



Global Biologics Testing Solutions

Kerstin Dolph
Corporate Vice President,
Global Biologics Testing Solutions

Premier, Global CRO to Support Biologics Manufacturing



>10%
Consistent,
strong revenue
growth

**Rapidly
growing
market** fueled
by increasing
number of
biologic drugs
in the pipeline



One of the
Leading
CROs in
\$1.4B-
\$1.7B
addressable
market

Ongoing capacity
expansion
expected to yield
**margin
expansion**
opportunities in
2020 and beyond

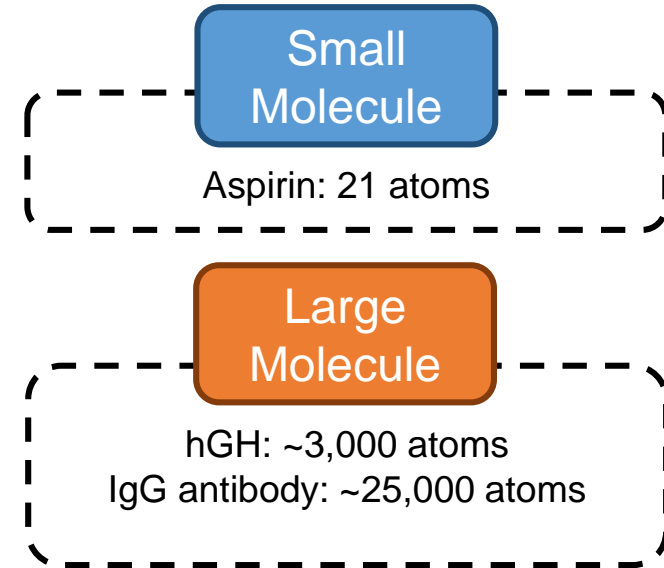
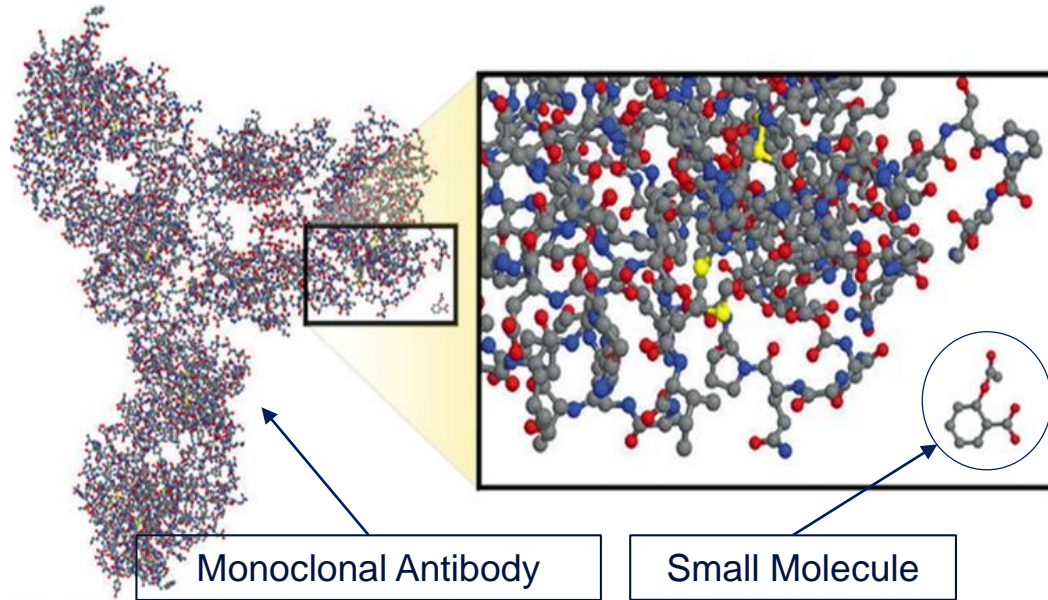


Biologics Testing Solutions Overview

- Premier global CRO providing services that support our clients' **manufacture of biologics**
 - Providing **testing and assay development** from drug development to market
- Biologics testing is an essential, fast-growing market, expanding in the **low-double digits** year-over-year
- CRL is actively **investing in capacity** and expanding capabilities through internal development and M&A to meet increasing client demand



Biologics vs. Small Molecule



Purity

Creating a biologic with hundreds or thousands of processes makes purity a challenge



Stability

Ensuring a protein that came from a living cell is exactly what it is supposed to be is much more difficult than ensuring bioequivalence of a small molecule



