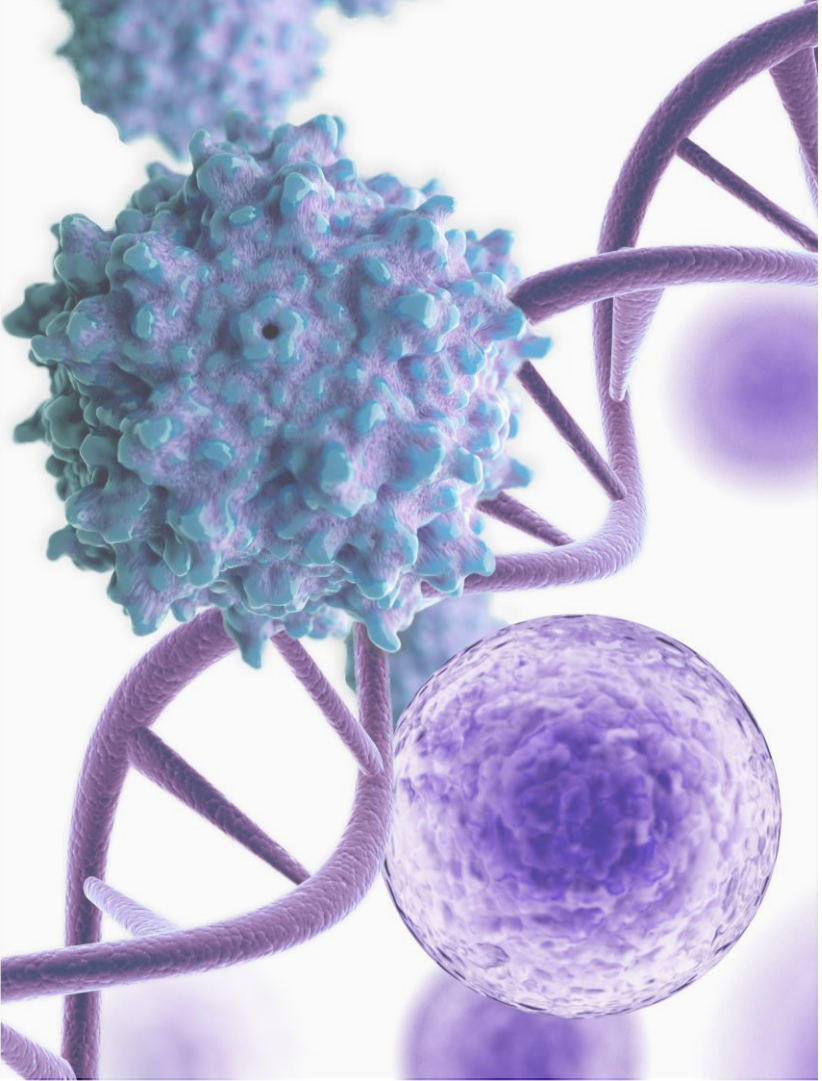


Catalent®
CELL & GENE THERAPY

Cell & Gene Therapy

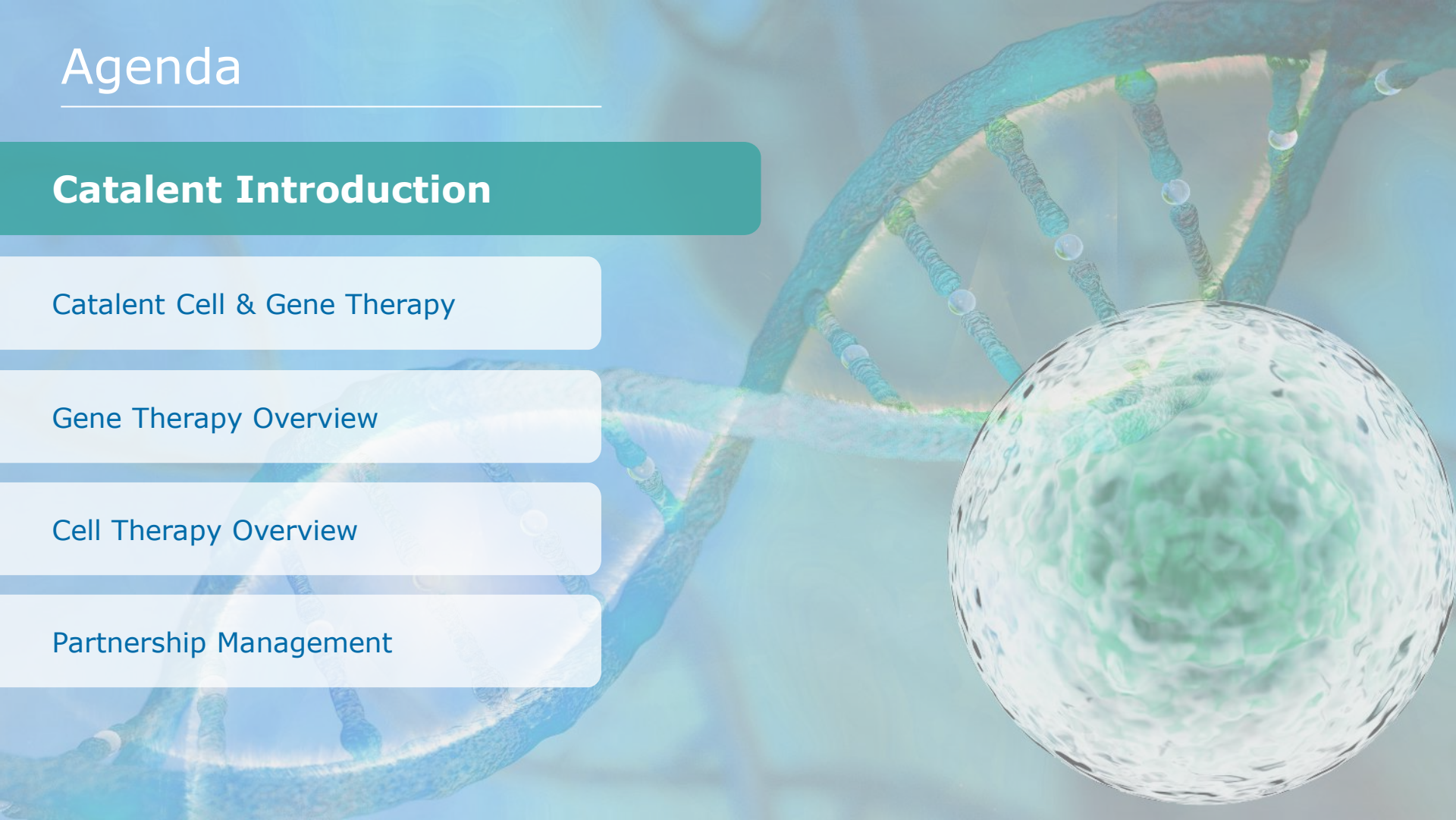
ACCELERATED DEVELOPMENT, ADVANCED TECHNOLOGY AND COMMERCIAL SCALE-UP SOLUTIONS

more products. better treatments. reliably supplied.™

Agenda

Catalent Introduction

- Catalent Cell & Gene Therapy
- Gene Therapy Overview
- Cell Therapy Overview
- Partnership Management



WE ENABLE OUR PARTNERS TO DEVELOP & SUPPLY BETTER TREATMENTS FOR THEIR PATIENTS BY KEEPING PATIENTS FIRST

At the core of Catalent's mission is developing and supplying products to **ENHANCE & IMPROVE THE LIVES OF YOUR PATIENTS**

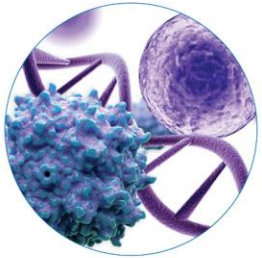
We are dedicated to using our passion, expertise, and advanced technologies in partnering with you to design better treatments that deliver for **PATIENTS FIRST**

With our responsibility for supplying thousands of products to patients worldwide, we share your view that when patients come first, **EVERY OUTCOME MATTERS**!

