PHARMACEUTICAL SPACES

The Next Generation of Vaccine QA/QC Facilities

Creating Flexibility & Team Environments for Pandemic Response

THE NEXT GENERATION OF VACCINE QA/QC FACILITIES

Case Study In the world of pharmaceuticals, the need for rapid vaccine responses to emerging strains is a constant pressure. Delays in production can cause critical shortages, increasing the risk of further infections, thereby increasing the human toll. Pharmaceutical companies must identify and isolate the virus, develop and test the vaccine, as well as produce and distribute the doses within a limited, critical time frame, all the while ensuring both the safety of their staff and the effectiveness of their product.

This process can be difficult enough under normal circumstances; however, the added pressure of responding to pandemic conditions can cause even greater challenges, forcing pharmaceutical companies to pursue every strategy to ensure their success in overcoming these obstacles.

Now, more than ever, the need for productive and effective vaccine manufacturing facilities is evident. Not only must these facilities perform at peak efficiency, they must allow for adaptation to working with both known and unknown biohazards.

When Novartis, a worldwide pharmaceutical company, selected Flad to design their new facility for quality assurance (QA), quality control (QC), and administration, their goals were to increase the efficiency and adaptability of their vaccine production. The challenge of the project was to find innovative ways to enhance productivity, while expanding the flexibility of the labs beyond normal capabilities.

Novartis planned for the building to function in two distinct modes. During normal operation, Novartis will produce seasonal flu vaccine with the capacity to provide 160 million doses per year, requiring a high level of efficiency. During enhanced operation, the facility will be converted to create vaccine for emergent diseases to address pandemic readiness, requiring the flexibility to possibly handle select agents with a biohazard safety level (BSL) of 3, higher than the level laboratories utilize during normal operation (i.e. BSL-2).

Dual Challenges

To achieve these goals, the design had to overcome two major challenges faced on pharmaceutical campuses; the inherent difficulties of interdepartmental interactions, and the cost and complexities of managing biocontainment.

A common challenge on pharmaceutical campuses arises from the intersection of the different departments; QC, QA, and manufacturing.

The goal of the QC department is to test product during specific steps of the process, confirming the product resulting from each production process matches expectations. The goal of the QA department is to monitor the processes of both manufacturing and QC to ensure the manner in which the product is being created and tested conforms to prescribed criteria. The goal of manufacturing is always to create product as fast as they can. Whether the objective is saving lives or producing product to bring in revenue, their focus is centered on the quantity of doses they can create per hour.

Through these interdepartmental checks from the QC and QA departments, a pharmaceutical company can ensure they are providing an unadulterated product.

However, historically all three of these departments tend to generate tension during their interactions, due to natural human reactions to oversight, correction, and delay. As a result of this friction, most production campuses experience a slowdown in team productivity and efficiency. In many instances, this problem is aggravated when, due to the size of the operations, the individual departments are housed in separate buildings on campus, fostering an "us vs. them" attitude.

These tensions (and their resulting disruptions) would be exacerbated during the enhanced operations of a pandemic, resulting in critical delays and possibly fatal errors.

The other major challenge within the facility arises from managing the biocontainment needs while balancing safety with energy use and costs.

While producing seasonal flu vaccine, this facility would only need to have BSL-2 testing and certification laboratories. However, during enhanced operation BSL-3 may be required, depending on the particular vector and mortality rate of the pathogen.

Because of the exponentially greater HVAC demands placed on higher levels of biocontainment, during normal operation it would be cost prohibitive to use a BSL-3 lab for tests that can be done in a BSL-2 space. However, the time it would take to construct a BSL-3 lab once a potential pandemic was identified would eliminate the possibility of creating a vaccine within an effective time frame.

