



Use Case:

Tailored DEA-Validated Vault Solutions for Pharmaceuticals

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Background

Convergent stands as a premier provider of DEA-validated vault and cage solutions, with demonstrated expertise in solutions for the pharmaceutical industry. For over forty years, Convergent CustomVault has been at the forefront of designing modular vault systems and wire cages that meet the rigorous standards of 21 CFR 1301.72 for the secure storage of Schedule I, II, III, IV, and V controlled substances. The company's comprehensive service range includes the design, engineering, installation, and servicing of modular vaults, addressing the secure storage needs for pharmaceutical manufacturers, pharmaceutical distributors, and healthcare facilities requiring DEA compliant physical security. Ultimately, Convergent CustomVault provides customized solutions and outstanding service end to end as evidenced in the following use case.

Objective

A major pharmaceutical company based in India, one of the few with annual sales reaching \$100 billion sought Convergent CustomVault's expertise when designing a sophisticated vault and cage solution for their new U.S. operations and distribution center. The facility, demanded a state-of-the-art security solution that adhered to stringent DEA regulations while accommodating both current operational needs and future growth. The engagement was rooted in a longstanding partnership with Convergent CustomVault that had expanded over the years via successful projects that included vault and cage solutions implemented in 2006, 2016, and 2018.



Challenges

Convergent CustomVault needed to deliver a vault and cage solution that met all customer requirements while navigating challenges that included:

1. **Regulatory Compliance:** First and foremost, the vault and cage needed to adhere to DEA regulations governing the storage of controlled substances. A compliant modular vault was required for Schedule I and II drugs, while the cage was intended to house Schedule III, IV, and V products. Compliance with 21 CFR 1301.72 is nothing short of essential to the success of the business and DEA validation is a most critical test.
2. **Pallet Capacity and Layout:** The vault was required to hold 100 pallets, while the cage needed to accommodate 252 pallets. The challenge was escalated by the need to integrate this capacity into a design that fits within the constraints of an existing building structure. The layout needed to accommodate obstructions, such as building columns, in order to facilitate efficient access.
3. **Material Handling Equipment:** The design of the vault and cage was needed to account for material handling equipment, specifically forklifts. Door openings with dimensions of 96” wide x 168” high were required to ensure the efficient operation of equipment within the space. Proper accommodation with this equipment is essential for smooth operations and material flow.
4. **Future Expansion:** Anticipating future growth was a key challenge. The design needed to incorporate provisions for potential expansion, such as “knockout” panels, which allow for seamless modifications without violating DEA compliance. This ensures that the facility can adapt to future needs without significant redesign or disruption.

Solutions

To address these challenges, Convergent CustomVault implemented a series of tailored solutions designed to meet the use case’s specific needs that included:

1. **Expert Design and Engineering:** Convergent’s in-house engineers developed a bespoke design for the vault and cage, considering the specific dimensions and pallet capacities required (vault: 26’6” inside; cage: 42’0” elevation). The design strategically avoided building column obstructions and optimized the available space while allowing more efficient paths for material handling.

2. **Advanced Technology Integration:** The vault and cage solutions incorporate innovative technologies to enhance security and support compliance. All components offered by Convergent CustomVault, including vault panels and doors, are UL listed, GSA approved, and DEA compliant. This integration of advanced technologies complements regulatory requirements and provides robust security.
3. **Material Handling Access:** To facilitate efficient material handling, the design incorporated door openings sized 96” wide x 168” high. This specification ensures that forklifts and other equipment could operate effectively within the vault and cage, supporting smooth and efficient operations.
4. **Returns Cage and Futureproofing:** A specialized returns cage was installed beneath an existing mezzanine to manage returns efficiently. Additionally, “knockout” panels were integrated into the design, allowing for future expansion while maintaining DEA compliance. This approach allowed that vault storage could be increased as needed without major modifications.

Results

The completed project successfully met all customer requirements. The design delivered the necessary pallet capacities, ensured efficient material handling, and accommodated future expansion. And importantly, the installation proceeded without issues, and the customer expressed a high level of satisfaction with the solution’s performance and scalability. Convergent CustomVault therefore proved its ability to deliver secure, scalable, and compliant solutions that address complex pharmaceutical needs.

Conclusion

Convergent CustomVault has a deep level of expertise in modular vault design, combined with its commitment to regulatory compliance and a reputation for customer satisfaction. This use case is witness to all of that. The company’s ability to customize solutions and integrate advanced technologies continues to not only meet but exceed expectations. Convergent CustomVault is dedicated to providing secure, scalable, and compliant solutions, reinforcing its reputation as a trusted partner in the pharmaceutical industry.

