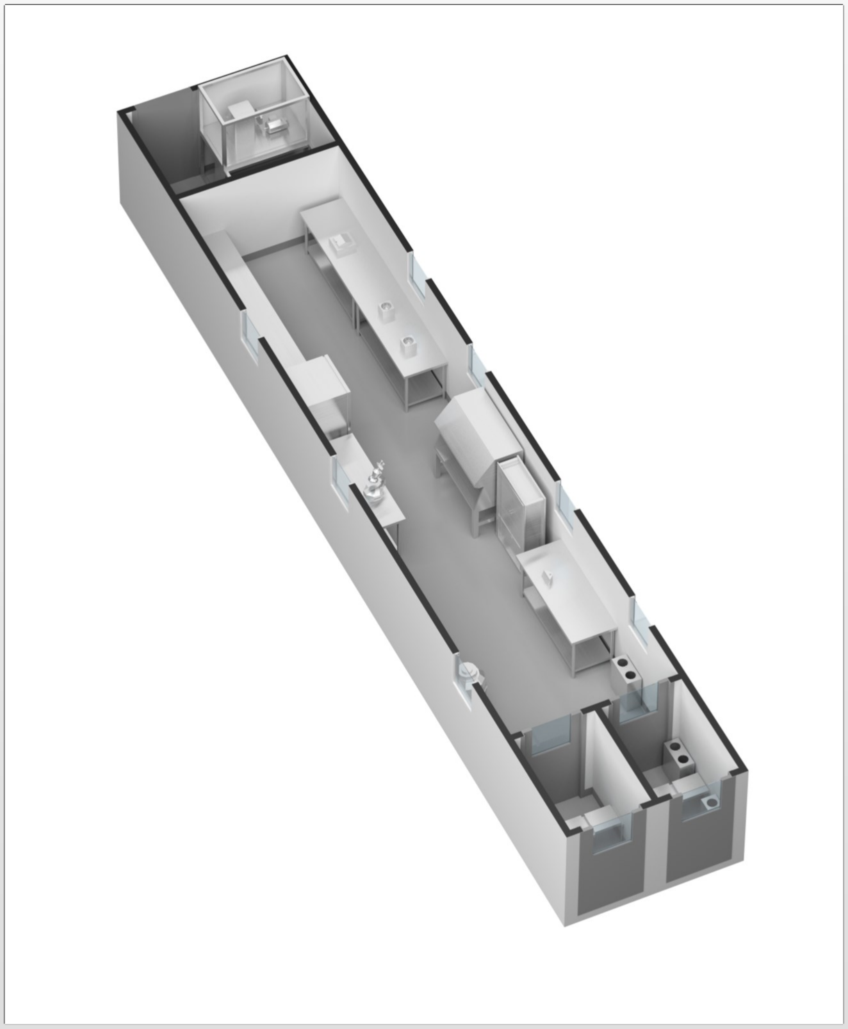
G-CON MANUFACTURING Inc.

WHITE PAPER

Transmissible Disease Containment

Using Flexible Mobile Biocontainment Units to Prevent the Spread of Transmissible Diseases



INTRODUCTION

Transmissible diseases are no longer scarce and limited to one location, but are becoming a more frequent occurrence, spreading rapidly due to rising population densities and modern travel modes. In addition, infectious diseases flourish in regions previously unsuitable for spread due to unfavorable climate and environmental conditions. Both types of diseases, therefore, have become a real threat for the global population and not just for few regions of the world.

The list of examples of transmissible diseases is long. Most are either difficult to treat or untreatable. A few examples are listed in the table below:

Viral Transmissible Agents	Microbial Transmissible Organisms
* Flu (H7N9, H1N1, H5N1…)	* Anthrax
* Pneumonia	* Pneumonia
* HIV	* MRSA
* SARS/MERS	* Typhoid
* Lassa	
* Ebola	
* Dengue	
* Hanta	
* Chikungunya	

These transmissible diseases are not any longer localized diseases, but can easily be transferred to other surrounding regions or globally. For example, the 1918 Spanish Flu was transmitted solely via troop transports. Today, such can be transported easily via business travelers or tourists. Hence, the world of new, unfamiliar diseases is not thousands of miles away, but is literally at every door step.

To prevent the spread of disease outbreaks, containment is the first line of defense. However, events like the 2013/14 Ebola hemorrhagic fever outbreak in West Africa, have revealed that current containment options are insufficient, difficult to use or manage and hard to sanitize.

Even special hospital wards may not be the optimal choice for containment. The 2011 *Klebsiella pneumonia* outbreak at the National Institutes of Health's very own clinical center shows that even the highest levels of traditional containment do not provide a reliable option. Radical measurements had to be taken including erecting walls to separate areas, demolish plumbing and sanitizing rooms with vaporized disinfectants. These radical measurements were only successful after a 6 month battle during which the organism continued to spread.

The radical measures taken by the hospital in that case could have been avoided entirely if an environment that allowed for strict patient segregation, easily cleaned surfaces (floor to ceiling epoxy coating) and sanitization with vaporized hydrogen peroxide (VHP), had been employed. Such a containment systems could have also been run at negative pressure to retain any transmissible agent. Air locks upon entry and exit also are of significant benefit. Most of all, such robust containment systems should be readily deployable and mobile.

LEARNING FROM THE LIVE VIRUS VACCINE INDUSTRY

There exits two key methods for controlling serious outbreaks of transmissible diseases: therapeutic countermeasures (i.e. vaccines) and transmission control through isolation and containment. For some of the transmissible diseases, there are no vaccines. Rather, only containment and measurements to support the patients immune system exist. In such instances, containment is key. The live virus vaccine industry provides such an example.

