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Standardisation Forecasts

Disposable Solutions for Biomanufacturing

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Pharma iQ
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Standardisation Forecasts: Single-Use-Systems

According to a recent study, the global single use technology biopharmaceutical market reached $1.7 billion in 2014, a $0.3 billion jump from the year prior. Looking at the period of 2014 – 2019, the market is predicted to expand at a compound annual growth rate of 11.7 per cent to almost $3 billion. (4)

The US market is expected to increase to $1.1 billion by 2019 from 2014's $573 million. However, Europe is expected to grow at a slightly slower pace, from $599m in 2014 to $1 billion in 2019.
Despite these healthy figures, the absence of standardisation between single use system suppliers is seen as a key discourager by end users in the face of the many advantages disposable systems provide to the pharma and biotech production process. Advantages of single use system standardisation include the avoidance of costs for system modification and faster implementation. Industry bodies such as United States Pharmacopeia, BioPhorum Operations Group and the Bio-process Systems Alliance are helping to set benchmarks for the single-use-system industry.

In regards to the initial shift towards the standardisation objective, in a previous Pharma IQ interview Jerold Martin, Sr. Vice President, Global Scientific Affairs for Pall Life Sciences, noted: "When single use was initially introduced process design engineers were very enthusiastic about the fact that there [were] so many options, so many flexibilities. People could design the connections on bags and transfer manifolds, in any number of ways and they liked that, but as single use is maturing, a lot of facilities are concerned about the number of different stock keeping units and part numbers of single use that they have. So they are seeking to internally standardise what configurations they are going to use to reduce the number of different variants that they have to source and inventory.…" This move to consolidate the SKUs would help to reduce spend.

Standardisation is an ongoing hot topic in the industry with the reality being harder to achieve than one may initially expect.

Some noted that the age of standardisation may need to be kickstarted by a cold shoulder from end users strategically positioning the flow of business for single use components. By collectively consolidating the suppliers of choice as a market, industry commentators proposed that this harsh move from end users could force the dominant suppliers as a group to work towards standardisation. (10) Critics of this theory questioned not only whether such a drastic measure is possible, but if it is in fact necessary.

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Is standardisation it actually feasible?

Ray Baldwin, Technical Sales Manager (Europe), Bio Pure Technology Ltd ventured to say that standardisation could in fact be a matter of months or even weeks away if based on a generic design for generic components. Although, a sticking point will be that the market needs to decide on the specifications. Celia Landers, Senior Product Manager, MilliporeSigma explains that there are many different specifications to be clarified between end users and manufacturers." When we think of standardisation we want to create an optimised portfolio for customers to standardise on the function they need for their disposable solution instead of on individual components or pre-designed solutions." She notes that in the long run, however, standardisation is an achievable concept specific to application, process and function.
After gathering insights from various experts, we explore the various focal points connected to the movement and their potential influences on the market if standardisation was come to fruition.

The Mechanical Performance of the Systems

Standardisation will comprise evaluating components' dimensions, materials, testing and documentation. (1) mentions that in the past tri-clamp connectors and hose barbs have encountered a certain amount of variability and issues. The performance – integrity and strength, of the systems will be of prime focus.
Standardised disposable systems will enable smarter portfolio management. Many end users have their eyes set on this with aims to become more future proof and have the ability to break down portfolios into basic building blocks.
This smaller portfolio of filters, bags and other components will allow for process flexibilities at later stages to meet relevant needs and requirements. End users will also have the flexibility to swap between suppliers to obtain desired lead times.

The next stage of standardization efficiency has been dubbed as a more 'plug-and-play' approach guiding product design and innovation. Tony Hitchcock, Pharma IQ columnist continues that this kind of standardisation is understood to also permit greater efficiency and lower costs.

Tony Hitchcock outlines that standardisation is likely to bring benefits to not just end users but suppliers too and establish basic performance requirements for new products and suppliers to achieve. However, as some suppliers have invested significant monies into product designs – for instance with bag designs and connection systems – some providers may be reluctant to give these up in favour of a standard connector or bag design.

