

Strong Rooms for Controlled Drugs

A Guide for the Pharma Sector



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Contents

Introduction to Controlled Drug Strong Rooms	3
Why Pharma Companies Need to Secure CDs in a Strong Room	4
Important Factors to Consider When Planning a Strong Room	5
What Design Changes Are Permitted for Pharma Strong Rooms	8
Key Factors to Consider When Looking for a Strong Room Supplier	10

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.

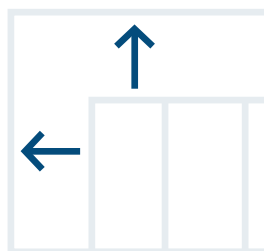
Type of drugs secured, and companies involved in the supply chain

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.

Important Factors to Consider When Planning a Strong Room



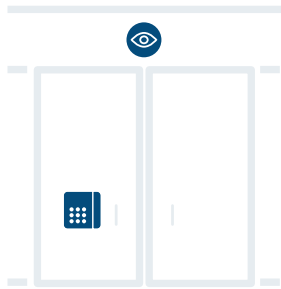
Location

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.



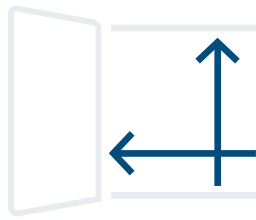
Door access and issuing

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

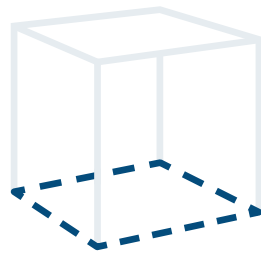
A standard door opening is 900mm wide but that is not wide enough for a euro-pallet. Therefore, a non-standard door with a minimum 1225mm clear passage is required and this needs to be specified from the beginning so price offers can be properly compared. On 5-sided rooms the threshold of the door is 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

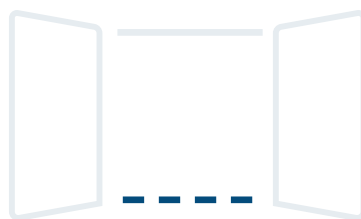
Concrete floors must be at least 150mm thick and the slab must of course be able to bear the weight of the strong room. In addition, consideration must be given to the positioning of penetrations or openings in the wall panels, so they can safely suit cable, alarm, sprinkler or any other service requirements.

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 sheer capacity of 124kN.



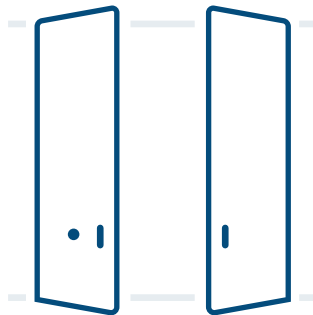
Door threshold sunk into floor

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.



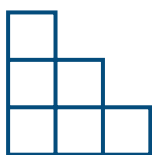
Provide necessary DFLU audit documentation

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.

