



charles river

Meeting with Management

Biologics Solutions (including CDMO)

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Focus Areas of Today's Discussion on Biologics Testing & CDMO



Biologics Focus

- Both Biologics Testing and CDMO have significant growth potential from the proliferation of biologics and cell and gene therapies (C>) in drug development pipelines
- Biologics Testing performs release testing required for every commercial batch – a more resilient revenue stream

Commercial Readiness

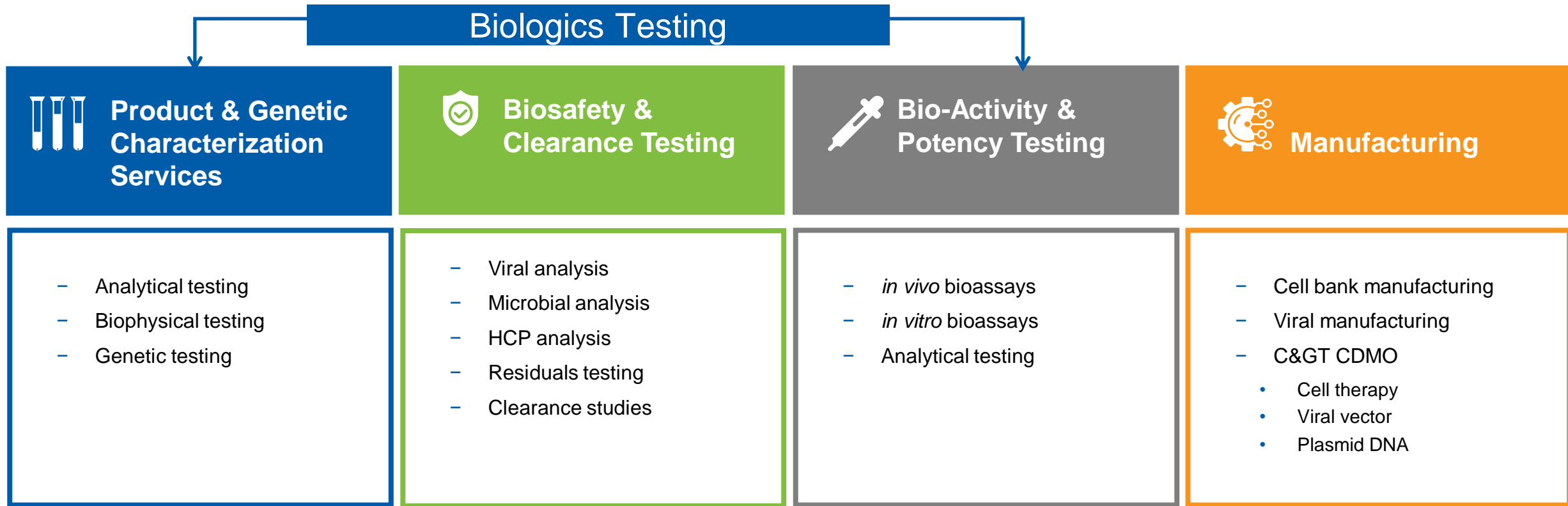
- Focused on regulatory compliance and after the completion of several regulatory inspections by our CDMO business, we are ready to grow and scale with our clients

Powerful Synergies

- Providing competitive timelines due to our comprehensive offering combining C> production and our extensive testing capabilities

Biologics Solutions

Providing reliable, innovative, scientific solutions to ensure the safety and efficacy of clients' products

