Speed to Biosimilars Market: How Digital Transformation Helps Win the Race

What to expect

With the global market for biosimilar drugs expanding rapidly, this white paper examines the importance for Indian pharmaceutical companies to effectively use digital tools to ensure they can conduct comprehensive, rapid data analysis throughout the path to market:

- See how data can help determine which biosimilars hold the most potential.
- Learn how digital tools can help break down the silos within a pharma organization and lead to better results.
- Discover what is required to complete the digital transformation of your enterprise so R&D can become more effective.

The biosimilar race

The race is competitive. The prize is huge.

But you can't win without your entire organization pulling in one direction and, if you have not completed your digital transformation journey, the benefits of enterprise-wide collaboration and data driven insights will continue to elude you.

The race is to get to market with biosimilar drugs ahead of the numerous other India-based pharma companies striving to do the same. Following the success of biologics, biosimilars offer a cost effective alternative to the high price point of patent protected, first-generation drugs. While generics must be identical in chemical composition to the original drug, biosimilars—which are far more complex—must be "highly similar" to another biological medicine in terms of structure, biological activity, and efficacy, safety, and immunogenicity profile.

The prize for overcoming the complexities of effective biosimilar scale-up is leadership of a sector that is undergoing a compound annual growth rate (CAGR) of more than 16 percent and is expected to be worth US$2.2 billion by 20251. And beyond a lucrative position in the burgeoning Indian market is the opportunity to compete effectively in a global biosimilars market that has a CAGR of approximately 30.9 percent and may reach a valuation of as much as US$60 billion by 20252. Since 2000, when the first Indian biosimilar was approved, the number that have successfully reached the market exceeds 95.

In the US, growth has been much slower, with only 33 biosimilars achieving FDA approval. Although the US proceeded slowly—judging each proposed biosimilar on a case-by-case basis, rather than establishing a so-called general guidance—it is anticipated the floodgates are primed to open since the approval in July 2021 of Semglee, an insulin therapy that became the first interchangeable biosimilar to be approved for sale in the country.

The need for rigorous analysis

To take advantage of that opportunity, the challenge that must be overcome lies at the very root of the difference between the creation of generic drugs and biosimilars.

Biosimilars have different challenges than small molecules due to their origin, manufacturing process, size, and structural complexity. Factors such as inherent biological variability, cultivation growth conditions, downstream processing, and purification techniques can pose safety, efficacy, and immunological risks—threatening the success of the project. The R&D costs associated with biosimilars are typically much higher than those for small molecules, and regulatory approval is based on the "totality of evidence" derived from the rigorous assessment of physico-chemical, biological characteristics, and the tight control of process parameters and stability assessment to ensure product integrity throughout the process.

The complexity of biosimilars means that workflows are also multifaceted, with many teams involved, and it demands they work in a highly agile manner, passing high volumes of data between them in ways unseen in typical drug development.

The absolute key question to be addressed is: How do you bring together data—which might be the source material, cell line, or whatever it is that is producing your protein or antibody—and relate that to the conditions in which it was grown, and then do that for all the samples and results that were collected?

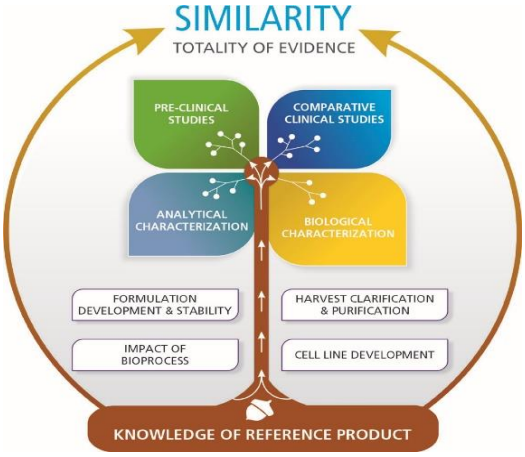

Figure 1: The Complexities of Biosimilar Development and Assessment Process

The keys to collaboration

One way to visualize the situation is as a tree, where each limb and branch reflects a different stage in biosimilar manufacturing. The level of variability in fruits from individual trees—as a result of their natural sensitivity to common growth conditions—impacts harvest quality, which determines total quality. In this regard, the entire tree and orchard represent different aspects of the manufacturing process, from cell culture to purification. As illustrated in Figure 1 the process leading to an ability to prove "similarity" has many steps and, as noted previously, it is not linear.

Promising "fruit" might well flower on individual branches, but unless you bring all the R&D outcomes together and analyze the full picture you can never really know if you have a successful harvest or not.

Is the fruit tasty? In good condition? Can the results on one branch influence what you do with all the fruit on all the other branches?

Complicating the process further, differing analytical techniques must be applied throughout this process. So, to extend the metaphor a bit further, how does an organization analyze the data from an entire orchard of trees and ensure results meet the demand for totality of evidence?

In the answer to that question lies the key to being able to scale up the ideal result quickly and efficiently, and replicate it at market scale. You cannot achieve that without effectively capturing the data produced by your various teams and analyzing it comprehensively.

Accomplishing that is virtually impossible if you are still using analog means to record data. Simply put, using spreadsheets will not work; aside from the high incidence of errors associated with paper-based records, spreadsheets just do not enable the pace required to scale up biosimilars quickly enough to compete with organizations that have already completed their digital transformation.