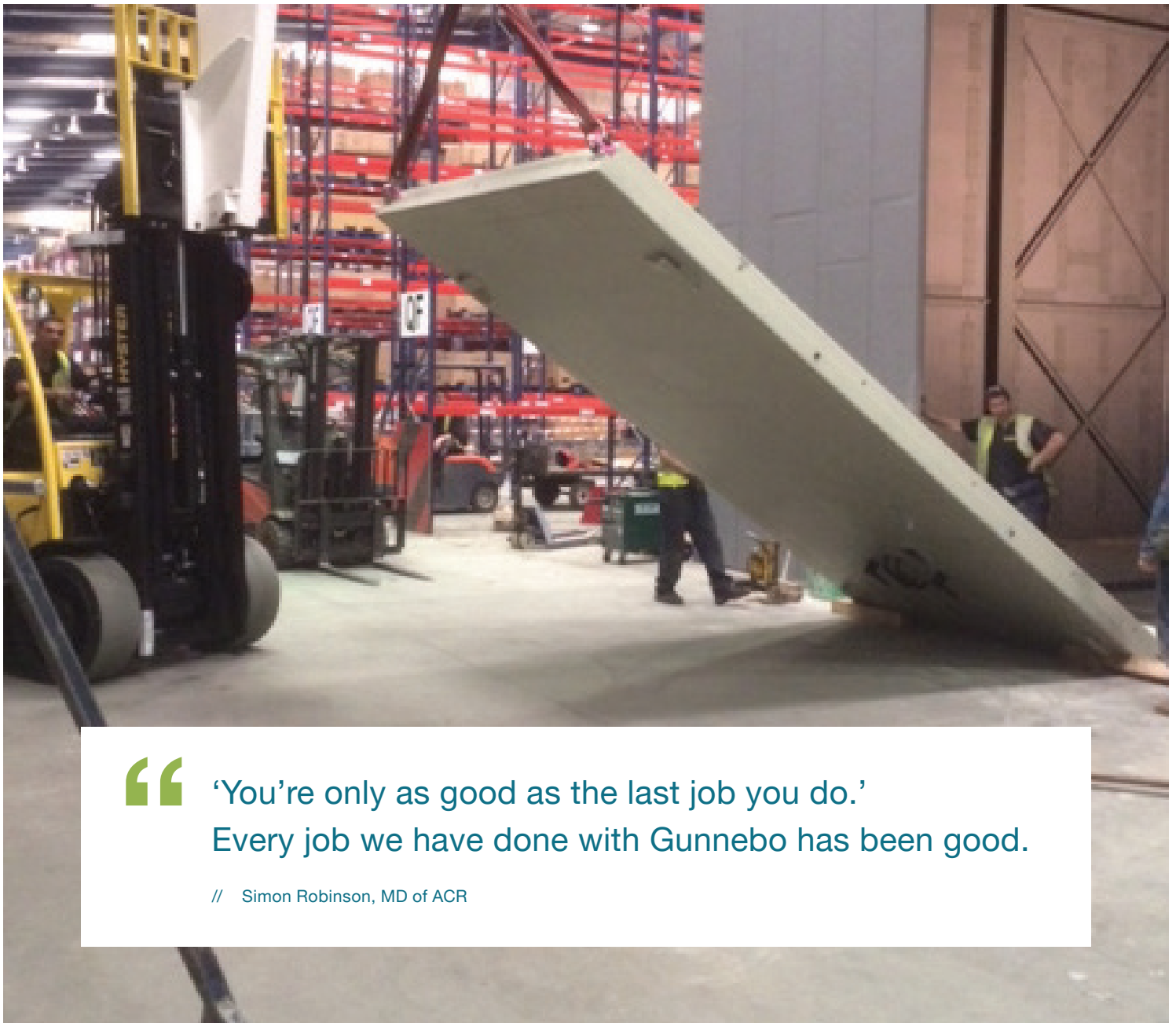


After-support and service packages

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.

Safe Storage of Controlled Drugs and Pharmaceuticals

ACR – A Successful Cooperation for Giant Strong Room Installations



‘You’re only as good as the last job you do.’
Every job we have done with Gunnebo has been good.

// Simon Robinson, MD of ACR

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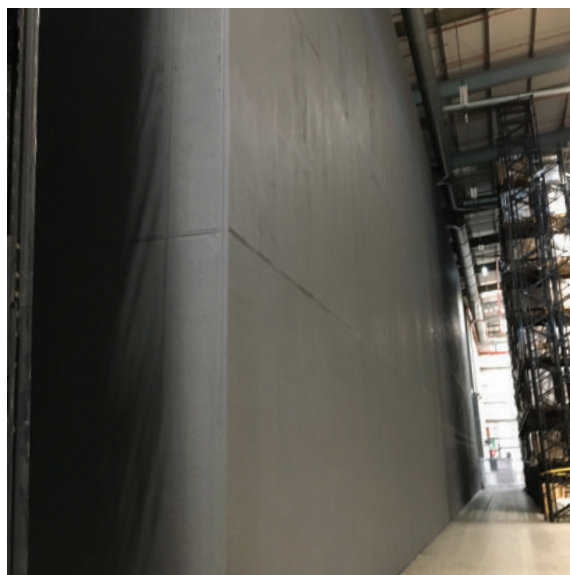
Background

ACR is a multi-disciplinary building practice in the UK that offers services from Building Design to Property Maintenance & Facilities Management. The skilled staff includes architects, civil engineers, structural engineers, project managers, health and safety consultants and facilities managers.

The company has existed for 50 years and Simon Robinson took

over from his father as managing director 20 years ago. Under Simon's leadership ACR has diversified from its initial focus on structural engineering to the broader services that it offers today. ACR works a lot with the pharmaceutical sector, which makes up around 60% of its business.

ACR has a long, positive history of working with Gunnebo on Controlled Drug (CD) strong rooms dating back 20 years. "We first started cooperation with Gunnebo around 2000 when they arrived on the market with custom-made CD strong rooms," explains Simon. "These solutions were approved by the Medicines & Healthcare Regulatory Agency (MHRA), and they offered big advantages over the previous, more complicated methods of building CD storage. Gunnebo offered a one-stop shop where they designed and certified the room, making projects much simpler."



Challenge

Over the years Gunnebo has worked closely with ACR and its pharmaceutical clients on numerous projects and supplied some of the largest strong rooms in the UK. Today pharmaceutical wholesalers often operate tall secure warehouses that have ceilings as high as 17 m. And, with floor space at a premium, they want their CD room to utilise the maximum height of the building.

