

 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, industrial hygiene laboratory, develops analytical methods to help our clients meet their workplace air monitoring and surface sampling requirements. We are accredited by the American Industrial Hygiene Association (AIHA) for the analysis of active pharmaceutical ingredients. AIHA-accreditation means the following:

- Operating a quality system that meets the requirements of the International Organization for Standardization (ISO) Standard ISO/IEC 17025. This standard incorporates the principles of ISO 9001 that are relevant to the scope of testing services addressed by the laboratory.
- Operating a laboratory in which sampling and testing procedures are performed with adequate controls by well-qualified personnel using appropriate equipment, Standard Operating Procedures and validated methods.
- Maintaining an ongoing Proficiency Testing (PT) program.
- Participating in an independent third-party auditing program to ensure compliance with requirements.

Analytical Methods Employed – The SafeBridge® Advantage

The occupational exposure limits (OELs) and acceptable surface limits (ASLs) specified by the manufacturer are commonly in the range of ng/m³ or below 1 µg/cm² respectively and, therefore, require highly sensitive analytical methodologies. SafeBridge® employs HPLC, LC/MS/MS and ELISA analytical technologies. Our methods achieve high specificity, ultra sensitivity and high recovery rate through the proper choice of filter media and extracting procedures as well as the optimization of air sampling parameters. The methods are validated with respect to analytical detection limits, precision and accuracy. Data on the stability of compounds relative to airflow volume and storage conditions are contained in these methods.

The SafeBridge® advantage is that we employ the most sensitive techniques in the industry to detect potent drugs at very low concentrations in the workplace – to quantitation limits as low as 5 picograms/filter.

Our Capabilities

SafeBridge® Consultants Analytical Laboratory:

- Routinely develops methods and processes samples that contain biologically active pharmaceuticals such as steroids hormones, peptide hormones, antibody drug conjugates (ADCs) and cytotoxic compounds.
- Performs surrogate monitoring with our field industrial hygiene staff and analyzes samples for verification of containment systems. We typically use naproxen sodium as a surrogate with a limit of detection as low as 5 pg of material on a filter. Lactose, with a limit of detection of 500 pg per filter, may also be used as a surrogate when a non-API surrogate is required.
- Conducts assessments of cleaning methodologies that are employed for both occupational settings and for QA cleaning validation purposes.



CONTACT OUR TEAM!

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

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