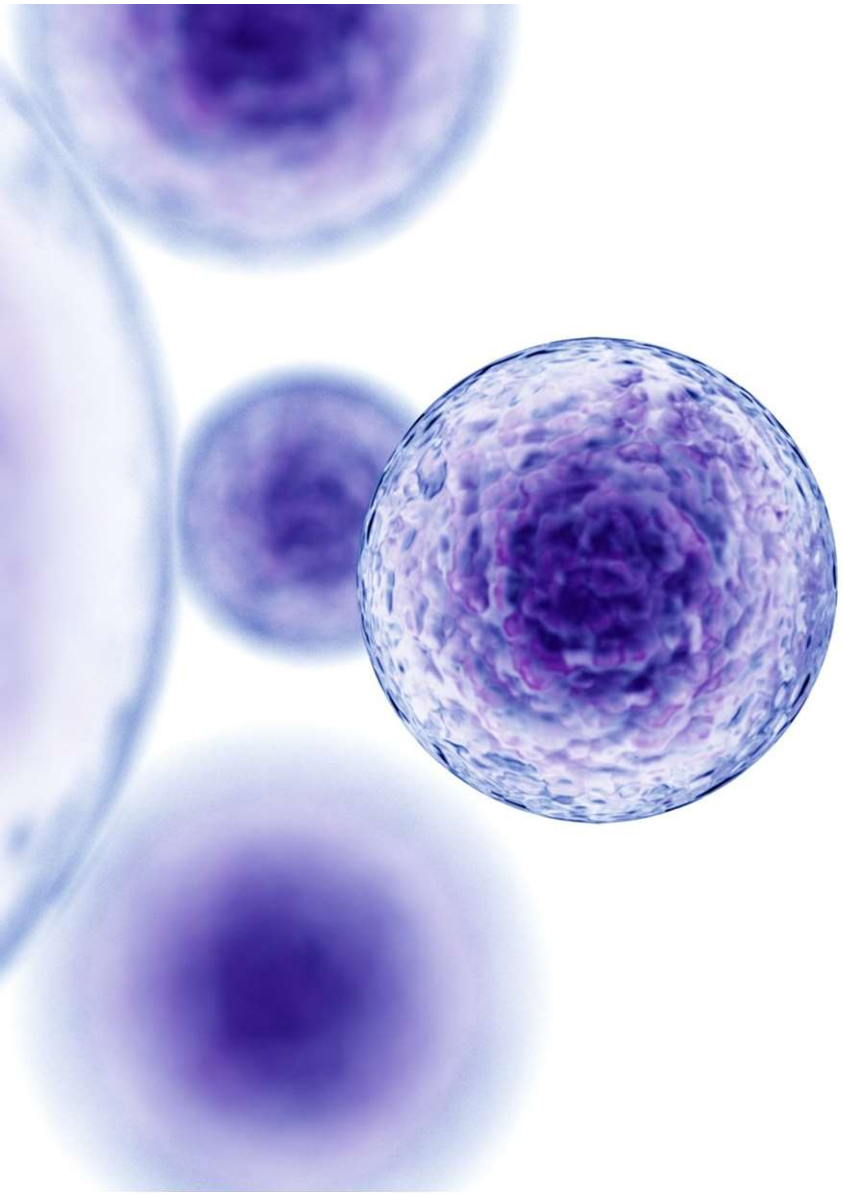


Catalent®
CELL & GENE THERAPY

Cell Therapy

BRIDGING THE GAP FROM BENCH TO COMMERCIAL READINESS

more products. better treatments. reliably supplied.™

Agenda

Catalent Introduction

Cell Therapy Overview

Capabilities & Expertise

Project and Partnership Management

Agenda

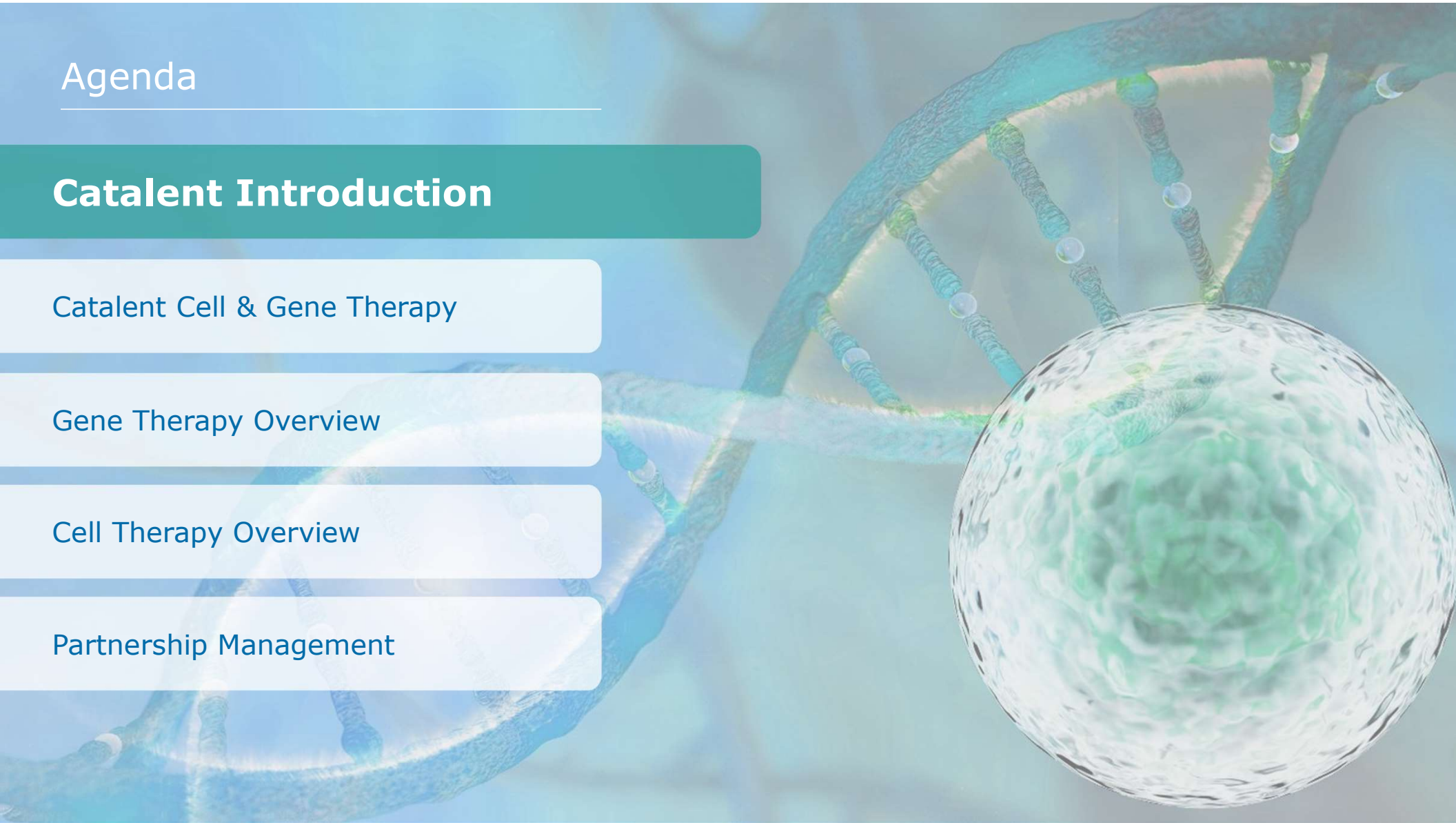
Catalent Introduction

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 PROMISE

more products. better treatments. reliably supplied.™

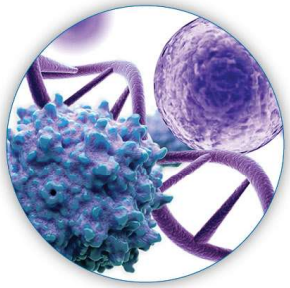
DEVELOPMENT	**MORE PRODUCTS** to clinic and market faster with our expert development solutions
DELIVERY	**BETTER TREATMENTS** with broadest portfolio of optimal delivery technologies and dose forms
SUPPLY	**RELIABLY SUPPLIED** with flexible solutions across our global multi-modality manufacturing network

EXPERTISE, TECHNOLOGIES, SCALE & SERVICE TO TRANSFORM YOUR MOLECULES INTO SUCCESSFUL TREATMENTS

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

ORAL

BIOLOGICS DRUG PRODUCT



BIOLOGICS DRUG SUBSTANCE

ANTIBODIES, CELL, GENE, MRNA, VACCINES & PLASMIDS

INHALATION

CONSUMER HEALTH

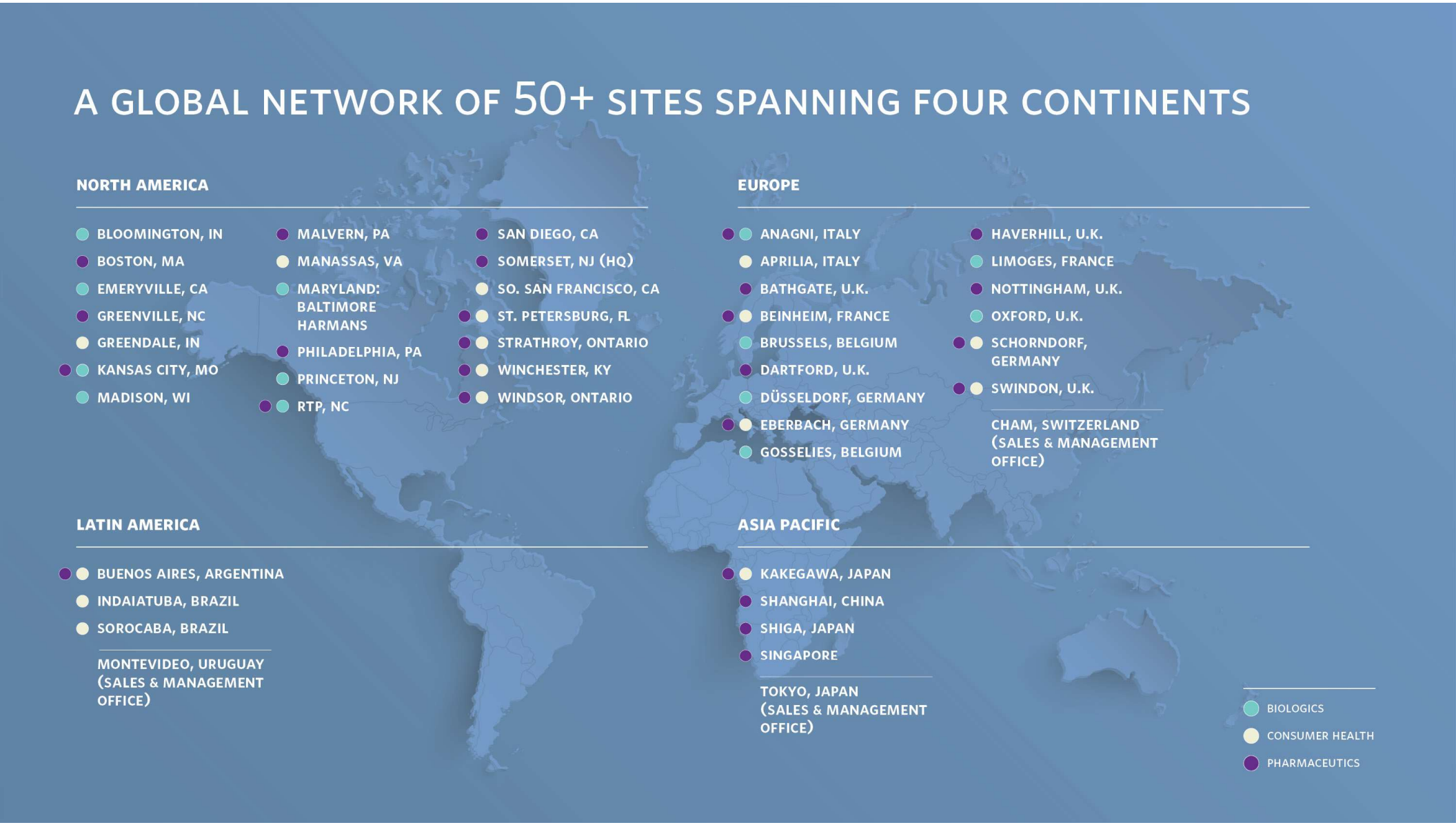
COMPREHENSIVE DEVELOPMENT

SUPERIOR DELIVERY TECHNOLOGIES

GLOBAL CLINICAL SUPPLY

MANUFACTURING & PACKAGING ACROSS MODALITIES

A GLOBAL NETWORK OF 50+ SITES SPANNING FOUR CONTINENTS



CORPORATE RESPONSIBILITY guides our actions & creates a positive social impact in everything we do

catalent cares

PEOPLE

Putting patients and our teams first in our actions and decisions.

