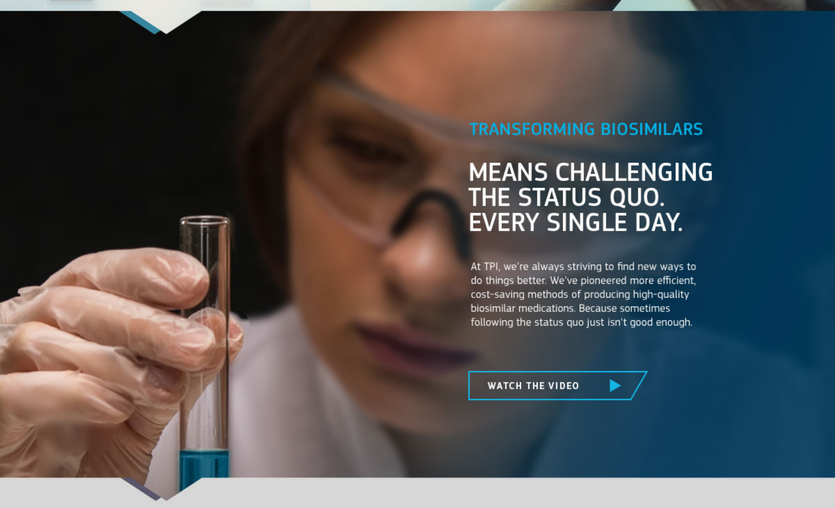
BIOSIMILARS ARE TRANSFORMING MILLIONS OF LIVES. AND ONE COMPANY IS TRANSFORMING BIOSIMILARS.

At TPI, our vision is to make affordable, high-quality biosimilar medications available to everyone in need. And we're determined to make that vision a reality.

SEE HOW



TRANSFORMING BIOSIMILARS

MEANS CHALLENGING THE STATUS QUO. EVERY SINGLE DAY.

At TPI, we're always striving to find new ways to do things better. We've pioneered more efficient, cost-saving methods of producing high-quality biosimilar medications. Because sometimes following the status quo just isn't good enough.

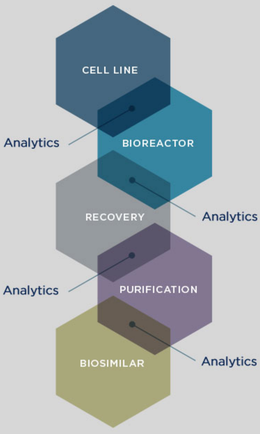
WATCH THE VIDEO

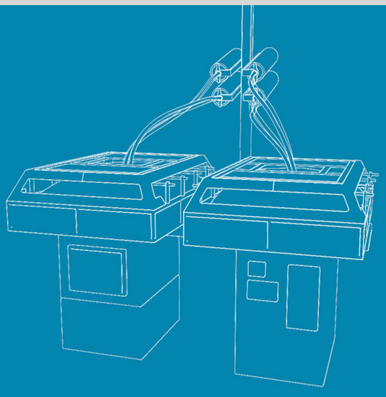
TRANSFORMING BIOSIMILARS

MEANS RIGOROUS TESTING EVERY STEP OF THE WAY.

TPI never compromises on quality. We have a rigorous, in-house characterization program that employs analytical testing throughout our streamlined process to monitor biosimilarity. Over 40 tests are performed to support biosimilarity, including proprietary test methods developed to support a strong foundation of analytics.

LEARN ABOUT OUR PROCESS





TRANSFORMING BIOSIMILARS

MEANS REINVENTING BIOREACTOR TECHNOLOGY.

Our patented single use, disposable MayaBio® technology is at the core of TPI's reimagined manufacturing process. This proprietary technology allows for increased efficency and flexibility. What's more, this technology also greatly diminishes the risk of cross-contamination.

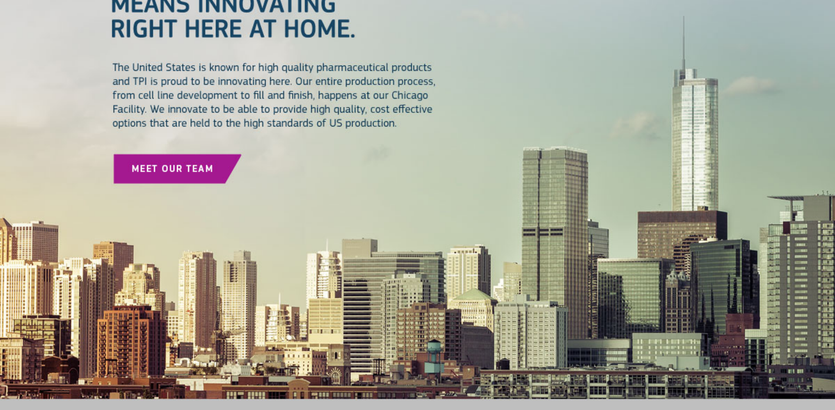
LEARN ABOUT OUR TECHNOLOGY

TRANSFORMING BIOSIMILARS

MEANS INNOVATING RIGHT HERE AT HOME.

