Security Planning and Design for Twenty-First Century Pharmaceutical Facilities

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Security has always been a major concern for pharmaceutical facilities, and security concerns have become even more prominent in response to recent incidents of terrorism. This article describes several elements of the security planning and design process for pharmaceutical facilities. The article is based in part on a 1991 Pharmaceutical Engineering article, updated to reflect Twenty-First Century responses to Twenty-First Century threats.

In today’s world, violence against people and property continues unabated. Pharmaceutical facilities of all kinds are subject to threats from a multitude of sources, including animal rights groups, other activist groups opposed to specific areas of research, drug addicts, common criminals, and possibly even terrorist organizations. These threats may include life threatening acts of aggression and theft or destruction of property. Some threats, such as the removal or release of disease causing agents, could have disastrous effects. The need for security planning is clear.

Pharmaceutical facility designers are concerned with providing functional and aesthetically pleasing environments. Successful facilities help to attract the best and brightest employees, and then support their efficient and productive work. Among other features, pharmaceutical facilities should provide a safe and secure environment, but the security features should not be so prominent or obtrusive as to foster a siege or fortress mentality. All employees need to be mindful of security, but successful security measures are designed to allow employees to keep their minds on their jobs.

Pharmaceutical facilities are best prepared to meet potential security threats when their owners, managers and designers have taken stock of their security position and acted to protect their assets from credible threats. A logical, step-by-step process can be followed to improve the security posture at a pharmaceutical facility. This process can benefit new facility design projects as well as renovations of existing facilities.

Security-conscious facility design can also enhance operational efficiency by minimizing the number of personnel and equipment complement necessary to achieve the desired level of security. In order to take advantage of this benefit, adequate security planning is required early in the facility design process. Protecting facilities not designed with an eye toward security can be expensive. The results of trying to graft
security requirements on top of a completed facility can be unsatisfactory from the standpoints of security, efficiency and perceived quality of the spaces. Security planning and design based on evaluation of security threats, coordinated with overall facility design, can provide cost-effective solutions that address both short-term and long-term business objectives.

Organizing for Success – The Project Team

Successful pharmaceutical facility design projects – whether new construction or renovation - consider security from project inception, and include security “proponents” on the team chart as shown in Figure 1. The best results come from consistent communication and balancing of the varying interests and viewpoints expressed by the stakeholders in a project. A “security committee”, whether or not officially designated as such, should include the owner’s facility management/engineering personnel and security personnel, the designer’s project team members and the security systems designer, who may be an outside consultant or a qualified specialist within the design firm. The owner’s facility user group representatives must also play an active role in the security planning process because they have intimate knowledge of the value of assets and operations in different areas of the facility. The facility user group is also best qualified to define requirements for personnel flow and material flow. In addition to this minimum recommended membership in the security committee, it is often helpful to have participation by the construction manager, particularly to evaluate potential budgetary impacts of alternatives.
Since the project team needs to address many diverse (and sometime competing) issues, the security committee should convene separately from main project team meetings to address security issues and establish security criteria and standards for the project. Selected representatives need to report results of their deliberations back to the project team for action and coordination. This interactive process is generally also an iterative process; the security committee may be required to reevaluate security criteria and standards several times as the design evolves, balancing opportunities and constraints established by the project team. In the final analysis security criteria and standards, similar to other facility characteristics, need to be balanced and moderated in light of budget constraints.

It’s Never Too Early

At what point in project development should security considerations bubble up to the surface? It’s never too early to start! Imagine the results if security was not considered in the facility design, and the security manager was faced with the task of adding security features during (or after) construction. Adding partitions for segregation of secure areas, coordinating access to electric power for security devices, retrofitting door frames and door finish hardware to accommodate security devices, assigning space for security equipment rooms – the construction headaches associated with this effort would be enough to ensure that anyone involved would consider security earlier on future projects.

Prudent pharmaceutical facility managers and designers have traditionally included security considerations in design, but sometimes not until after the major facility design elements have been cast in stone. Today, this is too late in the life of a pharmaceutical facility project to address security. Consider these issues that could be accommodated easily in conceptual or schematic design, but might be more disruptive at a later phase:

- Reception space considerations – Is a reception area required within the building, but outside the secure envelope?
- Equipment space considerations – Will security panels be located in telecommunication, electrical or mechanical rooms, or will they require dedicated equipment rooms?
- Circulation considerations – Is a dedicated circulation pathway required to access departmental areas without traversing another department’s secure zones?
- Protection of critical utilities – Should outside ventilation air intakes be elevated to avoid possible contamination? Should critical electric switchgear be located inside the building?
Security in Public Buildings - A Lesson from Uncle Sam

In response to the bombing of the Murrah Federal Building in 1995, the Federal Government established minimum acceptable security construction and operation requirements for all Federal buildings. These requirements are applied based on the established “Security Level” of a facility, which is determined based on the building size, occupancy, mission, and degree of interface with the public.