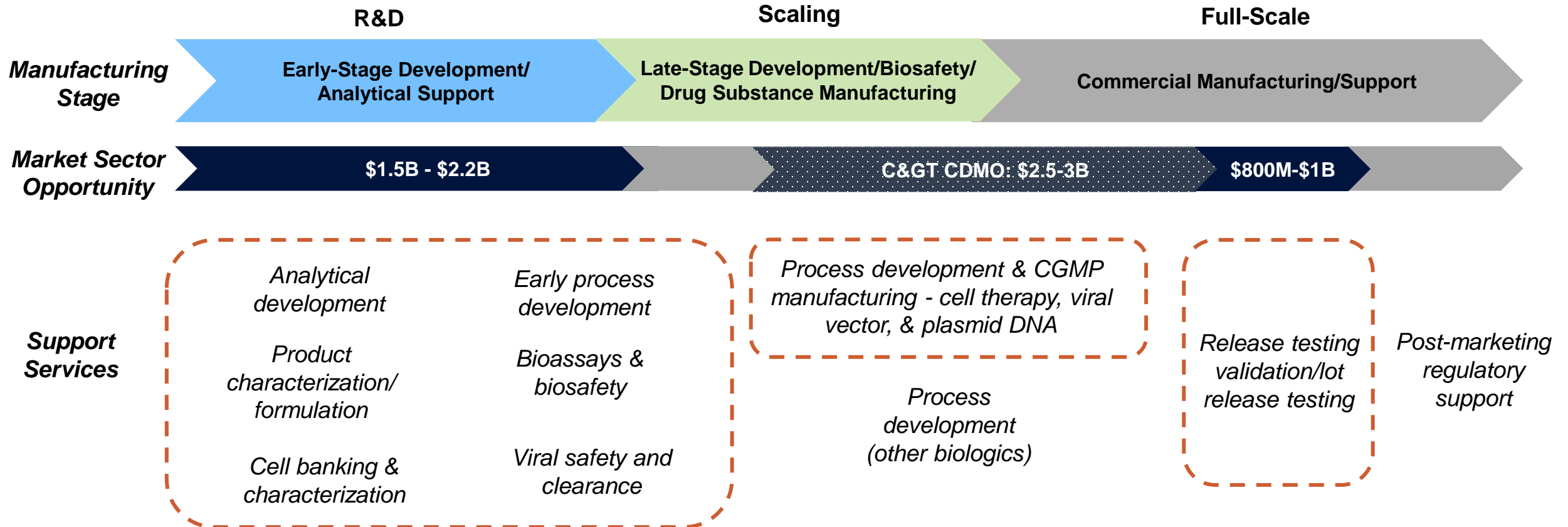


With 50 years of experience, CRL's comprehensive in-house testing portfolio supports biotechnology and pharmaceutical companies worldwide

Biologics Market Sector Opportunity

Key:

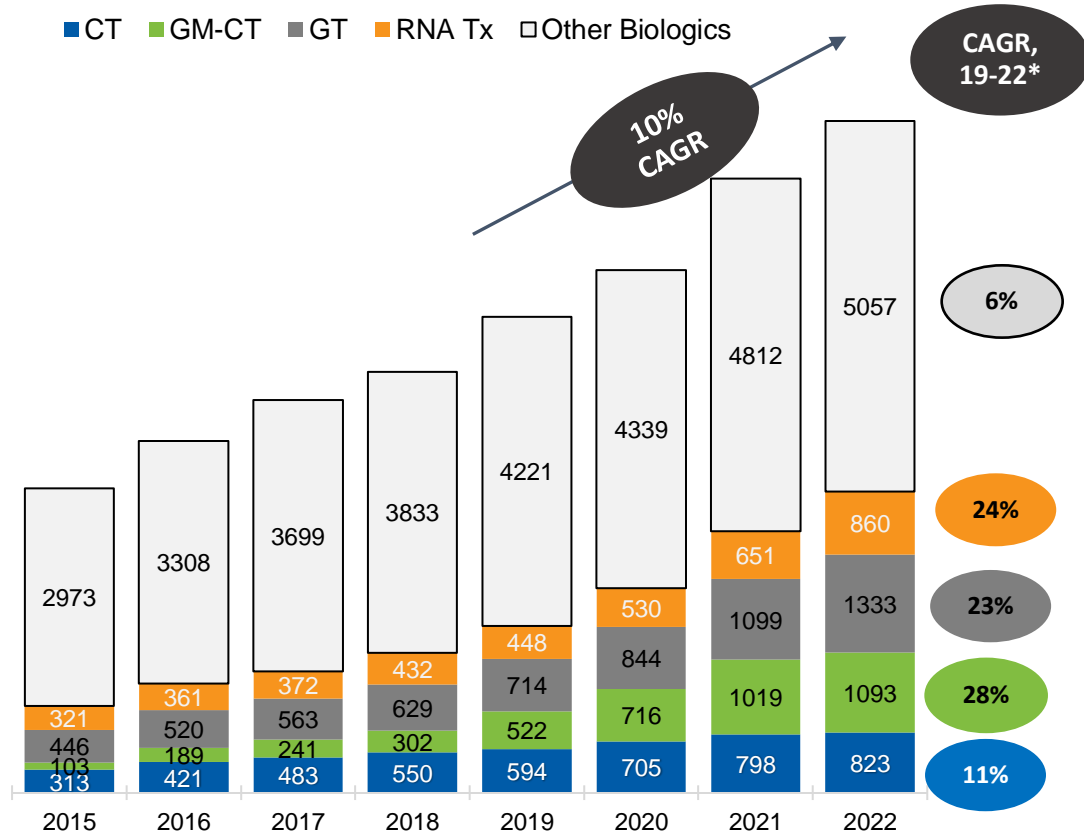
- CRL Biologics Offering
- CRL C> Offering Only