OUR MISSION IS TO DEVELOP & SUPPLY PRODUCTS THAT HELP PEOPLE LIVE BETTER, HEALTHIER LIVES

ORAL

BIOTHERAPEUTICS



CELL & GENE THERAPY

INHALATION

CONSUMER HEALTH

COMPREHENSIVE DEVELOPMENT

SUPERIOR DELIVERY TECHNOLOGIES

GLOBAL CLINICAL SUPPLY

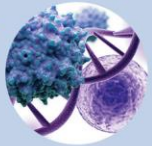
MULTI-MODALITY MANUFACTURING & PACKAGING

YOUR TOP PARTNER FOR EXPERT DEVELOPMENT, ADVANCED TECHNOLOGIES & FLEXIBLE MANUFACTURING SOLUTIONS ACROSS MODALITIES

BIOTHERAPEUTICS

COMPREHENSIVE BIOAVAILABILITY SOLUTIONS

CELL & GENE THERAPY



COMPLETE FORMULATION TECHNOLOGY TOOLKIT

ACCELERATED CLINICAL SUPPLY

DEVELOPMENT SOLUTIONS

PLASMIDS, CELL LINES & VIRAL VECTORS

BROADEST ORAL TECHNOLOGY PORTFOLIO

OPTIMAL DOSE FORM DESIGN & DEVELOPMENT

INJECTABLES & INHALATION

DELIVERY TECHNOLOGIES

FAST TECH TRANSFER & MARKET LAUNCH

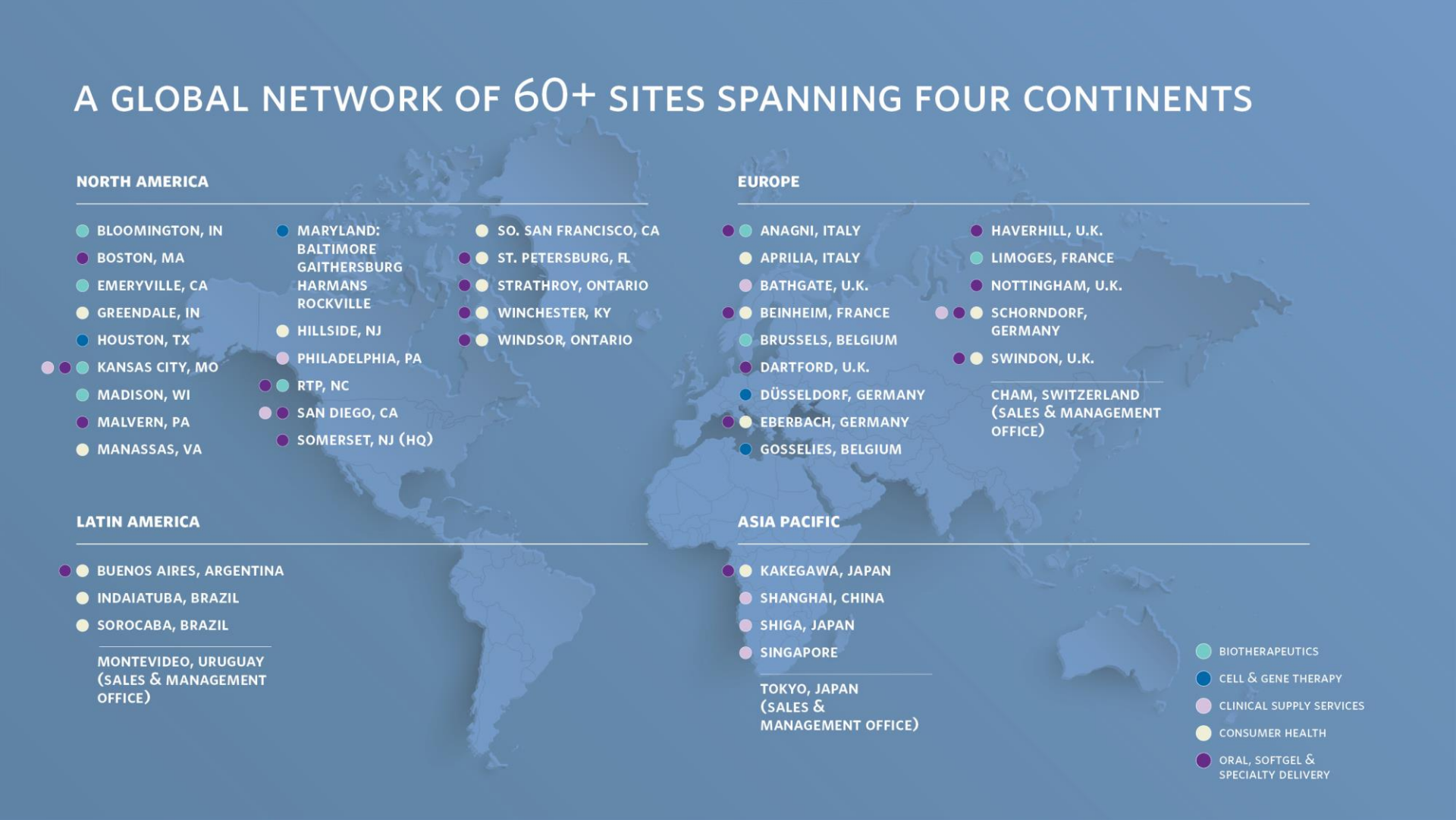
FLEXIBLE MANUFACTURING & PACKAGING SOLUTIONS

POTENT & CONTROLLED SUBSTANCE HANDLING

GLOBAL COMMERCIAL SUPPLY

RELIABLE SERVICE & SUPPLY

A GLOBAL NETWORK OF 60+ SITES SPANNING FOUR CONTINENTS



NORTH AMERICA

- BLOOMINGTON, IN
- BOSTON, MA
- EMERYVILLE, CA
- GREENDALE, IN
- HOUSTON, TX
- KANSAS CITY, MO
- MADISON, WI
- MALVERN, PA
- MANASSAS, VA
- MARYLAND: BALTIMORE GAITHERSBURG HARMANS ROCKVILLE
- HILLSIDE, NJ
- PHILADELPHIA, PA
- RTP, NC
- SAN DIEGO, CA
- SOMERSET, NJ (HQ)
- SO. SAN FRANCISCO, CA
- ST. PETERSBURG, FL
- STRATHROY, ONTARIO
- WINCHESTER, KY
- WINDSOR, ONTARIO

EUROPE

- ANAGNI, ITALY
- APRILIA, ITALY
- BATHGATE, U.K.
- BEINHEIM, FRANCE
- BRUSSELS, BELGIUM
- DARTFORD, U.K.
- DÜSSELDORF, GERMANY
- EBERBACH, GERMANY
- GOSSELIES, BELGIUM
- HAVERHILL, U.K.
- LIMOGES, FRANCE
- NOTTINGHAM, U.K.
- SCHORNDORF, GERMANY
- SWINDON, U.K.

CHAM, SWITZERLAND (SALES & MANAGEMENT OFFICE)

LATIN AMERICA

- BUENOS AIRES, ARGENTINA
- INDAIATUBA, BRAZIL
- SOROCABA, BRAZIL

MONTEVIDEO, URUGUAY (SALES & MANAGEMENT OFFICE)

ASIA PACIFIC

- KAKEGAWA, JAPAN
- SHANGHAI, CHINA
- SHIGA, JAPAN
- SINGAPORE

TOKYO, JAPAN (SALES & MANAGEMENT OFFICE)

- BIOTHERAPEUTICS
- CELL & GENE THERAPY
- CLINICAL SUPPLY SERVICES
- CONSUMER HEALTH
- ORAL, SOFTGEL & SPECIALTY DELIVERY

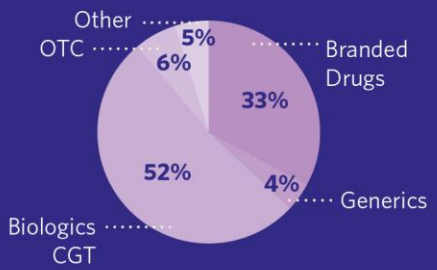
UNRIVALED EXPERTISE & SCALE TO HELP YOU SUCCEED

