



**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.

Containment and control performance assessments (CPA) are essential to understand the effectiveness of containment technology to control worker exposures to active pharmaceutical ingredients (APIs). SafeBridge, part of Trinity Consultants, employs surrogate and API air and surface monitoring techniques to verify the performance of isolators, ventilated enclosures, split butterfly valves, flexible enclosures, and other containment/control devices.

Surrogate testing involves using a low hazard surrogate material prior to using the device with a high hazard one. Surrogates typically used include naproxen sodium and acetaminophen (APIs), or lactose and mannitol (sugars). The expected containment/control performance target (CPT) should be verified during a factory acceptance test (FAT), performed where it was fabricated so any identified issues can be corrected. However, a CPA can also be performed after it is installed in a production facility during a site acceptance test (SAT). The actual API intended to be manipulated in the device can also be used, however, an analytical method for detecting the API may not have been developed and the actual API may be hazardous. Surface contamination may also be measured to determine the presence of compound carried out of the device.

SafeBridge, a Trinity Consultants team, has developed an analytical method capable of detecting naproxen sodium at levels as low as 5 pg/filter. While naproxen sodium is also a safe, non-potent, water-soluble material, it has a lower limit of quantification and a higher "dustiness quotient" presenting a more aggressive challenge to control than lactose or mannitol. It should be noted that since naproxen sodium is an API, validation of cleaning may be required after the CPA is performed.



SafeBridge has pioneered the use and detection of surrogate materials for CPAs and can perform all aspects of FAT, SAT and occupational exposure assessment studies. We can help you to:

- Design a CPA through the development of detailed sampling plan
- Conduct the study in the field with our extensive staff of experienced industrial hygienists
- Analyze the samples in our own AIHA-LAP accredited pharmaceutical industrial hygiene laboratory
- Provide reports of the study findings including recommendations for improvements, as appropriate

#### CONTACT OUR TEAM!

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

**Trinity Consultants | SafeBridge**

P 650.961.4820 / [info@safefridge.com](mailto:info@safefridge.com)

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