Outsourced market sector for current CRL service areas
~\$5-6B⁽¹⁾ with continued robust growth opportunities

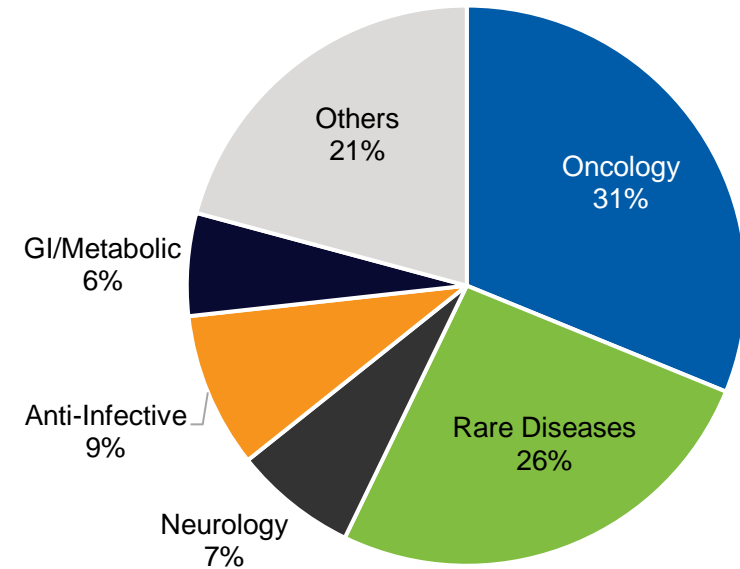
Robust Trends Remain Intact for Biologics and C> Drug Development

Biologics pipeline continues to support healthy growth



Oncology & Rare Diseases are lead TAs within C>

C> Pipeline by Therapeutic Area



Biologics Testing Business Overview

- Premier global CRO providing services that support the manufacture of biologics, including process development and quality-control testing
- Supports developers and manufacturers with their testing, characterization, and cell bank manufacturing needs
 - Providing testing and assay development throughout drug development, clinical and commercial manufacturing, and for final commercial drug product release
- Leveraging our scientific expertise, regulatory compliance, and extensive portfolio to provide fast, reliable results
- Clients are increasingly looking for end-to-end providers with a global footprint and a single point of contact for biologics program management
 - Harmonized testing and manufacturing strategy to optimize service offering for advanced therapies

CRL Biologics Testing Revenue Mix by Client Segment



High-single digit

CRL Biologics Testing revenue growth target for 2023-26E (CAGR)

Biologics Industry Pipeline By Subsegment



Biologics Testing: C> Offerings



Analytical Support

- Develop, qualify, and validate testing methods required for product identity, purity, & potency
- New state-of-the-art technology platforms (e.g., ddPCR)



Safety Testing

- Assure products are free of contamination from virus, microbial contaminants, or harmful process chemicals
- Rapid testing methods to achieve product release time for short shelf-life C> products



