

Three ways to promote biologics viability from production line to patient

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In an increasingly competitive market, expediting drug development, approval and commercialisation of biologics in a bid to bring vital medication to market and achieve return on investment is key.

In response to this, clinical trials are shifting from developed nations to emerging countries that possess greater disease variationsⁱ and can represent more efficient and cost-effective operations. Simultaneously, the larger financial investments synonymous with biologics is increasing pressure on sponsors to optimise supply and minimise waste. This pressure is magnified by lower yields, short expiration and lack of stability data, which can make safeguarding product integrity and viability, from the process of development through to patient delivery, incredibly complex and risk intensive.

To overcome these challenges, ensure product viability at each step of the process and mitigate risk of waste, it's vital that solutions and strategies are selected that ensure biologics supplies are usable throughout the clinical life cycle. To achieve this, appropriate packaging strategies, flexible production and timely planning must be prioritised.

So, let's take a look at three ways sponsors can promote biologics viability from production line to patient.

1. Prioritise effective packaging materials and design

It's crucial that sponsors consider how products will be packaged for the clinic, especially when chosen materials become part of the stability protocol. When picking material, sponsors need to think about how easily it will translate when trials progress through the phases, enrollment becomes higher and shipments more frequent. If the packaging design is too specialised and rigid it might become more expensive and difficult to procure when quantities are ramped up. Likewise, if the design is too bulky it might become a rate limiting factor on whether an investigator's site can store the material or whether a bulk shipment is too large to be accommodated on the preferred flight routes.

Another important consideration when choosing the packaging material is storage conditions and material handling capabilities. For example, some drugs have strict limitations on how long or how often the product can be handled outside of storage conditions due to the expensive nature of the product.

To ensure appropriate materials and designs are selected, planning ahead and working in partnership with a specialist CDMO vendor to design the right packaging solution will ensure products remain viable throughout the journey to patients.

2. Incorporate production flexibility

The second key to success is to incorporate flexibility into the clinical supply chain so supplies can be optimised across a study or program. A 'Just in Time' approach is one way sponsors can achieve this flexibility.

Just in Time can range from a partial late-stage customisation, where an auxiliary label is added at the time of dispatch, to full late-stage customisation, where drug supply is maintained in its primary pack, (such as naked vials, ampules & syringes) until there is an actual site or patient need.

Just in Time Labelling (JTL) is ideal for quick additions to an already clinically labeled kit and is typically best suited to small molecule operations involving wallets and bottles. When it comes to biologics, Just in Time Manufacturing (JTM) can help create optimised and adaptive supply chains that promote enhanced product viability.

With a JTM model, the process of label printing and kit assembly for full late-stage customisation is initiated by drug order forms. This brings several key advantages for sponsors looking to optimise use of clinical supplies. Firstly, this approach provides sponsors with the ability to utilise single panel, country specific labels. This has been proven to decrease study start-up timelines by up to 50%, helping sponsors meet key study milestones faster and more cost-effectively. Secondly, it empowers sponsors to print study-specific labels with the most current label variables, such as the most recently approved expiry date. This helps to reduce waste and improve bigger picture efficiency. Finally, by delaying labelling and kit assembly until a precise need arises, supplies remain usable for any country or study, which drastically reduces the risk of costly stock outs.

3. Be pro-active and inclusive with planning

Considering a JTM approach at the time of protocol development is crucial to reducing waste and optimising clinical supplies. It's also important that sponsors leave enough time between patient screening, randomising and dosing visits in order to allow time for order submission, packaging and labelling operations. This will help ensure sponsors are able to ship the right treatment group to sites that will utilise the supplies, instead of stocking sites 'just in case' patient need arises. In this latter scenario, valuable supplies may never be utilised and may ultimately be sent for destruction.

By planning early, sponsors are also more likely to be able to standardise vital elements across pooled studies to achieve economies of scale, without giving up the flexibility required to share product.

For example, utilising the same kit components will allow sponsors to buy in bulk, plus standardising the fixed text on a label (using variable fields to distinguish between studies), will reduce the number of label proofs required across a multi-study program.

Finally, it's worth remembering that JTM is a relatively new approach and, although well suited to studies involving biologics and personalised medicines, it can conflict with established processes within sponsor companies. For sponsor quality units to provide the necessary endorsement, it's important to involve them early in the decision-making process. If they understand how a JTM approach can promote product viability and supply chain flexibility - and if they are able to qualify the process - they will be more likely to grant support and adopt any procedural changes that may be required. In addition, defining clear responsibilities in the quality agreement and agreeing parameters for performance management will keep things on track, while demonstrating the value of this innovative service.

Find out more about Almac Adapt:

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References

¹ Grand View Research: Clinical Trial Market Size, Share & Trends Analysis Report 2019-2026

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