For one UK pharmaceutical wholesaler, ACR was asked to design a 15 m tall CD strong room. Working with heights like that, says Simon, can be very challenging but it is also a great way to use the space efficiently. “The higher you go, the more cubic meters of storage space you get based on the same square meters of floor space. You’re paying for those cubic meters of air, so why not use them for storing your product?”

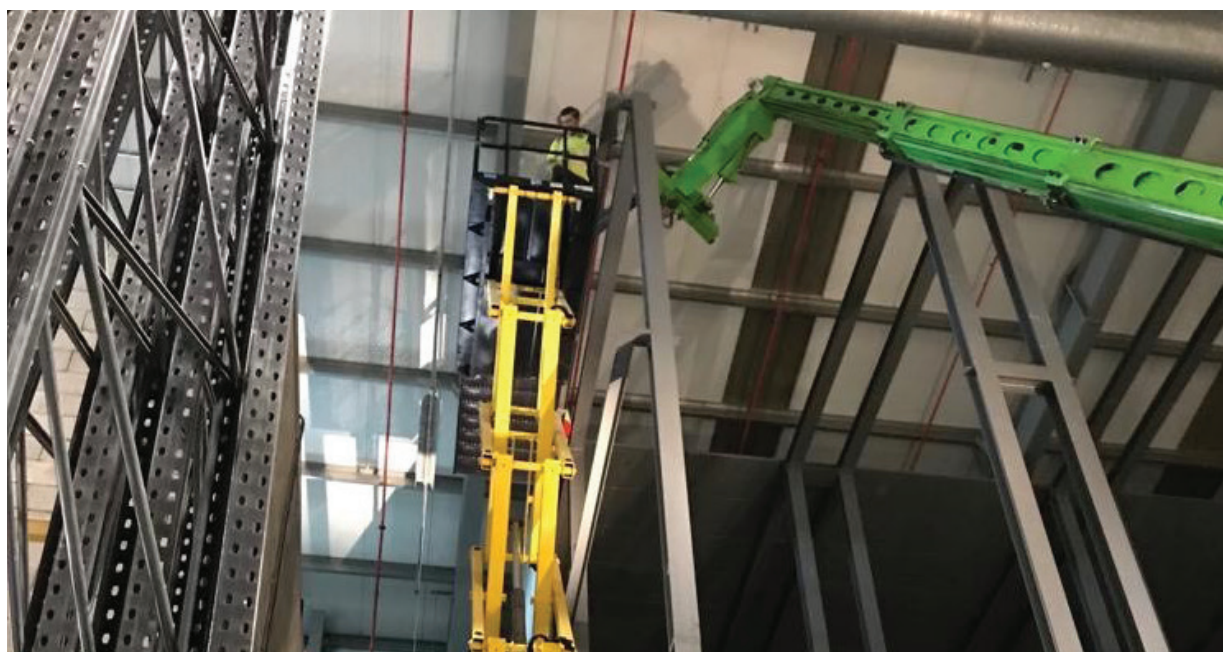
One of the challenges with such heights is that only certain types of forklift trucks can raise pallets that high. They have a very tall mast, so the strong room door needs to be up to 5 m high to give a clear opening for transfer of stock in and out.



For fire protection, sprinkler feed pipes need to be incorporated into the design without compromising theft protection. Another issue concerns warehouse floors which may not be suitable for the extra weight of the strong room and therefore require strengthening.

When it comes to building a CD strong room, it's not just a case of supplying some panels and a door; the total room needs to be safe, and security features need to be designed in from start. There are many challenges to be overcome, to make sure the Strong Room you get fully meets the Drugs & Firearms Licencing Unit (DFLU) guidance – to obtain a licence to operate the room.

Finally, it is rare that strong rooms are built inside an empty warehouse. Most often it is done in an existing building, and installation needs to be coordinated to ensure ongoing operations continue safely.



How Gunnebo solve challenges of large size strong rooms

By being involved from the beginning of a new feasibility study and visiting the location under consideration for a new strong room, we can better understand a customer's requirements. On this project, together with ACR, we presented our ideas and supported them with design drawings and structural calculations to satisfy building regulations. Gunnebo strong rooms are designed to minimise point load and make sure the internal rack layout and aisle width suit the forklift truck to be used. Furthermore, following DFLU guidance, we have provided ACR customers with solutions for strong room doors to suit high forklift masts and sprinkler pipes for fire suppression inside the strong room.



Because Gunnebo manufacture strong rooms, we can tailor the design to meet site restrictions and ensure installation of each strong room panel and door is co-ordinated, for the highest CD security.

Results

The strong room constructed by ACR and Gunnebo for this client was at the time the tallest in Europe, measuring 46 m long x 10 m wide x 15 m high. A total of 1137 panels from Gunnebo were supplied and two 1.8 m wide x 5 m high doors provide a clear opening for the forklifts. Combined weight, including the support structure, is 749 tonnes and the room provides secure storage capacity for 2050 pallets of controlled drugs.