Function

The function of a protein can vary widely with small changes to one of its many complexities

CRL Offers Solutions to Address Biologics' Complexity

Analytical/
Structural

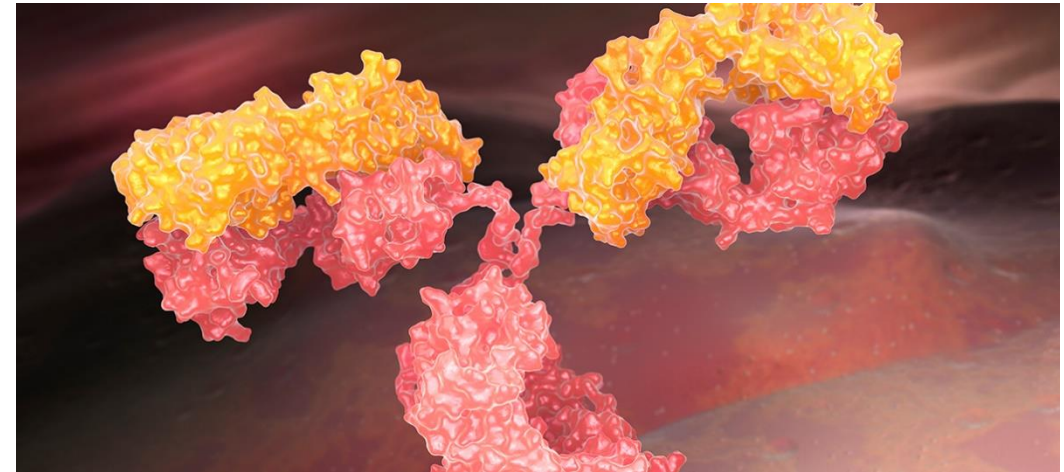
- **Characterizing biologics** is significantly more difficult than small molecules, involving numerous and complex tests

Clearance/
Biosafety

- **Production via living systems** (i.e., E.coli, yeast, or mammalian cells) requires additional biosafety testing assays

Potency/
Efficacy

- For **patient safety**, FDA requires more detailed structural and stability analysis of biologics and biosimilars

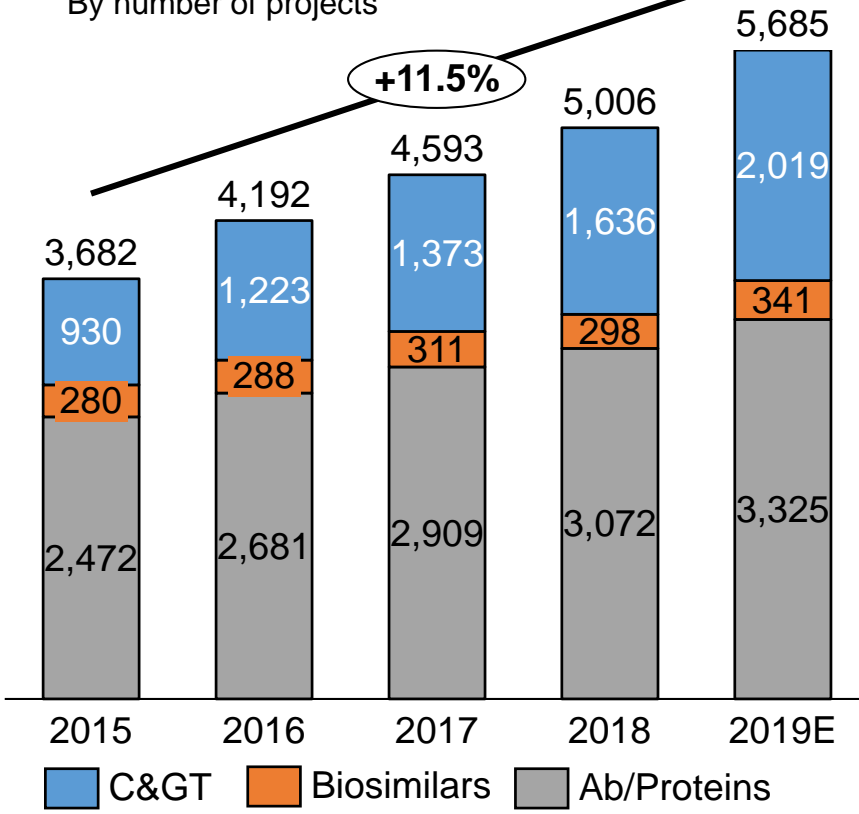


Biologics require significantly more analytical and biosafety testing from discovery through manufacturing and commercialization due to their larger size, complexity, and production in living systems