In simple terms, the minimum standards depend on the security risks to which the building is exposed.

Owners, managers and designers of pharmaceutical facilities need to follow this example and take a similar structured approach. Before designing solutions, first understand the issues. A formal facility security evaluation can usually be implemented as a cooperative effort between facility managers, facility designers and security managers, with a minimum commitment of time and resources.

Whether or not this formal security evaluation process is followed and documented, the basic analytical steps in evaluating pharmaceutical facility security are as follows:

- Define critical assets in your facility
- Define credible threats to these assets
- Evaluate Consequences if a threat is realized
- Evaluate likelihood threat may be realized
- Take action as appropriate to reduce likelihood or consequences
CPTED – Another Viewpoint on Security Design

According to the National Crime Prevention Institute’s web site, “the proper design and effective use of the built environment can lead to a reduction in the fear and incidence of crime, and an improvement of the quality of life.” This is the fundamental concept behind Crime Prevention Through Environmental Design – CPTED – a thirty-year old approach to security design. The basic concepts of CPTED are still valid today and should be incorporated in the facility design process. There are four overlapping CPTED strategies:

1. Natural Surveillance: A design concept directed primarily at keeping potential intruders easily observable. Promoted by features that maximize visibility of people, parking areas and building entrances: doors and windows that look out on to streets and parking areas; pedestrian-friendly sidewalks and streets; adequate nighttime lighting.

   For a pharmaceutical facility this might also mean building and landscape design that maintains clean sight lines and avoids potential hiding areas. Enforcement of a visible identification badge policy will also help to make unauthorized people visible. Natural surveillance will normally be complemented by video surveillance (closed circuit television or CCTV), especially on pharmaceutical campuses or larger facilities.

2. Territorial Reinforcement: Physical design can create or extend a sphere of influence. Users then develop a sense of territorial control while potential offenders, perceiving this control, are discouraged. Promoted by features that define property lines and distinguish private spaces from public spaces using landscape plantings, pavement designs, gateway treatments, and fences. Signage and finish colors can also be used effectively to define boundaries. For a large pharmaceutical campus, territorial reinforcement will often be accomplished with ornamental fencing, bollards or other physical barriers and security portals where visitors are required to sign in and be escorted to their destination. General employee, contractor and visitor parking should be outside of the fencing.

3. Natural Access Control: A design concept directed primarily at decreasing crime opportunity by denying access to crime targets and creating in offenders a perception of risk. Gained by designing streets, sidewalks, building entrances and neighborhood gateways to clearly indicate public routes and discouraging

access to private areas with structural elements. For a pharmaceutical facility, this often means providing circulation pathways outside of secure areas, and arranging spaces based on departmental or functional adjacencies. Natural access control will normally be complemented by an electronic access control system, with each access-controlled door programmed to allow access only to certain individuals within defined time periods.

4. Target Hardening: Accomplished by features that prohibit entry or access: window locks, dead bolts for doors, interior door hinges. For a pharmaceutical facility, this might include minimizing the amount of glass areas on the first floor level of a sensitive building, locating outside ventilation air intakes at a penthouse level rather than ground level, and securing critical utilities inside the building or in fenced and locked areas. A determined intruder can access even a hardened target, so security systems in pharmaceutical facilities often include intrusion detection sensors, such as door switches, motion detectors and glass-break detectors to alert security forces to a potential breach of security.

Planning Concepts – Rings, Threats and Arrows

Pharmaceutical facility managers and designers should become conversant with security design concepts, so they will be better prepared to include security considerations in their planning. Understanding a few simple concepts will also facilitate coordination with security managers and security designers. At the same time, security designers need to use straightforward planning concepts such as these in discussing security issues with facility managers and user groups.

One of the most fundamental security concepts deals with “concentric rings” of security. These rings typically progress from the exterior boundaries of a facility site, to the exterior shell of the building, to increasingly more secure areas within the building. As shown in Figure 2, the rings of security are not always concentric – security and efficiency are often both promoted by allowing adjacent, rather than nested security zones. Each zone boundary represents increasing hardening against security threats, and the coordinated facility design needs to
reinforce these boundaries. Each boundary should create an opportunity to deter unauthorized or undesired access to a more secure zone, to delay penetration of the barrier by a determined intruder, and to detect penetration when it occurs, to allow an appropriate security response.

