Reference products for biosimilar development

Durbin Global is a leading specialist medical supplier with over 50 years' experience. The company is a wise choice for any developer of biosimilars looking to outsource the acquisition of reference products for clinical trials.

The European Medicines Agency defines biosimilars as "biological medicine that is similar to another biological medicine that has already been authorised for use". The medicine with which a biosimilar is compared is known as the reference product, which must be an established medicine that has been authorised for over ten years, with an expired patent protection. Obtaining these products can present regulatory and logistical challenges, but Durbin Global offers services to alleviate the stress, allowing biosimilar companies to focus on running clinical trials.

Reference products can be sourced directly from manufacturers or from the open market. The former is the most direct route, but can be challenging if a company does not have existing relationships with manufacturers.

Sourcing directly from manufacturers

Going straight to biologic licence holders to obtain reference products is not easy. Unless biosimilar companies are working in partnership with the licence holder, they may encounter barriers to accessing these products.

Alternatively, licence holders may decide that the development of a biosimilar of their product is inevitable, and strategically seek out partnerships with biotechnology companies to develop it collaboratively.

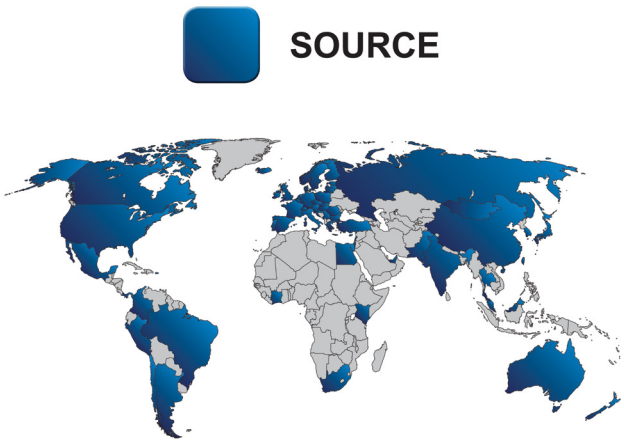
However, if a biosimilar developer chooses not to enter into a partnership, it may choose to outsource its reference drug supply to a specialist company such as Durbin Global.

Durbin Global has the market knowledge to deal with sourcing demands. It has excellent relationships with biologic licence holders and associated affiliates to leverage the supply of products.

When sourcing directly from the manufacturer is not possible, there are other options available. Typically, biotechnology companies opt for site sourcing, sourcing from the open market or using the services of a specialist comparator sourcing agent.

Site sourcing is when the pharmacy at each clinical trial location is given the responsibility of sourcing the reference products. This can enhance the efficiency of the process but does not provide an opportunity for the products to be blinded and is, therefore, only suitable for open-label trials.

An alternative strategy is to develop a network of global suppliers (typically wholesalers) and to source from them. However, this requires a team to identify and liase with, audit, approve and order from a large number of global suppliers, while also attempting to ensure the company incurs the lowest possible cost. The procurement process, therefore, can consume time and internal resources.



Durbin's sourcing network is composed of over 1,400 audited and regulatory-complaint suppliers spread across over 65 countries.

> "Specialists offer the ability to deal with origin-specific requests and have the market knowledge to navigate the challenges of the supply chain."

A more efficient option is to outsource this to a specialist comparator sourcing agent. Outsourcing gives a biosimilar developer instant access to a large, fully audited and regulatory-compliant supply chain. For example, Durbin Global has over 1,400 suppliers in more than 65 countries, allowing it to facilitate even the most difficult requests.

Specialists such as Durbin Global, are able to deal with origin-specific requests and have the market knowledge to navigate the challenges of the supply chain. They are also able to collate products at temperature-controlled, centralised warehouses, making shipments only when the client requires ensuring efficiency and minimising stock. ■

Further information
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