

Strong Rooms for Controlled Drugs

A Guide for the Pharma Sector



GUNNEBO®

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Introduction to Controlled Drug Strong Rooms

Any company working with or handling controlled drugs (CDs) in the pharmaceutical industry, including manufacturers, packaging companies, distributors, wholesalers and regional depots, is most likely required to obtain a license which ensures they are following correct procedures so that drugs which may be subject to theft and abuse are kept safe and secure.

As an example, in the UK the licensing process is overseen by the Drugs & Firearms Licensing Unit (DFLU) of the UK Home Office ministerial department. The requirements of this type of regulation, which of course may vary somewhat from country to country, are normally met through the construction of a strong room which controls and protects access to these drugs, to keep them out of the wrong hands.

When building or expanding any strong room for the pharma sector, there are numerous factors that must be carefully considered – to make sure the solution you end up with fully meets both the legal requirements and your own business needs. This is the key to handling CDs in a smooth manner, to support the efficient and profitable operation of your company.

Based on our long experience at Gunnebo as a trusted supplier of strong rooms for controlled drugs, we have written this PDF guide to share our knowledge with people like you: security managers, operations managers, building contractors and procurement managers in the pharma sector. By putting all this information together, we feel it can be useful both to experienced professionals working with controlled drugs handling, as well as others who are new to this business.

Note

This guide was originally prepared for the UK pharmaceutical industry, so the examples given concern the UK. Before constructing a strong room in any other country, make sure to check the guidelines and requirements that may apply to safe storage and handling of controlled drugs for that country.

Why Pharma Companies Need to Secure CDs in a Strong Room

Government licensing laws

Simply put, you need a strong room because governments and authorities require it. In the UK, for example, the Drugs & Firearms Licensing Unit (DFLU) has the task of issuing guidelines, for existing or prospective new operations, that must be followed by any pharma business to obtain a license for storage of CD.

For bulk CD stock which is too large to be stored in a smaller safe, the DFLU recommendation is to follow the European standard EN 1143-1 to use a Grade VI 6-sided strong room built with a welded or bolted construction. In actual practice, a 5-sided room secured to a concrete floor is permitted, provided certain criteria are met.

Type of drugs secured, and companies involved in the supply chain

Any business handling bulk storage of buprenorphine, diethylpropion, phenazepam and temazepam must guarantee safe storage using a strong room. This applies to any company involved in any aspect of the supply chain which is handling these drugs.

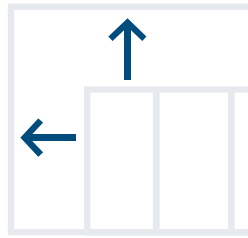
Typical customers can be the following:

- Drug manufacturers
- Drug packaging companies
- Drug distributors (third party warehouse storage and logistics)
- Drug wholesalers (third party resellers)
- Drug storage companies – regional depots supporting chemists, prisons, NHS, etc.

Basic overviews of the strong room and security standard

More specific official information from the UK Home Office ministerial department can be found in the [Home Office Security Guidance for Controlled Drugs](#). For other countries in which you may be operating, you can likely find similar guidelines regarding the legal requirements for safe handling of controlled drugs.

Important Factors to Consider When Planning a Strong Room



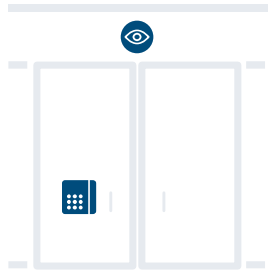
Location

The location of a strong room should always be at least 1m from any external walls of your warehouse. Considering logistics to keep your goods moving smoothly, without any bottlenecks, the location of your strong room relative to goods and lorries coming in and out must be carefully thought out. This is an important first step that must be done correctly, since it is quite difficult to rectify any positioning and logistical flow issues that might arise later.



Size and racking layout

The size of the strong room should be suitable for the chosen racking storage system. The forklift truck used inside must also be compatible with the height and layout of the racking, so that it can easily reach the highest levels. The positioning of the racking in relation to the turning circle of the forklift is also very important. The layout must be designed in a way that it works with any internal support structures that are needed, such as pillars for the roof.



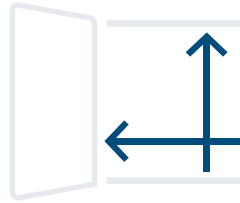
Door access and issuing

Door dimensions must be suitable for the forklift truck needed to transport pallets. In particular, special consideration should be given to accommodating both the height of the mast on your forklift and the pallet width used. Door access for issuing the materials must also be taken into account, to make sure that unauthorized people are not easily walking in and out. Depending on the situation this can be accomplished with a separate cage area and interlocks, although other measures are possible. Other security devices, such as CCTV, alarms and vibration sensors, are important to consider at an early stage. Also, the strong room door should be powered on a separate electrical circuit from the main alarm.



Type of forklift used

The type and size of forklift used and the matching of the forklift to the dimensions of the room, racking, doors and pillars is critical. This is covered in other sections above, but it is worth repeating it here.



Door openings

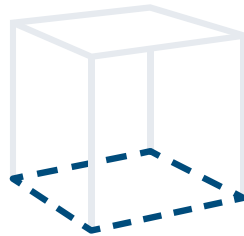
A standard door opening is 900mm wide but that is not wide enough for a euro-pallet. Therefore, a non-standard door with a minimum 1225mm clear passage is required and this needs to be specified from the beginning so price offers can be properly compared. On 5-sided rooms the threshold of the door is sunk into the concrete floor, to allow level access for pallet trucks. Emergency exits, to allow personnel to leave rapidly in case of emergency, also need to be assessed.