1,400
ACTIVE DEVELOPMENT PROGRAMS

25+
R&D TEAMS WITH OVER 2,500 SCIENTISTS & TECHNICIANS

ASSISTED NEARLY 50%
OF FDA APPROVALS IN LAST 10 YEARS

70+
BILLION DOSES



PRODUCT TYPE

PHARMACEUTICALS

GENERICS

BIOTECHS

WE SERVE

BIOLOGICS

45+
COMMERCIALLY APPROVED PRODUCTS FILL/FINISH

700+ ANTIBODIES
80+ RECOMBINANT PROTEINS DEVELOPED

EXPERIENCE WITH **100+**
CELL & GENE THERAPY PROGRAMS

CLINICAL SUPPLY

320,000+
PATIENT KITS ASSEMBLED ACROSS 1,200+ DIFFERENT PROTOCOLS EACH YEAR

150,000+
SHIPMENTS EVERY YEAR

Agenda

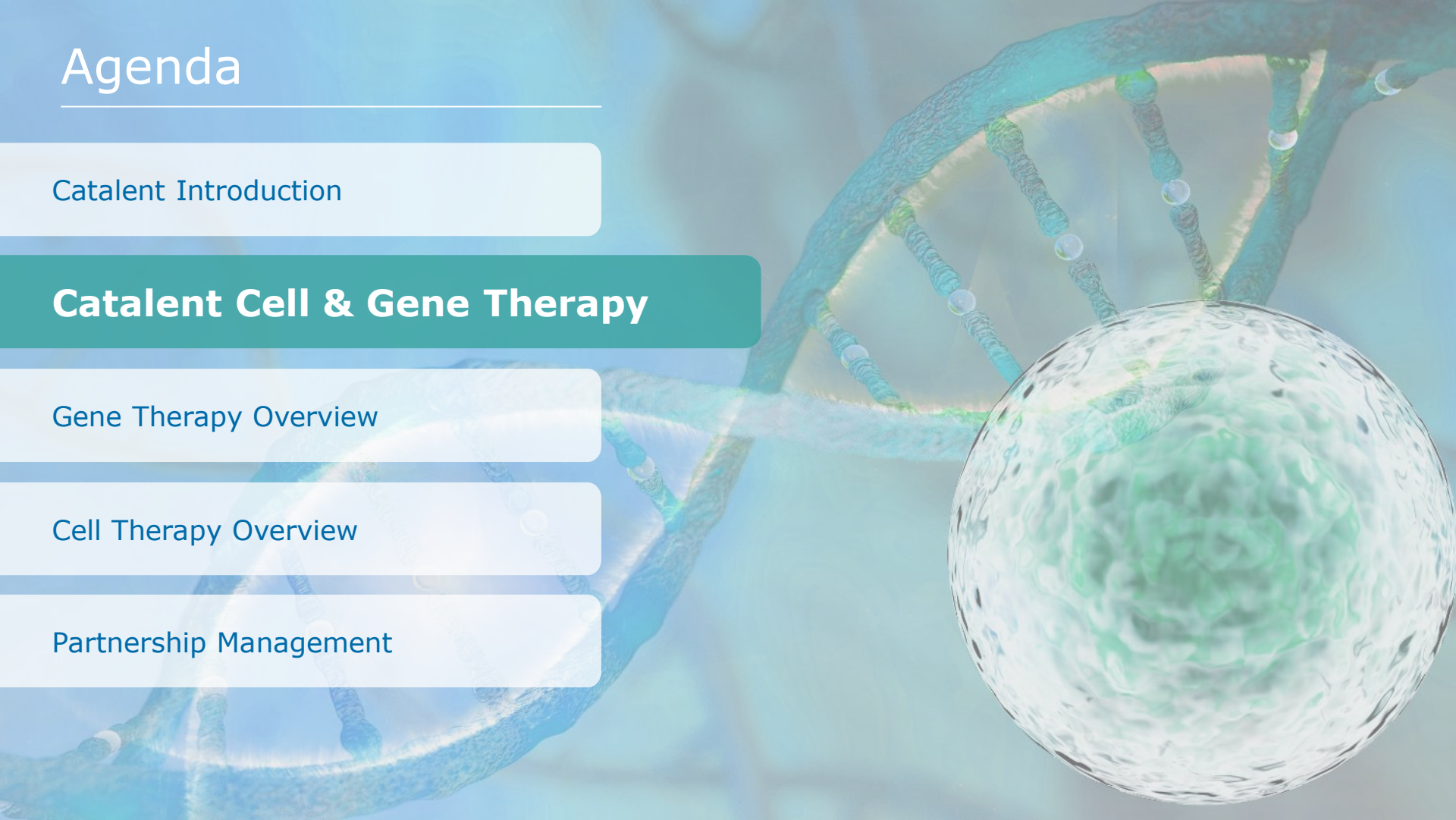
Catalent Introduction

Catalent Cell & Gene Therapy

Gene Therapy Overview

Cell Therapy Overview

Partnership Management



Comprehensive Solutions for Advanced Therapeutics

Catalent
CELL & GENE THERAPY

Plasmids | Viral Vectors, Autologous, Allogeneic Development & Manufacturing | Clinical Supply Services

Centers of Excellence

- Global footprint of clinical and commercial facilities
- EMA and FDA approved commercial gene therapy building
- From plasmid DNA through clinical trial packaging and logistics, customers have access to full supply chain control

Leading Customer Portfolio

- Partnerships with industry leaders
- Broad portfolio of projects across modalities and cell types

Talent and Expertise

- Over 30 years of experience
- Plasmid production expertise
- Deep AAV and lentiviral experience with a strong and growing talent pool

Full-service partner providing integrated solutions for advanced therapeutics

Helping innovators develop better treatments faster

Key Investments in Cell and Gene Therapy

Purchase of Paragon Bioservices and Expansion

Purchase of Paragon Bioservices for $1.2 B

- Development through commercial GMP manufacturing of viral vectors
- 10 commercial suites at BWI 1
- PD/AD at Biopark
- AAV, HSV, RSV, OV

$130 M investment at BWI 2 for 5 additional suites

Purchase of Gaithersburg and Rockville Facilities

$18 M purchase of two facilities in Montgomery county, Maryland

- Includes manufacturing equipment and personnel
- Additional capacity for Gene Therapy PD/AD
- Long-term agreement to support Novavax

Purchase of MaSTherCell

Catalent purchases Masthercell for $315 M

- Clinical GMP Cell Therapy Manufacturing
- EU and US locations (Belgium and Houston)
- Adjacent clinical site expansion in Belgium
- Commercial expansion underway

Expansion into Plasmid DNA

Plasmid DNA

- Investment in Rockville facility for clinical and commercial scale
- Purchase of Delphi Genetics in Belgium
- Purchase of additional building in Belgium for commercial scale

$1.6 B+ invested in Cell and Gene Therapy beginning in 2019

Catalent Cell & Gene Therapy at a Glance

DIVERSE EXPERIENCE AND COMMERCIAL SUCCESS

- Autologous and Allogeneic modalities
- Broad coverage of cell types (20+)
- AAV and Lentiviral expertise
- Clinical and commercial scale
- Dedicated commercial capacity

PART OF OUR GLOBAL NETWORK

- FDA approval of commercial GT facility in Aug 2020, EMA in 2021
- Added GT capacity with acquisition of additional sites in Jul 2019
- Added CT capacity with the purchase of MaSTherCell in February 2020 and additional sites in Oct 2020 & Apr 2022
- Added plasmid DNA through expansion and acquisitions in 2021

INNOVATIVE APPROACH

Enabling ground-breaking customer success

- Custom methodologies:
  - Manufacturing by Design
  - Fill/Finish
  - Analytical Development
- Primed to bring the first allogeneic CAR-T treatment to market
- Commercial-ready GT processes
- Innovative approach to analytic services

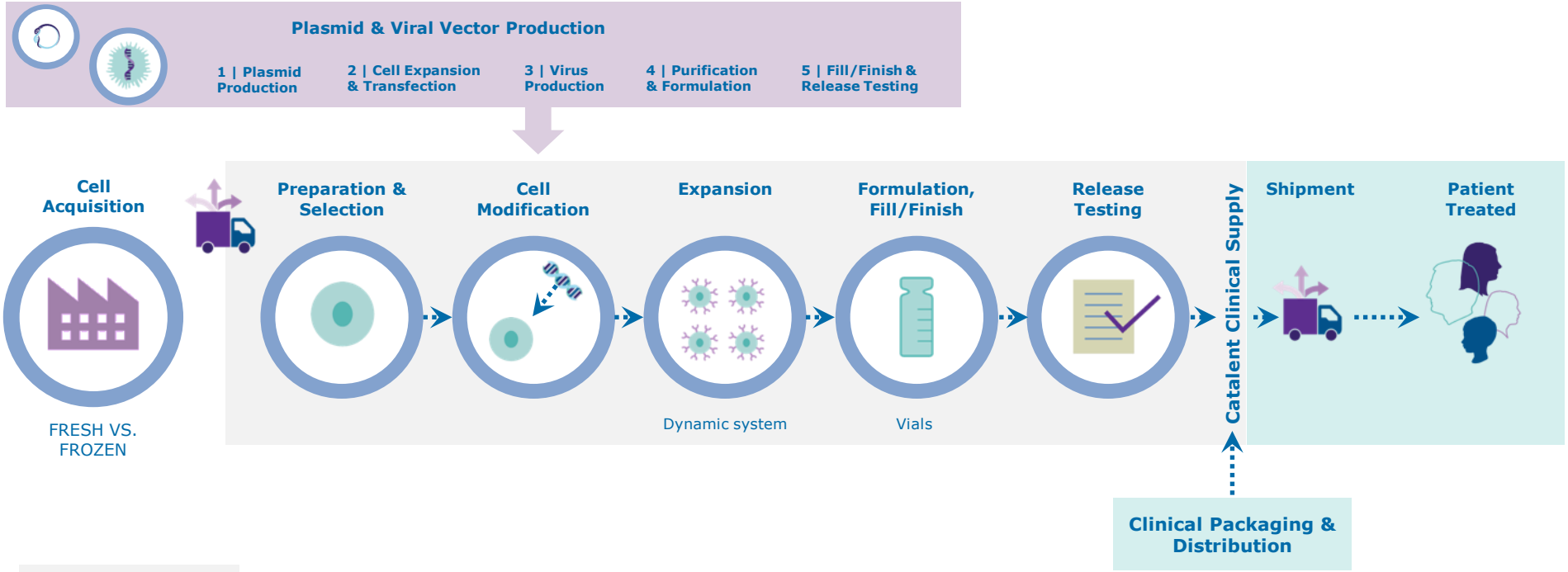
COMMITMENT TO EXPANSION

Meeting customers' capacity needs

- Approval for 8 new suites at Harmans/BWI campus
- Commercial in US and building in Belgium
- Integrated Catalent teams for global customer partnerships – raw material through clinical supply

