PPD® CONSULTING

BIOSIMILAR DRUG DEVELOPMENT

PPD® CONSULTING

ACCELERATING BIOSIMILAR DEVELOPMENT SAFELY AND EFFECTIVELY.

PPD CONSULTING:
OUR EXPERTS ARE YOUR EXPERTS

PPD provides consulting on a wide variety of product development and pharmaceutical issues across all major therapeutic areas. Our seasoned team of physicians, scientists, regulatory professionals and biostatisticians brings first-hand knowledge of clinical, regulatory and commercial program strategies to help ensure your product's success.

In a biopharmaceutical environment that has become increasingly competitive, biosimilars present a continuously evolving opportunity for the industry. This "follow-on" market is expected to grow significantly within the next three to five years—fueled by the fact that many innovator biologics are losing patent protection.

Biosimilars represent a viable way for companies to fill expanding pipeline gaps. They also expand access to life-changing and life-saving therapies for patients by providing less expensive versions of already-marketed biologics.

Along with the promise of biosimilars comes a host of challenges. Unlike small molecule generic drugs, the development of large molecule biosimilars involves significant complexities. A biosimilar must be "highly similar" to its parent biologic in safety, purity and potency.

PPD is at the forefront of helping our clients understand and navigate a growing, changing biosimilars environment. We offer a full range of biosimilar drug development services, from cell line development and characterization to clinical development and market approval. Our seamless approach includes structural and functional comparability of products; chemistry, manufacturing and controls (CMC) support (cGMP and bioanalytical labs); preclinical development; pharmacokinetic/pharmacodynamic (PK/PD) analysis; regulatory affairs; clinical development; and biostatistics.

PARTNERING FOR STRATEGIC SUCCESS

The biosimilar market is expected to grow to $3.7 billion by 2015.*

There's a tremendous amount of opportunity—and a lot at stake. PPD can help you realize success in this evolving landscape.

*SOURCE: Datamonitor

COMPREHENSIVE EXPERTISE IN EMERGING AND DEVELOPED MARKETS LEADS THE WAY TO DEVELOPMENT SUCCESS

THE GLOBAL RESOURCES AND NETWORK YOU NEED

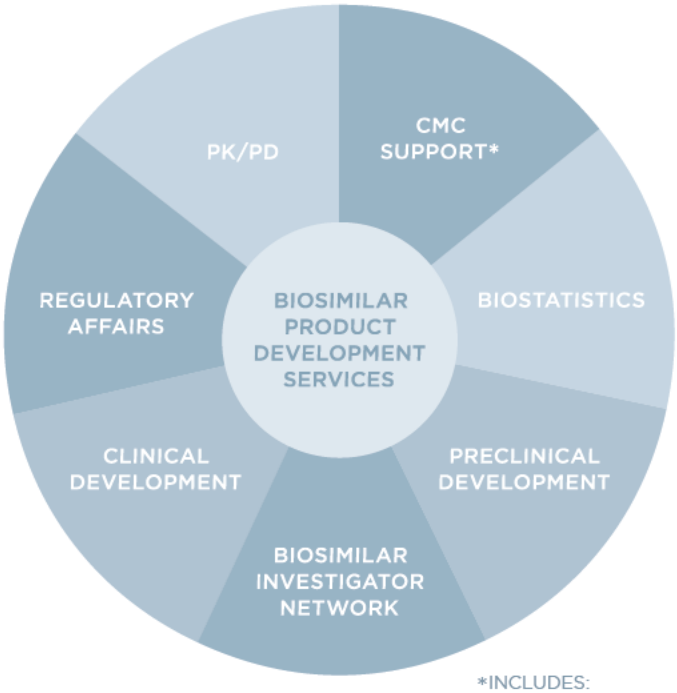
From beginning to end, PPD provides a solid foundation of expertise and the global resources to execute biosimilar product development programs. Partner with PPD and gain access to:

+ A multi-disciplinary team of experts who know how to meet all product comparability requirements in both emerging and developed markets
+ In-depth knowledge of the biosimilars regulatory landscape to ensure products meet regulatory requirements around the globe
+ Customized biosimilar programs that support the marketing authorization application process for both emerging and developed markets
+ End-to-end cell line development and characterization, clinical development and laboratory services
+ A global biosimilar investigator network consisting of investigators with a broad range of therapeutic specializations

The biosimilar development process is highly complex. It's also different for every client and every product. At PPD, you'll find the expertise and resources required to build the specific program you need.

SPANNING THE ENTIRE CONTINUUM OF BIOSIMILAR PRODUCT DEVELOPMENT

Regardless of where you are in the biosimilar product development process, PPD has the expertise you need—surrounding your product with the support it requires to recognize its full potential.