Another equally important security concept deals with threats. Threats are those organizations, individuals or events that pose a risk to the continued safe operation of the pharmaceutical facility. The facilities manager and facilities designer should review credible threats with the security manager – credible meaning those that will be considered in developing the facility design basis. Establishing the credibility of threats can be a difficult balancing game, but the practical experience of the facilities manager and facilities designer together with the security-related knowledge of the security manager and security designer is a good starting point to find that balance. When reviewing security threats, it is tempting to look only at external threats and restrict security design Protecting against internal security threats can be a thorny problem that needs to be addressed on multiple levels. From the standpoint of human resources, background checks of employees, especially those with access to sensitive areas or resources, are important. From an operations standpoint, traceability of critical data, materials and operations is crucial. From the facility design standpoint, internal barriers between different areas of responsibility, access control systems limiting (and documenting) access to sensitive areas, and CCTV monitoring of critical areas are useful tools to deter activities or behavior that could jeopardize the pharmaceutical firm’s security interests.
A third important security concept requires special attention to flows within a facility, represented by arrows. In evaluating facility security, you need to focus on the flow of people and materials into a facility and between different areas of a facility, and the flow of waste out of a facility. Flows of people, materials and waste are key consideration in a pharmaceutical facility design project, and security is just another important angle from which to view these flows. Each time an arrow pierces one of the rings, it represents a hole in the security zone boundary, and the security committee needs to establish appropriate security goals. Is it important to prevent unauthorized vehicles from penetrating the barrier? Unauthorized personnel? Is it essential to prevent unchecked materials from entering the facility, or to prevent unauthorized removal? Once the goals are established, members of the security committee should coordinate with other team members to establish effective security measures that do not compromise efficiency, personnel interaction or other important facility goals.

Security Toolbox – Not Every Problem is a Nail

There is an old saying that “To a person with a hammer, every problem looks like a nail”. That saying need not apply to a skilled carpenter, who has many other tools to work with, and the knowledge to apply the right tool to the job at hand. In the same way, the larger the security toolbox that pharmaceutical facility managers and designers have to work with, the easier it will be for them to find appropriate solutions to a wide range of security challenges. An assortment of tools and tips is provided below.

Parking

Three important issues to address in planning for parking security are standoff, control and personnel safety. Standoff refers to the distance between parked vehicles and occupied facilities. The 1993 terrorist attack on the World Trade Center and the tragic experience in Oklahoma City highlighted risks associated with parking under or adjacent to facilities. A commonly recommended minimum standoff distance is thirty feet, but this distance may be increased depending on the nature of the facility and the associated risks. This consideration applies to parking for employees, contractors and visitors, and the security boundary between the parking area and the facility should be designed to prevent unauthorized breach by a vehicle. While the standoff protects the facility from certain external threats, control of vehicular access to the parking area is still important to promote safety of employees and others authorized to use the parking area. Parking control often includes a combination of a security guard (for periods of high traffic volume) and an automatic gate activated by an access control system, often supplemented by CCTV surveillance, telephone or intercom communication, and remote gate control from a security monitoring center. Gate type selection requires a
balance between protection and operational convenience. Where these requirements collide, the balance can sometimes be achieved by selecting a semaphore-type gate (for normal operating hours) and a higher-security (but normally open) sliding gate to be closed during off-hours.

Additional measures to enhance the safety of employees in parking areas include providing adequate lighting (in accordance with recommendations of the Illuminating Engineering Society of North America) and providing emergency voice communication to a security monitoring center. Emergency communication can be provided by emergency call boxes, which typically provide a duress alarm button and a hands-free intercom or telephone. Effective response to an alarm from an emergency call box is facilitated by CCTV coverage. A fixed camera can be provided to view each emergency call box. As an alternative if pan-tilt-zoom cameras are used for general parking area surveillance, activation of the duress button could signal the CCTV control system to position the pan-tilt-zoom camera to view the emergency call box that is in alarm.

Recent advances in CCTV camera technology have greatly improved the effectiveness of CCTV surveillance in parking areas and similar locations subject to large variations in lighting levels. In the recent past, most outdoor CCTV applications used black-and-white cameras because color cameras had poor low-light sensitivity. The advent of the day-night switching camera provides the advantages of color video when lighting conditions are appropriate. This allows security personnel to distinguish the color of a vehicle or an individual’s clothing, for example. When lighting conditions are inadequate for full color video, the camera automatically switches to black-and-white mode, providing increased sensitivity and greater image clarity.

Vehicle Access

Vehicle access to the pharmaceutical facility or site should normally be restricted to pre-arranged, authorized deliveries or service vehicles (of course, planning must allow access for emergency vehicles such as ambulance and fire-fighting equipment). Clearing a vehicle for entry to the site requires either a stationary security guard at a controlled site entrance, or a remotely controlled gate with CCTV surveillance and telephone or intercom communication to a security monitoring center. The advantage of a stationary security guard, at least during anticipated peak traffic periods, is the ability to physically inspect the vehicle before providing access. During off-peak hours, a roving security guard could be dispatched to inspect the vehicle and grant access. The importance of physically inspecting the vehicle may depend on how critical the facility is to the pharmaceutical firm’s business. If vehicles are admitted based on remote visual and verbal
communication, procedures should be established to deny entry to vehicles that do not have confirmed business at the facility.