DIVERSE CUSTOMER BASE WITH SIGNIFICANT REPEAT BUSINESS

Gene-to-Patient Integrated Solutions
From Critical Raw Materials to Clinical Trial Supply



CELL THERAPY

GENE THERAPY

CLINICAL SUPPLY SERVICES

Agenda

Catalent Introduction

Catalent Cell & Gene Therapy

Gene Therapy Overview

Cell Therapy Overview

Partnership Management

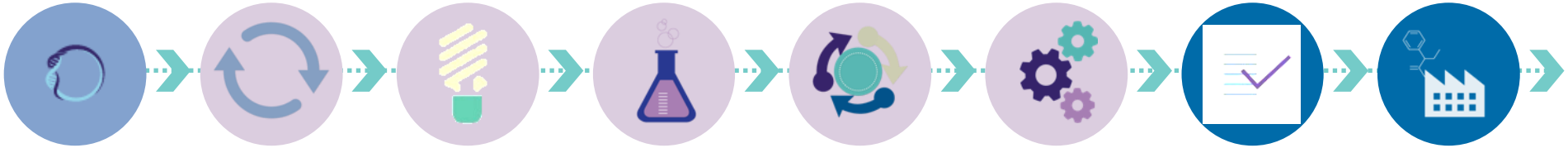
Gene Therapy Overview

GENE THERAPY HISTORY *Expertise in cutting-edge technologies for gene therapy*	Paragon Bioservices in business for nearly 30 years Specialty contract development and manufacturing organization (CDMO) for gene therapies, vaccines and oncolytic viruses Clinical to commercial manufacturing facilities in the US
PART OF CATALENT'S GLOBAL NETWORK	Purchased by Catalent in May 2019 for $1.2B USD
AAV COMMERCIALIZATION EXPERTISE	First FDA-licensed gene therapy commercial manufacturing facility
GROWING NETWORK *Dedicated to meet customers' capacity needs*	Added capacity with acquisition of two manufacturing facilities from Novavax in Jul 2019 Expanding footprint at Harmans/BWI campus Added plasmid DNA capabilities through expansion and acquisitions in 2021

OUTSTANDING CUSTOMER BASE WITH SIGNIFICANT REPEAT BUSINESS

Expertise in Bridging the Gap from PD to GMP Production
Creating Commercial-ready Processes

VIRAL VECTORS | VACCINES | ONCOLYTIC VIRUSES



- Rockville & Gosselies
- Gaithersburg & Baltimore BioPark
- Harmans/BWI

Catalent offers an integrated network of solutions from plasmid DNA to viral vector drug substance and drug product manufacturing

Gene Therapy & Viral Vector Capabilities and Expertise
Experience in Scale-up for Commercial Manufacturing

Services

Process Development
- Upstream / Downstream
- Analytical development
- Formulation development
- Toxicology production
- Process characterization

Clinical and Commercial GMP Manufacturing
- Commercial-ready processes
- Focused viral vector manufacturing facilities
- Master/working cell and virus banks
- Drug substance and drug product manufacturing

Platforms

Plasmid DNA
- R&D and GMP grade

Viral Vectors
- Adeno-associated virus (AAV)
- Adenovirus, HSV, lentivirus, and retrovirus

Vaccines
- Recombinant viral vectors
- Virus like particle (VLP)
- Mammalian proteins
- Microbial proteins and conjugates

Oncolytic Virus
- Adenovirus, HSV, RSV, Vaccinia, etc.

Fully Integrated Plasmid DNA Services
From Lead Identification to GMP Grade Manufacturing

Lead Identification

Lead identification to help with candidate selection & feasibility

- Strain screening
- R&D-grade production

Lead Development

Lead development to help meet critical quality attributes

- Process development
- Analytical development
- *E.coli* cell banking

Clinical & Commercial Manufacturing

Manufacturing to meet clinical & commercial needs

- GMP *E.coli* cell banking
- GMP grade production
- Plasmid linearization for mRNA production
- QC qualified assays for plasmid release and cell bank characterization

PRODUCTION

GMP grade plasmid production for TOX and clinical activities

Broad Capabilities in AAV Production and Purification
Expertise in All Production Platforms & Across Serotypes

rAAV Serotypes 1, 2, 5, 6, 8, 9, 10

Adherent and Suspension Culture

Conversion to Scalable Manufacturing Platforms

Experience with All Major Scalable Production Systems

- Transient Mammalian Production in Suspension 293 Cells
- Transient Mammalian Production with Adherent 293 Cells in iCELLis® Bioreactor
- BEVS Mediated Production in Sf9 Cells
- HSV Mediated Production in Suspension 293 and BHK cells

Experience with 60+ gene therapy programs for 40+ leading companies

iCELLis is a trademark of Pall Corp.

Baculovirus Capabilities
Over 20 Years of Experience in Viral Production

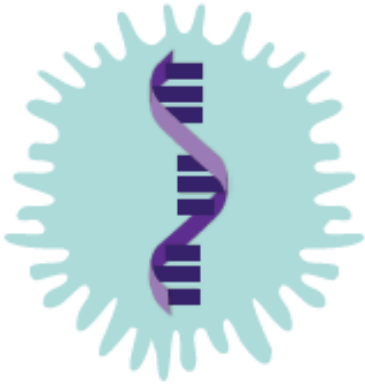
Viral Stock Generation

- Non-GMP and GMP
- All standard vector systems (e.g., BaculoGold, Bac-to-Bac, BaculoDirect, BacPAK)
- Protease-deficient vector systems (e.g., BacMagic, BestBac, MultiBac)
- Baculovirus Infected Insect Cells (BIICs)

Process Development for Expression Optimization

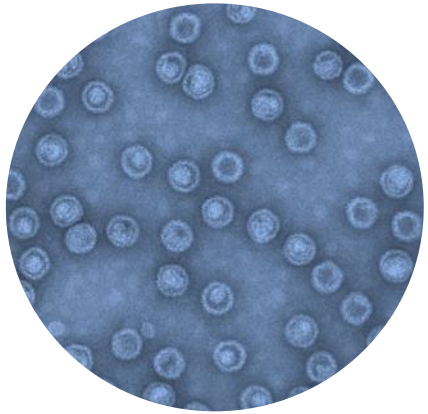
- MOI, TOI, Time of Harvest
- Sf9, Sf21, Tni, High Five

Scale-up Production – from bench-scale to 200L



Capabilities in Vaccines
Including Viral-based and Virus-like Particle (VLP) Vaccines

Expertise for a variety of virus types across all processing steps



VLP Candidate Vaccines (Mammalian, Insect)

- Influenza, HPV, Rotavirus, HIV, Ebola, JCV, CMV, BKV

Antigen Candidate Vaccines (including Conjugated Vaccines)

- *Salmonella, S. Pneumoniae, Cholera, Chlamydia*

VEE – Replicons (Ebola - Zaire, Sudan and Marburg Virus)

Live and Live-attenuated Viral and Bacterial Vaccines

- Adeno, RSV, CMV, Zika, Shigella, S. Pneumoniae (15 strains), C. Diphtheriae, Chlamydia

Adherent & Suspension Cell Culture Systems

Analytical & large-scale bio-separations

Assay Development (titer, AC, EM)

Full Suite of Industry-leading Analytical & Assay Services Supporting Gene Therapy and Other Viral Products

Assay development & qualification

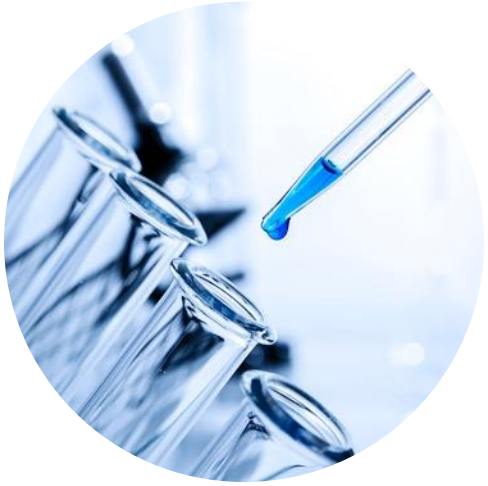
- Customer specific assays: potency concentration and identity
- Phase I/II GMP testing, assay qualifications

Analytical support for process development & characterization

Product characterization & comparability

Typical analytical methods include

- ddPCR and qPCR
- ELISA
- TCID50
- Chromatography
- Electrophoresis
- Electron microscopy
- Analytical ultracentrifugation (AUC)



Viral Vector / Gene Therapy Capacity

Dedicated suites and scale-up expertise for commercial manufacturing

BioPark
Phase I/II

~120,000 sq. ft.