The United States is known for high quality pharmaceutical products and TPI is proud to be innovating here. Our entire production process, from cell line development to fill and finish, happens at our Chicago Facility. We innovate to be able to provide high quality, cost effective options that are held to the high standards of US production.

MEET OUR TEAM



TPI IS REINVENTING THE BIOSIMILARS PARADIGM. TO PROVIDE QUALITY BIOSIMILARS TO PATIENTS.

TPI has deconstructed and reimagined every aspect of the traditional biosimilars manufacturing process. Our rigorous testing protocols, streamlined processes, and proprietary bioreactor technology help us make high-quality, life-altering biosimilars accessible to more patients around the world.

Watch Now

Rigorous Testing | Bioreactor Technology › | Streamlined Process ›

WE DO RIGOROUS TESTING. BECAUSE WE'RE COMMITTED TO QUALITY.

At TPI, we use multiple analytical tests to thoroughly characterize our product and confirm critical quality attributes are being met. We do that side-by-side with the reference product.

Each of the over 40 tests we complete evaluates a different attribute to tell a comprehensive story. At the end of the process we use this story, gathered at each step of the way, to support biosimilarity.

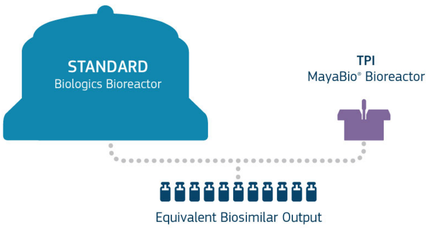
WE'VE REVOLUTIONIZED BIOREACTOR TECHNOLOGY. TO STREAMLINE THE MANUFACTURING PROCESS.

Our patented MayaBio® platform consists of a single-use bioreactor bag that can be used for both microbial and mammalian cell expression systems. It includes a proprietary system built to ensure that all cells are provided the optimal environment for growth. The gentle process takes into account the sensitivity required to develop high-quality biologics.

- Bioreactor Bag ›
- Oxygen Delivery ›
- Orbital Shaker ›

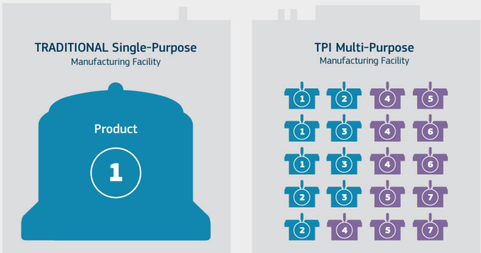
WE'RE OPTIMIZING BIOREACTOR INPUTS. WITHOUT SACRIFICING OUTPUT.

Bioreactor technology has evolved beyond the traditional stainless steel tanks. Our MayaBio bioreactor is a modular system with greater ability to provide a consistent, gentle environment for growth. The result is optimized product characteristics while maintaining equivalent expression.



WE EMPLOY AN AGILE, SCALABLE PROCESS. TO MEET EVOLVING DEMAND.

Traditional biologic manufacturing facilities focus on a single expression system while our MayaBio reactor can be used for both mammalian and bacterial fermentation in the same facility. The technology allows us to be agile so we can rapidly scale production or quickly transition between various products.



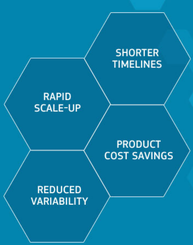
BACTERIAL OR MAMMALIAN
cell expression system

BACTERIAL AND MAMMALIAN
cell expression system

WE'VE SIMPLIFIED THE PROCESS. TO MAKE BIOSIMILARS MORE AFFORDABLE.

TPI utilizes a full integrated, multi-disciplinary approach to biosimilar manufacturing. Our streamlined approach simplifies the traditional process routinely used in manufacturing, without sacrificing quality. The result is shorter timelines, quicker scale-up, product consistency, and greater opportunities for cost savings.

TPI's production process is truly unique. Between 2009 and 2014, we've filed 36 patents, including patents for our bioreactors, cell harvesting, biosimilar purification, our facility, and characterization of biosimilars.



LEARN HOW BIOSIMILARS ARE TRANSFORMING HEALTHCARE ›

BIOSIMILARS: HELPING TO MAKE HEALTHCARE MORE AFFORDABLE.

Today, the healthcare landscape is rapidly evolving. One key factor driving this change is the increasing use of biologic medications. Biologic medicines offer important treatment options for disabling and life-threatening diseases.

Unfortunately, the cost of biologic drugs can be prohibitively expensive. With more patients now shouldering out-of-pocket medication expenses, there is an urgent need to provide greater access to more affordable biologics. Biosimilars offer the exciting possibility of providing patients with high-quality, affordable alternatives to biologic medicines.

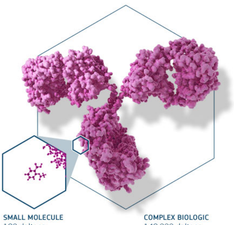
Biologics and Biosimilars | Regulatory Definitions › | The Approval Pathway ›

WHAT IS A BIOLOGIC?