Building design regulations

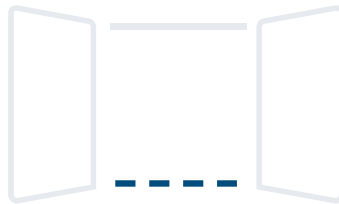
Concrete floors must be at least 150mm thick and the slab must of course be able to bear the weight of the strong room. In addition, consideration must be given to the positioning of penetrations or openings in the wall panels, so they can safely suit cable, alarm, sprinkler or any other service requirements.

What Design Changes Are Permitted for Pharma Strong Rooms



Five-sided room

According to the standards stated in the UK Home Office Security Guidance for Controlled Drugs, a strong room for pharmaceutical products should be constructed with six sides. In practice, however, pharma strong rooms are never built with 6 sides but are instead 5-sided rooms secured into a concrete slab, for which the UK Home Office ministerial department allow a concession. Specifically, strong room floor panels can be replaced with a minimum 150mm thick concrete floor, provided the wall panels are secured from the inside using 100x100x10 steel angles and M16 bolts with minimum shear capacity of 124kN.



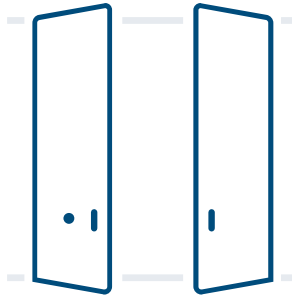
Door threshold sunk into floor

Another aspect to be considered when moving away from a six-sided strong room to a five-sided solution, is the easy passing of forklift trucks that are going in and out of the room. On a 5-sided room, you must sink the threshold of the door into the floor, to maintain level access for the forklift truck to pass over.



Sprinkler penetration holes in wall panels

Especially in strong rooms that are designed to store pharmaceutical products such as expensive controlled drugs, a sprinkler system makes good sense so that in the event of a fire, the damage can be kept to a minimum. To be able to install sprinkler piping to protect both people and the product being stored, there is a concession made to allow a penetration of 150mm, provided it fully plugs that hole and it is in the sidewall, set a minimum of 1m from the roof.



Doors suitable for forklift trucks with high masts

A further important aspect is to design the solution in a way that forklift trucks with high masts can access the strong room through a door that is wide and tall enough. The doors on Gunnebo's strong room installations can be single or double leaf, with Grade VI barrier material and provide up to 5m height x 2m wide clear passage for forklift trucks.

Key Factors to Consider When Looking for a Strong Room Supplier



A trusted supplier with a solid track record

Whenever you are making a capital investment, it is important to rely on an experienced supplier that has a reputation you can trust and who knows the regulations. They also should be able to support you with consulting and offer you the right solution whether it is large or small, that is best suited to your precise needs and growth plans.



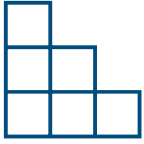
Provide necessary DFLU audit documentation

It is particularly important that any supplier of a strong room can reassure the customer that they can provide all documentation needed for audit purposes to satisfy both the DFLU or equivalent in other countries, as well as the local authorities. Examples of these documents include manufacturer's drawings, letter of conformity, design calculations, product certificates, etc.



Ability to offer all sizes of rooms

Regardless of whether you are highly experienced in the safe storage and handling of CDs, or completely new to this sector, when adding new strong room capacity it is advantageous if the supplier can provide whatever size room you need – ranging from as small as 12 square meters up to large sizes of perhaps 46m long, 16m wide and 15m tall.



Scale to support both new constructions, as well as expansions and rebuilds

It is also very advantageous, both in terms of future growth as well as best utilization of your assets, if the company chosen to provide your strong room also offers the capability to extend or relocate existing strong rooms in the future. If the project involves a capacity expansion at an existing strong room, it is very important that the project supplier can do the expansion work without interfering with the ongoing materials handling operations. The ability to offer both welded construction as well as bolted construction, which avoids the necessity for hot works such as welding on-site, is also an advantage.



Certified safe locks to provide linked access control and audit trails

For high-security access control and the possibility to provide an audit trail if needed, it is important that the strong room supplier can also deliver certified safe locks for its vault doors. Typical high-level access control includes a two-step authentication process, which requires the user to have both a swipe card and a PIN code.



After-support and service packages

To keep your strong room functioning smoothly and efficiently for the long term, the supplier should be able to provide maintenance and service packages. An annual preventative maintenance is recommended. And in case of any unexpected issues, it is important to know that help is not very far away since serious problems with, as an example, the vault door can have life or death impact for some patients.

We can help support your controlled drugs storage operations

Based on our long experience at Gunnebo as a trusted supplier of strong rooms for controlled drugs, we are happy to support you in any project for which you need a professional, well-reputed and reliable partner.

Talk to an expert

GunneboSafeStorage.com



Gunnebo Safe Storage

Protect your valuables and confidential data.
Get peace of mind at home, in transit and at work:

- High-Security Server Cabinets
- High-Security Locks
- Automated Safe Deposit Lockers
- Mechanical Safe Deposit Lockers
- Strong Rooms
- Vault Doors
- Safes

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