REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Biosimilar Services

What are Biosimilars?

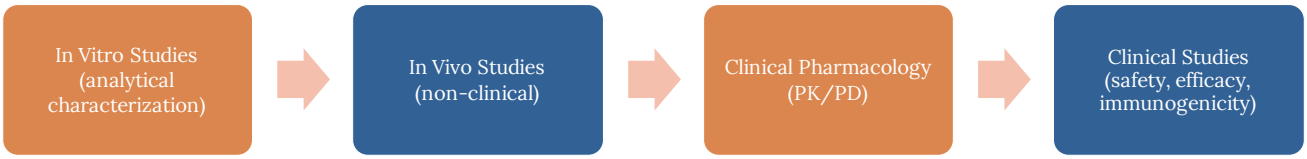
Biosimilars

- Biosimilars are biologics that have been proven to be as safe and efficacious as the innovator biologic drugs
- Biosimilars deliver comparable clinical, quality and safety results as innovator biologics
- Biosimilars can cost 20-30% less than innovator biologics

Biologics

- Unlike small molecule drugs that are synthesized in a laboratory, biologic drugs are produced from a living organism
- From bio engineering utilizing the right cells, scientists are able to produce biologic medicines
- Biologics can cost >$100,000/year

What is the Biosimilar Development Pathway?



For a successful biosimilar, a sponsor must be able to demonstrate comprehensive analytical similarity, from molecular structure and stability through receptor binding and functional activities. Following a successful demonstration of structural and functional similarity, it is necessary to demonstrate the safety and equivalent efficacy of the proposed biosimilar in a nonclinical setting through the use of animal toxicity studies, PK/PD studies and other testing as necessary.

How RCA can help you with your biosimilar?

At Regulatory Compliance Associates Inc. (RCA) we understand the extraordinary complexities involved in biosimilar drug development. As former FDA officials and industry leaders, RCA's Subject Matter Experts understand what FDA's Pharm/Tox reviewers will be expecting from a successful application and we can provide guidance on which approaches, studies and tests will best alleviate the Agency's concerns while minimizing development costs and time to market. We pride ourselves on understanding the factors involved in the FDA decision-making process at every stage of the development process and leverage that expertise to position our clients for successful outcomes. Our expertise allows us to recommend strategies that minimize a product's time to market.

Product Development

1. Our consultants will collaborate with your team to:
    - Assess your biosimilar development plan
    - Define all applicable scientific and regulatory requirements
    - Craft a customized product development strategy that minimizes cost and time to clinical trials, regulatory approval and commercialization. We will assist you every step of the regulatory path.
2. RCA has an established referral network that works for sponsors of all sizes. It allows you to choose resources needed while leaving the upfront vendor qualification and scope of work oversight to us.