Cell Bank Manufacturing

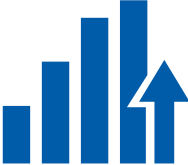
- Prepare & characterize the cell banks used in biologics manufacturing process
- Capability enhancements to accommodate storage for C> products



Product Potency Testing

- State-of-the-art flow cytometry tools to develop & validate novel potency assays for C> products

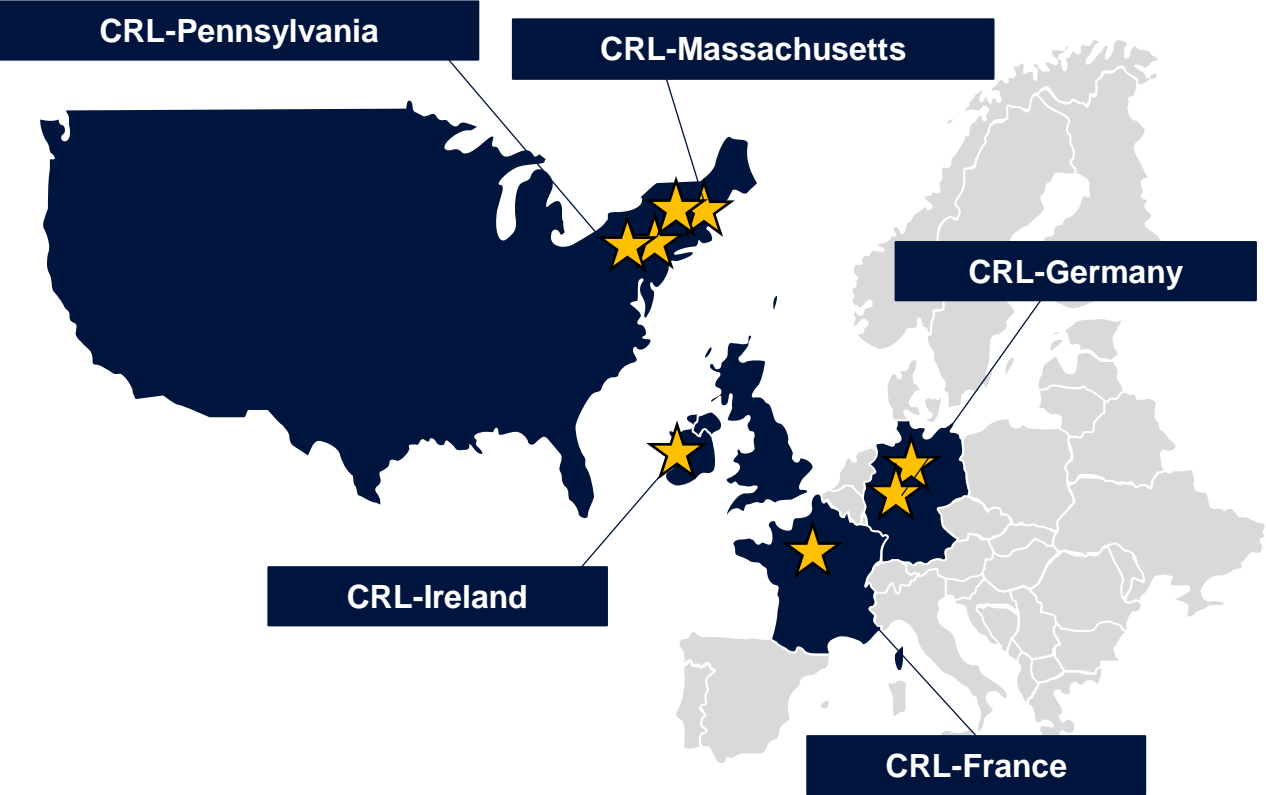
Global Biologics Testing Footprint Proximate to Clients



Global expansion in recent years, with capacity expansions in U.S. and Europe to accommodate client demand