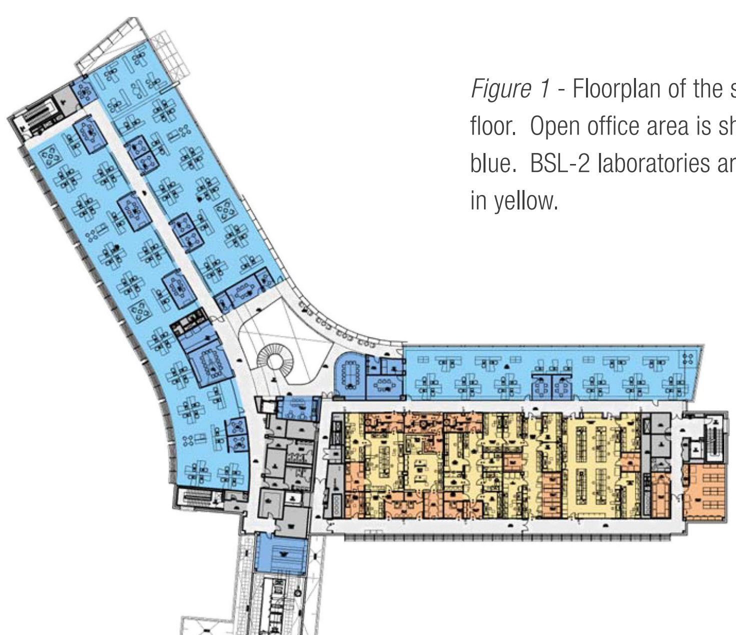

Figure 1 - Floorplan of the second floor. Open office area is shown in blue. BSL-2 laboratories are shown in yellow.

Parallel Solutions

To address these challenges, Flad pursued two parallel design strategies; first, create a space that encourages interaction between the different departments and promotes a unified team, and second, design a BSL-2 laboratory with designated internal areas that can be converted to BSL-3 facilities within a short time period.

Reinforce the Team

To reduce the "us vs. them" attitudes fostered by locating the departments in separate buildings, we created a facility with different wings for QC and QA, as well as an interior connection to the adjacent manufacturing plant. These separate areas of the building are bound together by a central commons area and a shared "front door." As a result, all staff enter and exit the facility through the same path, reinforcing the message that they are all members of a unified team.

One of the wings is the two-story QC testing operation, the other wing provides open office space for QA and administration on the top floor, while the bottom floor is allocated to support areas, including training, a shared dining facility, and conference centers.

A central staircase (figure 2) is positioned at the intersection of the two wings, providing a shared vertical path to the different levels. The landing at the mid-point on the stairway has been designed to include a podium, where a speaker can address a large audience. The open space below, including the cafeteria, can accommodate the entire staff of the facility.

This space can be used for company wide announcements and celebrations, as well as facility wide issues such as an announcement to begin the transition from normal operations to enhanced operations to address an emerging pandemic.

Through the use of these common spaces, we created an environment where the different departments are brought together to interact, forming bonds and interdepartmental connections. The social aspect of the interaction actually works to increase operational efficiency within the facility. By knowing their co-workers, they are able to resolve conflicts faster through shared collaboration and problem solving. Understanding each other as people, instead of their job title, reduces the stresses and conflicts caused by the constant pressure of the work they are doing. In addition, establishing a collaborative work environment better prepares the entire team to meet the challenges of enhanced operations during a pandemic response.

As a result of these architectural elements, the building itself helps facilitate teamwork by transforming the "us vs. them" mentality into an team mentality.

Figure 2

Transform the Space

The strategy for enabling a space to be transformed from a BSL-2 laboratory into a BSL-3 laboratory required fully designing the space for the higher level of biocontainment, but stopping short of installing all necessary equipment. In addition, the access into and out of the space was built to match the BSL-3 requirements, however, extra access was created to accommodate easier passage when functioning in BSL-2 mode.

The area shown in *figure 3* indicates the section of the 2nd floor of the QC laboratories that was designed as BSL-3 capable.

When the transition to BSL-3 is initiated, normal access to the room will be closed (*figure 4*). The doorways will be sealed and gaskets will be installed, forcing ingress and egress only through the BSL-3 protocols. Between two automatic doors, a changing area is provided for donning the appropriate protective clothing when entering the lab and showering when exiting.

Other exits from the laboratory are sealed by installing autoclaves, providing a route for waste to be removed from the lab, but ensuring the waste is fully sterilized in the process.

