



**CELONIC**  
BEYOND BIOMANUFACTURING



# BIOPHARMA BUSINESS EXCELLENCE



# ABOUT US

<b>Established</b>	1982
<b>Employees</b>	450
<b>Locations</b>	Basel, Switzerland (HQ) Stein, Switzerland Heidelberg, Germany
<b>CEO</b>	Dr. Konstantin Matentzoglou
<b>Ownership</b>	Private, JRS Group, Germany

## Bringing Health Science to Life



EXCIPIENTS

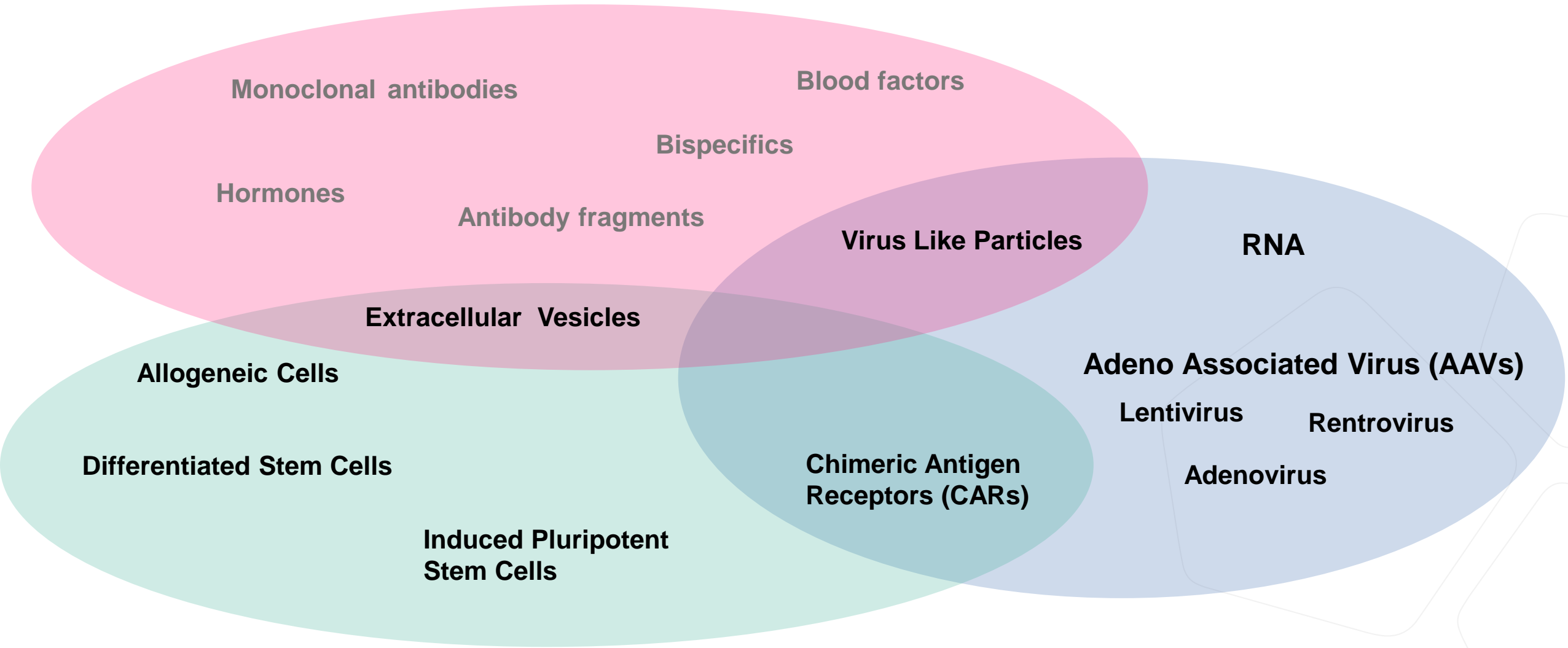


FIBER  
SOLUTIONS



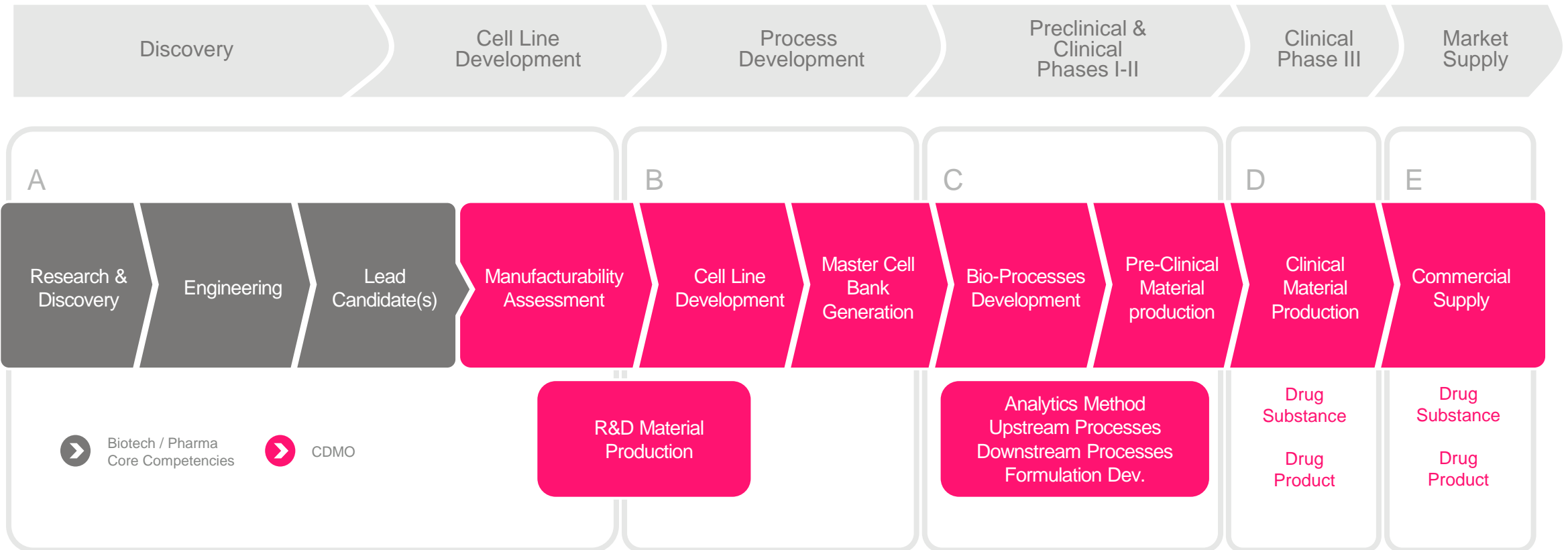
COATINGS

# CELONIC OFFERING



EXTRACELLULAR VESICLES, RECOMBINANT PROTEINS,  
CELL THERAPIES AND GENE THERAPIES

# BIOLOGICS: FROM LATE DISCOVERY TO MARKET SUPPLY



# CELL & GENE THERAPY MANUFACTURING SERVICES



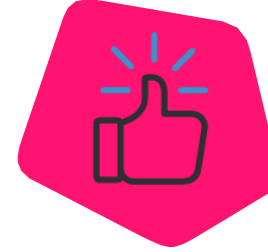
## Process Development

- Cell Therapies
- Exosome
- Secretomes
- Gene Vectors
- Scale-Up
- 3-D Bioreactor Suspension Cell Line
- Gene Vector Formulation Development



## Manufacturing

- Cell Therapies
- EVs
- Gene Vectors (AAV, LV, RV)
- Phase I / II Unit
- Phase III / Commercial Expansion Sites



## Experience

- 35 years CDMO experience in Biologics
- mAb
- recProteins
- Cell Lines
- Bioreactors