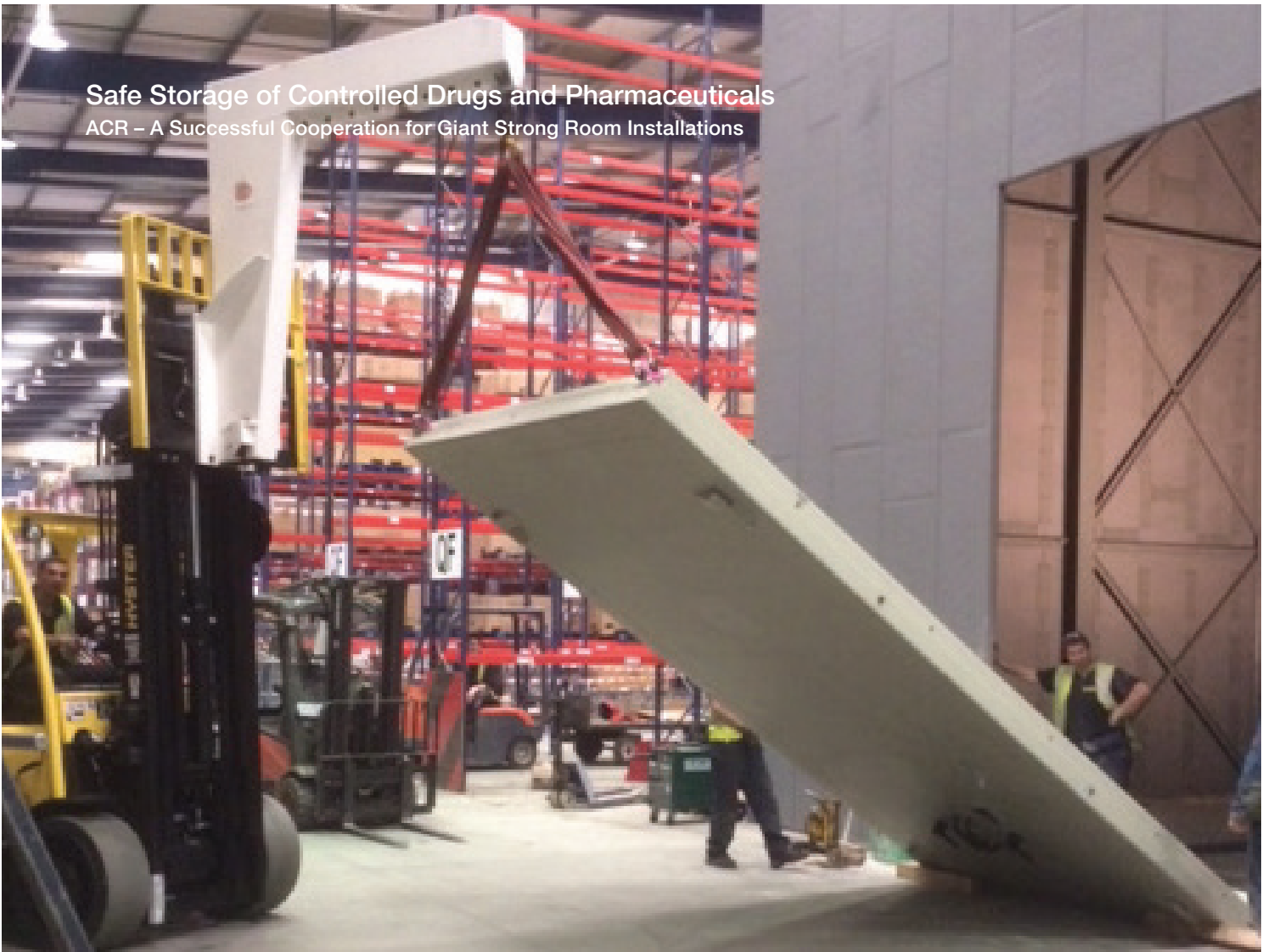
We work closely with Gunnebo and recommend them based on our long and successful cooperation. There is an old saying which states ‘You’re only as good as the last job you do.’ Every job we have done with Gunnebo has been good.

// Simon Robinson, MD of ACR

As far as the cooperation with Gunnebo, Simon Robinson at ACR is clearly satisfied. “We have been specifying Gunnebo’s custom-made Controlled Drug Strong Rooms for over 20 years. From Feasibility Stage to Handover, their professionalism and customer service is excellent. With Gunnebo you know you are in safe hands.”

Safe Storage of Controlled Drugs and Pharmaceuticals

ACR – A Successful Cooperation for Giant Strong Room Installations



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Gunnebo Safe Storage

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

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