ENVIRONMENT

Using science-based targets to minimize our carbon emissions and enabling water-efficiency and waste-reduction goals.

COMMUNITIES

Investing our time, talents and resources to give back, serve patients, and promote STEM.

RECENT ACHIEVEMENTS

97% renewable energy

$1.2M+ in community grants, driven by our COVID-19 response

Completed third-party human rights assessment

Increased diversity in global leadership & expanded employee resource groups

SUSTAINABILITY GOALS

Reduce our Scope 1 & Scope 2 emissions by 42%

No residual active pharmaceutical ingredients (APIs) above predicted no-effect level in wastewater

Reduce water intensity to 500 m^3 / M$ revenue

Zero waste sent to landfill

CEO ACT!ON FOR DIVERSITY & INCLUSION

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

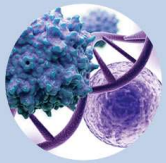
SCIENCE BASED TARGETS
DRIVING AMBITIOUS CORPORATE CLIMATE ACTION

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

WE WILL HELP YOU ACCELERATE & DE-RISK THE DEVELOPMENT & LAUNCH OF YOUR TREATMENTS AT EVERY STAGE

PREFORMULATION

FORMULATIONS FOR SAFETY ASSESSMENT STUDIES

CLINICAL SUPPLY SERVICES

FORMULATION & PROCESS DEVELOPMENT

CLINICAL & COMMERCIAL MANUFACTURING:
BIOLOGICS, CELL, GENE, PLASMID, IPSC, MRNA, VACCINE, SOLID ORAL, SOFTGEL, PARENTERAL & INHALATION

PRE-CLINICAL | PHASE 1 | PHASE 2 | PHASE 3 | COMMERCIAL

SOLID-STATE & SOLUBILITY SCREENING

PLASMIDS & VIRAL VECTORS

CELL LINE DEVELOPMENT

IPSC GMP LINES

FIRST-IN-HUMAN CLINICAL SUPPLY MANAGEMENT

ADVANCED DELIVERY TECHNOLOGIES

BIOAVAILABILITY SOLUTIONS

BIOMANUFACTURING

INTEGRATED ANALYTICAL

REGULATORY SUPPORT

FINAL DOSE DESIGN

PRODUCT OPTIMIZATION

SCALE-UP

VALIDATION

TECH TRANSFER

GLOBAL SUPPLY ACROSS MODALITIES

LINE EXTENSIONS

DOSE IMPROVEMENTS

ACCELERATED INTEGRATION SOLUTION SUITES

GPEx® CELL LINE DEVELOPMENT

PLASMID, CELL & GENE THERAPY TECHNOLOGIES

SOLID & ORAL TECHNOLOGIES

ZYDIS® FAST-DISSOLVING TECHNOLOGIES

STERILE FILL/ FINISH

PULMONARY & NASAL TECHNOLOGIES

FLEXIBLE MANUFACTURING

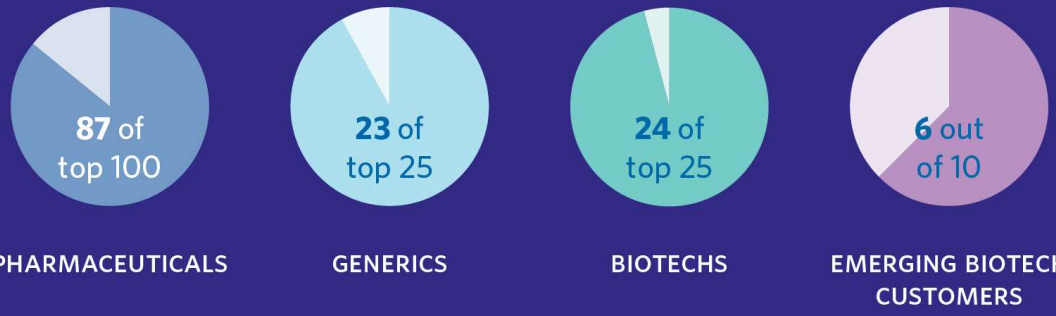
UNRIVALED EXPERTISE & SCALE TO HELP YOU SUCCEED

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



WE SERVE

BIOLOGICS

45+
COMMERCIALLY APPROVED PRODUCTS MANUFACTURED & PACKAGED

700+ ANTIBODIES
80+ RECOMBINANT PROTEINS DEVELOPED

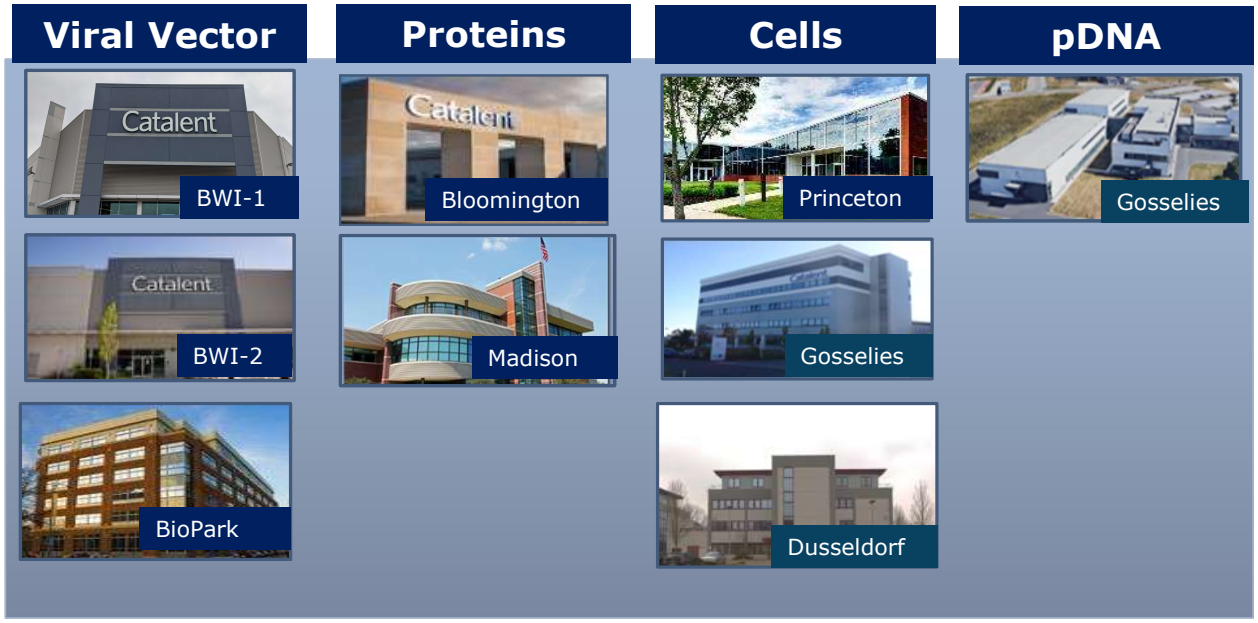
EXPERIENCE WITH 100+
CELL & GENE THERAPY PROGRAMS

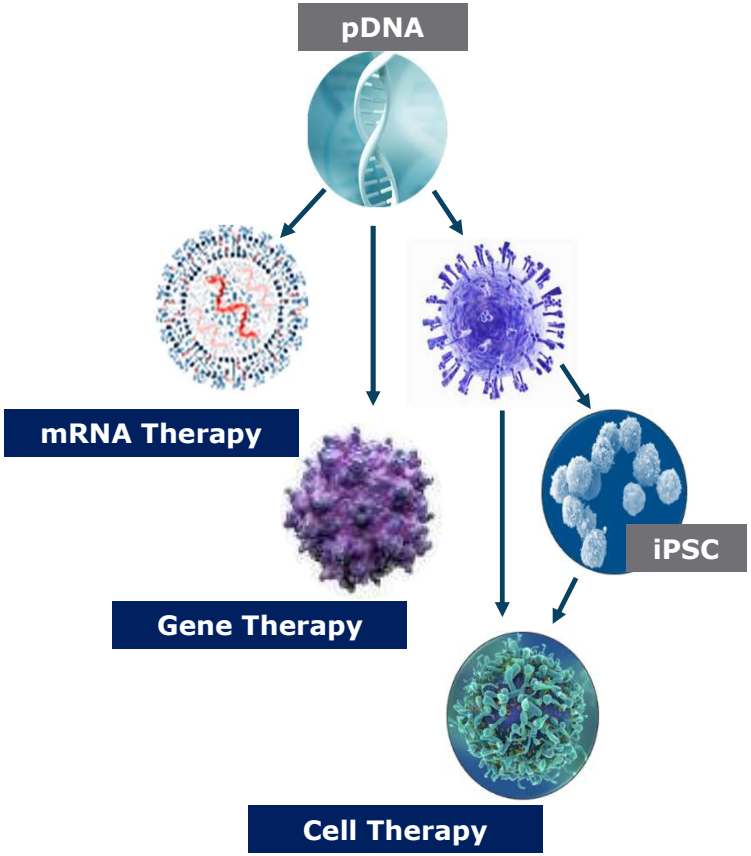
CLINICAL SUPPLY

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

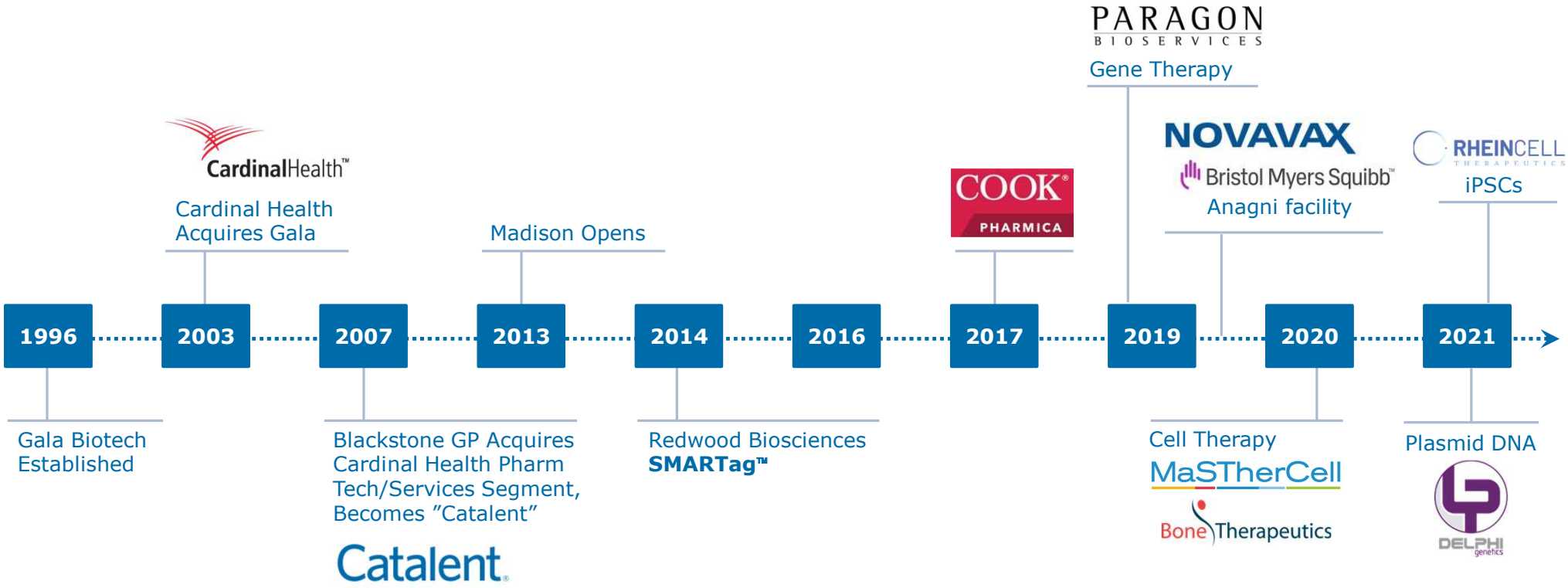
150,000+
SHIPMENTS EVERY YEAR

Catalent BioModalities Site Network
From Building Block To End Product





Evolution of Catalent Biologics



From Small Molecules Formulation (SOFTGEL) focused manufacturing organization…
to a **LEADING** Biologics/Cell & Gene Therapy CDMO