- PD and Phase I/II
- PD labs
- 8 GMP suites
- Single-use bioreactors: 2, 50, 200 and 500L
- Central services labs
- Testing labs
- Fill/finish suite
- Traditional AAV programs, lentivirus and baculovirus

Gaithersburg
Phase I/II

~54,000 sq. ft.

- GMP manufacturing & PD facility
- 3 GMP suites
- Single-use bioreactors: 200L
- Formulation development labs
- Testing labs
- Oncolytic virus and viral vaccines

Harmans/BWI-1
Phase III/Commercial

~200,000 sq. ft.

- Phase III/Commercial facility, FDA & EMA approved
- 10 GMP suites
- Single-use bioreactors: 50, 200, 500, 1000 and 2000L
- Central services and testing labs
- Fill/finish suite
- Customer dedicated clean room suites as well as spot suites

Harmans/BWI-2
Ph III/Comm. - In Process

~145,000 sq. ft.

- Phase III/Commercial facility
- 8 GMP suites
- Single-use bioreactors: 50, 200, 500, 1000 and 2000L
- Cold storage capabilities

Phased Opening Begins in H1 CY 2022

Manufacturing capacity challenges for industry

Expanding our manufacturing footprint to address growing demand

Plasmid DNA Capacity
Expanding to Meet the Future Needs of Our Partners

Gosselies, Belgium
Plasmid Manufacturing

R&D / GMP

- 4 GMP suites
- R&D/PD and QC labs
- Master and Working Cell Banks
- Single-use fermenters: 4, 10 and 50L
- Complete panel of QC assays
- Large scale clinical and commercial manufacture
- Clean suite for up to 500L
- Multiple DSP suites

Rockville, MD
Plasmid Manufacturing

R&D / GMP

- 1 GMP suite (current) expanding to 4 GMP suites
- R&D/PD, AD and QC labs
- Master and Working Cell Banks
- Single-use fermenters: 3, 10 and 50L
- Complete panel of QC assays (HPLC, ddPCR methods)

Clinical through commercial-scale plasmid development and manufacturing
Complementing viral vector and cell therapy services to provide integrated cell and gene therapy capabilities

Catalent's Differentiated Approach
Focus on Viral Vectors and Customized Solutions

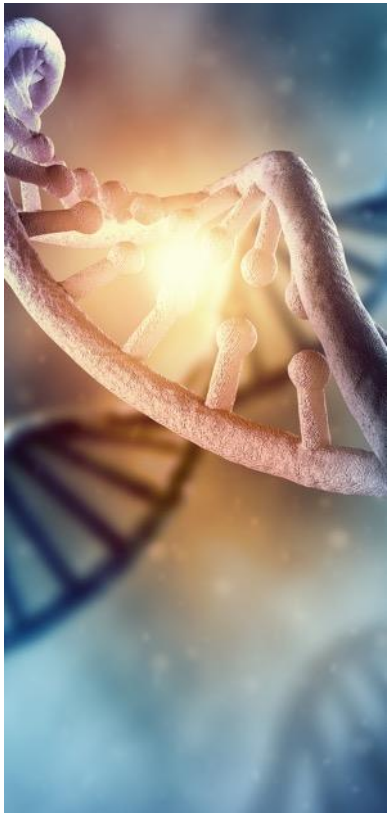
COMMERCIAL-READINESS | Superior scientific and technical expertise ensuring an efficient and optimized manufacturing process that is both scalable and commercially-viable

PARTNERSHIP-MENTALITY | Our demonstrated ability to work hand-in-hand with customers throughout the entire process allows us to tailor a solution and deliver best-in-class service

OPERATIONAL EXCELLENCE | State-of-the-art facilities offering customers access to the latest manufacturing technology, specifically designed and built to meet the significant industry demand for adeno-associated virus (AAV) vectors

INDUSTRY EXPERTISE | Deep gene therapy expertise developed through a long history of viral particle manufacturing, with a highly experienced workforce and a strategic focus on viral vectors

ACCELERATING TIMELINES | Ability to increase speed to clinic by shortening timelines, efficiently managing programs, and integrating essential process workflows such as product development, raw material & GMP production, and quality



Agenda

Catalent Introduction

Catalent Cell & Gene Therapy

Gene Therapy Overview

Cell Therapy Overview

Partnership Management

Our Proven Expertise to Accelerate and De-risk Cell Therapy Programs

FROM BENCH TO COMMERCIAL SCALE

30+
CELL THERAPY PROGRAMS

15+
ALLOGENEIC CGMP BATCHES RELEASED

275+
AUTOLOGOUS CGMP BATCHES RELEASED

300+
ALLOGENEIC CAR T VIALS PRODUCED

10+
CELL MODALITIES

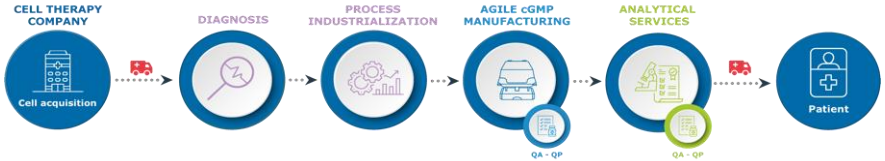
20+
LEADING COMPANIES

60+
GENE THERAPY PROGRAMS

35+
COMMERCIALLY APPROVED BIOLOGICS THROUGH FILL FINISH

50%
AUTOLOGOUS

50%
ALLOGENEIC PROGRAMS



Broad Capabilities & Expertise

SERVICES

Diagnostic
- Process design and analytical development plan
- Recommendations for cGMP manufacturing & scale-up

Process Development
- Process Development (Upstream/downstream)
- Process characterization/validation
- Scale-up strategy

GMP Manufacturing
- Drug product manufacturing
- Aseptic fill/finish platform
- Clinical to commercial scale
- Release

Analytical Services
- Assay development
- Method qualification / validation
- Product characterization
- Safety testing
- Release testing
- Stability study
- Raw material performance

EXPERTISE

Cell Therapy
- Autologous
- Allogeneic
- Native and genetically-modified cells

Cell types
- CAR-T
- TCR
- TIL
- Treg
- Mreg
- iPSCs
- ESC
- MSCs
- HSCs

Cell Therapy Process Diagnostics

Our 5 Step Approach Enables Manufacturability of Your Discoveries

REFERENCE PROCESS

Understand your process first

- Supporting documentation provided by you
- Observation runs performed at your site

TARGET FOR THE CLINICAL STUDY

Accommodate customer Target Product Profile

- TPP and CQA (Number of cells, % of CAR-T)
- Target manufacturing process

GAP ANALYSIS

Perform gap analysis between step 1 and step 2

- Manual or variable steps
- Uncontrolled processes
- Suboptimal ancillary materials
- Complex bill of testing

RECOMMENDATIONS

Share development and manufacturing plan

- Process optimization scope
- Fitting your clinical and timeline priorities
- Forward-looking plan with a commercial readiness mindset

IMPLEMENTATION PLAN

Tech Transfer

- Training runs
- Raw material procurement
- Equipment installation and qualification

Development

Analytical development

- Assay development and validation
- Rationalization of sampling plan
- Development of analytical methods
- Process and product characterization
- Product comparability studies

Process development

- Streamlining
- Automation
- Scale-up and scale-out
- COGS optimization
- Phase-appropriate approach

Translation

- GMP documentation
- Engineering runs
- Reproducibility runs
- Aseptic Process Simulation runs

Manufacturing by Design
More Effective in Overcoming Cell Therapy Manufacturing Challenges

Manufacturing by Design (MbD): Our custom methodology focuses on alleviating cell therapy manufacturing challenges by elevating attributes that are absent within the traditionally adopted QbD methodology for bioprocessing.

