

Rigidity makes the difference

The pressure on pharmaceutical companies to bring new ingredients quickly and safely to market has never been greater. Karl Rix, **Eppendorf's** vice-president of sales and support, Bioprocess Europe, explains how single-use bioreactors are helping clients stay ahead of the game.

Which pharmaceutical bioprocessing tasks are currently the most challenging?

Karl Rix: When talking to our clients, I see that they are facing a couple of challenges. A combination of the evolving generics trade and expiring patents for blockbuster drugs increases the pressure to bring promising active pharmaceutical ingredients (APIs) to market quickly. The processes that are developed must meet all regulatory requirements on one hand and be as cost-effective as possible on the other.

Therefore, the industry is searching for bioprocess equipment that accelerates research, process development and eventually manufacturing. Single-use technologies, options for process automation, and comprehensive data and information management are of great interest, as they can rapidly reduce labour, facility and R&D costs.

How is Eppendorf meeting its client's needs?

Our commitments to the customer's success are premium products. With a broad portfolio of liquid, cell and sample handling products, we are a renowned provider to pharma clients. The epMotion workstation for automated pipetting and the new cell culture consumables are just two examples I'd like to mention.

Our bioprocess offerings are designed for applications from R&D to production and support seamless scale-up. They include shakers and incubators, conventional glass and unique, single-use benchtop products for single and parallel processing, as well as pilot-to-large-scale stainless steel bioreactors and fermentors.

Several distinct software products enable us to meet our client's requirements with regard to precise monitoring, control and data acquisition. Besides, the DASware software suite fits the demand of what I call "next-generation bioprocess information management". It provides solutions for remote control, automation by integration of external lab devices, like analysers, and can be used with most common third-party benchtop bioreactors.

Do you feel that single-use technology in upstream bioprocessing is as efficient as it is perceived to be?

Single-use bioreactor technologies are undoubtedly seen as a state-of-the-art solution to the problem of coping with increasing time and cost pressures, especially in biopharmaceutical cell culture process development. As usual, though, the devil is in the detail. In my opinion, most single-use bioreactor technologies suffer from a couple of drawbacks at the moment.

Major and widely discussed aspects are leachables and extractables (L&E). The multilayer film structure of commonly used bags and softeners can influence the culture process by releasing chemical components, potentially affecting growth, titre and/or product quality. Scalability is also an issue; the process



Scalability the rigid way: Eppendorf's BioBLU single-use vessels from working volumes of 65ml to 40L.

behaviour and control in inlay bags or rocking systems are not always exactly comparable to the stirred-tank design vessels that are still mainly used in large-scale manufacturing processes. Technology transfer, from development stage in single-use bioreactors to a conventional manufacturing suite, may become more challenging than initially expected.

However, like other suppliers we are convinced that single-use bioreactors are a smart and easy way to accelerate bioprocess development. Therefore, we just chose a different approach. Our BioBLU single-use vessels are designed as rigid-wall, stirred-tank bioreactors.

Their geometry is comparable to that used in large-scale production bioreactors and they can even be used with industry-standard sensors and one-piece, rigid plastic walls all but eliminate the aforementioned L&E problem.

Why are there so few single-use bioreactor products dedicated to microbial applications on the market at the moment?

Microbial applications have quite high demands, due to the need of much higher mass and heat transfer. This is a challenging approach for every manufacturer. We are one of only a few suppliers also able to serve the fermentation market. Our BioBLU single-use vessels are designed specifically to cultivate bacteria, yeasts and fungi.

The combination of high-performance agitation drive, innovative cooling strategies and the use of top-quality materials ensure outstanding process conditions and fully address fermentation needs. ■

Further information

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