Significant Biologics Market Growth

Biologics Pipeline Projects (2015-2019E)

By number of projects



- C>**
21% CAGR
- Biosimilars**
6% CAGR
- Ab/Proteins**
8% CAGR

Key Information

- “New Biologics,” emerging market
- Smaller opportunity, moderate growth
- “Old Biologics”
- Strong but slowing growth
- “Old Biologics”

Key Drivers

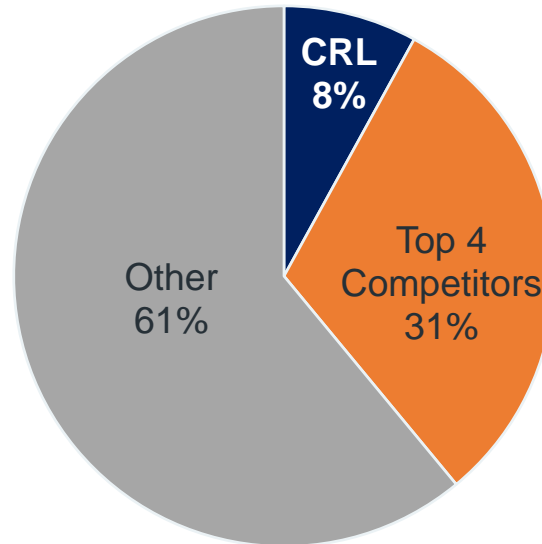
- Includes cell, gene, and stem cell therapies, and some viral vaccines globally
- Biosimilar development in Asia/ROW
- “Old” innovator (or novel) biologics represent a large and more mature manufacturing/testing area in North America and Europe

Biologics market is growing in the low-double digits, primarily driven by cell/gene therapy projects



Biologics Testing Market Environment

Biologics Testing Market Share



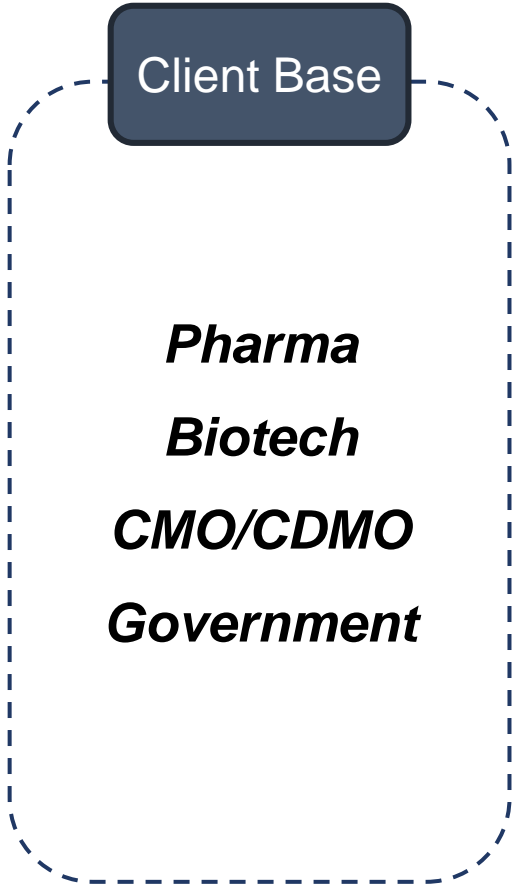
Source: CRL management estimates

Clients

- Need **end-to-end** solutions
 - Including global regulatory expertise
- Many **lack infrastructure** and must **outsource**

