSP(ABSA), Dana-Farber Cancer Institute, and Barbara Johnson, PhD, RBP(ABSA), Biosafety Biosecurity International, and Associate Editors David Gillum, PhD, RBP(ABSA), and Scott Patlovich, DrPH, CBSP(ABSA), CIH, CSP, CHMM, CPH.

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