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
- 60+ Gene Therapy programs
- 20+ Cell Therapy tech transfers into cGMP

Talent and Expertise

- Over 30 years of experience
- Plasmid production expertise
- Deep AAV and lentiviral experience with a strong and growing talent pool
- 500+ Cell Therapy batches manufactured
- 2000+ Gene Therapy batches manufactured

Full-service partner providing integrated solutions for advanced therapeutics

Helping innovators develop better treatments faster

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 an additional site in October 2020
- 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 build in Belgium onboarding US/EU customers
- Integrated Catalent teams for global customer partnerships – raw material through clinical supply

DIVERSE CUSTOMER BASE WITH SIGNIFICANT REPEAT BUSINESS

Combining Leaders Across the Biologics Industry
To Help You Get to Market Faster

TRUSTED

30+ years experience in Biologics services

60+ gene therapy programs with partnerships with **20+** industry leaders

Experience working with **10+** of established and emerging cell modalities

600+ antibodies and **80+** recombinant proteins developed

PROVEN

35+ Commercially approved products through fill finish

Successful **AAV** platform experience including the **first Gene Therapy on the market**

Working with **industry leaders** and **pioneers** in the cell therapy field **(e.g., CRISPR)**

13 approved products using GPEX® technology

COMMITTED

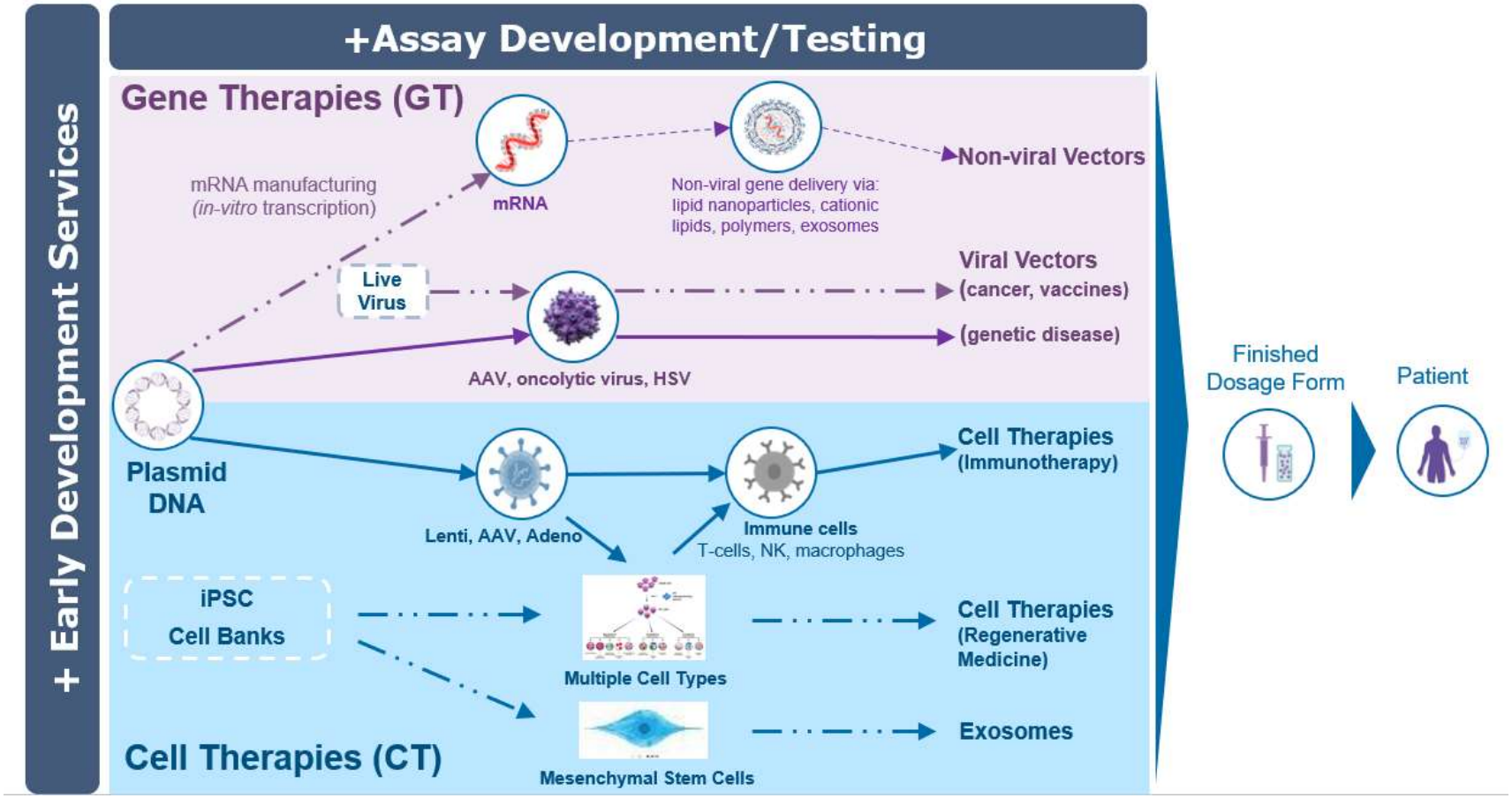
$2.5 Billion+ invested by Catalent

400+ open positions in cell and gene therapy with **1000+** employees overall

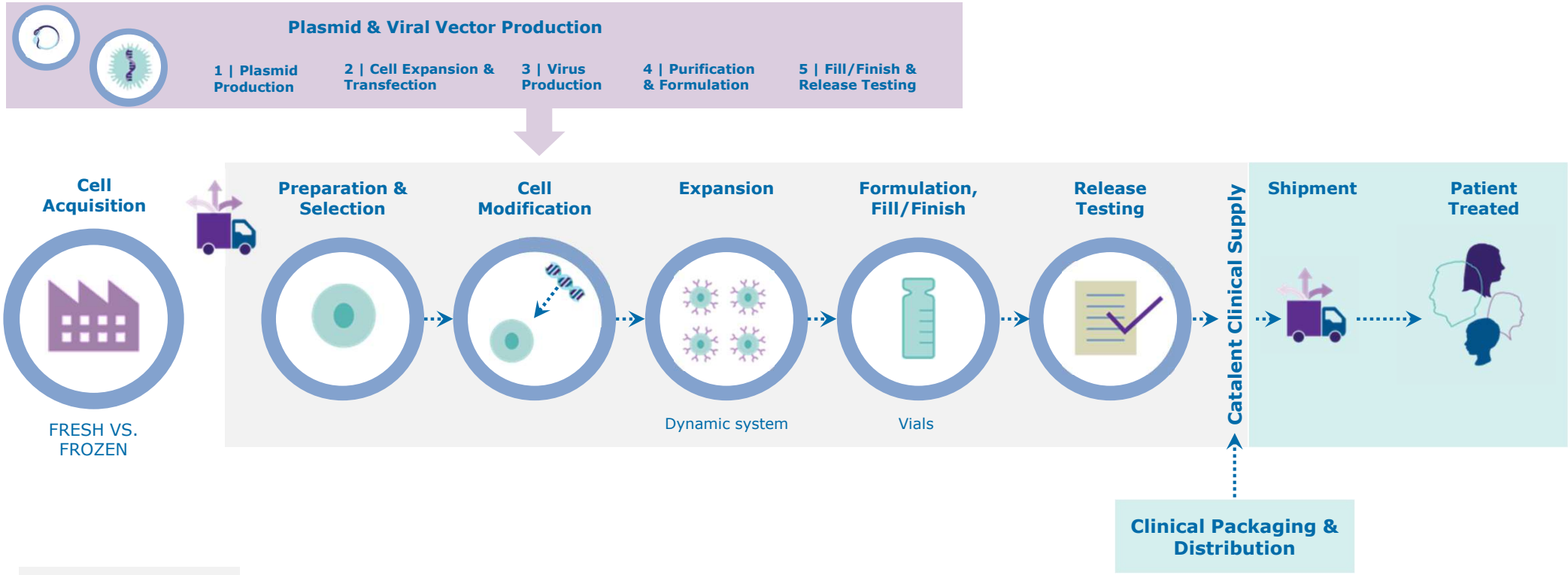
Catalent's **commitment** bring cell and gene therapy manufacturing to **scale**

18,000+ employees worldwide

Catalent provides integrated pathways for Cell & Gene Therapy product development



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



CELL THERAPY

GENE THERAPY

CLINICAL SUPPLY SERVICES

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

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

Our Clinical Supply Services
Comprehensive Capabilities to Support Studies of All Sizes

When you work with Catalent, you have access to our world-class facilities, suite of services and deep global expertise.

- Clinical Supply Management
- Packaging & Labeling
- Commercial Product Sourcing
- Specialty & Cold Chain Handling

- Clinical Storage & Distribution
- Import/Export Expertise
- Returns & Destruction
- Low-Volume Commercial Packaging

In addition to our core capabilities, we have an array of specialized and integrated services to support clinical supply excellence.

Clinical Supply Services Footprint
Global Reach with Local Presence

Our global scale combined with local presence provides optimal support for your clinical development efforts anywhere in the world. Global, harmonized capabilities enable us to map the best solution tailored to your specific study requirements with an eye to time, budget and product efficiencies.