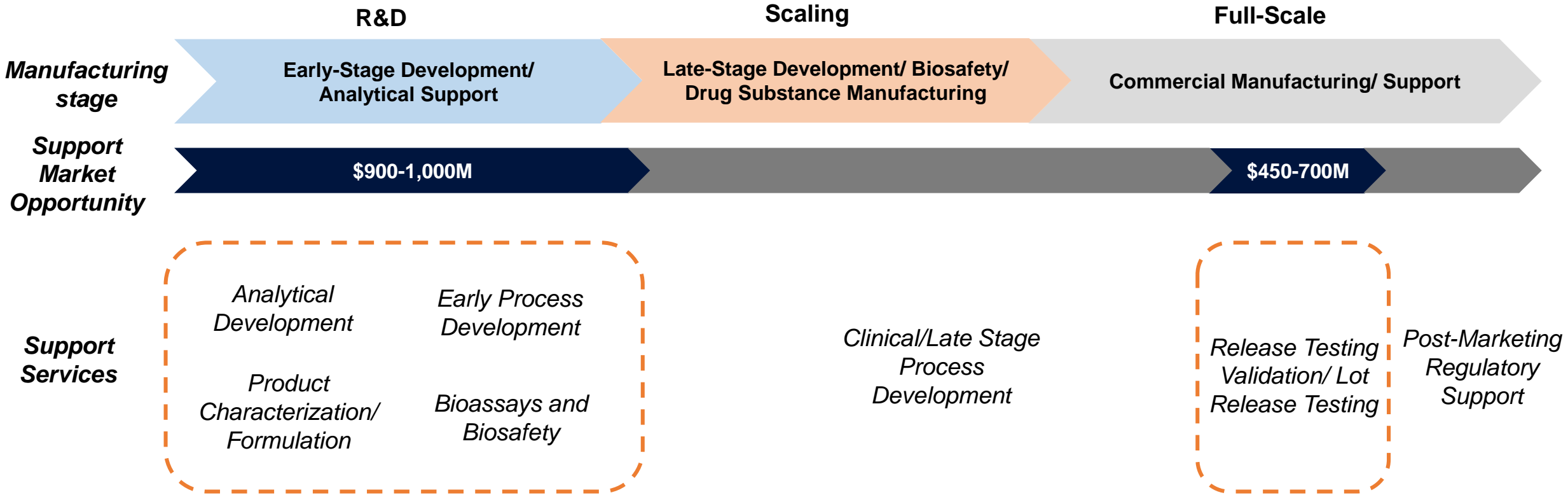
Fragmented Market

- **Highly fragmented** landscape
- Only 6 global full-service providers
- Many small/niche players



Biologics Market Opportunity

Key:
 CRL Biologics Offering
 Limited or No Offering



**Outsourced Market for Current CRL Service Areas
 \$1.4B-\$1.7B**

Cell and Gene Therapy (C>) Offerings at CRL



Analytical Support

Develop, qualify, and validate testing methods required for product identity, purity, and potency



Safety Testing

Assure products are free of contamination from virus, microbial contaminants, or harmful process chemicals



Cell Bank Manufacturing

Prepare and characterize the cell banks that are used in large-scale biologics manufacturing process

Who do we serve in C>?

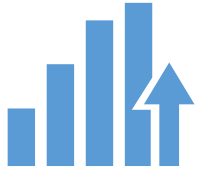
Recombinant and Monoclonal Antibody Therapeutic Proteins