In a previous piece of editorial, Aidan Sexton, Senior Process Validation Engineer at Janssen Biologics Ireland clarifies that if standardised designs are interchangeable from vendor to vendor - the potential market for each single-use system manufacturer should increase accordingly, allowing for a cost reduction in terms of producing those items, because it becomes standardised. Also, the volume of sales they should see should increase.
Celia Landers highlights that standardisation will reward suppliers with more accurate visibility. The consistent production required for components and configurations will allow them to streamline operations where necessary.

Forecast: Standardisation could:

- Reduce lead time and pricing for component acquisition
- Facilitate direct comparisons between suppliers
- Allow for vendors to have more visibility and control on raw material spend to negotiate with suppliers.

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Extractable and Leachables

Standardising extractables and leachables testing for components and plastic films will allow biomanufacturers and regulators to make better decisions and focus on important elements influencing patient safety.

Forecast: Standardisation could:

- Bring benefits to end users in regards to extractables and leachables testing
- Establish basic extractable and leachable testing performance requirements for new products and suppliers to achieve.

Customisation

Aidan Sexton has highlighted that one disadvantage of the lack of standardisation is that providers often view any modification request from end users as customisation which often attracts a charge. Customised assembly often costs more in comparison to off-the-shelf assembly when certain solutions are needed to fit at manufacturing sites. On the other hand, Ray Baldwin notes that customisation will always be needed on some level in order for end users to fit components to their current layouts and process flow. He adds that currently standard products tend to represent the minority of a supplier's requests.

Forecast: Standardisation could:

- Incur less flexibility for bespoke SUS process flows.

Vendor instincts protect home revenue streams

Some maintain that one of the reasons why standardisation has not seen much progress from suppliers is because vendors want to standardise according to their own respective needs. Also, providers may be hesitant advance to this standardised plug and play state as it may neutralise their ability to be competitive. (2)

By refusing to standardise across single-use system manufacturers, end users are effectively forced to remain within a given SUS environment once the initial decision has been made to go with a particular SUS manufacturer. For example, Aidan Sexton explained: "There is a number of storage bag manufacturers out there. They make their storage bags according to a particular design. They might want you to purchase their totes or bags, etc., and any other types of their proprietary systems."
Dr. Simone Biel, Field Marketing Single Use Technology, Process Solutions, Merck noted that design will be the hardest aspect to standardise in regards to sterile connectors and other components. A vendor's complete single use kit will have bespoke designed geometries that are incompatible with equipment from other suppliers.

Forecast: Standardisation could:

- Face supplier reluctance

Setting the Standard

Tony Hitchcock asks the very important question of who would set the standard? "There would appear to [be] no shortage of bodies working on the generation of standards; large multi-national corporations, whether suppliers or end-users have extensive standardisation within their organisations. They appear to be very keen to have industry wide standardisation based on their own standards, which are inevitably different from other large corporations, so there clearly needs to be compromise. Additionally, there are several industry wide bodies such as the PDA who have been working on generating guidelines for a number of years.

"The process of generating standards is further complicated by the fact that it would appear that there are multiple standardisation bodies within multiple territories looking to develop their own standards with no group taking an obvious lead in the area or routes to harmonise the

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guidelines or standards that may emerge from these various groups."

Many agree that reaching a consensus to standardise the type of testing will be a real challenge.

Also, the prospect of standardization is complicated by the fact that each supplier will want to be perceived as the standard, with more and more diverging types of solutions entering today's marketplace. (2) There are a lot of variables in the supply chain and various connections which need to be agreed. For example, will a certain design of silicon tubing need to be defined including the contact for the end fitting? Ray Baldwin asks whether a standard will rise to act as a block to innovation on how products can be processed.

Therefore, in order to progress towards standardisation, buy-in will need to be established with end-users to agree on the desired process flow. This may be straightforward for new programs however, standardising the work flow of existing programmes which may encounter complications.