9 cGMP locations across the US, Europe & APAC

58+ audited depots across 6 continents

Agenda

Catalent Introduction

Cell Therapy Overview

Capabilities & Expertise

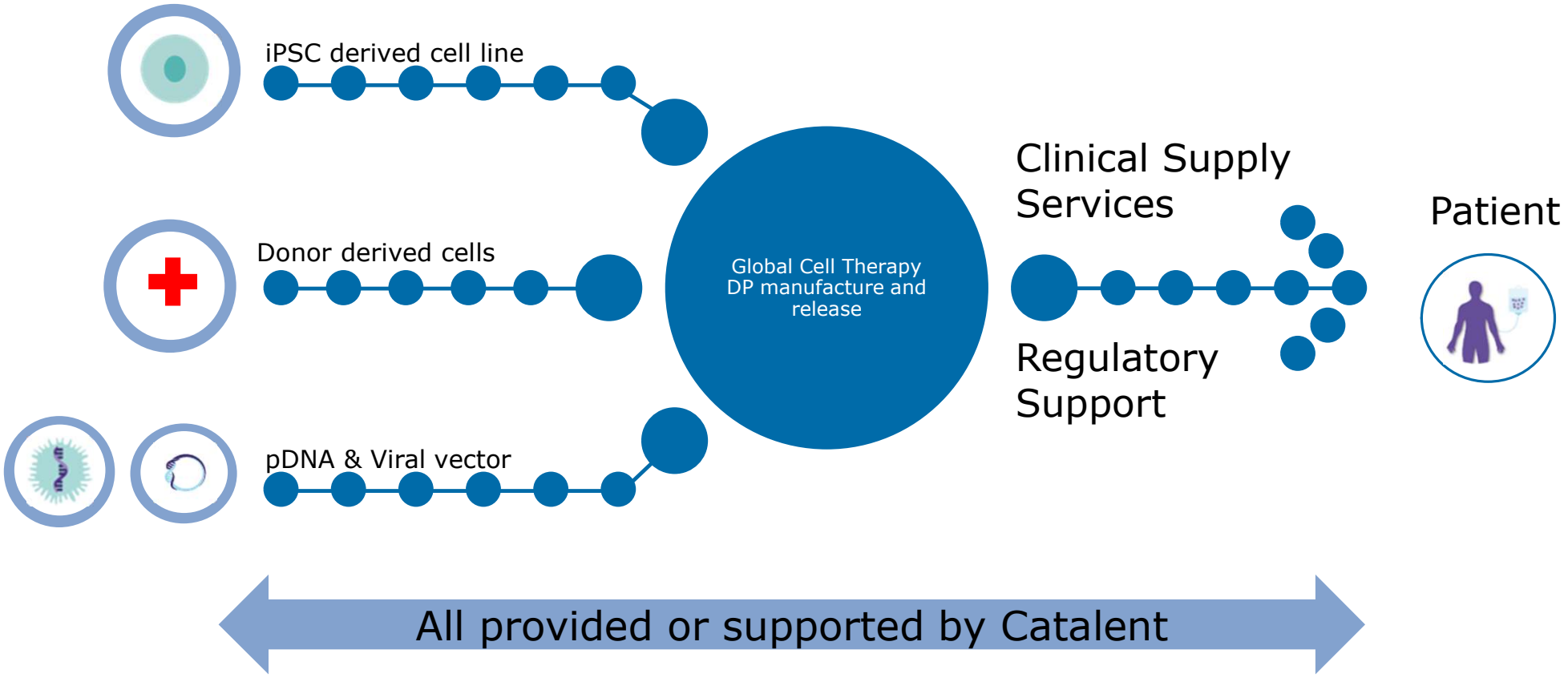
Project and Partnership Management

Catalent Cell Therapy at a Glance

CUTTING-EDGE CELL THERAPY EXPERIENCE	PART OF OUR GLOBAL NETWORK	INNOVATIVE APPROACH Enabling ground-breaking customer success	COMMITMENT TO EXPANSION Meeting customers' capacity needs
• Autologous and Allogeneic therapy manufacturing • Clinical and commercial scale • Broad coverage of cell types	• Purchased MaSTherCell in February 2020 • Expanded capacity in October 2020 and April 2022 • Purchased RheinCell Therapeutics in August 2021 • Leverages capabilities across Biologics, Clinical Supply Services, Gene Therapy	• Custom methodologies - Diagnostic, Manufacturing by Design, Fill/Finish, Analytical Development • Primed to bring the first allogeneic CAR-T commercial treatment to market	• Clinical manufacturing facilities in Belgium and US • Commercial in US and building in Belgium • Integrated teams enabling global customer partnerships

DIVERSE CUSTOMER BASE WITH SIGNIFICANT REPEAT BUSINESS

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



Our Cell Therapy Network

Global Campuses, Early Stage Through to Clinical and Commercial-scale

R&D & EARLY-STAGE DEV

PD/CLINICAL/COMMERCIAL

Dusseldorf,DE

- Our iPSC Centre of excellence
- Dedicated teams & facilities for iPSC innovation, development services and characterization
- CGMP suites and storage for producing and storing your iPSC cell banks
- Off the shelf iPSC cell banks

Gosselies, BE

- Our European Cell Therapy Centre of Excellence
- 86k ft^2 / 7.9k m^2 serving your cell therapy process and analytical needs
- 22 Grade B/C CGMP clean rooms
- Full process, analytical, formulation development capabilities
- Dedicated QC facilities & QP services

Princeton, NJ

- Our US Cell Therapy Centre of Excellence
- 30k ft^2 / 2.8k m^2 serving your cell therapy process and analytical needs
- 16 Grade B CGMP clean rooms
- Dedicated QC facilities
- Significant capacity for future expansion

INTERNATIONAL COVERAGE FOR YOUR CLINICAL & COMMERCIAL NEEDS

Catalent Demonstrates 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

Cell Therapy Overview

Capabilities & Expertise

Project and Partnership Management

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

Our Experience
Delivering Cell Therapy CDMO services

TECH TRANSFERS & SCALE-UP

20+ tech transfers into GMP

500+ batches manufactured for 20+ customers

PEOPLE

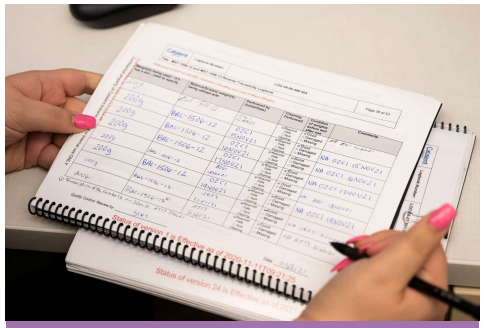
10+ years experience in Cell Therapy

Global organisation experienced in clinical & commercial launch

PRODUCTS

Equally experienced in Autologous & Allogeneic

Cell types including: **CAR-T, NK, iPSC, MSC, HSC, TCR, TILs**



QUALITY

Strong GMP track record

Global team experienced in IND & BLA support to clients

DELIVERING CELL THERAPY CDMO SERVICES FOR 10+ YEARS

Support at all stages of development

EARLY STAGE

- iPSC cell line generation
- Off the shelf iPSC cell banks available under license
- GMP Cell Banking
- Cloning, differentiation and expansion services
- Dedicated centre of excellence for iPSC

CLINICAL SUPPLY

- Extensive process & analytical development capabilities
- Strong expertise in 3D expansion capabilities
- 38 CGMP clean rooms across US & EU to produce your Autolgous & Allogeneic product
- Dedicated QC facilities
- Clinical supply services to cover your post manufacturing needs

COMMERCIAL

- HTP, commercial scale facilities across EU & US
- 116k ft2 / 10.8k m2 space designed for commercial supply
- Dedicated QC facilities across EU and US
- Leverage Catalent's strong history in bringing products to market
- Experienced regulatory support teams

EARLY-STAGE DEVELOPMENT → **PROCESS AND ANALYTICAL DEVELOPMENT** → **TECH TRANSFER, GMP MANUFACTURING, DP RELEASE**

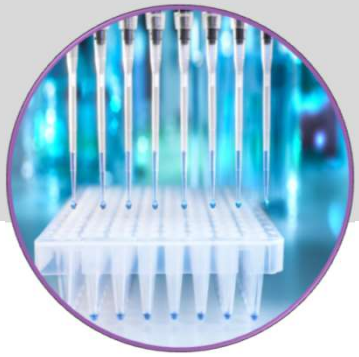
Our Services and Expertise

PROCESS

- Cell banking, cloning, characterization, editing
- Process characterization, validation and scale up
- Expertise with all industry leading technologies:
  - ✓ LOVO, Sepax, CliniMACS®[1] Prodigy
  - ✓ Xuri Bioreactors, G-Rex, STR®[2] Bioreactors

ANALYTICAL & QC

- DS, DP and raw material testing
- Phase dependent method qualification / validation
- Extensive capabilities in flow cytometry, qPCR, safety, cytokine quantification, microbiology
- Extensive 3rd party network of laboratories



QUALITY & REGULATORY

- QP Release Services (Importation, Release)
- Tissue Establishment
- Third Party Auditing
- Regulatory submission preparation and support
- Rapid batch release to support fast vein to vein times

1. Trademark of Miltenyi Biotec
2. Trademark of Sartorius

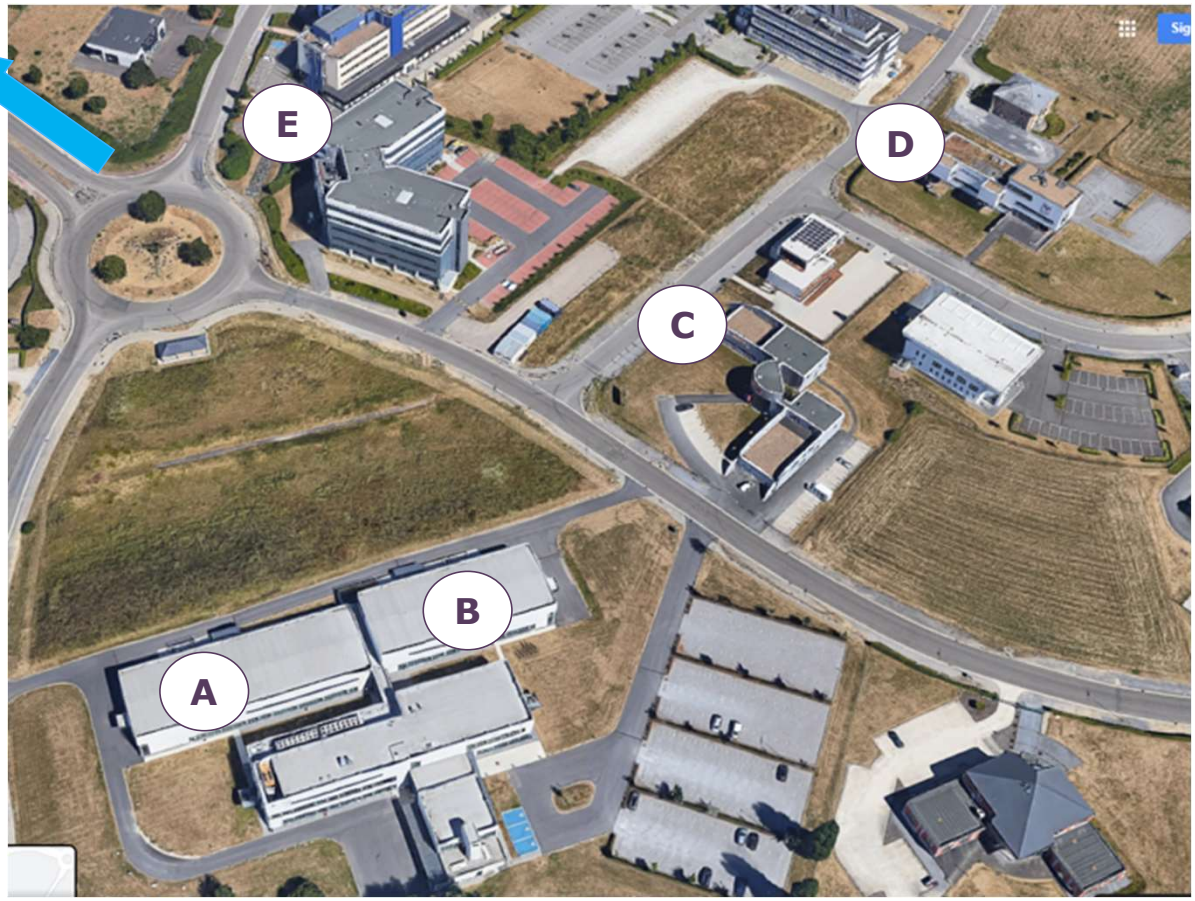
Gosselies Campus – Cell Therapy
Development to Clinical and Commercial Scale Manufacturing

- **60,000 sq. ft** dedicated to late-stage and commercial manufacturing
  - **13 CGMP grade B clean rooms**
  - 4 suites designed for allogeneic bioreactor manufacture
  - 2 suites designed for fill/finish at small and large scale
- **44,000 sq. ft.** dedicated to development and clinical stage manufacturing
  - **11 CGMP grade B clean rooms**
  - **5 process development labs**
- **Autologous and allogeneic** capabilities
- **Cell types** including: CAR-T, NK, iPSC, MSC, TILs, TCR, Treg, Mreg, ESC
- On site warehouse, Nitrogen storage, fill/finish, and QC
- **Training centre** on campus for on-boarding and continuous training





European CGT Center of Excellence in Gosselies



A: Cell Therapy

B: Plasmid DNA

C: Training center

D: Plasmid DNA

E: Cell Therapy

F: Cell Therapy

Dusseldorf, Germany
iPSC Centre of Excellence

- **Our Centre of Excellence dedicated to iPSC R&D and GMP manufacturing**
- **World class labs and teams performing:**
  - iPSC isolation, cloning and banking
  - Differentiation and expansion development
  - Characterization services
- **Fully characterized, donor-consented, clinical-grade, universally applicable HLA-homozygous iPSC lines derived from cord blood** available off-the-shelf
- **GMP suites for cell banking**
- **On-site QC and support services** leveraging Catalent's global systems and services

Technologies available:

High scientific competencies

Own differentiation protocols for
- NK cells
- Mesenchymal stem cells
- Cardiac cells
- Retinal Epithelium cells
- Endothelial Progenitor cells
- T-cells (in preparation)
- Others in development.