The vaccine industry utilizes strict environmental and area control and segregation. Vaccines are produced in biosafety level classification (BSL) from 1 to 3. Strict gowning, air lock designs, pressure cascades and sanitization cycles assure that none of the infectious agents escape the containment area. These containment options must be sophisticated and robust. BSL cleanroom structures are designed with enhanced, autonomous air handling and HVAC structures (Figure 1). Segregation of the air handling and HVAC systems greatly reduce the risk of excursions. In addition, these designs utilize a controlled environment that is easily cleaned and decontaminated using various methods, such as vaporized hydrogen peroxide and chlorine dioxide. Full isolation, as described, can be achieved with new podular cleanroom structures, which contain their own air handling system in its own mechanical space. These units are widely available for vaccine production purposes, but now are modified to achieve patient containment options.

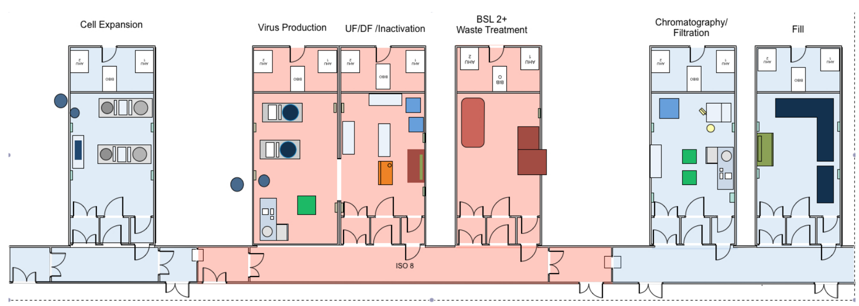


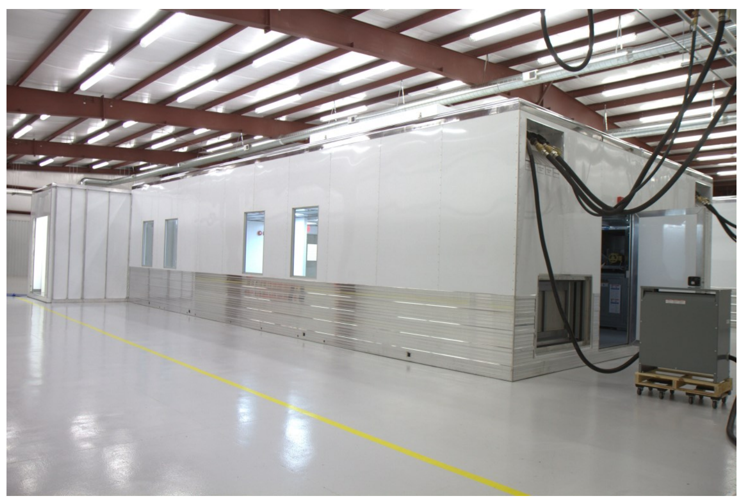
Figure 1: Example of a vaccine processing flow with cleanroom POD containment

Flexible cleanrooms designed for transmissible disease containment (TDC), such as G-CON's TDC PODs, offer a robust patient biocontainment option solution that manages potential environmental exposure to the transmissible agents. These systems are easily deployable, having dimensions that allow for simplistic transportation and delivery across the globe. As self contained cleanrooms, PODs have their own air handling system with double bag-in/bag-out HEPA filters on the return air and cleanable epoxy flooring and walls that are compatible with vaporized hydrogen peroxide and chlorine dioxide for decontamination. These cleaning methods can be integrated into the POD to make cleaning and decontamination as simple as the push of a button. The TDC PODs can either be transported via tractor trailer, since the standard size is 8.5' wide and 50' long or receive their own axle system to be pulled to any location. Personnel flow is enhanced by an air lock from one side and exit via a decon bay from the other side. Waste fluids are pumped into kill tanks and gowning bagged for disposal. The units also have their own generator unit to make them an independent environment.

ADVANTAGES TO USING FLEXIBLE CLEANROOMS FOR BIOCONTAINMENT

Highly flexible yet secure facilities of maximum biosafety and containment levels are required to manage issues related to exposure to highly hazardous transmissible pathogens. Flexible containment systems like the TDC POD allow for each room to be cleaned separately, and in the case of an emergency occurring in one room, operations in other rooms can continue as normal. Advantages of flexible, mobile containment facilities that are deployable for use in biosafety and containment include:

- ⇒ Fabrication and delivery in 15 weeks
- ⇒ Close monitoring and separation of patients
- ⇒ Easy scalability of the containment options without interruptions
- ⇒ Biosafety level cleanrooms can be decontaminated and properly sanitized for repeated uses
- ⇒ Ability to hold a number of patients and equipment in a larger area than typical inflatable bag systems
- ⇒ easily deployable due to a robust yet light aluminum structure
- ⇒ optimal containment due to redundant air filters



CONCLUSION

The first line of defense against transmissible diseases is containment. Often containment options are not robust enough to retain the agent in its environment or fail due to less than optimal working conditions.

Durable aluminum based containment POD constructions, with an optimal surface finish for cleaning and sanitization represent the paradigm shift for containment. These negative pressure systems can be constructed in weeks are mobile once onsite. Redundant air filtration systems assure that the disease agents remain retained. The cleaning and repurposing of autonomous cleanroom spaces make them an ideal containment option to enforce the measures required to control the spread of transmissible diseases. Ultimately, flexible containment systems, such as G-CON's TDC PODs are the optimal choice of containment.