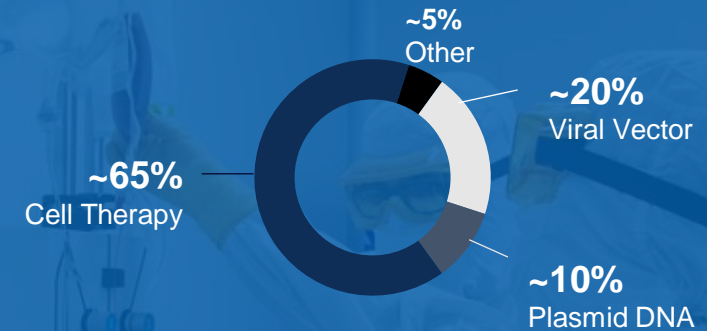
~1,000 clients across 45 countries



C> CDMO Business Overview

- A premier CDMO partner for clients' comprehensive C> development and manufacturing needs
- CRL has solutions across the major CDMO platforms for C>
 - Primary area of expertise is CGMP gene-modified cell therapy manufacturing
 - Also has gene therapy capabilities in the production of viral vectors and plasmid DNA
- ~3,300 C> programs currently in the biopharma R&D pipeline
 - Represents a long runway for growth with ~2/3 of programs in preclinical phase
- Synergistic fit with CRL's broader, non-clinical portfolio
 - Biologics Testing Solutions: Establishes a premier partner for analytical testing and manufacturing for advanced drug modalities
 - Cell Supply (i.e., HemaCare and Cellero): Provides cellular products that can be the starting point for clients' cell therapy programs

CDMO Revenue Mix by Service Area (2023E)



~20%

CRL CDMO revenue growth target from 2023-26E (CAGR)

Global C> CDMO Capabilities

Our established global network of facilities includes C> CDMO sites powered by dedicated testing facilities (centers of excellence)