## Mission 2022

Established, integrated, global CDMO service provider of Cell & Gene Therapies with Process Development, clinical trial manufacturing and commercialization

# DELIVERING SUCCESS TO CLIENTS ACROSS THE GLOBE



# FACILITIES AND SERVICES

## 1 Basel

SWITZERLAND

Development  
& GMP production

**Employees: 150**

## 2 Heidelberg

GERMANY

GMP production

**Employees: 300**





# INNOVATIVE INDUSTRY-LEADING CELL EXPRESSION PLATFORMS

## CHOvolution®

Powered by Celonic's proprietary SEFEX® technology

Cell line based on CHO-K1 (non genetically modified CHO)

High productivity (>8 g/l for mABs)

### SIMPLIFIED LICENSING MODEL

(e.g. no royalties from sales)

Cell line adapted to serum-free  
**EMA and FDA COMPLIANT MEDIA**

### HIGH SCALE-UP STABILITY

**GMP COMPLIANT**  
From R&D to market

Cell line in several  
**CLINICAL TRIALS in EU/US & Asia**

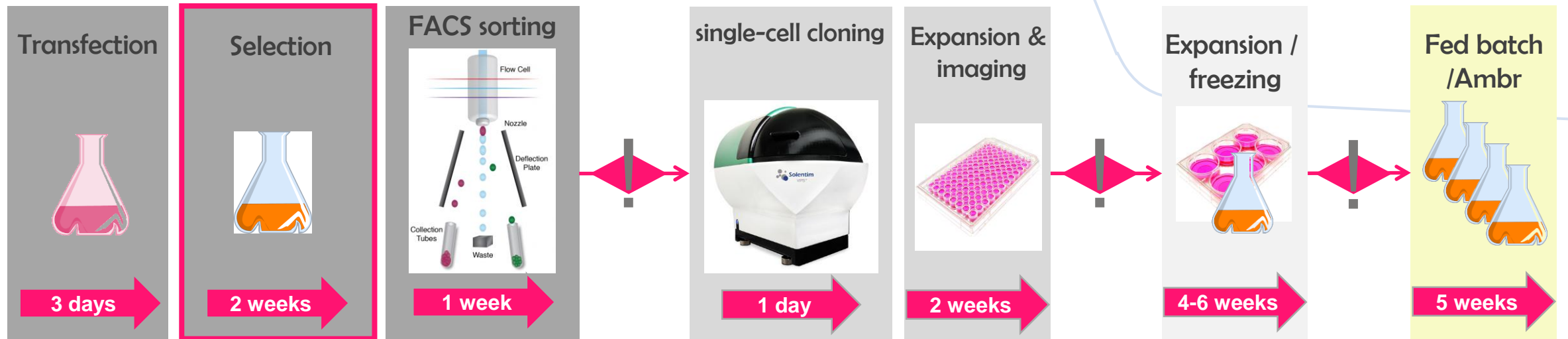
## GEX®

Human cells for fully-human glycosylation

Optimized for complex and sophisticated biopharmaceutical product

Stable product quality over full run time for R&D and/or GMP

# CELL LINE DEVELOPMENT WORKFLOW



# BEYOND FED-BATCH

Perfusion is the latest frontier in continuous manufacturing.

