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# Beyond biologics bottlenecks

*Single-use technology is undoubtedly the perfect partner for the biologics market, offering a complete fluid pathway.*

Novel biologics provide access to targeted treatments for some of our most pressing medical conditions and meet the needs of an ageing global population. Biologics promise fewer side effects and the first steps towards personalised medicine, but the field is still in its infancy.

It is important to make one point clear: the rise in biologics does not foretell the end of the small molecule. The US FDA-approval rate for small molecules and biologics shows a steady increase in new molecular entities in both categories.[1] There is clearly a market for both products, but biologics show a departure from mass-produced and mass-consumed drugs.

From monoclonal antibodies, interleukins and therapeutic vaccines to emerging cell and gene therapy treatments, highly complex and multimolecular treatments simply can't be processed in the same way as their small-molecule counterparts.

Working with live cells while ensuring drug integrity and sterility requires a fresh manufacturing approach. For example, growth vectors and end products are more susceptible to aggregation and degradation due to temperature and light sensitivity. Demand for robust equipment is higher than ever as processes become more intensive. Finally, with new formulations and delivery methods in development, there are fresh challenges for critical processing and filling steps.

With a variable end product, the process has to become the regulated and tested entity, bringing a new approach to quality assurance. Collectively, these challenges lead us into uncharted territory, with possibilities and pitfalls that only a collaborative, multi-pronged approach can navigate.

Biomanufacturing capacity is on track to increase 45% by 2023 to reach a total global manufacturing volume of 6.4m litres,[2] but with demand growing at 10%/year, the current growth plans will not satisfy this need.

Hurdles remain in the developing world, particularly high-capital investment and strict regulatory requirements resulting in high cost of therapies and limited patient access. With lower price points, we'll also see biosimilars rising to meet the demand of the developing nations and this will bring its own challenges.

Process intensification, as a means in itself, and also as a route to continuous bioprocessing, will further springboard the viability of biologics for broader use. As each process is intensified another bottleneck will be identified and will, in turn, be intensified itself, leading to a more streamlined and efficient manufacturing system.

Hand-in-hand with this approach comes a focus on scaling-out as a means of moving from the lab bench to production. Small systems will be run in parallel to achieve the capacity needed, rather than the scaled-up batch systems so prevalent in small molecule production.

Single-use technology is undoubtedly the perfect partner for the biologics market, offering a complete fluid pathway. With sterility safeguarded and fast changeovers guaranteed, companies are adopting this technology as the solution to efficient biologics manufacturing.

Reducing bioburden and eliminating the risk of particulate and endotoxins in the end product is central to biologics production. Single-use technology is already being used in novel ways, and this 'single-use' may run into months of service. To reduce risk and provide parameters in which our equipment can operate, Watson-Marlow Fluid Technology Group has been testing its fluid paths portfolio to meet these evolving performance requirements.

There are no regulatory frameworks for single-use technology in this space but by working with other suppliers, biologics developers and the regulatory bodies, we are defining best practice, addressing issues and creating robust criteria that will drive success.

With biologics we can fight the dual threat of ageing populations and evolving pathogens while reducing side effects and treating conditions more effectively. The next few years will present huge progress, and as advanced therapy medicinal products (ATMPs) reach patients we will see the impact that they will make.

Not only do we need to develop more effective treatments, we need to do this faster, more cost-effectively, at scale and at a regional level. Without investment and focus on these goals, we will limit the number of novel therapies that can reach patients.

One thing we aren't lacking is brainpower. As a group, we have the answers and we will solve them through collaboration. By continuing to bring stakeholders together, from the regulatory bodies to the manufacturers, license holders and suppliers, we can create a culture of open dialogue, where we all understand the challenges and solve them together.

1 https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products (accessed 15/04/2021)
2 https://bioprocessintl.com/bioprocess-insider/facilities-capacity/biomanufacturing-capacity-45-growth-but-new-blockbusters-could-leave-shortage/ (accessed 15/04/2021)