

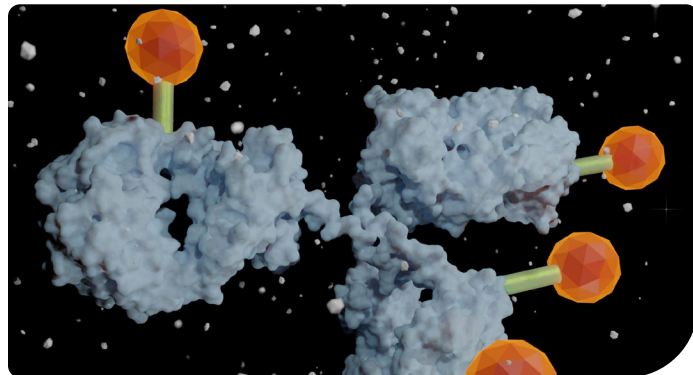


**Trinity Consultants** is a leading global environmental consulting firm that brings 50 years of experience providing services and solutions in the EHS Regulatory Compliance, Built Environment, Life Sciences, and Water & Ecology markets. Trinity has the technical expertise and acute industry knowledge to provide optimal solutions to highly complex pharmaceutical development, process, safety, and facility design challenges.

SafeBridge, a Trinity Consultants team, has been the leader in potent compound safety initiatives for over 25 years. SafeBridge is widely recognized for its expertise in the evaluation and safe handling of novel and toxic materials. In addition, SafeBridge has broad experience in toxicology, industrial hygiene, and industrial safety. Our team includes toxicologists who determine and document safe workplace exposure levels for new chemicals, industrial (occupational) hygienists who assess worker exposure and recommend controls, safety professionals who develop regulatory compliance programs and on-site inspection services, and chemists who are knowledgeable in analytical techniques capable of detecting novel chemical materials at extremely low levels.

Our services to the industry in support of the safe research, development, and manufacture of ADCs include the following:

- Develop robust and scientifically supportable Occupational Exposure Limits (OELs), Acceptable Surface Limits (ASLs), and Permitted Daily Exposure (PDE) values to support worker safety and product protection (to establish cleaning limits)
- Develop cutting-edge industrial hygiene air and surface sampling and analytical methods capable of analyzing picogram quantities of conjugated and unconjugated materials
- Conduct containment performance testing using surrogates or the ADCs and other potent drugs in research, development, and production environments
- Assist in conceptual design of facilities, facilitate the design of containment for processes, and review existing containment and controls for ADCs and other potent drugs
- Develop decontamination, cleaning, and cleaning verification protocols for ADCs and other potent drugs
- Conduct toxicological assessment of leachables and extractables from the process or final dosage form



SafeBridge can also provide Safe Handling Guidelines for ADCs and other potent drugs to include:

- Toxicology Assessment (Occupational Health Category/Band, OEL, ASL, and PDE)
- Employee Selection (Reproductive Hazard Considerations)
- Employee Training
- Containment and Controls
  - Personal Protective Equipment
- Work Practices, Process Designs, and Engineering Containment and Controls
- Powder and solution handling
- Decontamination, Clean Up, and Waste Disposal
- Spill Response (Emergency)
- Industrial Hygiene Air and Surface Monitoring
- Medical Surveillance
- Safety Data Sheet (SDS) for mAb, warhead/drug, linker, drug linker, and ADC

#### CONTACT OUR TEAM!

For more information about how we can help your organization, please contact us.

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