Cell Therapy CDMO

1. Hanover – PD/AD & Early-Phase Clinical
2. Memphis – Late Phase & Commercial Production



Gene Therapy CDMO

3. Rockville, MD – Viral Vector (RUO, GMP)
4. Alderley Park, UK (HQ Plasmid DNA)
5. Keele, UK (GMP Plasmid DNA)

5
CDMO
LOCATIONS

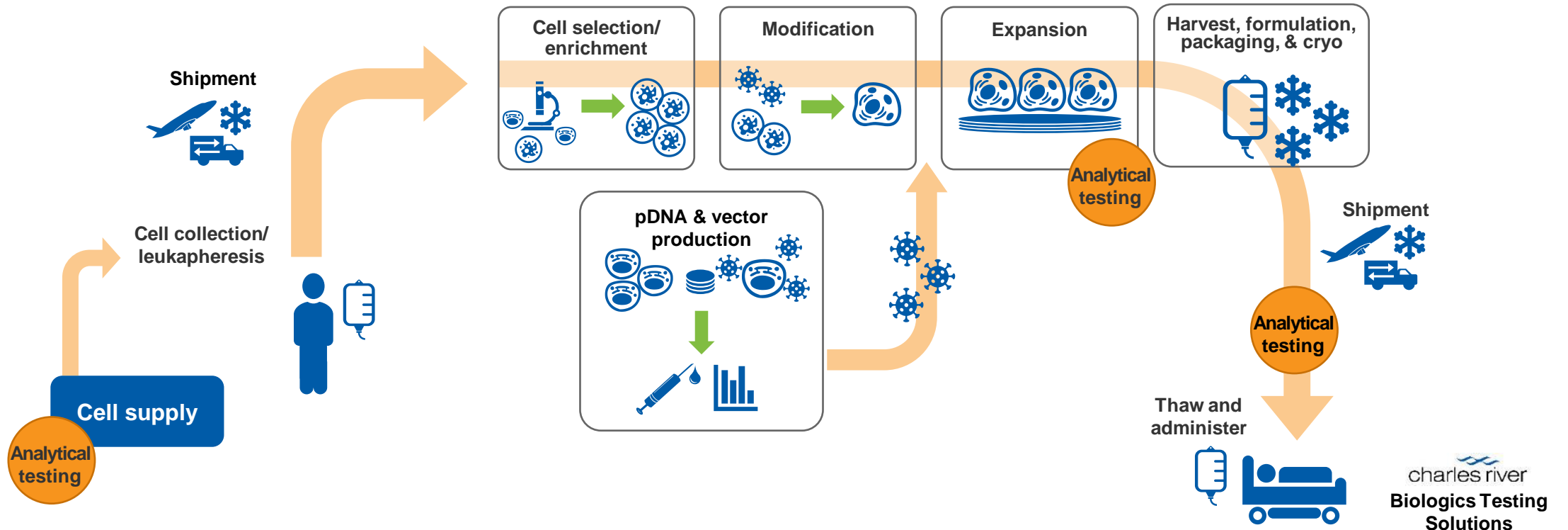
800+
CDMO
EMPLOYEES

~400K
CDMO
SQUARE FEET

Servicing the Entire C> Manufacturing Supply Chain

Fully integrated and experienced C> CDMO partner who can manage the entire process

Example gene modified cell therapy workflow



Proven Partner for GMP Manufacturing to Market



- Manufacturing aligned with quality
 - QA/QC for critical analytics and review
- First North American CDMO to receive EMA approval for commercial allogeneic cell therapy drug product production
- Cleared several regulatory inspections in recent months that reinforce expectations for additional commercial clients
 - Pleased with our progress and focus on regulatory compliance
- Dedicated support teams for tech transfer, client program management, clinical operations, and regulatory experience in EU and other countries
- Supported multiple large-scale autologous/allogeneic manufacture at pivotal stage

Manufacturing Revenue Growth Targets

Current Target:
~10%

2023-2026E MFG organic revenue CAGR

Current Business Trends – Biologics/CDMO:

- Biologics Testing impacted by clients' budget tightening and pipeline reprioritization
 - Particularly for viral clearance and cell banking services as clients can choose when these project are conducted during the development process
 - Believe 2023 is a “reset” from peak growth from 2020-22 that was fueled by COVID vaccine testing and favorable funding environment
- Transition to *in vitro*, next-generation testing methods
- CDMO growth rate will rebound in 2023 due to strategic initiatives
 - Centers of Excellence established for cell therapy, viral vectors, and plasmids
 - Investments and operational focus on commercial readiness
 - Strengthening sales funnel of new projects

Long-Term Growth Drivers – Biologics/CDMO:

- Biologics pipeline continues to support healthy, future growth trends
 - Biologics pipeline likely to grow at a similar rate as 2017-19 period
- Enhanced focused on biologics development over small molecules over the next 5-10 years (i.e. IRA)
- Vaccine development expected to grow at a higher rate than 2016-19
 - Albeit at a slower rate than the peak of the COVID pandemic
- C> continues to grow much faster than other Biologics sub-segments
 - Expected to represent 50%+ of biologics pipeline in 10 years (vs. ~40% today)
- 2nd generation antibodies will be a larger proportion of the pipeline (i.e., multi-specific Abs, ADCs)

Biologics and CDMO Strategic Imperatives



Operational Excellence

Foster culture of operational harmonization and regulatory compliance

- Continue to invest in commercial readiness to move to commercial phase with our CDMO clients
- Anticipate 2-3 more commercial clients in the next 2 years



Emerging Modalities

Remain current with therapeutic modality shifts and growing modalities

- Enhance testing capabilities around “new” biologics like RNA and ADCs
- C> remains an important growth driver with ~20% growth expected in this modality



Portfolio Enhancements

Evaluate innovative technologies and add new capabilities and service offerings

- Validate and operationalize technological advancements like next-generation sequencing (NGS)
 - PathoQuest NGS partnership advances the *in vitro* detection of viral contaminants in biologics
- Enhance service offering with new assays and unique offerings like RightSource™ on-site testing labs



Digital Enablement

Leverage digital transformation to decrease timelines, enhance operational efficiency, and accelerate client go/no-go decisions

- Launch of Apollo™ for Biologics this month enables client access to real-time sample testing data and tracking



Advance Culture

Engage, hire, and retain the best people by developing, appreciating, and empowering our people and allowing them to make fast decisions



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