

Modular Process Design

Foster Wheeler Biokinetics, Inc.

Foster Wheeler Biokinetics has a proven track record in the custom design of pre-assembled process modules for the Biopharm and other FDA-regulated industries, covering the full range of pilot and manufacturing scales of operation. These include individual “skidded” unit operation systems, as well as entire pre-assembled process trains and suites.



Our modular system designs include:

- Fermenters and bioreactors
- CIP/SIP systems
- Media and buffer prep systems
- Bio-waste inactivation and neutralization systems
- Chromatography systems
- Filtration and other product purification systems
- Custom blending and formulation systems
- High-purity stainless-steel tanks and vessels
- USP and WFI water systems

Why Modular?

Modular fabrication of process and utility systems allows us to separate the fabrication and testing of these systems from the building construction activities, so these activities can be completed in

parallel to compress the project schedule. In a traditional “stick-built” approach, the concentration of various trades in the process suites and attempts to compress schedule with additional labor at premium overtime rates can result in low productivity and poor quality. A shop environment with trained labor that specializes in modular systems can complete the fabrication and testing in a controlled environment at a higher productivity level, thus decreasing costs to the client.

A modular approach also allows the process to adapt to changes. Purification schemes, for example, may need to adapt to changes that result from increased protein yields in the bioreactor or introduction of new products. This may have some impact on chromatography and ultrafiltration systems, which are typically provided as process skids. There is also an impact on the buffer prep and hold operations that support the purification systems. A modular approach in the buffer operations can facilitate replacement of vessels with others of a more suitable size or installation of additional vessels.



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Our Approach to Modular Process Design

Foster Wheeler Biokinetics is experienced in transforming a process design concept into fully operational and tested process modules. Utilizing state-of-the-art design and productivity software, we ensure that equipment is delivered on time and meets all customer requirements. Clients can follow the progress of their project from conception through design and fabrication, including detailed 3D model reviews, over the Internet. Manufacturing procedures and turnover documentation exceed cGMP requirements.

Our modular approach also extends to critical utility systems, such as pumping/cooling/heating skids for WFI and purified water systems. Point-of-use coolers can be fabricated as modules that are integrated into the water distribution loop.

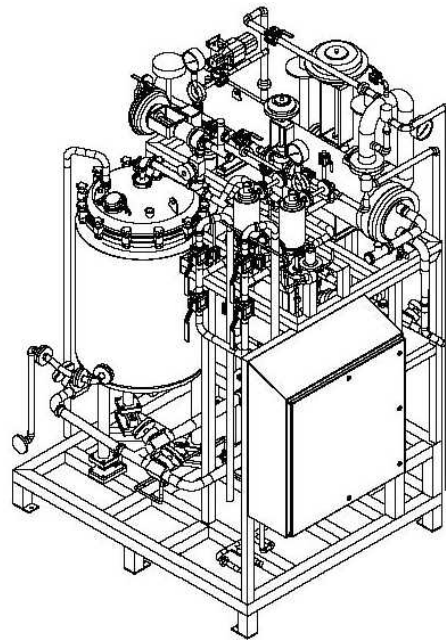
During the early design phases of a project, the facility design team will consider the need to bring in large modules during the construction phase. Our design expertise, coupled with the process design team's experience working with Foster Wheeler Biokinetics, allows us to properly evaluate this approach. We may also consider the need to add or replace modules after the facility has been completed, with minimal impact on current operations. Design of access panels in exterior walls, interior walls and roof, and proper sizing of access corridors would enable us to reap the full benefits of a modular approach.



The Modular Process Suite

The modular process suite is an evolution of the traditional skidded, self-contained, unit operation products that are familiar to the industry. The approach is to combine several unit operations into one large, fully integrated module. The modular process

suite may contain multiple vessels, transfer panels, pumps, filters, heat exchangers, purification equipment, interconnecting process and utility piping, platforms, power and control wiring, and control system. An entire process suite is fabricated and tested in the shop before the system is shipped for installation. Large modular suites are disassembled, in a planned modular approach, into smaller modules that can be shipped by ground, air, or sea transport. The modular process suite concept can be applied to buffer prep and media prep, buffer hold, cell culture, and purification areas.



The use of utility chases and mechanical "gray space" is typical in the biopharmaceutical industry. Piping and process equipment is located in gray space to facilitate maintenance and decrease the size of costly "clean space." We can design the gray space as modules that support the operation of modular process suites or traditional skid-mounted unit operations. In either case, the interconnecting piping between the modular gray space and process systems can be made in the field to adapt to any variations in construction and fabrication tolerances.

For more information, please contact FW Biokinetics at 215.656.2500, or Email us at info@fwbiok.com, or visit our website at www.fwbiok.com.