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Future facility needs, flexibility and cost evaluations

Over the last few years, biopharmaceutical-processing platforms moved from rigid traditional stainless steel to flexible single-use technology. The platforms created the ability to run the process more efficient and with higher agility. The need to evolve from fixed and rigid to flexible and agile systems did not stop with processes, but now shifted focus to facility designs. Traditionally, the facilities built were product dedicated, large if not convoluted and involved lengthy time-to-run periods. To build such facilities thorough planning is required, especially capacity planning since the inflexibility of the structure does not allow easy scaling of the cleanroom space required. Overall, these types of manufacturing systems do no accommodate the need for flexibility of scale, multi-product purposes, neither the benefits of single-use technology processes. Therefore, new facility systems are being introduced into the industry, ones that can be scaled, easily deployed and moved, if necessary. Prefabricated clean-room units now replace so-called flexible modular structures, which did not show the necessary flexibility. These units are built off-site in a few weeks and moved into the shell building erected parallel to the manufacture of the clean-room units. Such structures create flexibility, scalability, and moreover, re-purposability. However, the cost comparison of these units versus traditional panel built represents the same comparison as apples and oranges. The total cost ownership requires to be applied to determine, which facility design tool in the tool box is best for the specific project.

Biography

Maik W Jornitz, President of G-CON Manufacturing Inc., is a distinguished industry leader with close to 30 years of experience in bioprocesses, especially sterilizing grade filtration and single-use technologies, including regulatory requirements, integrity testing, systems design, and optimization. He has published multiple books, book chapters and over 100 scientific papers. He is a member of the PDA Science Advisory Board, Marketing Advisory Board and Audit Committee, as well as an advisory board member of Artemes Technologies, Biotechnology Industry Council and multiple science trade journals. He received his MEng in Bioengineering at the University of Applied Sciences in Hamburg, Germany and accomplished the PED program at IMD Business School in Lausanne, Switzerland.

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