*INCLUDES:

+ cGMP Labs
+ Bioanalytical Labs

BENEFIT FROM COMPREHENSIVE EXPERIENCE THROUGHOUT THE PRODUCT LIFE CYCLE

PPD's comprehensive biosimilar development experience brings you confidence that your development program will stay on track. And, our expertise spans the therapeutic spectrum—from hematology and oncology to autoimmune diseases and other therapeutic areas where biologics are frequently used.

EXPERIENCE YOU NEED

From cell line development and characterization through post-approval and labs, PPD has extensive and growing biosimilar product development experience:

cGMP LABS	BIOANALYTICAL LABS	DEVELOPMENT PLANS	CLINICAL TRIALS	GLOBAL FEASIBILITY	REGULATORY CONSULTING
Etanercept	Pegfilgrastim	Pegfilgrastim	Epoetin	Trastuzumab	Epoetin
Rituximab	Filgrastim	Filgrastim	Filgrastim	Rituximab	Filgrastim
Trastuzumab	Rituximab	Rituximab	Infliximab	Epoetin	Infliximab
Filgrastim	Trastuzumab	Trastuzumab	Rituximab	Infliximab	Rituximab
Insulin	Bevacizumab	Cetuximab		Pegfilgrastim	Adalimumab
Adalimumab	Etanercept	Adalimumab		Adalimumab	
Somatotropin	Cetuximab	Bevacizumab		Etanercept	
Erthyropoetin	Epoetin	Etanercept			
Calcitonin	Dalteparin	Epoetin			
Enoxaparin	Enoxaparin				
Dalteparin	Insulin				
Interferon B	Salmon Calcitonin				
Leuprolide	Somatotropin				
Infliximab					

PPD has supported all of the top 10 selling biological products and has conducted studies on biologics involving more than 260,000 patients and 20,000 sites globally.

A SEAMLESS APPROACH TO DELIVERING END-TO-END SERVICES KEEPS YOUR PRODUCT ON TRACK

The complexities of biosimilar product development demand the same level of support and expertise found in novel product lifecycle development. PPD has the industry-leading capabilities and experience to provide this level of expertise.

Our biosimilar development services group ensures that your program is fully integrated and streamlined in a way that results in maximum efficiencies and effectiveness. Our seamless development approach includes integrating structural and functional comparability assessments with the clinical program and regulatory submission strategy in a step-wise fashion to reduce residual uncertainty. This approach may minimize the clinical program needed to demonstrate similarity. At every point, your program receives comprehensive, multi-disciplinary oversight through services that include:

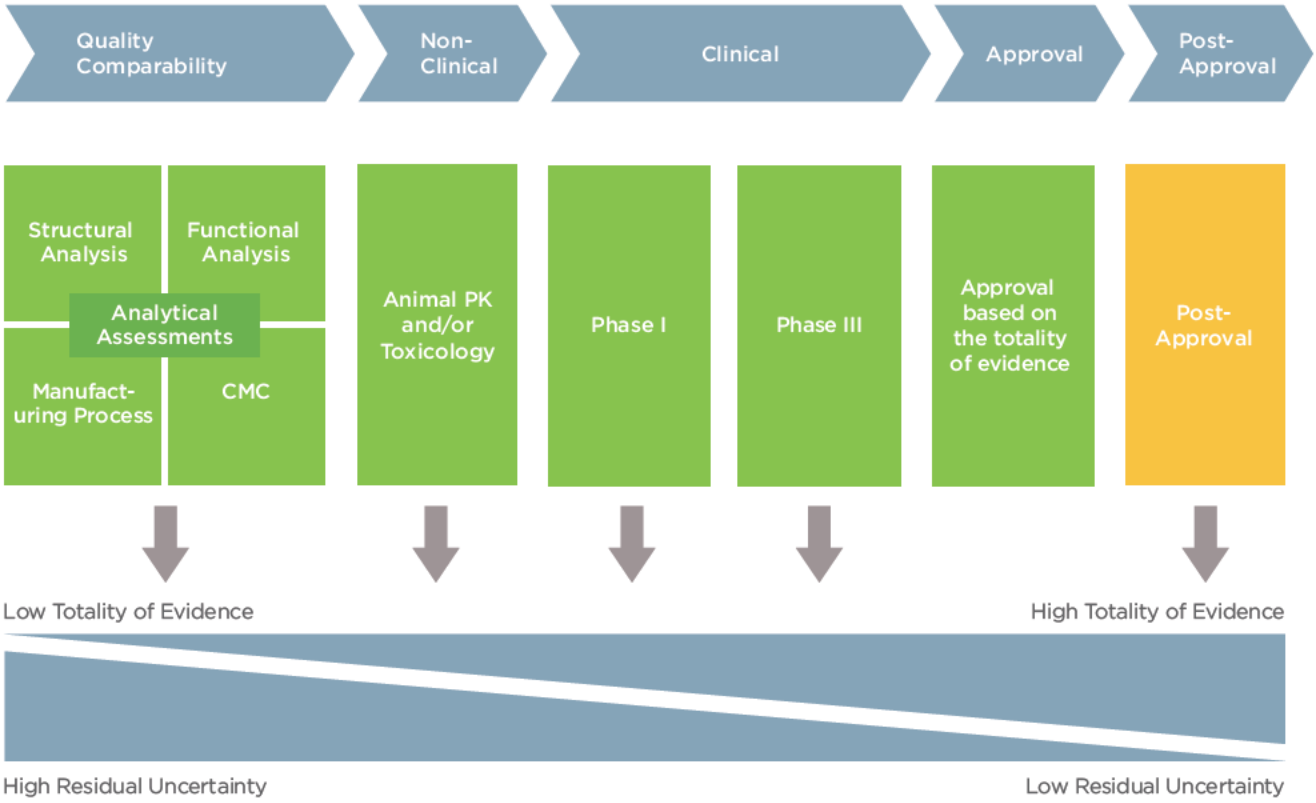
+ CMC development
+ Biophysical characterization
+ QC comparability analysis
+ Preclinical planning and assessment
+ Bioanalytical and PK analysis
+ Immunogenicity analysis
+ Regulatory strategy
+ Biosimilar clinical development planning and trial design
+ Clinical operations and study execution
+ Biosimilar investigator network

