

Disposable Process Solutions

Specialists Experienced in the Design and Operation of Disposable Systems

Foster Wheeler Biokinetics has diverse, in-depth experience in the application of disposable process solutions. Our specialists have experience in the design and operation of disposable systems for cell culture/fermentation, solution preparation, and product hold, ranging from 5L to 10,000L. Biokinetics has expertise in all of the following areas:

- Design of manufacturing facilities utilizing disposable systems
- Evaluating the economics of disposable systems vs. traditional stainless steel systems
- Detailed design, construction, installation, and validation of disposable process systems

Foster Wheeler Biokinetics has taken a leading industry role in the design of disposable systems on all scales. Our collective design experience includes the following types of systems:

- Modular Media and Buffer Prep systems ranging from 10L to 10,000L
- Small scale rocker-style bioreactors
- 1000L vessel-style batch bioreactors
- Intermediate product hold bins ranging from 500L to 2500L
- Buffer hold bins ranging from 500L to 3000L

Foster Wheeler Biokinetics has also completed numerous studies to evaluate the economic feasibility of disposable systems vs. traditional stainless steel systems. These rigorous studies have taken into account all costs, capital and operating, that contribute to the total cost of ownership for a disposable system. Such studies have allowed our clients to make objective decisions regarding selection of systems and evaluate their sensitivity to variable production rates.

Select Project Experience

- **Lonza, Portsmouth, NH**

By developing a comprehensive financial analysis template, Biokinetics was able to compare over a dozen case studies using disposable solutions in lieu of traditional systems. Systems studied included:

- 1000L fed-batch bioreactor
- 200L, 500L, and 1000L media and buffer preparation systems
- 3500L solution hold

The template was developed to take both capital and operating costs into consideration, including solid waste removal, warehousing costs for consumable items, and manpower costs for maintenance and process operations. The template allowed for manipulation of financial parameters, and provided an analysis of NPV over a range of throughput values in order to estimate the break-even point for disposable vs. traditional solutions. This allowed the client to make objective decisions on selecting disposable systems based on their forecasted production rates.



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- **Biogen IDEC, Cambridge, MA**

Foster Wheeler Biokinetics performed an evaluation to compare both the operational and economic impact of using disposable bag technology in lieu of stainless steel vessels for a new Purification Suite at Bio-2 in Cambridge, MA. Disposable technology was explored due to the processing suite requiring flexibility to allow for faster changeover and to minimize cross contamination between product campaigns. Operational advantages and disadvantages of stainless tanks vs. disposables were compared for several process applications.

- **Haemacure, Sarasota, FL**

Foster Wheeler Biokinetics was contracted to design a manufacturing facility for Haemacure Corporation a specialty biotherapeutics company developing human, high-value therapeutic proteins based on a patented, high-yield fibrinogen and thrombin extraction and purification technology derived from human blood plasma. Disposables were used in mixing, thawing and as surge tanks throughout the process. The only non-disposable systems are chromatography, centrifugation and ultrafiltration. Biokinetics performed conceptual through detailed design of the process and in addition supplied (8) HyNetics® Single-Use mixing systems ranging in size from 30 to 750 liters.

- **National Cancer Institute, Frederick, MD**

Foster Wheeler Biokinetics supplied (5) HyNetics units to this pilot plant used to manufacture clinical trail material for various vaccines. The units range in size from 100 to 3,000 liters and are used for Media/Buffer Prep, and a cell lysing step post bioreactor. The mixing dynamics of the HyNetics systems has increased yield 5 fold, compared to a conventional stirred tank, for the cell lysing step. This yield increase has resulted in a significant product cost improvement for NCI.



- **Centocor, Malvern, PA**

Foster Wheeler Biokinetics developed of an order-of-magnitude estimate with the primary objective of evaluating the capital and operating cost benefits of preparing media for a non-GMP pilot bioreactor. For this study, we considered a traditional stainless steel system versus several options, including the Hynetics Single-Use Mixing System®. In addition to the economic analysis, a labor time and motion study was performed to assess the impact of using disposable technology.

- **CytoGenix, Houston, TX**

Foster Wheeler Biokinetics executed a conceptual process design effort for a cGMP pilot/manufacturing facility for the production of DNA material. For this facility, we engineered and fabricated a prototype DNA production unit comprised entirely of disposable components, including a disposable bag lined reactor unit and disposable ultrafiltration membrane system.

- **Kirin, Takasaki, Japan**

The biopharmaceutical division of Kirin in Japan renovated existing space to install a 750 liter HyNetics® system. The unit is used for the hydration and preparation of media and buffers.

Contact Us

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