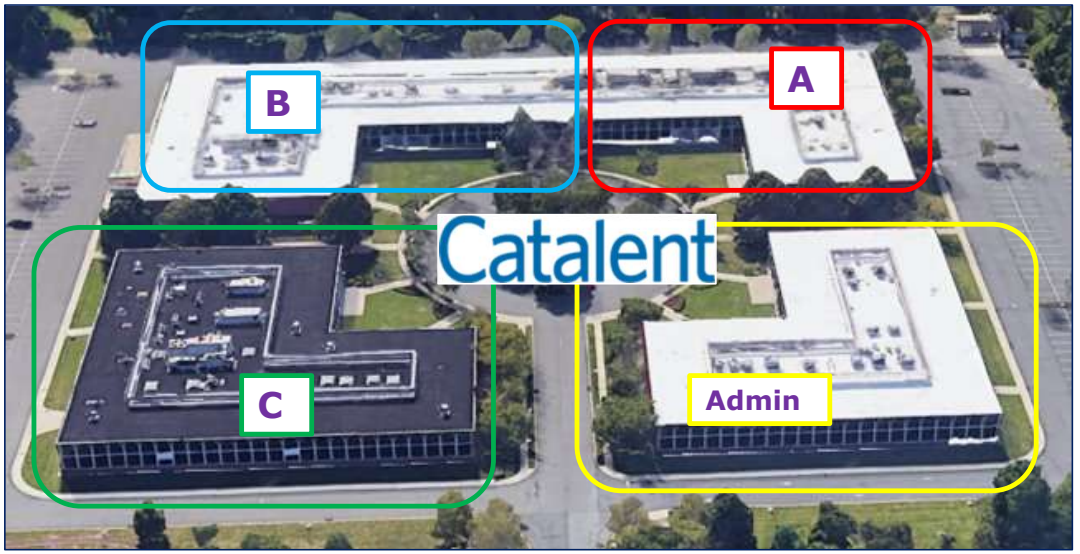
Gene editing services

Princeton Campus – Cell Therapy
Development, Clinical and Commercial Manufacturing

- **~30,000 sq. ft state-of-the-art CGMP** facility
  - **16 CGMP clean rooms**
  - **QC labs**
- Experienced with CGMP manufacture and release of autologous treated red blood cells (turn around in 48 hours)
- **Significant expansion capacity ~80,000 sq. ft.** on campus which has been secured by Catalent
  - CGMP expansion space to double capacity
  - AD/PD building
  - Expansion of warehouse and QC
- **Close proximity** to Philadelphia and Baltimore facilities, allowing for a **robust and integrated supply chain** for viral vectors and clinical support service

Princeton Cell Therapy Campus

- Building a **US Cell Therapy Center of Excellence**
- Catalent has now secured all buildings on campus with **majority of space** (some additional tenants)
- Campus high level design:
  - **Building A:** CGMP manufacturing, warehouse and QC
  - **Building B:** CGMP expansion space. Additional 23,000 sq.ft. allowing for a duplication of existing manufacturing space
  - **Building C:** 33,000 sq.ft P&AD laboratories
  - **Building D:** Dedicated for offices, meeting rooms and hosting client visits



Our Global Quality Expertise

GLOBAL QUALITY SERVICES

- Tissue Establishment (GOS)
  - Biobank
  - Intermediate Structure
  - Medical Doctor
- QP services
  - QP Office
  - Importation
  - Release
- Third Party Auditing
- Responsible Persons
- Global Regulatory Support with submission authoring, reporting and review
- Inspection management

EXTENSIVE EXPERTISE IN ALL YOUR QC AND ANALYTICAL NEEDS

- Cell culture
- Flow-cytometry (characterisation, potency, plate/antibody assays)
- Cell Count & Viability
- Endotoxin (multi region compliant)
- qPCR
- Cytokine quantification
- Sterility testing, incl bacT/Alert®[1]
- pH & Osmolality
- Container content (filling volume)

ENSURING PERFORMANCE ACROSS OUR SITES

- Active monitoring of KPIs with all levels of organisation
- Active implementation of latest digital tools and systems including TrackWise® [2], ComplianceWire® [3], LIMS, electronic batch records
- Active engagement with authorities and agencies ensuring our systems remain aligned with rapidly evolving systems

1. Trademark of Biomerieux, Inc
2. Trademark of Sparta Systems Solutions
3. Trademark of EduNeering, Inc.

Our Global Supply Chain and Procurement Services

STORAGE AND DISTRIBUTION

- Extensive onsite cold storage capabilities (2-8, -20, -80, -150 ° C)
- Shipments at -160° C to RT provided through our validated, global suppliers
- Experienced in release and shipment of DP 24-48hr after production

MATERIALS MANAGEMENT AND PLANNING

- Extensive onsite & 3rd party storage network for materials and their testing
- Leverage Catalent's global network and buying power to secure best prices and supply
- We have ensured supply throughout Covid19 with no delays due to material shortage

ENSURE PERFORMANCE

- Monitor KPIs with our suppliers to ensure performance
- Procurement is managed at site and global levels to ensure flexibility and coverage

World Class Development and Support Services

Process Development

- Diverse experience with multiple cell types including iPSCs, CAR-T, NK, etc. (40+ programs)
- Full development services from process design through to optimization incl formulation
- Routine use of QbD approaches, expertise in DoE, biostatistics
- Static and dynamic cell expansion capabilities incl Bioreactors (Wave, STR, vertical wheel, hollow fibre)
- Downstream + F&F capabilities with commonly used technologies

Analytical Development

- Development of methods for characterization, DP release, intermediates and stability
- Delivery of methods that are ready for method validation/qualification
- Development capabilities include flow cytometry (identity, purity, multicolour flow panels), potency, qPCR and ddPCR, cell counting/viability.

MSAT and Tech Transfer

- Dedicated teams at all sites supporting manufacturing, development and QC with:
  - Tech transfer
  - Continuous improvement
  - Process validation
  - Process and analytical lifecycle management
  - Knowledge and data management
  - Process and analytical investigations
  - Process and product characterisation

Delivering Our Client's Programs
Getting Late Phase/ Commercial Ready

Review client's status and map path forward for clinical and/or commercial supply
- Simple gap assessment or process diagnostic
- Manufacturing by design (MbD)
- Observation runs with client

Bring your program to a manufacturing ready state
- Process and analytical development; or
- Process and analytical optimisation; or
- Direct transfer to manufacturing and QC

Tech transfer and scale up
- Training and aseptic qualification
- Materials and equipment readiness
- Engineering batches, method validation and qualification

Fast to Clinic
- Regulatory support with preparation of clinical dossier (IND, IMPD, etc)
- Manufacture and release for clinical and/or comparability studies, stability
- Build process & analytical know how, identify facility & resource needs for commercial

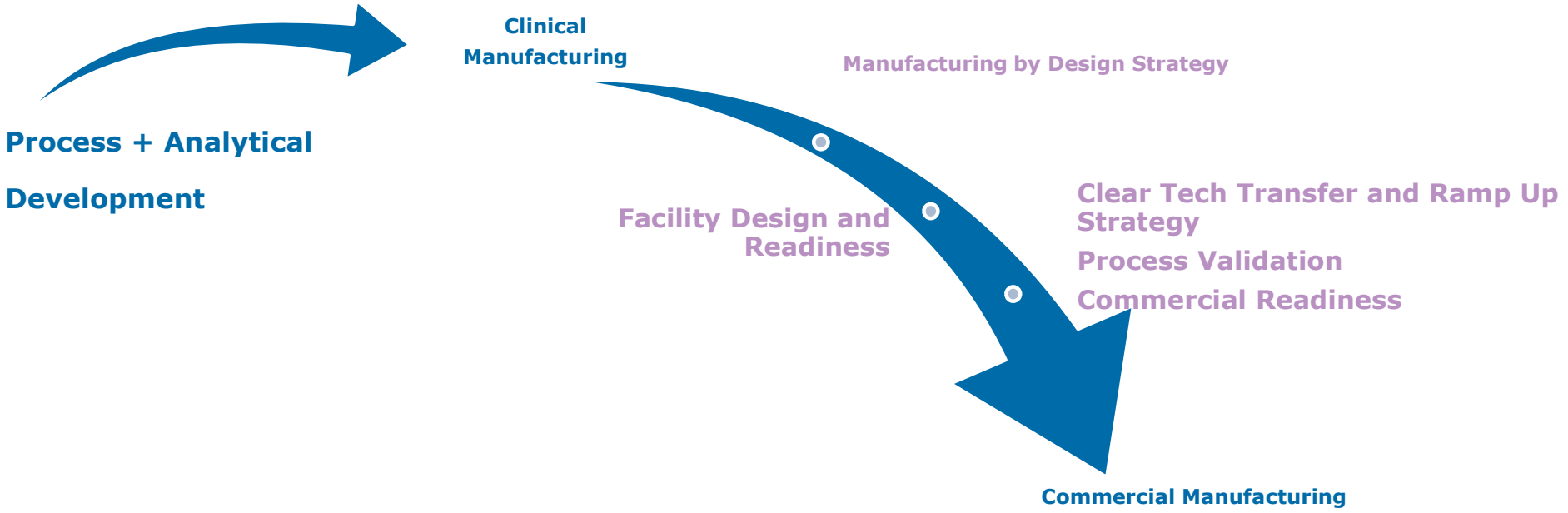
Commercial Ready
- Regulatory support with preparation of commercial dossier (BLA etc)
- Process and analytical validation
- Commercial launch, continued ramp up, Lifecycle management

Catalent Delivers Scale-up Excellence For Therapies In Late-stage Development

Our Strategy

Optimize infrastructure to deliver larger-scale and/or high-throughput capabilities

Optimize supply chain to assure high-quality production



Why is Manufacturing by Design Strategy Critical to Your Process?

Companies need to look into strategies to achieve efficiencies & drive cost-savings:

- Labor-saving strategies
- Process automation
- Integration of manufacturing steps
- Process closure

Manufacturing by Design (MbD): optimized methodology focused on alleviating autologous and allogeneic cell manufacturing challenges by elevating attributes that are absent within the QbD methodology.