Protein and Viral Vaccines

Gene and Cell Therapeutics

Microbiome Therapeutics

Global Footprint Proximate to Clients



Global Expansion

Capacity expansions in U.S. and Europe to accommodate increasing client demand



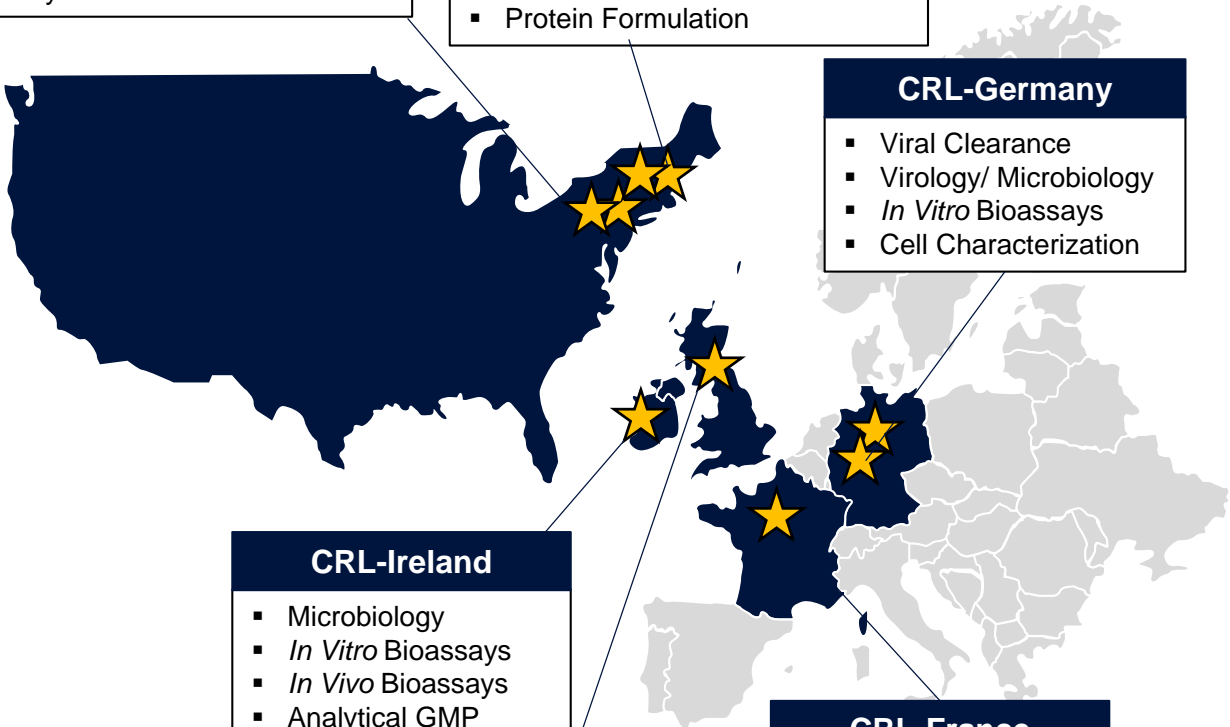
Expansion in action at Pennsylvania

Transition to new Pennsylvania site throughout 2019; Provides capacity to support U.S. growth for next 3-5 years

- ### CRL-Pennsylvania
- Cell Banking/ Characterization
 - Biosafety
 - Viral Clearance
 - Analytical GMP

- ### CRL-Massachusetts
- Analytical GMP/ Stability
 - In Vitro Bioassays
 - In Vivo Bioassays/ Lot Release
 - Protein Characterization
 - Protein Formulation

- ### CRL-Germany
- Viral Clearance
 - Virology/ Microbiology
 - In Vitro Bioassays
 - Cell Characterization



- ### CRL-Ireland
- Microbiology
 - In Vitro Bioassays
 - In Vivo Bioassays
 - Analytical GMP

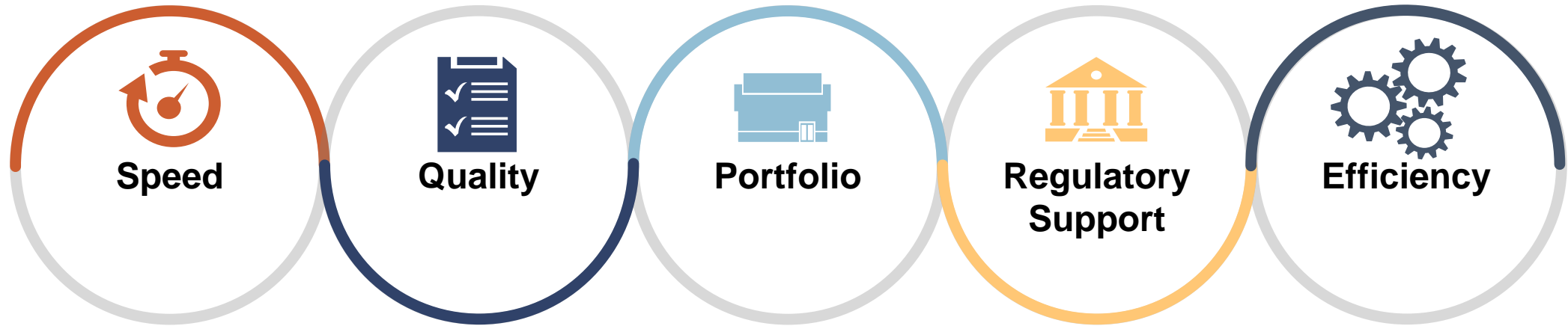
- ### CRL-UK
- Analytical Dev.
 - Analytical GMP
 - In Vitro Bioassays
 - In Vivo Bioassays

- ### CRL-France
- In Vivo Bioassays

➤ **Short-term** margin headwind from capacity expansion will yield long-term benefits and operating margin leverage

- Pennsylvania expansion reduced 1H19 Manufacturing segment operating margin by ~60 bps
- Margin headwind will be eliminated by year-end 2019 and Biologics profitability expected to meaningfully improve in 2020

Biologics Growth Strategy



Speed

*Expand **global footprint** and **capacity**, and invest in **technologies** to enhance speed & responsiveness to our clients*

Quality

*Maintain and enhance reputation for **best-in-class** service and **customized** solutions*

Portfolio

*Continue to build **full-service testing portfolio** to support “New Biologics” through industry-leading scientific expertise*

Regulatory Support

*Focus on regulatory compliance through best-in-class **regulatory expertise** and **IT platforms***

Efficiency

*Focus on optimizing operational efficiencies through **automation** and enhanced **process analysis** resulting in operating margin improvement*