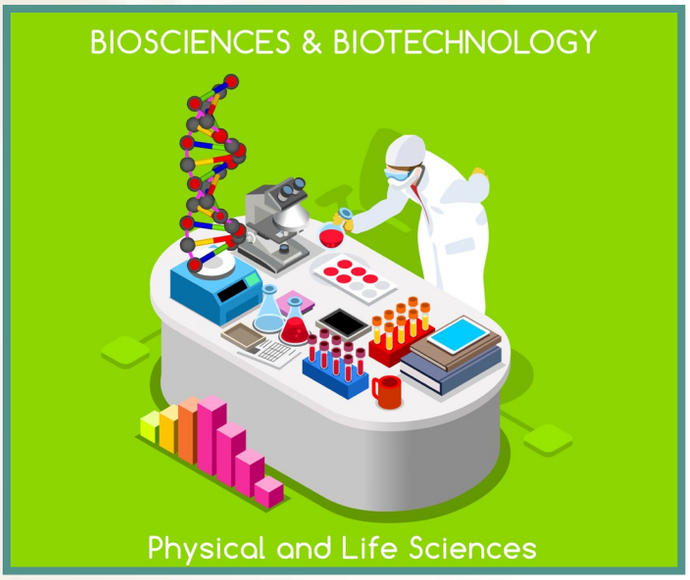
Forecast: Standardisation could:

- Curb process innovation
- Encounter complications in reaching consensus on defining the standard

Trading In Today's Market & Looking Ahead

Ray Baldwin notes that the market rests at a 'wait and see' point in regards to the definitive route to standardisation. Dr. Simone Biel notes that to navigate today's market end-users must not compromise on performance quality, and as long as that isn't impacted flexibility can be afforded on design.

The main drivers behind standardisation are swift lead times, on-time delivery and regulatory documentation. Celia Landers adds that customers want not just fast lead times but predictable lead times for their plants and their processes. They also need the right balance of design flexibility. She has noticed that most suppliers are moving towards a form of plug and play standardisation, but are choosing to deploy different approaches.
Dr. Simone Biel noted that in order to cater for the



tastes of end-users Merck reviewed historical component usage across the thousands of SKUs for custom items that were created over the past several years. This information was used to reverse engineer and validate optimised components needed to configure high quality assembly. This way customers can be sure these components are available off the shelf, allowing for improved lead times. Premium suppliers are being used on stocked components to provide enhanced regulatory documentation for the validation requirements.

To find out more in regards to standardisation within the disposable solutions for biomanufacturing consider attending the 2017 event on the subject Celia Landers, Ray Baldwin and Simone will be on-site at this conference.

Resources

1. http://www.pharma-iq.com/manufacturing/interviews/standardisation-of-single-use-technologies-with
2. http://www.pharma-iq.com/manufacturing/columns/where-next-for-single-use-systems
3. http://www.pharma-iq.com/manufacturing/interviews/wide-scale-adoption-of-single-use-systems-in
4. http://www.pharma-iq.com/manufacturing/articles/trends-and-successes-in-disposable-tech
*5.https://disposablebiomanufacturing.iqpc.co.uk/standardisation-within-single-use-systems--an-inevitability-but-does-it-have-to-be-painful-*mc?ty-m=

DISPOSABLE solutions

27 - 28 February, 2017 |
Munich, Germany

Europe's BIGGEST and LEADING Disposable Solutions Event

Achieve Operational Excellence in Biomanufacturing with Single Use Technologies

By 2021 the knowledge and application of Single Use Systems will equal and even exceed that of Stainless Steel today. Where Disposable products and Single Use Technologies are becoming more widely used than ever before, this revolution has led to more questions than answers

Reasons to Attend:

- Ensure compliance and update yourself on the critical interpretation of new regulations with **exclusive presentations from USP, BPOG and BPSA.**

- Improve your biomanufacturing process and plan for future single use innovations through technical case studies from a variety of different pharmaceutical companies and CMOs.

- Overcome key challenges that surround disposables and single use systems including **system integrity**, extractable and leachable testing and standardisation to enhance your own operation.

- Discover how to achieve the **best strategy for implementation** of disposable products and overcome.

Download Agenda

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