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

Cell Therapy Process Diagnostics: *Our 5 Step Approach Enables the Manufacture 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 client 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 focus on tech transfer and commercial readiness

IMPLEMENTATION PLAN

Tech Transfer

- Training & TT runs
- Raw material procurement/qualify
- 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
- Optimization of CoGS
- Phase-appropriate approach

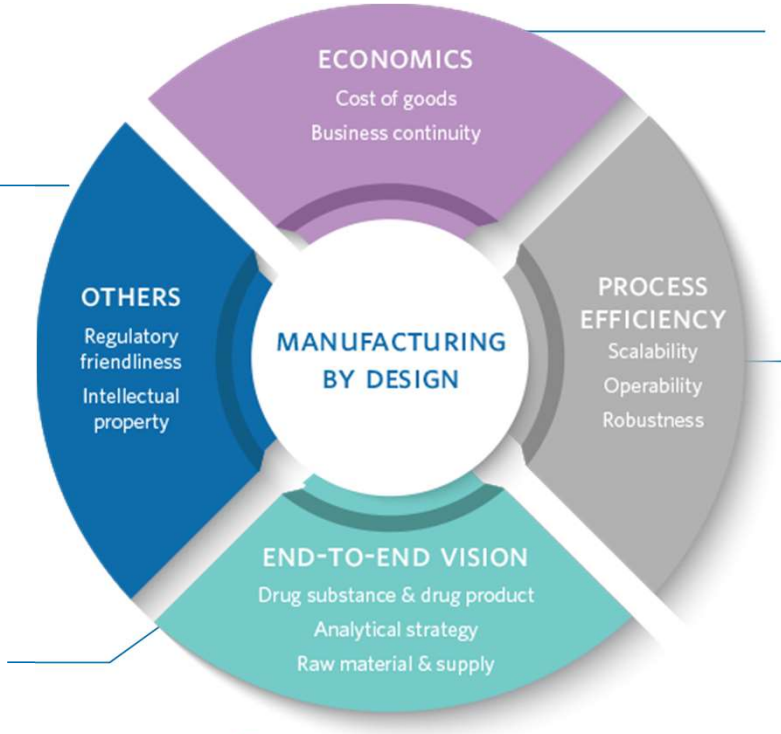
Translation

- GMP documentation
- Engineering runs
- Reproducibility runs
- Aseptic process simulation runs

The Target Manufacturing Profile

- Meet regulatory requirements
- Meet requirements of a successful business model

- Logistics (collection & distribution)
- In-process analytics
- Pharma grade or GMP raw material

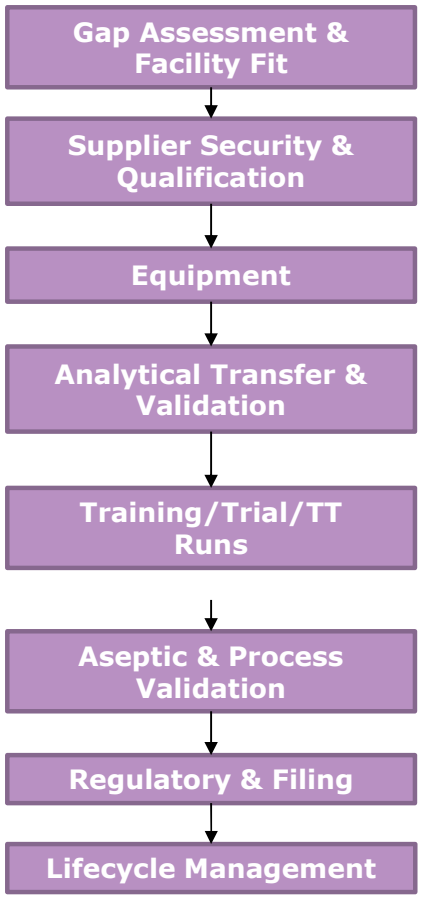


- Fast and cost-effective release testing

- Scalable volume controlled system
- Close process for predictable cell expansion, automated manufacturing
- Maintenance of cell phenotype and function

MbD ANALYSIS → **OPTIMIZATION PRIORITIES & IMPLEMENTATION** → **SCALE OUT MANUFACTURING**

De-risking the Tech Transfer Process



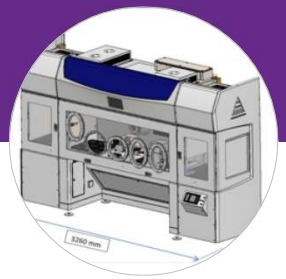
- Confirm process and product fits with facility and is ready for scale/ramp up
- Risk assessment driven, confirm what is needed for filing
- Ensure suppliers can meet clinical/commercial needs
- Qualify second sources for supply and testing
- Platform vs. product specific equipment
- Qualification and robust management program
- Method validation and comparability
- Capability to support high and rapid throughput
- Perform first batches in facility, finalize documentation
- Train staff to ensure continuous coverage/contingency
- Generate material to supply validation + comparability
- Dependent on product development stage
- Clinical or commercial submission
- Manage product lifecycle, continuous improvement

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



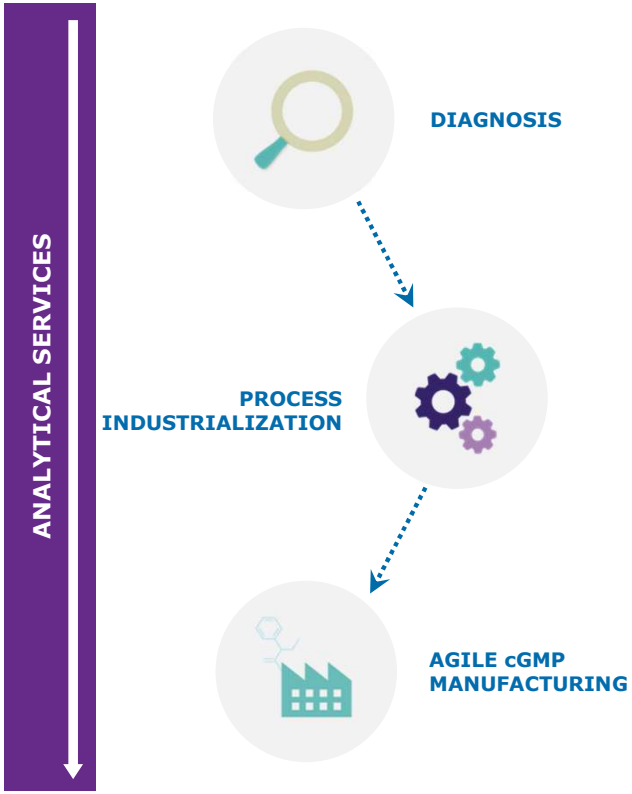
Crystal® Pure M1
Isolator

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

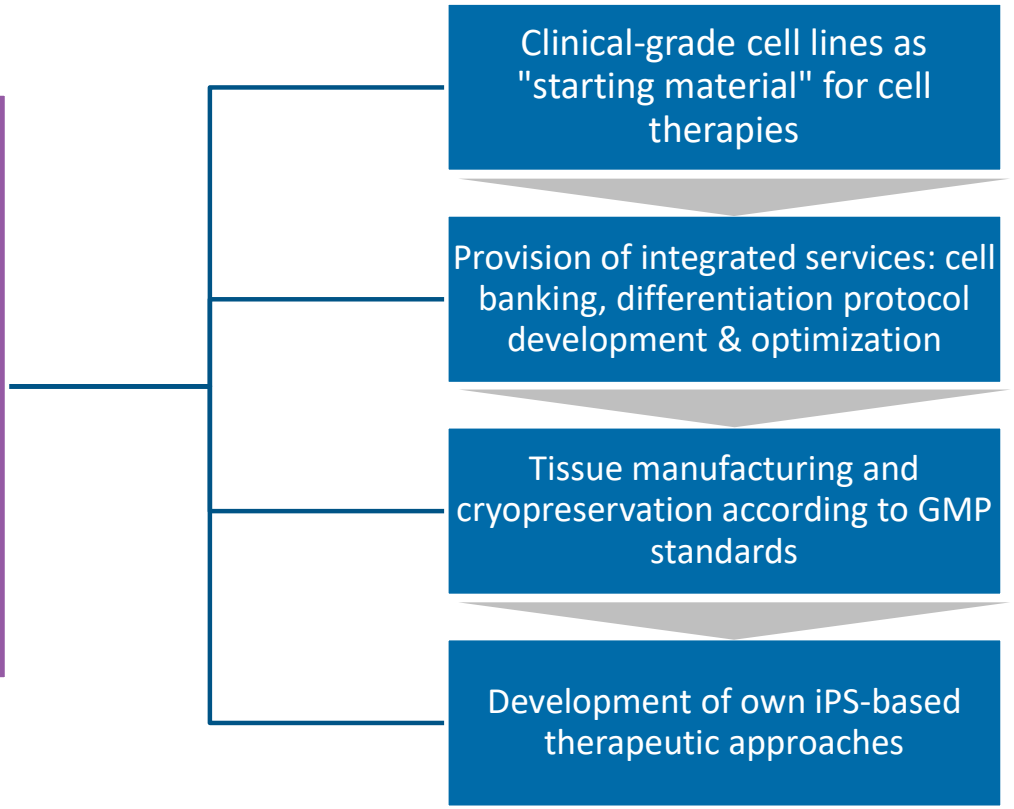
- Transparency of the raw data
- GMP certified – ICH Q2 (R1)
- EU & US pharmacopeia
- State-of-the-art equipment

WHAT WE DO

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

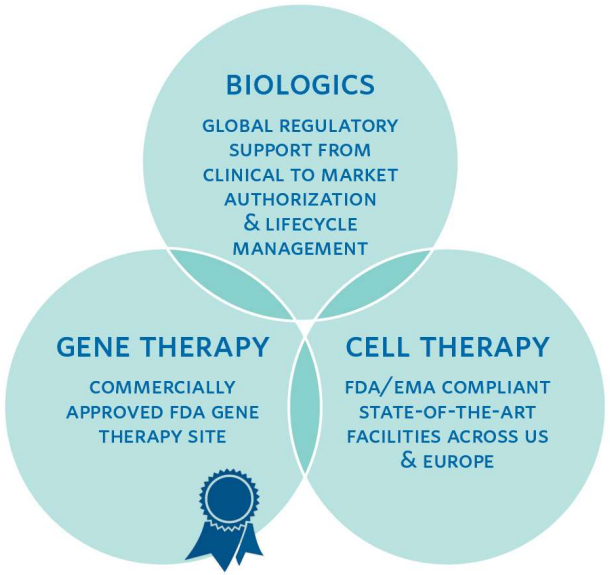
Accelerating your iPSC program with the expertise and infrastructure

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

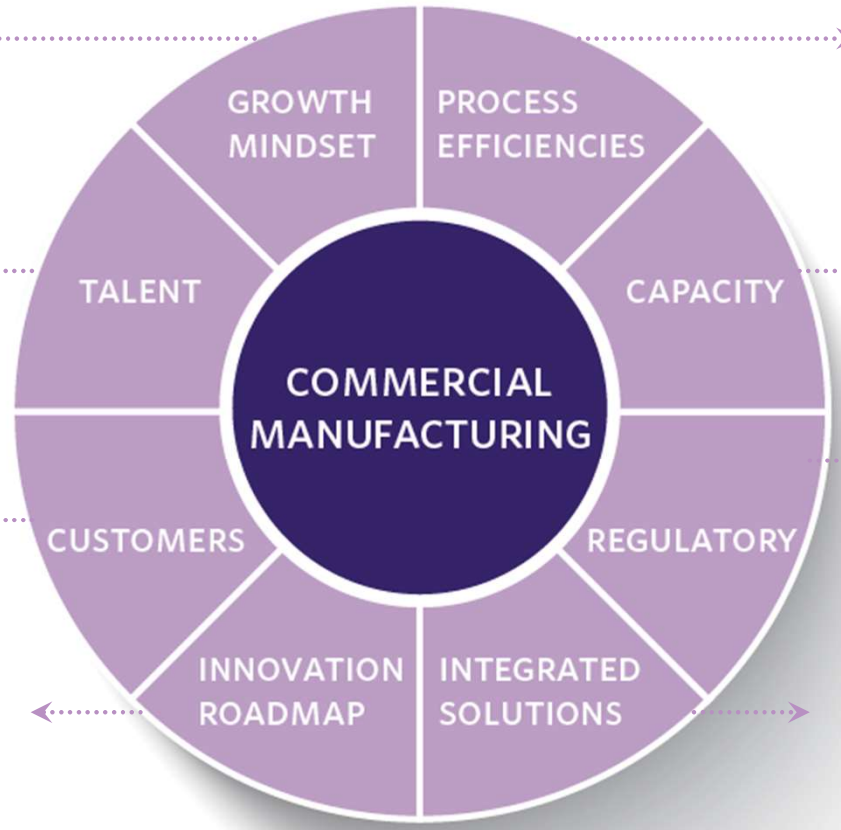
INNOVATION ROADMAP

- 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



First to Commercially-Scale Allogeneic Cell Therapy

Anticipated first allogeneic CAR-T to market

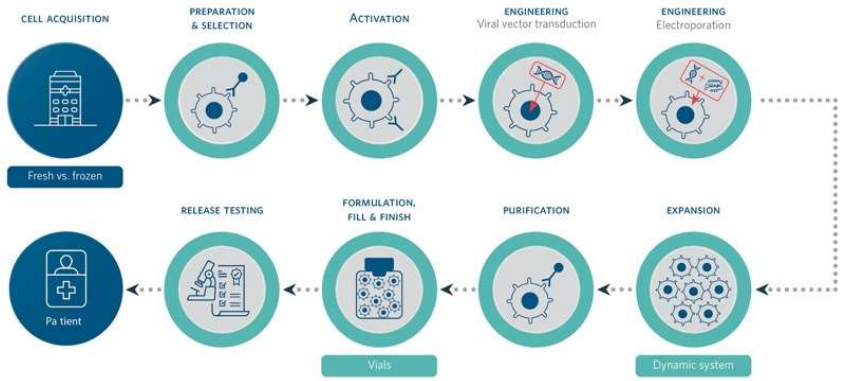
Strong allogeneic expertise with 50% mix of our customer programs

Uniquely positioned to product the first CAR-T allogeneic therapy setting a groundbreaking market standard

Our manufacturing methodology accelerates proof of principle

CRISPR Therapeutics and MaSTherCell SA sign service agreement for the development and manufacturing of allogeneic cell therapies

BASEL, Switzerland and CAMBRIDGE, Mass. and GOSSELIES, Belgium, June 06, 2017 (GLOBE NEWSWIRE) -- CRISPR Therapeutics AG (NASDAQ:CRSP), a leader in gene-editing based therapeutics, and MaSTherCell SA, a full service contract development and manufacturing organization (CDMO), wholly-owned subsidiary of Orgenesis Inc. (OTCQB:ORGS), today announced the signing of an agreement to develop and manufacture allogeneic CAR-T therapies.