Focus on science, not software

As in all scientific processes, critical thinking and analysis lead to discovery, and with so much data associated with biosimilar R&D, only advanced data mining has the power to enable thorough analysis.

It must begin with effective digital data capture. An advanced electronic lab notebook (ELN) is essential if you are looking to create the ideal starting point for true, end-to-end digital transformation, with all the attendant benefits an enterprise-wide transformation can bring.

Revvity Signlas' ELN solutions—Signals Notebook and E-Notebook—were designed specifically to drive data transformation, enabling organizations to improve productivity and data transparency through enhanced collaboration, improved workflows, and lab automation. Delivering an outstanding user experience, our ELNs cover a comprehensive set of use cases, spanning biology, chemistry, formulations, analytical, and more. With a contemporary user interface that works and feels like those on many personal apps, our ELNs require little training, yet include a rich set of features that include:

- Scalable with powerful global search performance (i.e., access all data available via an ELN)
- Effective collaboration (i.e., re-use peer experiments and data for greater efficiency and productivity)
- APIs and interfaces that promote integration with other tools such as LIMS, CDS, bioreactors, and other systems
- Robust rule-based access control model with support for CROs
- Template management with table and form design
- Structured data capture with processing and analytics

As the leaders in the enterprise market, Revvity Signals', Signals Notebook and E-Notebook are ideal for both large- and small-molecule research. They support DNA and protein sequences, and have the flexibility and breadth to support a wide range of workflows, including chemistry, biology, formulations, and analytical sciences.

But capturing the data accumulated as you scale up your biosimilar R&D is just one piece of the puzzle.

Adding an analytics layer

It's also essential to conduct critical analyses of your data, and have the visualization tools required to accelerate research, drive innovation, and facilitate collaboration.

TIBCO® Spotfire® software—available exclusively from Revvity Signlas for scientific research and development applications—is the leading enterprise-class visual analytics and data discovery platform to enable your organization to easily mine scientific data and gain insights to make data-driven decisions in real time. Pr oviding unmatched performance, scalability, and security, TIBCO Spotfire's differentiating hybrid in-memory/ in-database analytics architecture supports the most demanding enterprise needs, easily scaling to thousands of users and limitless of rows of data. TIBCO Spotfire allows you to quickly uncover insights into your R&D data with features that include:

- Faster data exploration, interactive visualization, and intuitive filtering options make it easier to handle big data sets, limit the data size, and communicate the results effectively, without requiring IT interventions.
- Real-time display and analysis of bioreactor parameters, allowing users to better understand their correlations and apply control strategies.
- Unification of complex analytical and biological characterization data to efficiently create and visualize complex data models for instant insight.
- Immersive dashboards and advanced analytics, enabling everyone to explore and gain new insights into data.

TIBCO Spotfire uniquely offers inline data wrangling through a unified visual analysis and preparation interface to help you easily and rapidly clean and enrich data while performing analyses.

The analytic applications are easily customized, and the insights are yours to mine. It allows you to import data quickly and run visualizations almost instantly, with just a few clicks between set-up and critical insights into the effectiveness of your R&D efforts and the realistic market potential of your nascent biosimilars. By efficiently capturing and analyzing your data, with software that works the way you anticipate, you can get on with the important work at hand. As illustrated in Figure 2, Revvity Signlas' solutions can help accelerate the development of biosimilars from upstream to downstream processing and formulation by providing unified data management to acquire, explore, and analyze information from varied sources and make data-driven decisions.

Currently, more than one million scientists at 4,000 organizations are using Revvity Signlas' solutions to help them streamline their workflows, ensure they have the data required to make the best decisions, and to quickly and comprehensively analyze the information at their disposal.

Fueling up for the race

It has almost become a truism to state that, as a global whole, we will have squandered an opportunity if we were not to take important lessons from the pandemic that has dominated the world since 2020. One critical lesson related to pharmaceuticals is how much the sector can accomplish if it applies creativity, and moves beyond the traditional methodologies.

Like mRNA-based COVID-19 vaccines, biosimilars hold enormous potential to alter the worldwide environment for pharma development and to treatments. The projections of a near-40 percent CAGR and a valuation of US$60 billion may, in fact, prove to be conservative. More efficient R&D for biosimilars, a more open regulatory approach in the world's largest single market, and faster pathways to the market could upend those predictions, as optimistic as they are.

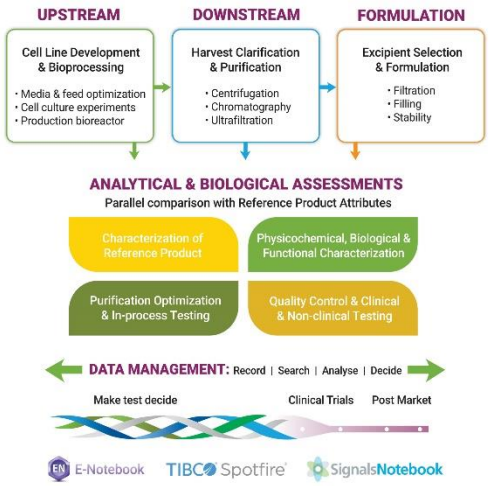

Figure 2: Leveraging Revvity Signlas' technology for faster data insights and decision making in biosimilars development

For any organization hoping to compete, the essential keys to success are effective, forward-looking management, control, and data analysis. It is no exaggeration to state that data is the fuel that will make India's biosimilar hopefuls serious contenders in this race. Conversely, ineffective collaboration will condemn potential competitors to the status of also-rans.

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