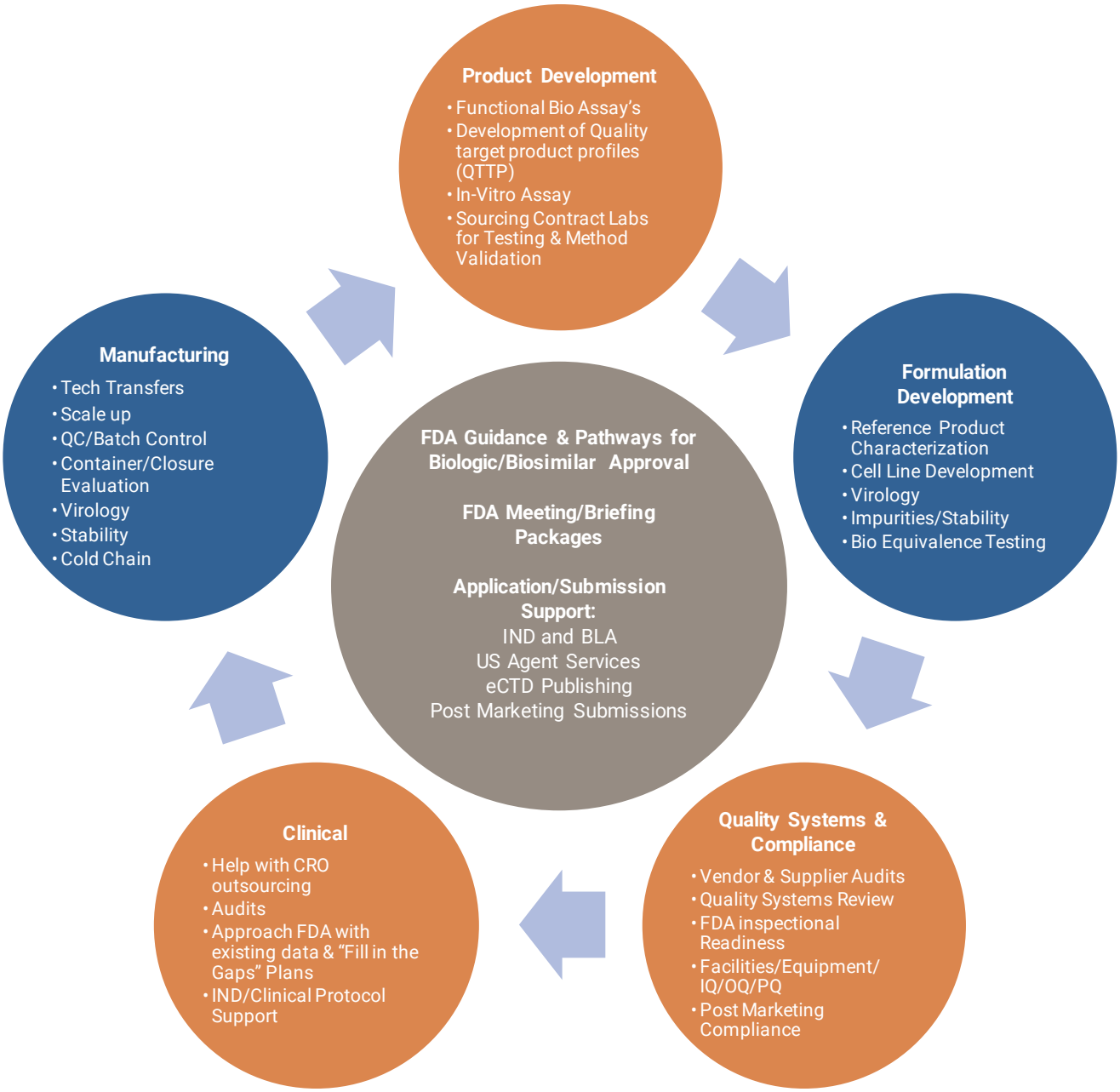
Throughout your product development process, we focus on helping to design processes that gather the molecular, nonclinical and clinical data necessary to justify extrapolation to other clinical indications, thereby maximizing your market opportunity while lowering development costs.

Regulatory Affairs

RCA has an established regulatory team composed of full-time employees and former FDA Officials to:

- Create or assist with the refinement of regulatory strategy
- Advise on regulatory options and potential pathways
- Assist with preparations for FDA and Advisory meetings
- Represent clients in interactions with FDA and author
- Review and publish original briefing packages, IND, and BLA applications, amendments and supplements.

Biosimilar Development Process:



Why Choose RCA?

- We are widely recognized within the life science industry for our ability to help companies successfully deal with complex regulatory challenges.
- We have the know-how and insight on how CDER and CBER think. We maintain current FDA contacts and are able to get in touch with FDA on your behalf when time is critical.
- We know how to partner with your executive, legal and communication teams.
- We support management to assist with the growing and changing concerns.

Quick Facts About RCA:

- Founded in 2000
- Headquartered in Southeastern Wisconsin with offices in West Central Florida, Northern Colorado & Central Eastern Europe
- Expertise backed by over 500 industry and FDA subject matter experts
- Regulatory Submissions in 196 different countries / dependencies
- Engagements on four continents

RCA SERVES *the* WORLD

ISO 9001:2015 CERTIFIED

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