Innovative technology combined with process expertise for speed to market

Agenda

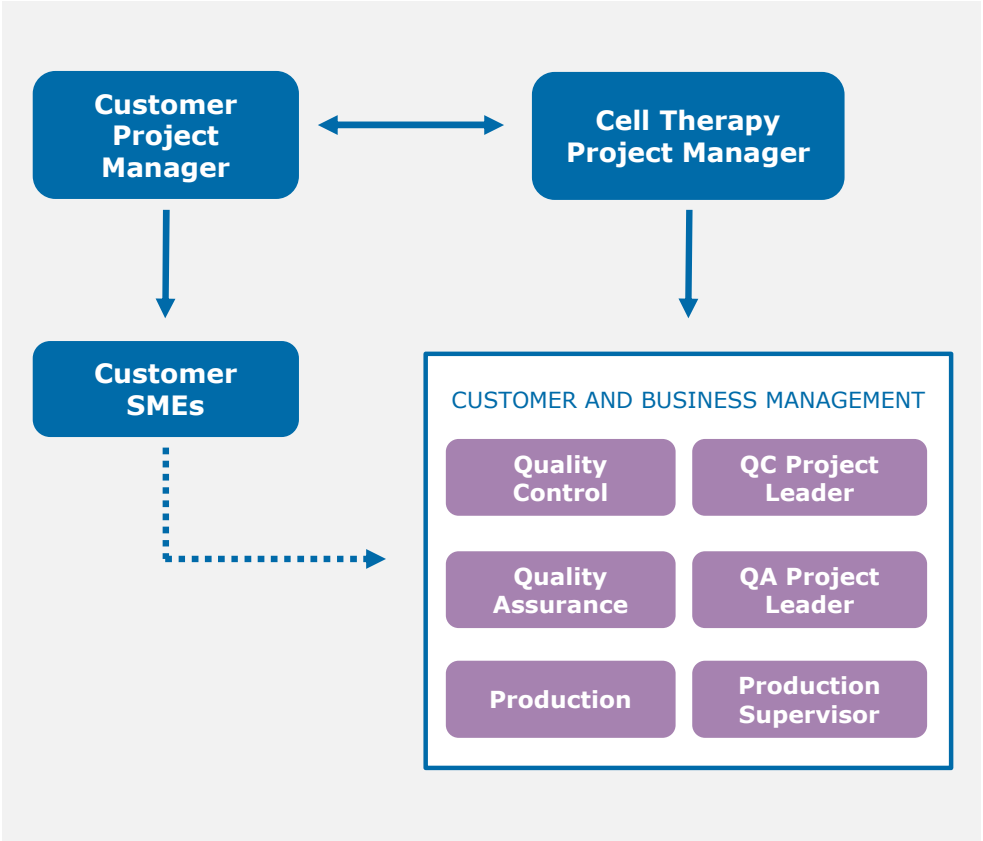
Catalent Introduction

Cell Therapy Overview

Capabilities & Expertise

Project and Partnership Management

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 Cell Therapy 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
Secure Product Supply Through a Model That Suits Your 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

Quality Management Systems (QMS) Focus on Patient First

CELL THERAPY REGULATORY LANDSCAPE

Demand highest quality standards with direct patient impact integrated into product manufacturing

Require process efficiencies in patient/donor material acquisition, processing, handling and shipping

Maintain patient and donor confidentiality throughout the process

HOW WE WORK

Robust QMS to support SQPP

Safety First: Patient First culture, personnel training, material controls

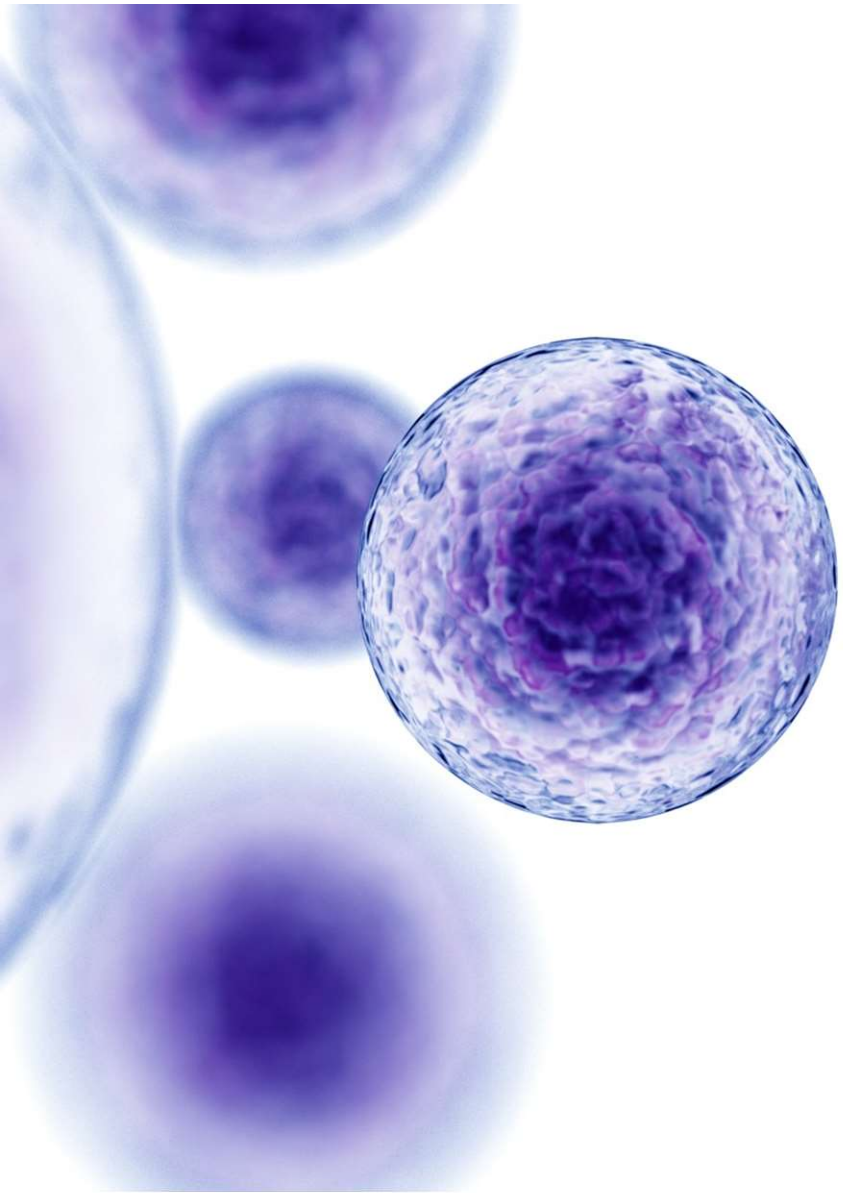
Quality Always: Process driven QMS to ensure diligent label controls, testing, segregation, and disposition

Performance Mindset: Collaborative production planning to ensure delivery per agreed timelines

People Driven: Empowered personnel and speak up culture to ensure continuous improvement, risk mitigation, and effective communication

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

discover more.

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6041, GOSSELIES, BELGIUM
US: +1 877-587-1835

EU/ROW: 00800 88 55 6178

BIOLOGICS.CATALENT.COM/CELL-THERAPY

WWW.CATALENT.COM

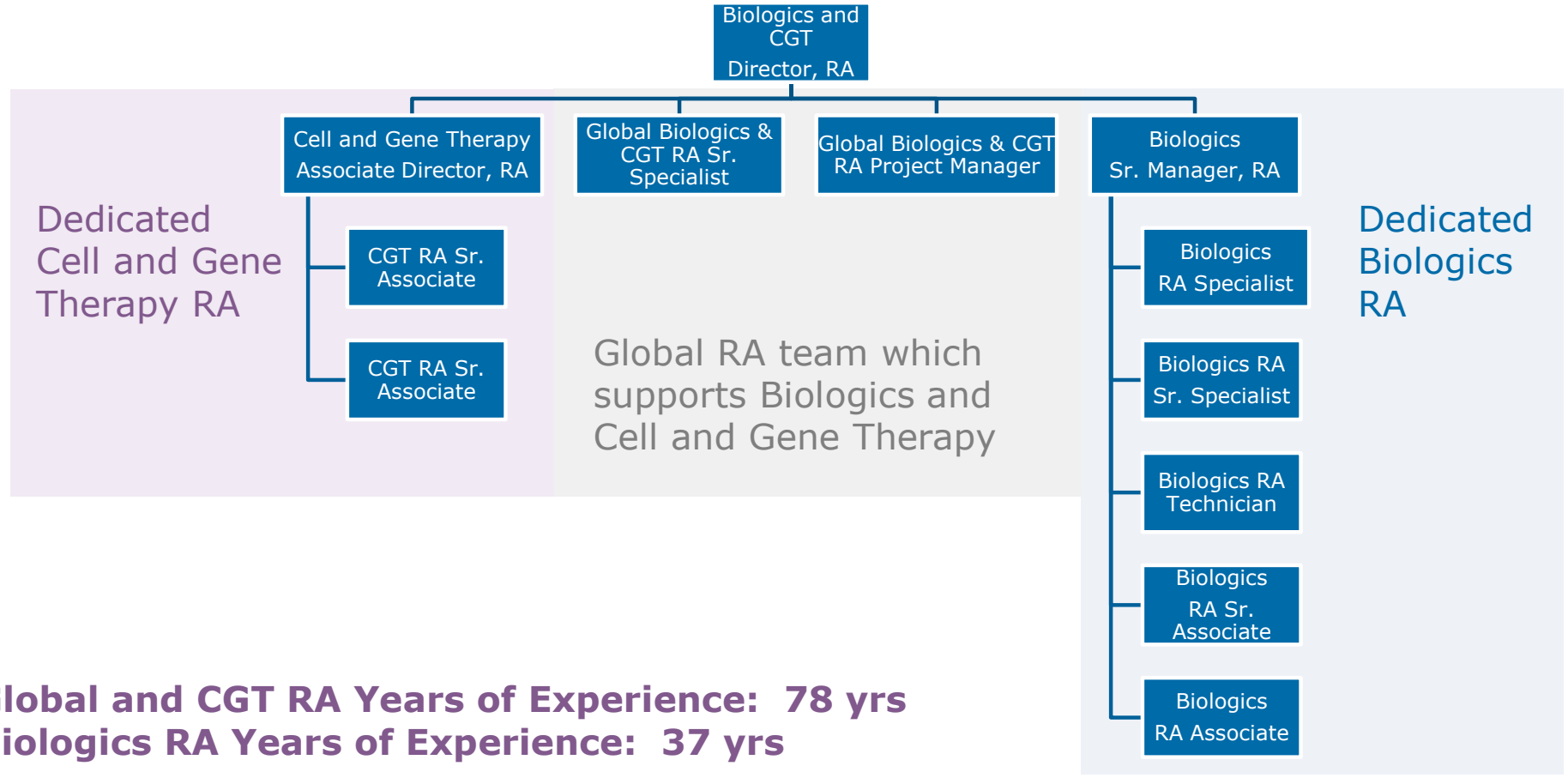
more products. better treatments. reliably supplied.™

