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Martin Birch

Thomas Hauser

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PRE-FABRICATION FOR PROVIDING BIOCAPACITY TO SUPPORT VACCINE MANUFACTURING

Martin Birch RIBA. Process Architect G-CON
mbirch@gconbio.com

Thomas Hauser, Business Development Manager G-CON
thausen@gconbio.com

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The industry landscape is evolving rapidly and requires new and innovative approaches for more rapidly addressing the growing global demand for drug products as well as the challenges of unpredictability and inflexibility that have historically burdened the industry. Over the past two years, the industry's herculean response to the COVID-19 pandemic has proven that with the proper focus, investment, science, and manufacturing technologies, these historic challenges can be overcome as well as establishing new benchmarks for how the industry can perform in the future to ensure availability of drug products and therapies to the global patient base.

Prefabricated modular construction of cleanrooms, utilities, and facility structures, is an innovative approach to building new manufacturing facilities that the industry has benefited from and is currently being utilized in critical COVID related projects. Prefabricated and modular facilities have been utilized in many industries such as food, chemical, and consumer products in the past, and have started to see significant adoption within the pharma and biopharma industries over the past ten years. This has largely been driven by the need to reduce project timelines, improve capability and flexibility, and minimize the risks associated with traditional construction for manufacturing facilities. It has helped as well to make Biopharma manufacturing more accessible to emerging regions, where in the past biomanufacturing was too complex to establish.

For a drug manufacturer to shift its strategy for designing and building its new manufacturing facilities using a prefabricated approach, it typically must perform its own comparative assessment of prefabricated modular construction to traditional construction which will include critical factors such as capital investment, speed to market, schedule, return on investment, flexibility for new products and network capacity, cost of ownership through facility lifecycle, etc. Multiple stakeholders including but not limited to the C-Suite executives, engineering, operations, quality, regulatory, and EHS should all have their input considered as part of the evaluation.

The presentation will include a summary of the typical performance requirements for cleanrooms and an overview of the different types for cleanroom construction. We will then evaluate the impact of using prefabricated cleanroom construction. The project drivers and influences which will help determine the best construction approach to meet the overall project goals and achieve the manufacturing objectives will be discussed. A short introduction to G-CON and its modular POD cleanroom technology will also be provided as well as the benefits of implementing the prefabricated approach for cleanroom construction.

