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Disposable Bioreactors Become Standard Fare

New Product Offerings Reflect Integration of System Components

Vicki Glaser

Increasingly users of traditional bioreactor and fermentor systems are looking to integrate disposable reactors and system components, or even make the switch to completely disposable systems in order to minimize the need for complex cleaning, sterilization, and validation procedures.

Disposable reactor bags, mixing and storage units, and the necessary connectors and valves needed to link these components are becoming standard fare in the industry.

Wave Biotech (www.wavebiotech.com) introduced its Wave Bioreactor, an inflated plastic bag that relies on wave-induced agitation for fluid mixing and oxygenation, in 1998 (see Technology Review on p. 74). Seven years later, disposable reactors and related accessories grace the catalogs, websites, and new-product announcements of suppliers better known for their steel tanks, spinner flasks, and glass benchtop reactors.

Though serving a limited (but rapidly growing) sector of the bioprocess market, disposables can no longer be considered niche products suitable only for small-scale projects.

Vijay Singh, Ph.D., founder of Wave Biotech, envisions the day when pipeless manufacturing facilities will be the norm. When a start-up company that needs to produce 10 g of protein for a clinical trial will simply convert a warehouse into a clean environment, roll in disposable culture equipment, and, in 10–12 weeks, be able to operate a pilot-scale facility and produce GMP material.

At the other end of the spectrum, making tailored cell-based therapeutics for individual patients, versus large-scale manufacturing of one-size-fits-all therapeutics, Dr. Singh anticipates a sizeable potential market for disposable technology.

He talks of disposable reactors as medical devices in a "one person/one bioreactor" scenario in which cells are removed from a patient, expanded, and in some way treated or modified, and then returned to the patient.

Producing enough material to yield a therapeutic effect will require high density cell culture systems capable of producing hundreds, and perhaps even thousands or millions of cells, Dr. Singh predicts. He believes that stem cell-based therapies will also require greater numbers of cells than are currently thought to be needed.

Toward the end of this year, Wave Biotech plans to introduce a 2,000-L bag system with a working volume of 1,000 L. This larger reactor will operate on the company's existing mechanical rocking unit.

The latest product development at Wave is its FlexMixer™ 1,000-L, single-use mixing bag. It contains a perforated disk that moves into and out of the headspace to promote mixing. The company has also introduced reuseable fiber optic dissolved oxygen probes for online monitoring.

The DOOPT-PROBE can be inserted into the Oxywell2™ port of Wave's Cellbags. Optical sensing as a means of noninvasively monitoring control parameters in disposable reactor bags is the wave of the future, and Dr. Singh sees it as a key growth business in coming years.

In their short history, disposable reactors have primarily targeted human and animal cell culture for GMP protein production.

But Dr. Singh is seeing a trend emerging in which disposables are spilling over into the fermentation arena for growing bacteria, yeast, and other fungi. Accompanying this shift, Dr. Singh sees growing interest in disposable reactor technology outside the biotechnology sector and, in particular, in the food and beverage industry. GEN

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