

## Disposable Bioreactors: Prognosticating the Future

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The steel, stirred –thank bioreactor has been the dominant technology for over 50 years, however, the requirements in the pharmaceutical industry are now quite different from those 50 years ago. Disposable systems are clearly an attractive alternative for traditional bioreactors and have gained a strong following for a variety of reasons, including easy of use, elimination of cleaning and sterilization, and reduced risk of cross-contamination. Although many in the biopharmaceutical industry have introduced disposable systems for use in the production of clinical and commercial therapeutics, there remains the misconception that disposables cost more than reusable, sterilizable systems. This is not true when the actual cost of validation and operating labor are calculated. Validation of traditional stainless steel bioreactors requires users to test the functionality of a system in terms of its cleanliness and sterility, whereas with disposable bioreactors the device is supplied clean and sterile with the appropriate certification. Patient-specific therapy is the new frontier for pharmaceutical research. Knowledge of the human genome and the ability to cultivate cells outside the body will require new types of bioreactors. Basic applications will include the development of single-use devices for autologous therapy. This is the enormous bioreactor design challenge.

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