Manufacturing by Design

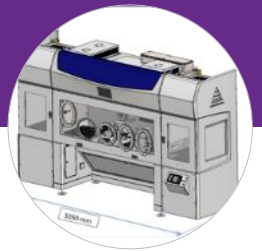
QUALITY	MANUFACTURING
QbD – Quality by Design	MbD - Manufacturing by Design
TPP – Target Product Profile	TMP - Target Manufacturing Profile
CQA- Critical Quality Attribute	CMfA- Critical Manufacturing Attribute

Fill & Finish
Our Commitment to Efficiency Enables High-fill Capacity and Scalability

Our commitment and advances in Fill & Finish Capacity:

- 3 fold increase in visual inspection throughput
- Move from manual filling to semi-automated L1 vialing
    - Upgrade from Aseptic Technologies Crystal® M1 to Pure M1 in progress
    - Planned upgrade to L1 robot line to achieve 1000 vial capacity
- Higher capacity control rate freezer

Crystal® M1
Filling Station



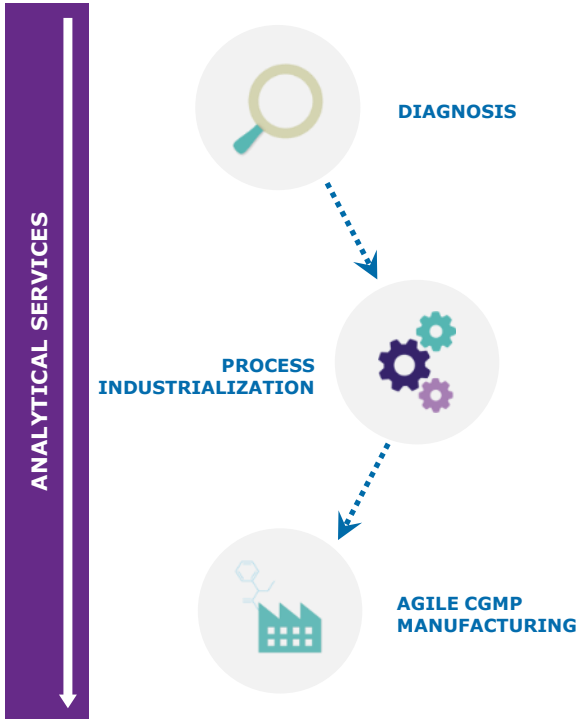
Crystal® Pure M1
Isolator

Isolated Crystal®
L1 robot line

Choice of Closed Vial System from Aseptic Technologies

Analytical Services: Forward-looking Mindset with Operational Excellence, Every Step of the Way

The Path to Industrialization



Faster regulatory filings, approval and accelerated launch

Ensure identity, purity, safety & potency of your cells throughout the process

Broad coverage of in-house capabilities from equipment to the testing methodologies

HOW WE WORK

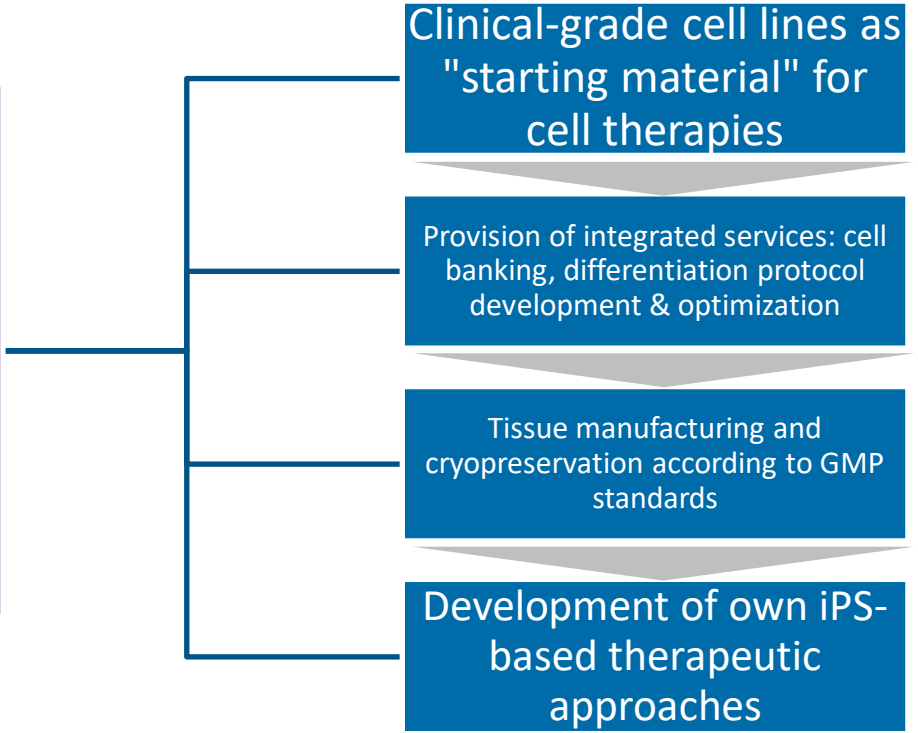
- Transparency of the raw data
- GMP certified – ICH Q2 (R1)
- EU & US pharmacopeia
- State-of-the-art equipment

WHAT WE DO

- Method Development
- Characterization
- Safety testing
- Validation
- Release Testing
- Stability Study
- Raw material performance

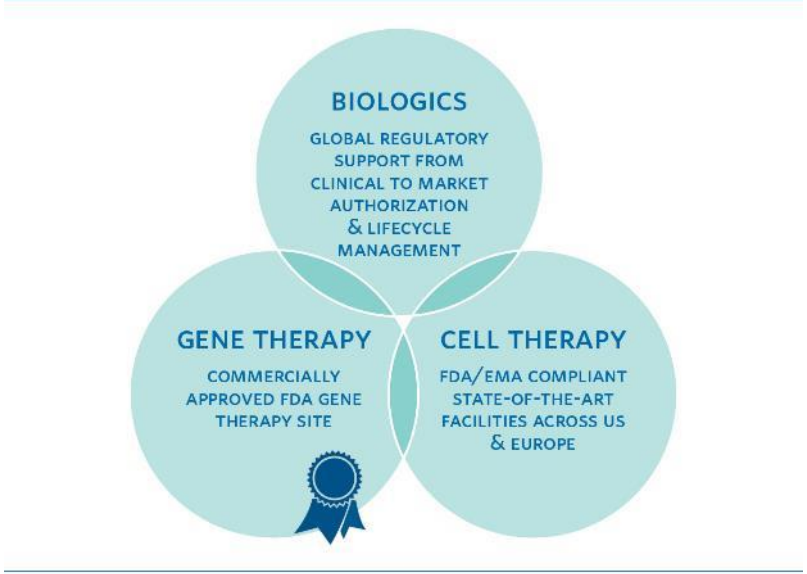
Accelerating your iPSC program with the expertise and infrastructure

With state-of-the-art cell culture and processing facilities, we manufactures GMP-compliant iPSC's and offer expert services along the complete workflow



Regulatory Expertise
Support from pre-IND to Commercialization

A Powerhouse of Combined Leaders



WE IMPLEMENT FULLY INTEGRATED TEAMS ACROSS OUR BUSINESS AREAS THAT FOSTER EFFECTIVE CROSS-COLLABORATION AND LEVERAGE EACH OTHER'S COMPETENCIES

Our Cell Therapy Expertise

PRE-CLINICAL → CLINICAL TRIALS → APPROVAL → MARKET

- FILING & RESPONSE SUPPORT PRE-IND TO COMMERCIAL AUTHORIZATION
- COMMERCIAL-READY GMP IMPLEMENTATION
- SITE-SPECIFIC REGULATORY SUPPORT
- DRAFT & REVIEW CMC SECTIONS OF THE FILING
- PROVIDE DETAILED CMC INFORMATION
- FOUNDATIONAL QUALITY & REGULATORY ELEMENTS EARLY ON FOR FASTER TECH TRANSFER & SCALE
- PRE-APPROVAL INSPECTIONS
- PRE-LICENSING READINESS AUDITS
- LIFECYCLE MANAGEMENT SUPPORT - TRACK & TREND, DATA SUBMISSIONS, MONITOR CPPs
- QUALITY EXPERTISE FOR CELL ACQUISITION, PROCESSING, & SHIPPING
- REGULATORY SUBMISSION STRATEGY DEVELOPMENT
- COORDINATION WITH HEALTH AUTHORITIES

