A modular approach to the cleanroom

Cleanrooms provide aseptic work environments. With the modular ExyCell system, Siemens and Exyte – experts in the development and delivery of controlled and regulated manufacturing environments – are quickly and flexibly supplying cleanrooms for medical research and manufacturing.

The coronavirus pandemic has plunged societies around the world into an exceptional situation:

What was considered normal yesterday no longer applies today. Rules for protecting the general public are changing the way we interact with one another. Under these circumstances, medicine is extremely important: In the event of illness, it stops the worst from happening and gives people hope. If the right vaccine is found, the virus will be contained. Time is a crucial factor, because the faster that medical devices like ventilators become available, the better the medical treatment and the quality of intensive care will be. And the faster a vaccine is market-ready, the sooner life will return to something like normal. That's why researchers and developers in hospitals, laboratories, and companies are working at top speed to find effective and sustainable solutions

Sought-after workspace: Cleanrooms

When pharmaceutical products, sterile drugs, vaccines, and even medical devices are being manufactured, it's important that they not be contaminated by even the most minute particle. That's why laboratory work and production are performed in cleanrooms. In these rooms, the concentration of airborne particles is extremely low. Airborne particles are particles and materials suspended in the air that are mostly invisible to the naked eye but can nevertheless interfere with work, contaminate products, or put people at risk. Depending on their class, cleanrooms allow only a maximum number of particles per cubic meter. Cleanrooms are sealed off from their surroundings and can only be entered via airlocks. In the current situation, the heightened search for medical solutions increases the demand for aseptic environments.

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Solution: A modular system

ExyCell is based on the principle of interconnecting individual prefabricated standardized cleanroom building elements called cells. The modular system gives researchers, developers, and manufacturers total flexibility for the layout. The cleanrooms can be deployed more rapidly, be installed anywhere, are scalable, and can be custom-equipped according to requirements and be digitalized if necessary.

The focus of ExyCell is on the clean-room ceiling where all the technology is installed. The false ceiling of the cleanrooms is fully accessible, which means that maintenance of filters, fans, and cooling coils can be performed from the cleanroom. One cleanroom cell measures 2.4 m x 9.6 m for 24 square meters, allowing it to fit into any shipping container. This means that the project partners can manufacture the cells centrally and ship them by truck, train or sea to any location. Individual cells are easily integrated into existing brownfield plants when a new cleanroom or cleanroom expansion is needed. By grouping multiple cells, customers can implement new, turnkey bio plants (greenfield plants) with unlimited dimensions from 50 square meters up to whichever size is required by the process layout. Because the cells are simply combined together, operators can easily scale the size of the cleanroom and design almost any

floor plan, providing even more flexibility.

But the key advantage of the modular system over conventional construction is that the cleanroom is available guickly. Customers can start using smaller units within months and larger units within a year. The cells are also process-neutral, meaning that customers have the option of equipping them to meet their own requirements. The equipment mainly comprises single-use process equipment that can be purchased and set up quickly. Their flexible design and rapid deployment also make these modular cleanrooms suitable for use by startups in the pharmaceutical industry and in laboratories and hospitals. Thanks to the modular system, it's possible to begin production of vaccines and medical devices much more rapidly.



Model of a biopharmaceutical facility consisting of pre-configured ExyCell[®] modules and an integrated power supply by Siemens. *Copyright: Exyte*

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"Our partnership with Siemens enables us to preintegrate Siemens" technology into ExyCell modules, thus offering clients an end-to-end solution for their facility."

Luca Mussati, Vice President Pharmaceuticals and Biotechnology at Exyte, summarizes the benefits of the collaboration between Siemens and Exyte on the ExyCell modules: "Our partnership with Siemens enables us to pre-integrate Siemens' technology into ExyCell modules, thus offering clients an end-to-end solution for their facility. Clients can therefore reap the benefits of industry 4.0 without needing to engineer them anew each time, thus saving time and money. ExyCell modules are suitable for new buildings as well as for the retrofit of existing buildings, and can be provided in standard, off-the-shelf plant configurations, or modules can be combined to meet specific customer requirements."

Project partnership: Strong together

Siemens and Exyte are experienced partners that have maintained a good relationship for many years. With its extensive digitalization expertise and in-depth industry knowledge, Siemens supports EPC (engineering, procurement, and construction) when delivering turnkey ExyCell plants to customers. "The size of our company benefits the collaborative project. Services from our Smart Infrastructure and Digital Industries Business Units can be provided from a single source, allowing us to keep the manufacturing process lean and flexibly respond to customer requirements," explains Eckard Eberle, CEO Siemens Process Automation.

Equipped: Technology in the cell

The process control system sets the pace in every plant. It controls and monitors all plant processes

and delivers digitalization all the way down to the field level. Using the latest version of Simatic PCS 7, plant operators can manage automation processes in the ExyCells and, for example, prevent attacks from the network (cybersecurity). They can also control the room climate: the heating, ventilation, and air-conditioning (HVAC). A supply of power to the cleanroom cells is ensured by the Sivacon low-voltage switchgear. Siemens also offers solutions for fire protection and access control. On request, the company also provides support for plant digitalization with the Digital Enterprise portfolio, which contains solutions from process management tools and paperless production to automated guided vehicle (AGV) applications.

Looking ahead: Current and future projects

The first buildings with the standardized ExyCell modular turnkey bio plants are currently in the planning phase in China and Europe.

Published by: Siemens AG Pharmaceutical Industry Germany Subject to change without prior notice

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