In the mechanical area, the HVAC unit is designed to include HEPA filters, required for ensuring the air vented from the room is safe. When running in BSL-2 mode, the filters are not installed, leaving an open duct in that section. Once the laboratory is sealed the air pressure is rebalanced and the space is ready for commissioning to ensure it meets all BSL-3 standards.

Novartis originally asked that the transition from BSL-2 to BSL-3 be able to be performed within 90 days. With the features designed into the space, the transformation of the space is now estimated to be able to be done within 30 days.

Why Place the BSL-3 Space on the Second Floor?

To reduce risk and energy consumption, the BSL-3 capable laboratory area was located on the second floor. During enhanced operations the HVAC system will include HEPA filters, which use a large amount of energy to move air through them. These filters are required to ensure any biocontaminants are contained within the BSL-3 environment. By placing the BSL-3 capable space on the second floor, with the HVAC unit directly above the lab, the system does not have to waste energy moving the air through extensive duct work. Also, as there is no duct work spanning non-BSL-3 areas, minimizing the risk of exposure.

The Path to Success

The secret to successfully overcoming these two challenges is the organizational flow designed into the facility. The paths of movement for the staff in the different departments brings them together to build social connections and reinforces the idea that they are all equal members of the same team, working in the same building. The paths of movement for material and product allow for efficient testing and certification but also allow for the changes necessary to augment the facility and transform it from a BSL-2 laboratory to BSL-3.

To create the most efficient and effective facility, the design must manage both the social interaction and the technical space. The environment itself must allow for the stresses imposed on the Novartis' staff in these highly technical spaces. It requires extremely skilled people to create the vaccine, test it, and deliver it to the marketplace in a safe and effective manner. Ultimately, the facility's design is about those people understanding each other, working together, and communicating to solve real-world problems that can save lives.

