Contract manufacturing organisation Rentschler Biotechnologie will add a 2,000-litre single-use bioreactor to be fully operational end of the first quarter of 2015 to its facility in Laupheim, Germany, to match the growing demands for production capacity for all clinical phases.

Single-use technologies have gained broad acceptance in biomanufacturing within the past few years, supporting flexible and cost-effective clinical production. Beyond this, the first manufacturing processes for market products using disposable equipment (Shire, Protalis) have already been approved by European and US authorities. Currently, two thirds of all new bioprocesses are carried out in single-use equipment. Thousand-litre single-use bioreactors (SUBs) represent the common standard, although 2,000L SUBs are on the advance. In general, an optimistic growth market in the double-digit range is predicted.1

Compared with bioreactors made of stainless-steel, single-use production plants not only have a low contamination risk, but are also more cost-effective and faster to implement. The initial investment costs are approximately 40% lower, and since systems for cleaning and sterilisation (CIP/SIP) are obsolete and time-consuming pipework is not required, the project lead-time for implementation of single-use production plants is reduced by at least eight months compared with stainless-steel reactors, which still have their place in commercial production. Pharmaceutical customers also benefit from lower energy and maintenance costs. Of particular note, however, is the high degree of flexibility. It is possible to design processes modularly using single-use production systems and so to scale them easily; very rapid product changeovers are possible, and as a result an overall faster time to market can be realised.

Single-use systems with disposable components made of plastic are also far less damaging to the environment than widely believed – particularly when compared with stainless steel reactors. Stainless steel reactors need continual cleaning and sterilisation, which results in a high consumption of chemicals and ultrapure water. Single-use plants have a 46% lower total water consumption and a 35% more favourable CO₂ balance than stainless steel reactors.2

Due to the heating of large quantities of water for CIP and SIP, the energy consumption of stainless steel reactors is considerably higher than the production and disposal of plastic bags, the burning of which can also be used to recover energy.3 Rawlings and Pora have calculated that the total energy consumption of single-use systems is about half of that of stainless steel reactors.4 This means that the disadvantages of disposable systems – above all the higher costs for consumables – are more than offset by savings in water, energy and chemicals.

Challenges of single-use bio processes

For demanding processes – particularly in the case of high cell densities and product titers – the classical production process in stainless steel reactors is still superior, especially during product harvesting. During harvesting, all cells and cell fragments are separated from the process liquid normally using centrifugation and subsequent filtration. The centrifugation step in single-use processes, however, must be mapped with a cascade of deep-bed
Advances in single-use technology

By enabling high levels of modularity and flexibility as well as significant energy savings, single-use bioprocesses represent a paradigm shift in the production of clinical material. Some products, however, are better suited to production in stainless steel reactors, and commercial scale production is also usually more cost-effective in reusable stainless steel reactors. But here, too, a rethink is taking place. Rentschler is one of the first toll manufacturers worldwide to establish a complete single-use manufacturing chemist October 2014

that implementation is cheaper and faster. The initial investment is about 40% lower in comparison with a stainless steel facility at same scale. Furthermore, the project lead time for implementation is reduced by at least eight months. In the near future, the design of single-use production systems will be even more modular to meet increasing and varying demands. Further technological developments of single-use equipment, in particular centrifuges, sensors, chromatography and membrane adsorber, will help to resolve operational limitations.

REFERENCES

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