Chemical drugs, like aspirin, are small molecules that are synthesized in a laboratory. Because they are derived from chemicals with fixed structures, they can be fully characterized by analytical techniques.

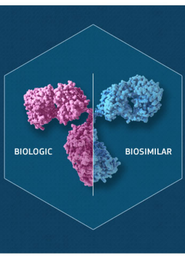
In contrast, biologic drugs, or biologics, are large, complex molecules designed to specifically interact with other protein molecules in the body. Due to their complexity, biologics can only be manufactured in living cells.

Because of this, biologics cannot be fully characterized, as can chemical drugs. Consequently, biologics require robust, extensive testing programs to ensure quality and consistency.



SMALL MOLECULE
180 daltons

COMPLEX BIOLOGIC
148,000 daltons



WHAT IS A BIOSIMILAR?

Simply put, a biosimilar is a reproduction of a previously approved, or reference biologic. Since a biosimilar protein has the same structure, and has been proven to be "highly similar" to the reference product through comprehensive analytical testing, a biosimilar can be approved to treat the same medical conditions.

Biosimilars follow a new FDA approval pathway, which is collaborative and focuses on strong analytics as a foundation. Because biosimilars may not require as extensive clinical trials as the reference biologic and their development process can be accelerated, the result is more cost-effective options for the patient.

WHERE ARE BIOSIMILARS CURRENTLY AVAILABLE?

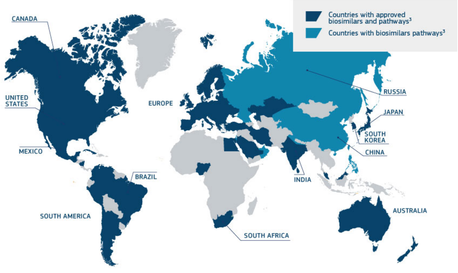
Biosimilars are not new. They are available worldwide through biosimilar approval pathways implemented in countries across the globe.

The European Union has been approving biosimilars for almost 10 years. Multiple biosimilar products have been authorized in the EU since 2006. Other highly regulated markets such as Japan, Australia, and Canada have been approving biosimilars for more than 5 years.

To date, millions of patients have already received treatment in highly regulated markets with the same level of safety and efficacy as the reference biologics. The first biosimilar was approved in the United States in 2015.

As biosimilars continue to become more prevalent and accessible, experts predict savings could range from $44 to $250B over the next 10 years.[2]

GLOBAL BIOSIMILAR ACTIVITY



HOW ARE BIOSIMILARS DEFINED BY REGULATORY BODIES?

The common thread across definitions of biosimilars articulates the essence of what biosimilarity aims to achieve: a safe product with no clinically meaningful differences from the reference biologic product.

The US Food and Drug Administration:

> A biological product that is highly similar to a US licensed reference biological product notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product.

Read more ›

The European Medicines Agency:

> A biosimilar is a biological medicinal product that contains a version of the active substance of an already authorized original biological medicinal product (reference medicinal product). A biosimilar demonstrates similarity to the reference product in terms of quality characteristics, biological activity, safety and efficacy based on a comprehensive comparability exercise.

Read more ›

The World Health Organization:

> A biotherapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product.

Read more ›

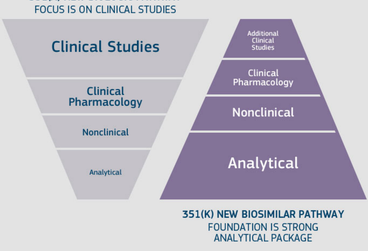
HOW DOES THE FDA ASSESS BIOSIMILARS?

Biosimilars were enabled in the US through the Biologics Price Competition and Innovation Act (BPCIA) of 2009 and the passing of the Affordable Care Act (ACA) in 2010, followed by FDA draft guidelines in 2012. These events established a new streamlined regulatory pathway specifically for approval of true biosimilars, the 351(k) pathway. After the FDA approves a biosimilar through this pathway, the biosimilar may be indicated for the same medical therapies as the reference biologic.

ASSESSING SIMILARITY | APPROVAL PROCESS › | 351(K) PATHWAY › | NEW PARADIGM ›

HOW DO THE 351(K) AND 351(A) REGULATORY APPROACHES DIFFER?

The foundation for approval of biologics under the 351(a) pathway is an extensive clinical trial program, while the foundation for approval of a biosimilar under the 351(k) pathway is a robust analytical package that ensures meticulous similarity to the reference biologic.



LEARN ABOUT OUR PRODUCTS ›

References

1. Blackstone EA, Fuhr JP. The economics of biosimilars. *Am Health & Drug Benefits*. 2013;6(8):469-477.
2. Mulcahy AQ, Predmore Z, and Mattke S. The cost savings potential of biosimilar drugs in the United States. Available at http://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf. Accessed February 10, 2015.
3. TPI "Biosimilar Global Outlook", IMS, 2015 Express Scripts Drug Trend Report.