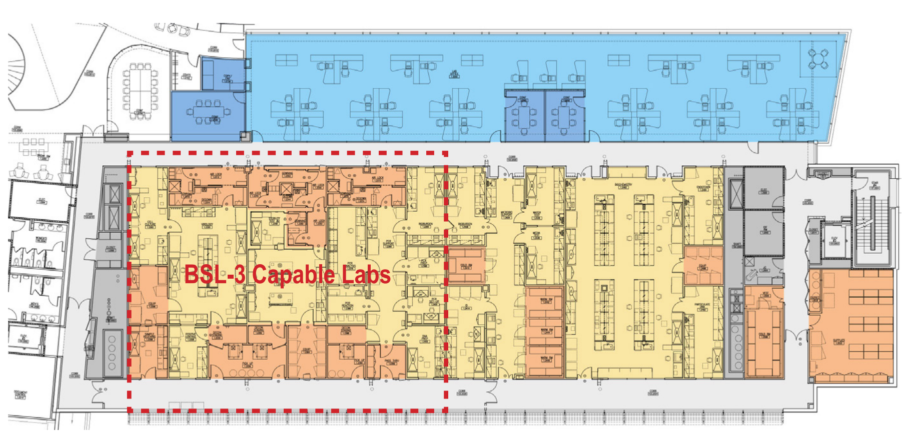

Figure 3

The Next Generation of QA/QC Facilities

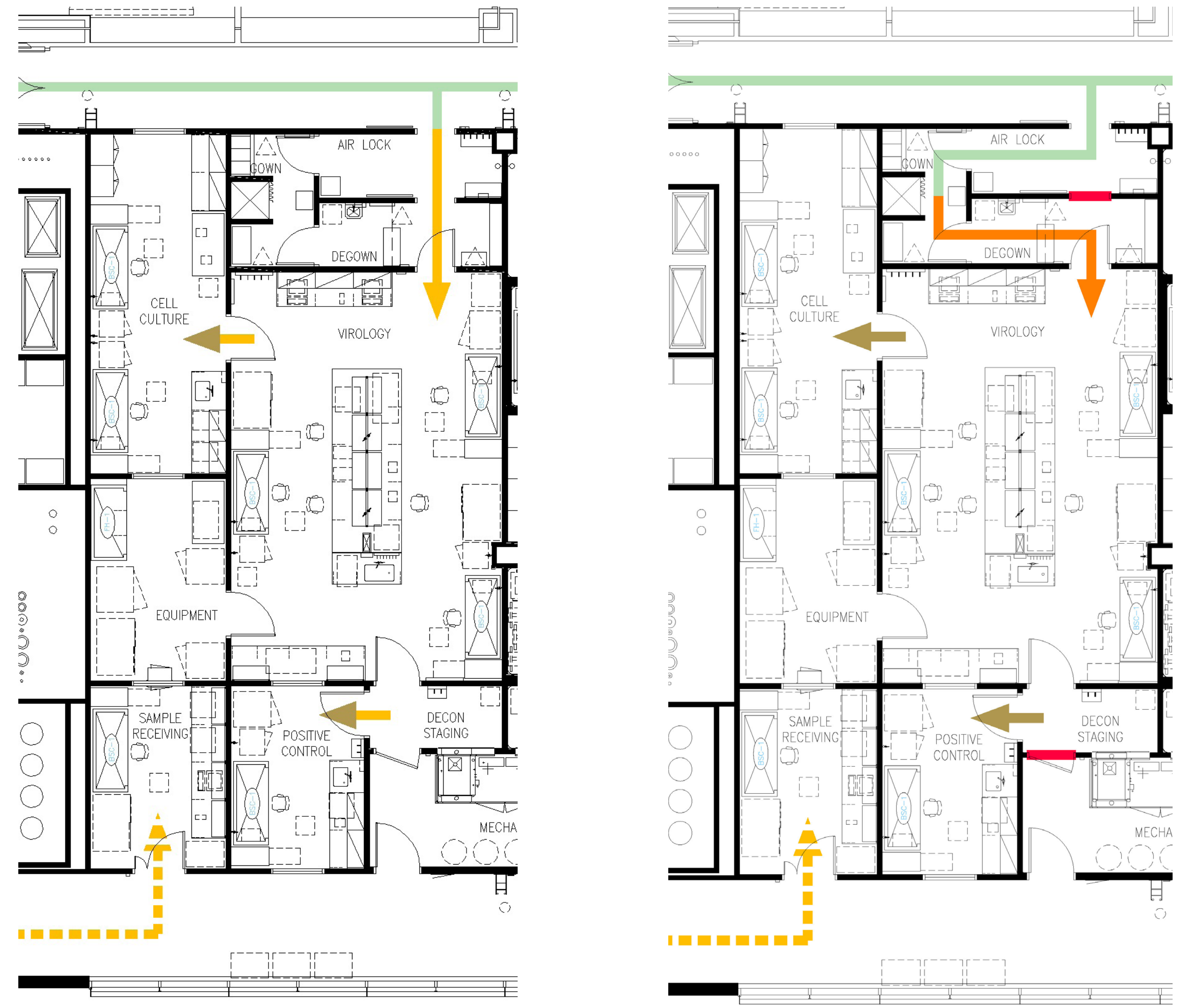

Figure 4 – The same laboratory shown as BSL-2 (left) and BSL-3 (right). Access to the lab is sealed (shown in red) forcing access through the BSL-3 dressing area.

LEGEND

- STREET CLOTHES
- ZONE 4 TRANSITION
- ZONE 4 - TYPE 1 GOWNING - NORMAL OPERATIONS & PANDEMIC NON-INFECTIOUS - LAB COAT & SAFETY GLASSES & SAFETY SHOES (AT ENTRY TO LABS AND SUPPORT AREAS)
- ZONE 4 SAMPLE TRANSPORT - TYPE 1 GOWNING
- ZONE 4 - TYPE 1 GOWNING - COAT SUBSTITUTION
- ZONE D - TYPE 2 GOWNING - PANDEMIC OPERATIONS - REQUIRING CLEAN ROOM CLASSIFICATION
- ZONE 4 - PANDEMIC GOWNING
- ZONE 4 - PANDEMIC GOWNING - COAT ADDITION