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

Following Slides to be shared under CDA only

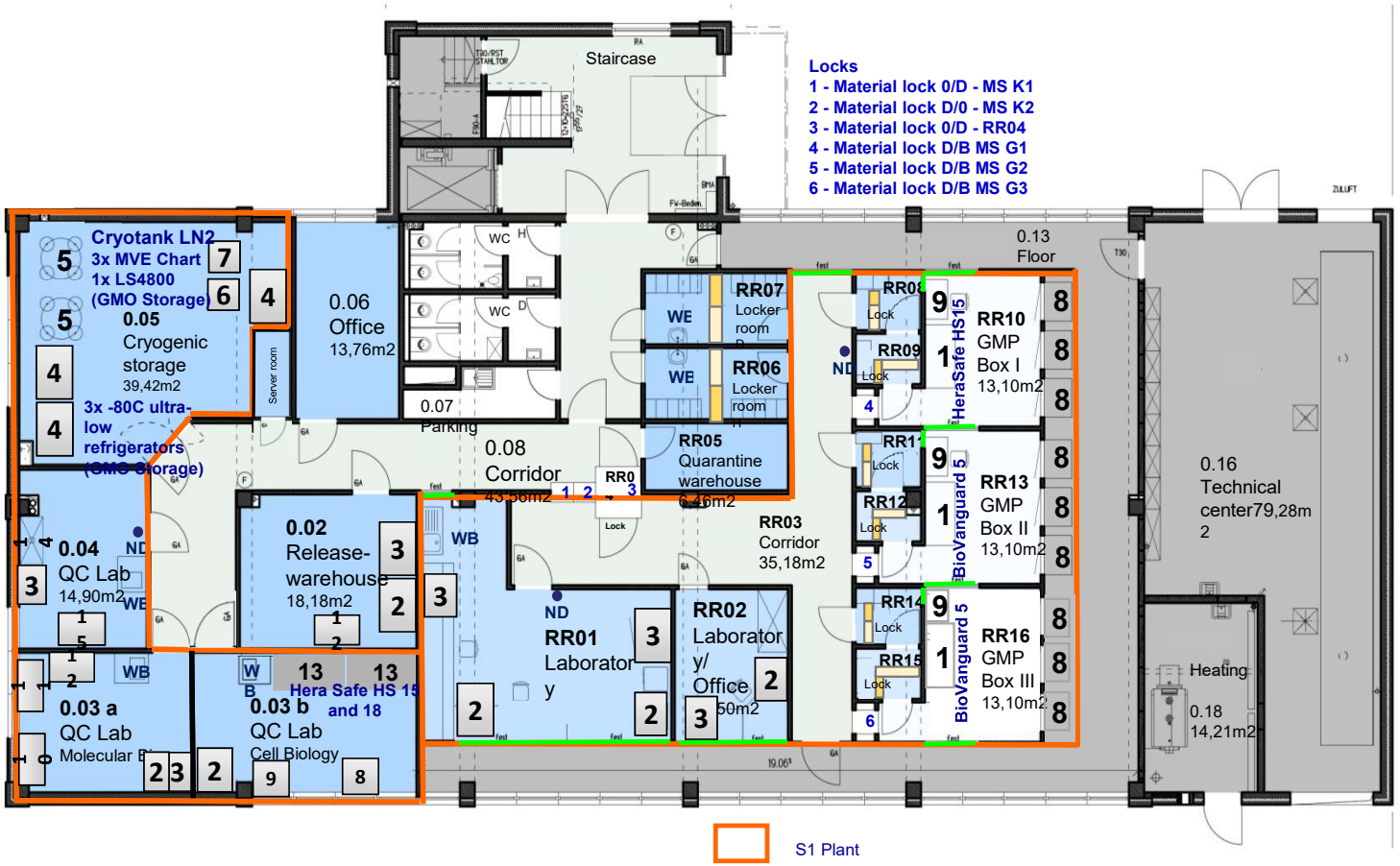
Please remove floorplan slides if providing a pdf copy of the deck to a customer

Our Manufacturing Facilities in Gosselies, Belgium

- 2.400m² (26,000 sq. ft)
- EMEA/FDA compliant
- 9 cGMP clean rooms (30m²)
- 4 Process development labs
- Grade B storage
- Fill and Finish services
- In-house quality control
- Nitrogen storage

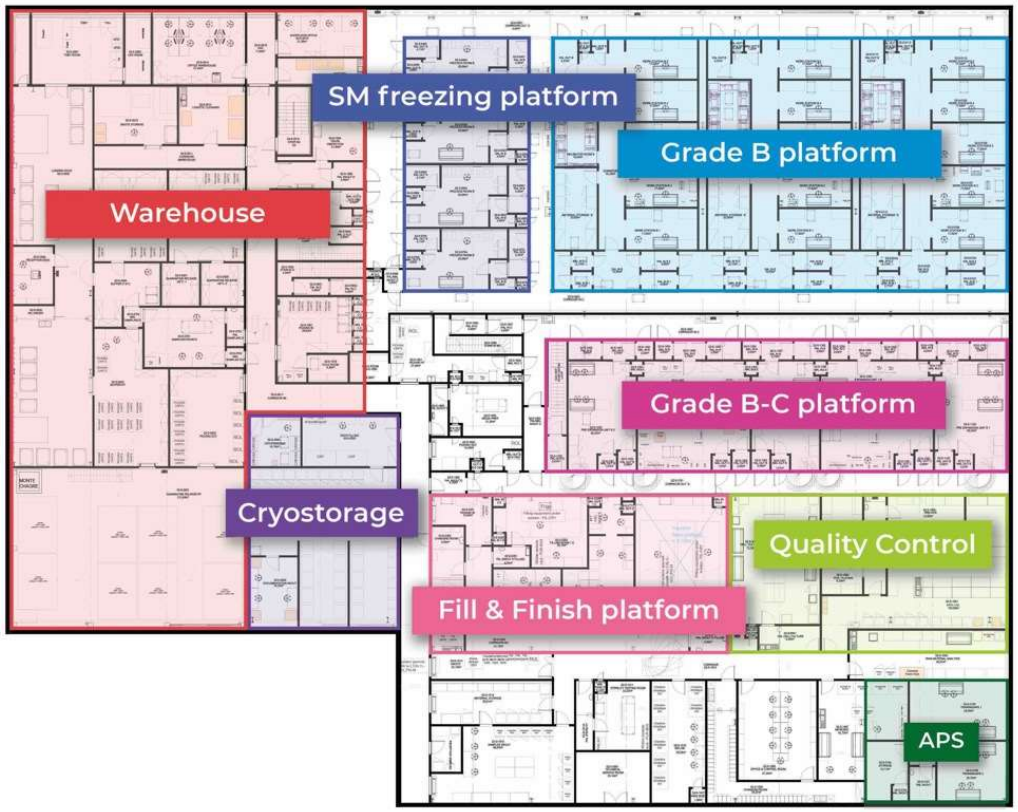
- 3.800m² (41,000 sq. ft)
- EMEA/FDA compliant
- 2 cGMP clean rooms
- 4 Process development labs
- Grade B storage
- Fill and Finish services
- In-house quality control
- Nitrogen storage

Our iPSC Clinical Facility in Dusseldorf, Germany



- 750m² (8,070 sq. ft)
- GMP certified
- iPSC culture, S1 labs & equipment
- Cleanrooms, Class A–D
- 2 development labs
- 3 QC labs
- High-security cryostorage

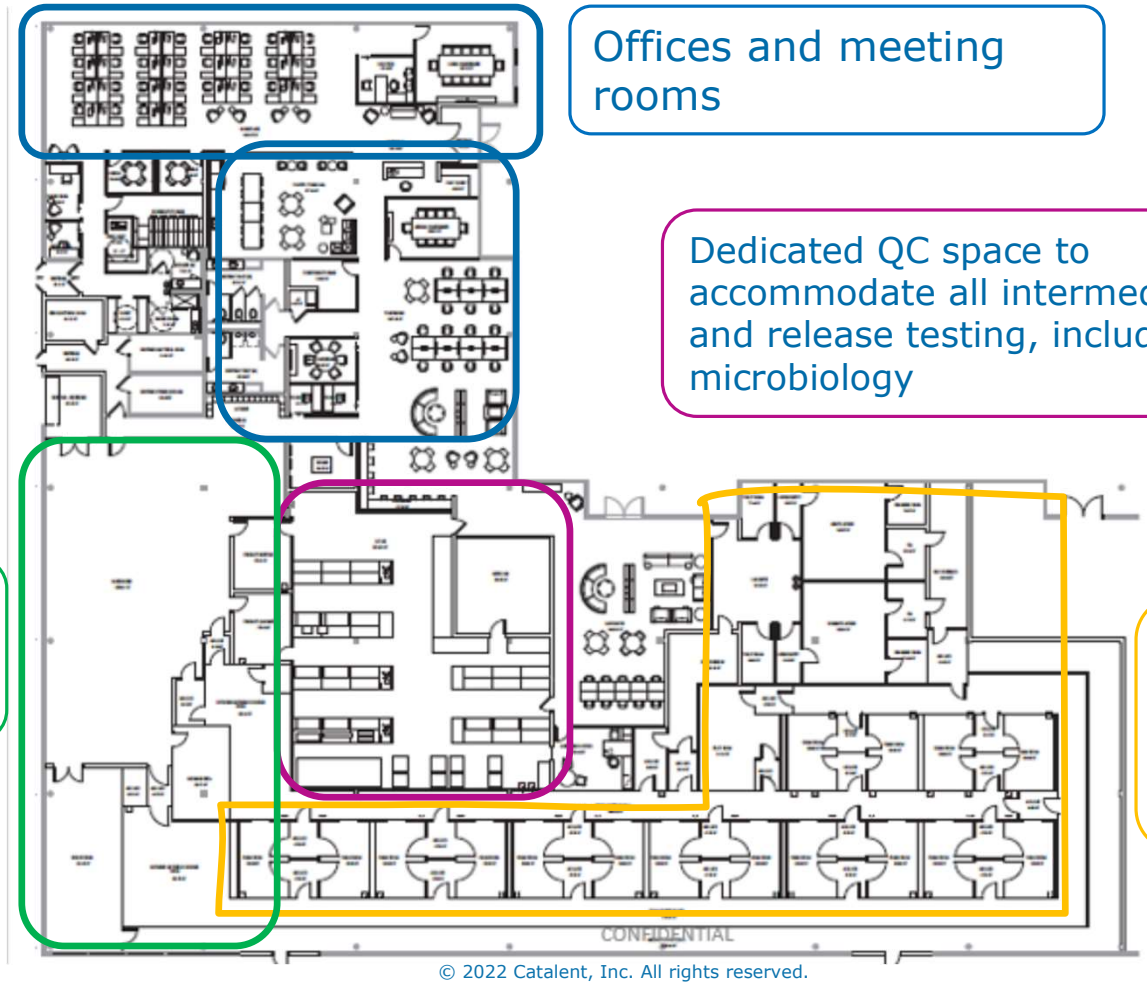
Our Commercial Manufacturing Facility in Gosselies, Belgium



- 5.574m² (60,000 sq. ft)
- EMEA/FDA compliant
- Autologous and Allogeneic Platform
- 1000s batch / year
- Dedicated commercial suites
- Dedicated Fill and Finish space
- Starting material platform
- Space for training & tech transfer
- In-house quality control
- Operational in 2022

Princeton Floor Plan

** ONLY TO BE USED UNDER A CDA
DO NOT EMAIL OR LEAVE WITH CUSTOMERS



Offices and meeting rooms

Dedicated QC space to accommodate all intermediate and release testing, including microbiology

Materials, DP storage and warehouse space

- 16 cGMP ISO7 suites
- Unidirectional flow of materials/personnel,
- Client viewing corridor