

FROM SAFETY TO BUSINESS GROWTH:
THE STRATEGIC VALUE OF SAFEBRIDGE CERTIFICATION





The rise of personalized medicine and advanced therapies has transformed the pharmaceutical industry. These treatments, particularly those containing high-potency active pharmaceutical ingredients (HPAPIs) such as oncology drugs, targeted biologics, and antibody-drug conjugates, are not only highly effective but also highly potent, requiring far greater levels of containment and control than traditional small-molecule tablets or capsules.

THE OUTSOURCING SHIFT

As the science has advanced, so too has the business model. Big pharma increasingly turned to contract manufacturing organizations (CMOs) and contract development and manufacturing organizations (CDMOs) whose specialized capabilities could handle the complex production demands of these therapies. But outsourcing created a new challenge: How could drug innovators be sure that external manufacturing partners were managing these potent compounds with the same stringent safety standards they maintained internally?

That question became the catalyst for the development of SafeBridge Potent Compound Safety Certification. Already trusted by leading pharmaceutical companies for its expertise in industrial hygiene, toxicology, and potent compound safety, SafeBridge, part of Trinity Consultants, formalized its knowledge into a rigorous, repeatable program that examines every aspect of a manufacturing site before granting its stamp of approval. In a global market valued at \$239 billion in 2024 and projected to reach over \$465 billion by 2032, certification gives CMOs and CDMOs a way to prove they can consistently protect both people and products, giving them a measurable competitive edge and offering clients peace of mind that their compounds will be handled safely from start to finish.

FILLING THE SAFETY VACUUM

Unlike other areas of pharmaceutical manufacturing, there is no single, universally enforced standard for occupational safety and health when it comes to handling highly potent compounds. Each company is responsible for setting its own procedures, which means approaches can vary widely from one organization to the next. That's a serious concern when even trace exposure can cause serious long- and short-term health effects. It also creates a barrier for clients trying to compare facilities to quickly assess whether their compounds will be handled with the level of care they expect.

"This industry moves fast, and safety has to keep pace," said Charlyn Reihman Lis, Senior Technical Advisor at SafeBridge. "When you're dealing with highly potent compounds, there is no margin for error. Without a consistent standard, gaps can exist that no one sees until something goes wrong."

TURNING SAFETY INTO A SCIENCE

The SafeBridge Potent Compound Safety Certification was developed to create a benchmark for excellence in handling potent compounds. It's a thorough, science-based process that examines a company from the inside out. The evaluation covers both physical systems—such as containment equipment, ventilation, and facility design—and operational practices, including the procedures, training, and culture that keep safety front and center.

The process starts with a self-assessment, where the company answers in-depth questions about how it handles potent compounds. This step allows organizations to take a hard look at every part of their operation, and it often surfaces gaps they didn't realize existed.

Once that groundwork is laid, SafeBridge experts arrive for a comprehensive on-site evaluation. They walk the facility from end to end, inspecting containment equipment and verifying that systems are functioning as intended. They review critical documents and SOPs to ensure that they're not only thorough but also actively in use. They also bring toxicological expertise, ensuring that every compound has been properly evaluated, occupational exposure limits (OELs) set, and controls matched to the actual hazard level.

Just as importantly, they sit down with employees at all levels, asking questions, listening to how tasks are performed day to day, and gauging how deeply safety knowledge and awareness are embedded in the organization's culture. The most advanced containment equipment in the world can't keep people safe if it's not used properly, and the most dedicated staff can't protect themselves without the right infrastructure in place. SafeBridge Certification ensures that programs, controls, and communication are strong and working together.

"We're not just looking for compliance on paper," Reihman Lis said. "We want to see safety in action—how people use the equipment, how they respond to real-world challenges, and whether leadership has built a culture where safety isn't just a checklist, but a shared responsibility."

STANDING OUT IN A CROWDED FIELD

Competition in this quickly growing market is fierce, and SafeBridge Certification helps companies stand out. Many drug innovators now ask about certification during the CDMO selection process, and in some cases, it's even a non-negotiable requirement.

For companies that meet the standard, SafeBridge Certification isn't just a plaque on the wall. It's a signal to employees that their health matters. It's a signal to clients that they can trust this partner with their most sensitive, high-value projects. And it's a signal to the industry that the facility is committed to excellence, both in what it makes and in how it operates.

"A SafeBridge Certification communicates to employees that their company cares," Reihman Lis shared. "Many CMO and CDMO clients have reported that it has helped in multiple areas of their business, including employee retention, engagement, and satisfaction."

Certification also aligns closely with what regulators look for during inspections. While the safe handling of potent compounds is largely self-regulated, being audit-ready at any moment can prevent costly delays or shutdowns. The systems and practices that earn certification also reduce the likelihood of exposure incidents, environmental events, or contamination events.

RAISING THE BAR FOR THE WHOLE INDUSTRY

In an industry moving at the pace of innovation, where new compounds and new production demands are constantly emerging, the protection that comes with SafeBridge Certification is worth more now than ever before. Those that can show they have the expertise, infrastructure, and culture to handle these compounds safely will be the ones best positioned to grow.

Certified facilities set an example that others aim to follow, raising the overall standard for potent compound safety. For CMOs and CDMOs, that means being part of a community of leaders who see safety not as a cost, but as an investment in their people, their clients, and their future.

"SafeBridge Certification is a mark of excellence that's recognized across the industry as both a safety credential and a powerful business advantage," Reihman Lis said. "It doesn't just help our clients win business; it helps them keep it. Because in the end, clients remember the partners who protect their products and their people."

WHAT'S EVALUATED IN A SAFEBRIDGE CERTIFICATION ASSESSMENT?

- ▶ **Hazard evaluation:** Reviews whether there is a robust process for evaluating the hazards of all compounds handled in the facility, ensuring that appropriate exposure limits are set and that the right level of control is applied to protect workers and products.
- ▶ **Engineering controls:** Includes isolators, ventilation, and other containment systems designed to prevent airborne exposure and cross-contamination. Evaluators confirm that these systems meet performance standards and are used correctly in day-to-day operations.
- ▶ **Facility design:** Reviews the physical layout to ensure that high-risk areas are separated from clean zones, minimizing the chance of contamination or accidental exposure.
- ▶ **Occupational hygiene:** Assesses exposure monitoring programs, PPE usage, and control measures to ensure that worker protection matches the actual hazard level of the compounds handled.
- ▶ **Waste management:** Examines procedures for safely collecting, storing, and disposing of hazardous waste, ensuring compliance with environmental and safety regulations.
- ▶ **SOPs:** Evaluates whether written safety protocols are not only comprehensive but also actively followed and kept up to date.
- ▶ **Training and competency:** Looks at the frequency, quality, and effectiveness of training programs to ensure that staff at all levels understand safety risks and mitigation measures.
- ▶ **Leadership commitment:** Confirms that management systems and leadership behaviors actively reinforce a strong safety culture, from resource allocation to regular safety reviews.

