

Aging facility considerations in pharmaceutical and biopharmaceutical processing

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G-CON's autonomous, cleanroom POD

Background

Aging facilities are a reality and are on the rise. These facilities can work smoothly without problems, but that is often the exception and not the rule. Well-trained personnel with a process ownership mentality make such facilities run, but it is a question of time when such personnel will move or retire and the facility or processes see their first excursions. Facilities, processes and analytics become obsolete and lose the necessary performance parameters. At a minimum, improvements are required. More often the

situation demands totally new innovations. If such steps are not taken, it is a matter of time when problems will arise.

In addition, some facilities may still run sufficiently, but the product, which was produced in these dedicated processes, loses patent protection or has been replaced. These processes, if not total facilities, are mothballed and become underutilized assets or more aptly liabilities.

The question posed here is, how can aging facilities present new opportunities instead of being a mothballed problem?

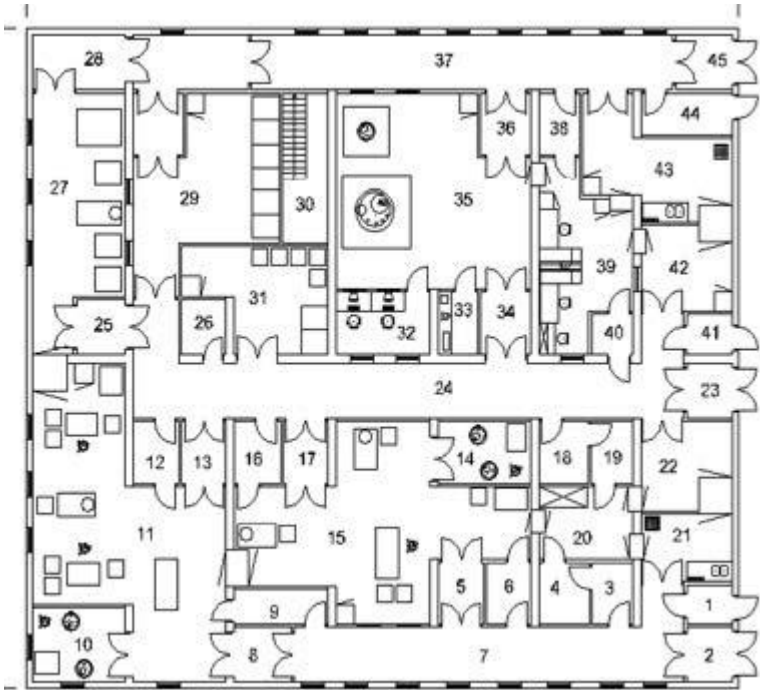
Examples

Most facilities that are shut down are brick & mortar sites. They produce one product and are generally not capable of anything else. When the product reaches its life-cycle and generics overtake it production of the product stops. The process and facility used to manufacture the product, often though, are product dedicated. Costs to revamp, clean, refurbish, etc. the production line, and the building infrastructure, including the HVAC system, are considerable. In such a formidable task, evidence has to be established that there is no chance of a cross-contaminating the new product with the old product. To avoid such risk, the entire infrastructure has to be gutted and rebuilt. During that process additional issues reveal themselves which can further increase costs and project time.

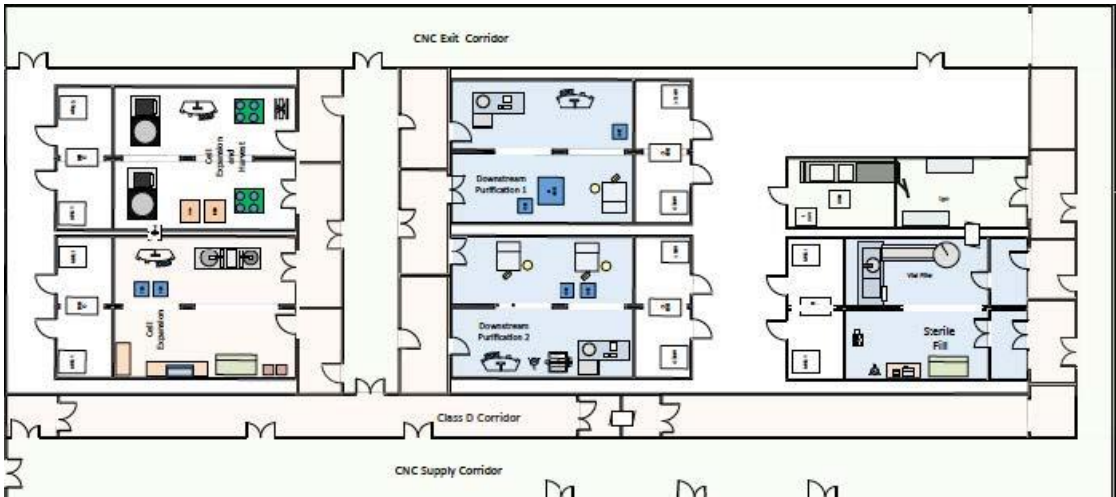
A better solution for the described problem could be to "gut" the infrastructure and create one large shell space, test the utilities' quality and availability and add flexible, autonomous cleanroom PODs. The PODs provide the new processing space into the otherwise empty grey space. Since the PODs have their own HVAC system possible cross contamination is eliminated. If the utilities, water, chilled water, steam, electricity, etc. are suitable, these utilities can be distributed to the POD infrastructure via a centralized

line quick connected via flexible line to the mechanical space of the PODs. Such a solution efficiently updates an inflexible infrastructure to a flexible, highly agile one.

From this:



To this:



Conclusion

Aging facilities are on the rise and more assets become unutilized liabilities. Instead of mothballing such facilities, such facilities can become assets again, when gutted, and used to host autonomous cleanroom PODs. The two examples above show a glimpse of the possibilities, which are available with new, innovative cleanroom PODs. Single-use process technologies utilized within such POD structures furthers its flexibility, as the single-use technology is only as flexible as the surrounding infrastructure. And no other facility solution can provide the flexibility that can be achieved with PODs.

STEQ America proudly supports G-CON Manufacturing in supplying autonomous cleanroom designs, and creating prefabricated, turnkey cleanroom systems that represent a significant transition to forward thinking in pharmaceutical and biopharmaceutical processing.

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What we can offer

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