Partnering with you to meet your submission needs every step of the way

Partner of Choice with Comprehensive Commercial Infrastructure Strategic Customer Programs, Expansions, and Innovation

GROWTH MINDSET

Accelerated growth
- Capacity expansions
- Capability extension

PROCESS EFFICIENCIES

Manufacturing by Design
Fill/Finish capacity

TALENT

Industry & adjacent markets
- Scientific know-how
- Scalable process expertise

CAPACITY

Commercial facility
Agile ramp-up in a fast-paced market

REGULATORY

Pre-IND to Commercialization
- FDA approved sites
- Biologics scalable expertise

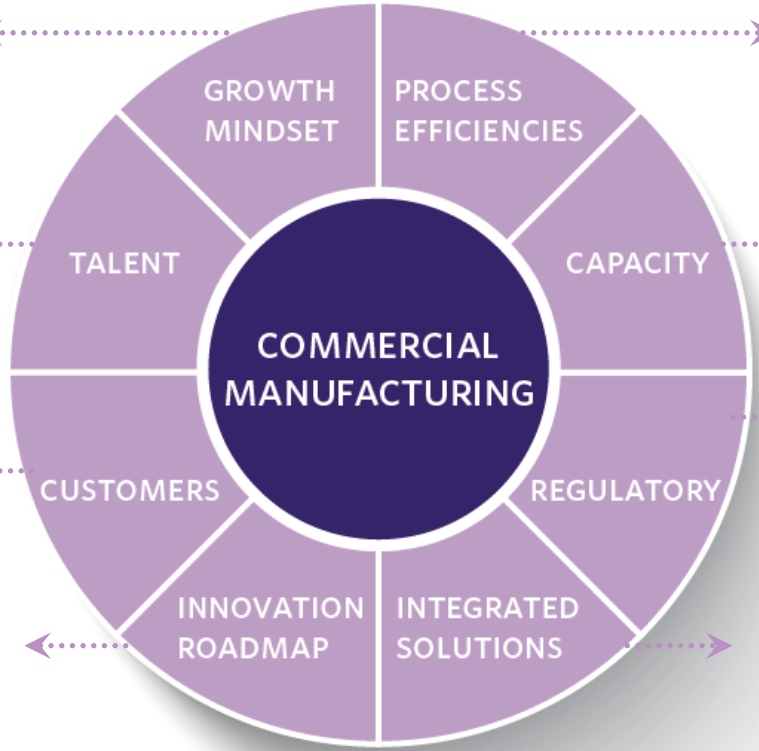
CUSTOMERS

Commercial-scale programs with leading biopharma

INNOVATION ROADMAP
- Drive scalability
- Support emerging modalities

INTEGRATED SOLUTIONS

Control of supply across full cell therapy value chain
- Plasmid DNA manufacturing
- Viral vector production
- Autologous/allogeneic manufacturing



Worldwide Cell Therapy Manufacturing Presence
Expanding Our Global Network

EUROPE (BELGIUM)

Clinical

~26,000 sq. ft. or 2.400m²

~41,000 sq. ft. or 3.800m²

- FDA/EU compliant
- 4 development labs each
- 11 clean rooms combined (9 and 2, respectively)
- Grade B storage
- Nitrogen storage
- Fill/Finish platform
- In-house Quality Control

Commercial Coming Soon

~60,000 sq. ft. or 5.700m²

- FDA/EU compliant
- Commercial throughput suites
- Under construction and expected to be commissioned in 2022

US (TX, NJ)

Clinical (TX)

~32,000 sq. ft. or 2.900m²

- FDA/EU compliant
- 3 development labs
- 8 clean rooms
- Grade B storage
- Nitrogen storage
- Fill/Finish services
- In-house Quality Control

Clinical & Commercial (NJ)

~30,000 sq. ft. or 2.800m²

- FDA/EU compliant
- 16 clean rooms
- Fill/Finish services
- In-house Quality Control

Worldwide Presence
Expanding Our Global Network

Germany (Dusseldorf)

Clinical iPSCs

~8,070 sq. ft. or 750m²

- GMP certified
- iPSC culture, S1 labs & equipment
- Cleanrooms, Class A–D
- 2 development labs
- 3 QC labs
- High-security cryostorage

Clinical iPSCs

iPSC offering supports full CT network

Clinical Cell Therapy

Commercial Cell Therapy

Clinical Cell Therapy

Late-stage Clin/Com CT

Commercial Cell Therapy

- **Dusseldorf, Germany**
- **Research, Development and GMP**
  - Research: iPSC differentiation, universal iPSC bank
  - Development: Custom made iPSCs, process development
  - GMP: Suites (class A/B), clinically approved iPSC cell banks
  - Talent and experience: Sophisticated skills in stem cell reprogramming, differentiation, cell banking

We Demonstrate Agility with Customer Programs within a Dynamic Market

ACCELERATED CLINICAL LANDSCAPE

First commercial autologous treatment launched

Emerging commercialization potential with allogeneic therapies

Shifting technologies from single-modifications toward genome-edited iPSC cells

Influx of new drug targets outpacing manufacturing capacity

Evolving regulatory landscape to fast-track cures for emerging disease

INDUSTRY-EXPERTISE | Scientific and manufacturing expertise with superior talent delivering scalable and commercially-viable processes

PARTNERSHIP-MENTALITY | Work hand-in-hand with customers and deliver on short-term needs with a long-term vision

OPERATIONAL EXCELLENCE | State-of-the-art facilities managing complexities of autologous and allogeneic manufacturing

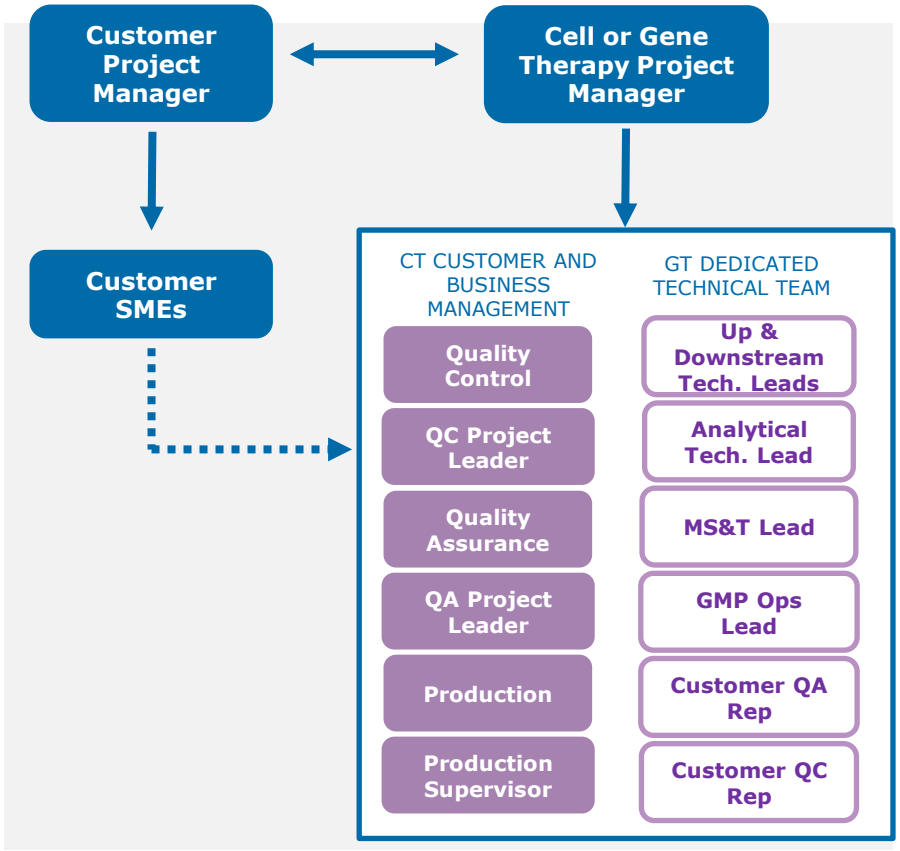
EFFECTIVE CHANGE MANAGEMENT | Continuous innovation and expansion while adapting to an evolving market

FORWARD-LOOKING APPROACH | Speed to clinic with scalable programs early on deployed with a fully-integrated transition team

Agenda

- Catalent Introduction
- Catalent Cell and Gene Therapy
- Gene Therapy Overview
- Cell Therapy Overview
- **Partnership Management**

CGT Program & Alliance Management
Ways of Working and Governance



Project Management

- Capacity to adapt the project management based on customer expectation
- Designated PM serves as main point of contact
- Strongly encourage PM to PM communication
- F2F kickoff meeting to initiate program
  - Present and finalize project plan, involvement from all functional groups
- External meeting (TC between Customer team and the CGT Team)
- Weekly internal meeting
  - Share data, updates on program, forum for decision making, review timeline. Minutes with actions provided

Joint Steering Committee

- Quarterly strategic meeting with senior management from Customer and Catalent
- High level overview of the program, forum for decision making and touch on critical topics

Manufacturing Partnership Management for Cell Therapy
Secure Supply Through a Model That Suits Your Program Needs

2 MANUFACTURING STRATEGIES TO RESERVE SLOTS

Dedicated Clean Room

- Clean room dedicated for manufacturing
- Slot dates provided by us every month
- Clean room is booked ahead of time
- Minimum volume requirements each month

Suitable for autologous manufacturing

Manufacturing Slots/Release Timelines

- 1 year rolling forecast supplied by the customer
- Production is scheduled by us accomodating customer release timelines
- Regular training runs are performed to maintain production teams expertise and training

Suitable for allogeneic manufacturing

EXPERIENCE YOUR MANUFACTURING WITHIN OUR FACILITIES

Configure your clean room with the equipment of your choice on our iPad application. Visit your labspace virtually on and iPad and in virtual reality with the Oculus Rift device.