Requirements for vehicle access to a pharmaceutical facility could be routine, such as mail or express package delivery, basic maintenance such as a repair electrician or other contractor, or highly sensitive in the case of delivery of research animals to a quarantine area. Layout of access roadways and signage should be clear to avoid problems or (at least) disruption that could result from the repair contractor arriving at an animal loading dock, or an animal delivery arriving at the general loading dock. When a site contains multiple types of facilities, it is sometimes appropriate to provide a secondary vehicle access control point between the circulation roadway and an animal research facility or other sensitive facility, to prevent unauthorized access and to make sure that the appropriate receiving managers are available to control receipt of authorized deliveries.

Mail delivery and handling, which were once considered completely routine, have received increasing scrutiny because of the potential for explosive devices or disease-causing agents to be delivered through the mail. It is good practice to have a single mail receiving and handling area, adjacent to a delivery dock and segregated from the rest of the facility, to check and sort mail for internal delivery. If the security goals for the facility include protection against the spread of disease-causing agents received through the mail, the mail handling area should have floor-to-structure partitions and a separate air handling system.

**Internal Security – Access Control**

A primary internal security consideration for a pharmaceutical facility is access control. Access control can be provided through lock and key or through a card access system. A card access system uses an encoded access card instead of a key (or a key ring full of keys). A centralized card access system provides many advantages over the use of keys; the access card can be imprinted with an individual's photograph and additional information to double as an identification badge, the access card is operationally more convenient (especially for doors requiring frequent access), and the access control system provides an electronic record of who entered an area at what time. Many different types of encoded cards are available, but the type most commonly used in pharmaceutical facilities is the proximity card, which does not need to touch or enter the card reader to allow access. This provides the greatest operational convenience, basically allowing hands-free access (if the appropriate door finish hardware is selected) for an employee who may be carrying records or pushing a cart.
For a pharmaceutical firm with multiple facilities, the normal practice is to use the same card access system at all facilities. The major advantage of this approach is that employees with requirements to access multiple facilities can do so with a single card. The operational efficiencies are even greater when the facilities are networked together and a centralized card access system database is maintained. The database information is transmitted to the card access controllers in each building so that access decisions are made locally, but the cost of administration is reduced because data input is centralized. Access to highly sensitive or critical areas, for example the animal holding suites in an animal research laboratory, may require an authorized access card plus an additional credential to prevent access by an unauthorized individual using a stolen card. A common secondary credential is manual entry of a personal identification number (PIN) similar to an automated teller machine. For the most critical or sensitive areas, which might include controlled substance storage areas or infectious disease suites, some facilities now use biometric readers (such as hand geometry readers) that automatically check a person’s physical characteristics to confirm a match with the presented access card.

Whatever types of access control devices are used, one of the most important design considerations is safe egress. Avoiding locking any doors in a path of egress is a prudent design approach. When requirements of security and free egress conflict, many local codes will allow a specially designed delayed egress device. Delayed egress devices meeting requirements of the National Fire Protection Association and both National and International Building Codes are available from several manufacturers.

**Internal Security – CCTV**

CCTV surveillance is also frequently used in pharmaceutical facilities as a deterrent to individuals who might consider violating security procedures. When coupled with intrusion detection alarm devices such as door switches, motion detectors or glass-break detectors, CCTV can be used effectively for alarm assessment. Some of the newer technology cameras and camera control systems can provide video motion detection, providing both alarm and assessment functions. The third important use of CCTV is for historical investigation when a security breach has been discovered. Traditional CCTV recording uses video cassette recorders (VCRs) and magnetic tapes, which must be changed on a daily schedule, marked and stored for a time period determined by the security manager, and then rotated back into use. Some of the drawbacks of the magnetic tape are cost, storage space requirements, and degradation after several uses. New technology digital video recording systems address some of these drawbacks by storing CCTV images in digital format on a computer hard drive, with periodic archiving to digital audio tapes or similar magnetic
media (at a higher cost than traditional VCRs). Taking advantage of recent computer technology
development, video archiving can now use recordable DVDs, providing even greater convenience, with the
promise of lower prices as the technology matures.

Summary
Effective security planning and design for pharmaceutical facilities requires people, organization,
communication, logical procedures, and sound concepts and tools. In order to provide the greatest benefit,
security considerations must be addressed early in the project life cycle. The benefits of effective security
planning and design can include a safe and secure workplace, operational efficiency and positive
perceptions of facility quality.

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