PPD provides comprehensive Phase IV and pharmacovigilance services that help you remain in control of ongoing safety monitoring for your product. Post-approval services include:

+ Individual Case Study Reports (ICSR) assessment, triage and processing, as well as follow-up requests
+ Global regulatory reporting
+ Safety and immunogenicity evaluation
+ Global literature surveillance
+ Aggregate reporting (e.g., periodic safety update reports and periodic adverse drug event reports)
+ Risk management strategies

Our pharmacovigilance group consists of more than 400 highly skilled medical and safety professionals who have a comprehensive understanding of local and global regulatory standards and who provide safety coverage 24 hours a day, seven days a week.

SEAMLESS DEVELOPMENT



TAKING THE LEAD IN BIOSIMILAR DEVELOPMENT MEANS **LEADING THE WAY WITH SCIENCE**

First and foremost, success in biosimilar development requires a deep understanding of the science. Our multi-disciplinary team of scientists has an average of 16 years' experience dedicated to biologics. This team has been intricately involved in the development of novel biologics for large pharmaceutical companies prior to joining PPD. Our experience includes developing customized biosimilar development programs aimed at supporting marketing authorization application for emerging and developed markets.

+ Reviewing manufacturing, packaging, testing and preclinical development
+ Customizing pharmacologic and statistical methods to demonstrate comparability
+ Conducting safety and immunology assessments
+ Serving as advisors on global regulatory assessments
+ Providing design or input and support for ongoing clinical programs
+ Executing clinical programs and conducting feasibility assessments

NAVIGATING THE REGULATORY LANDSCAPE — LOCALLY AND GLOBALLY

The regulatory landscape is constantly evolving. PPD has experts with intimate knowledge of local regulatory requirements in developed and emerging markets. We have forged relationships with treatment specialists, and our clients can be assured that their products are moving through the development process safely, effectively and in full compliance.

BIOSIMILAR ADVISORY BOARD

PPD has established a global Biosimilar Advisory Board made up of investigators who are pioneers in biosimilars within their respective countries. PPD's Biosimilar Advisory Board members represent various specialties in the area of biosimilar development and work with PPD to evaluate, design and execute biosimilar clinical development programs.

PPD clients engage our advisory board members to provide insight into biosimilar protocol designs and study conduct to maximize investigator's interest in biosimilar trials and optimize clinical trial enrollment.

PROVING COMPARABILITY WITH CUSTOMIZED ASSESSMENTS

When developing biosimilars, the focus is on proving comparability with the reference product in regard to safety, purity and potency. With PPD as your partner, you can be confident your product will demonstrate its full potential.

Our seamless approach to ensuring that comparability is successfully addressed involves providing our clients strategic consultation and designing customized programs that include:

+ Structural and functional comparability assessments
+ Pharmacological studies to establish comparable potency and biological activity
+ Toxicology studies
+ Clinical trials designed to demonstrate comparability
+ Post-approval commitments

To learn more about how a partnership with PPD can help you enhance your biosimilar product development program at any stage, please contact us at ppdinfo@ppdi.com or +1 877 643 8773.