Download on the App Store | oculus | 3D

Your Cell & Gene Therapy Leadership Team

Manja Boerman
PRESIDENT

Joe Codamo
HEAD OF GLOBAL CELL THERAPY BUSINESS

Jo Dalle
HEAD OF GLOBAL PLASMIDS BUSINESS

Jean-Noel David
VP BUSINESS TRANSFORMATION & CHANGE MANAGEMENT

Colleen Floreck
VP GLOBAL MARKETING & STRATEGY

Marc Goemans
VP GLOBAL BUSINESS DEVELOPMENT

Randy Henrickson
VP HEAD OF GENE THERAPY BUSINESS

Barry Oliver
REGIONAL HEAD OF QUALITY, CGT EU

Jesse Boyd
VP FINANCE, CGT

Philip Wills
CHIEF COMMERCIAL OFFICER

Lauren Smith
VP QUALITY / US

Kamia Taylor
VP GLOBAL PROGRAM MANAGEMENT

Joel Tobin
VP GLOBAL HUMAN RESOURCES

Tom VanCott
GLOBAL HEAD OF PRODUCT DEVELOPMENT

Your Comprehensive Cell & Gene Therapy Partner

- Variety of established and emerging cell modalities across both autologous and allogeneic systems
- Experience across both *in vivo* and *ex vivo* gene modification technologies
- Clinical through commercial manufacturing expertise across both cell and gene therapy
- Global technology and scale-up experience from industry-leading scientists

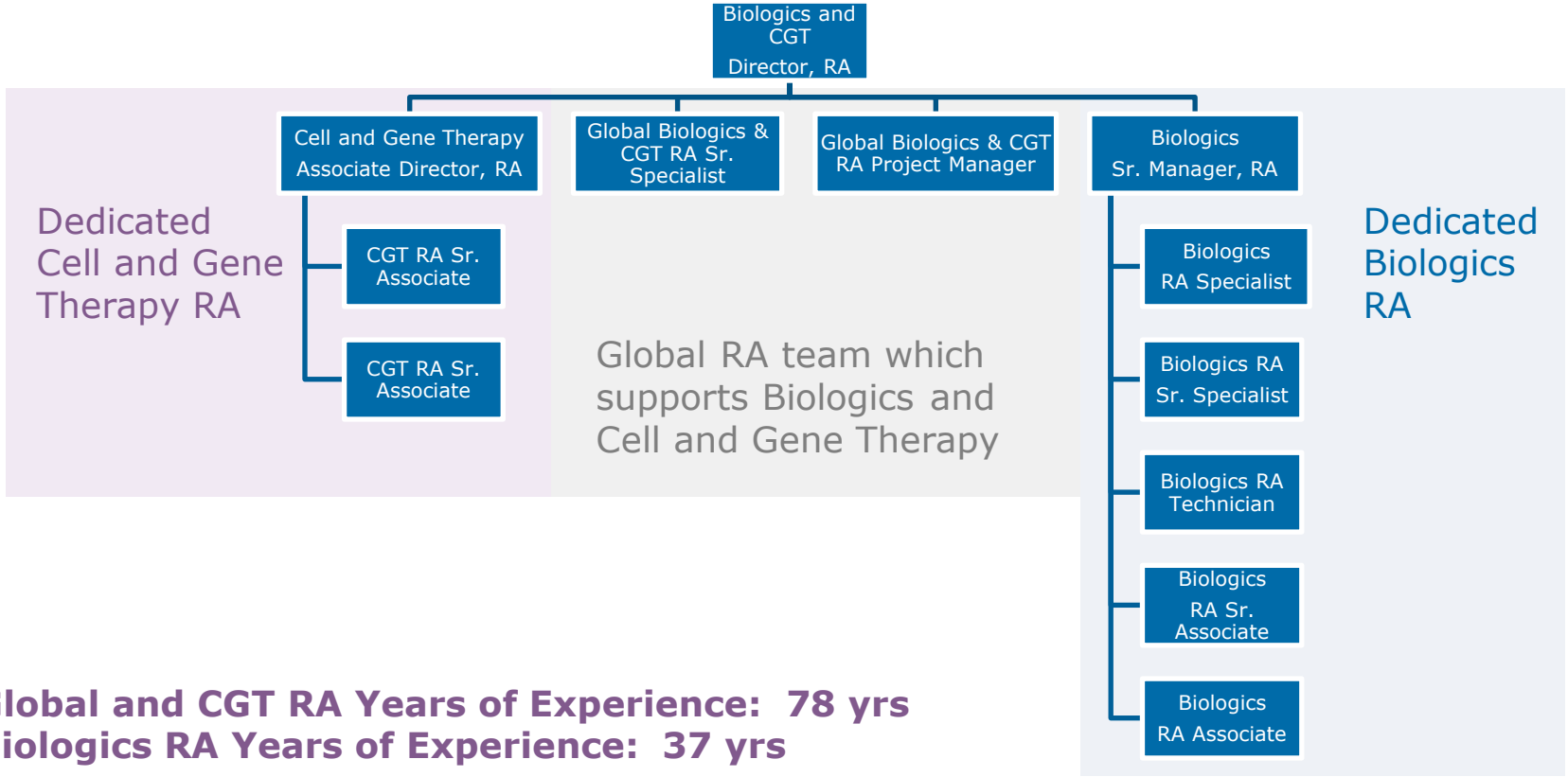
Catalent®
CELL & GENE THERAPY

Range of Services
Global Regulatory Affairs

Global RA Team – based in US, CA and UK

- Cell and Gene Therapy and Biological products are supported by the US based team.
- Publishing Operations are supported by the UK based team.
- Facility aligned RA team provides in depth knowledge of manufacturing processes and validation philosophy through partnership with Quality and Technical teams.
- Regulatory support for major markets as well as ROW countries.

Catalent Biologics and CGT RA Team



Global and CGT RA Years of Experience: 78 yrs
Biologics RA Years of Experience: 37 yrs

Range of Services
Global Regulatory Affairs

Support from pre-IND through post-approval

- Regulatory advice
- Complete dossier authoring
- Submission & document review
- eCTD & publishing support
- Full regulatory strategic planning
- Updates & maintenance
- Regulatory triage & health authority meetings
- Due diligence
- Gap assessment & advisement

Cell and Gene Therapy
Global Regulatory Affairs Tailored Solutions

	IND	PHASE I-III	BLA	COMMERCIAL
Silver Support	• Summarize Catalent test methods/qualifications and equipment qualifications • Facility information to support 3.2.A.1		• Author Facility Section • Module 3 compliance check	• Submission review • Post-approval support
Gold Support	• Author Module 3 product section • Feasibility & regulatory advice • Review product development reports & source documents • Includes provision to publish	• Updates to IND	• Author Module 3 product section • Review source documents • Advisement on Module 3 • Includes provision to publish	• Submission support for each new market
Platinum Support	• Author complete Module 3 • Full regulatory advice and document strategy • Review product development reports and source documents • Includes provision to publish	• Updates to IND	• Author complete Module 3 • Review of source documents • Advisement on Module 3 • Includes provision to publish	• Submission support for each new market

Catalent®
CELL & GENE THERAPY

discover more.

CATALENT PHARMA SOLUTIONS
14 SCHOOLHOUSE ROAD
SOMERSET, NJ 08873
1 866 720 3148

BIOLOGICS.CATALENT.COM/CELL-GENE-THERAPY

WWW.CATALENT.COM

DEVELOPMENT DELIVERY SUPPLY

more products. better treatments. reliably supplied.™