- Human as well as CHO cell lines
  - ✓ ~15-22 g/L IgG antibody
- Mabs as well as complex biologics including: fusion protein, blood factor, bispecific, fragments with varying glycan profile
  - ✓ ~10-15 g/L IgA antibody
  - ✓ ~ 3 g/L IgM antibody
  - ✓ ~0.2 - 1g/L for complex glycoproteins (e.g. FSH blood factors, hormones etc.)



Over two decades of optimizing perfusion technique

**1998**

Production of perfusion batches begins

**2009**

First Expansion of GMP facility Perfusion and fed batch

**2014**

Second Expansion of GMP facility Perfusion and fed batch

**2019**

130 GMP perfusion batches  
Up to 1,000L bioreactor  
Very stable environment over the full run time

# BROAD SPECTRUM OF ANALYTICAL METHODS

## Chromatography

- SEC
- CEX
- RP, HIC
- Protein A, LysSepharose
- HILIC

## Electrophoresis

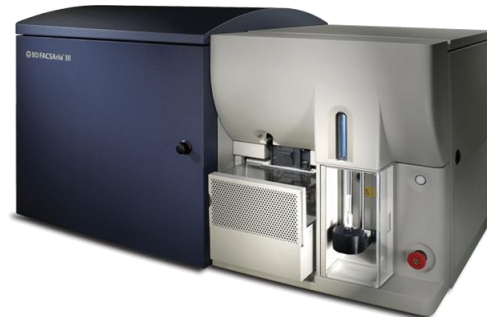
- SDS-PAGE
- cIEF
- CE-SDS

## Assays

- Flow cytometrical Assays
- Immunological Assays
- Cell-based Assays
- *in-vitro* potency Assay

## Mass Spectrometry

- Intact Mass
- Peptide Mapping, incl. PTMs
- Glycan Analytics



# BROAD SPECTRUM OF ANALYTICAL METHODS

## Glycosylation

- 2AB-labeling
  - Sialic Acids
- ## Cell Bank Testing
- Thawing Test

## Physical Methods

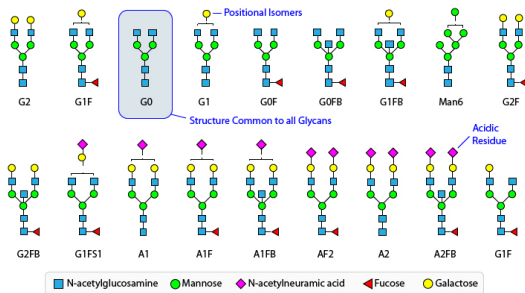
- pH
- Osmolality, Conductivity
- Turbidity/Opalescence
- Visible Particles
- Light Absorption

## Contaminants

- Endotoxin
- Host Cell Proteins
- Residual Protein A/L

## External Analytics

- Cell Bank Testing
- Microbiology
- Molecular Biology
- Characterization



# ANALYTICAL METHODS



## Electrophoresis (DNA/RNA)

- DNA/RNA quantification
- Exosome/RNA fingerprint



## Nucleic Acid quantification

- (Absolute) DNA/RNA quantification (viral titers)



## Protein quantification

- Western Blot
- Protein, Viral vector & Vesicle quantification
- Cell surface marker identification



## Nanoparticle count

- Exosome quantification and particle count

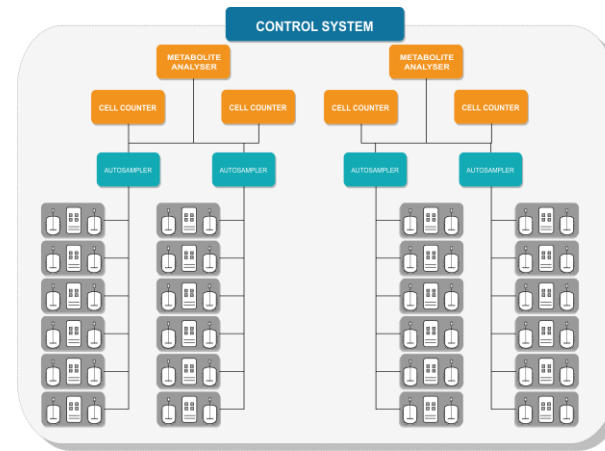
# PROCESS DEVELOPMENT: EQUIPMENT



2xAmbr15



24x3L BR



2x10L BR



2xÄkta pure



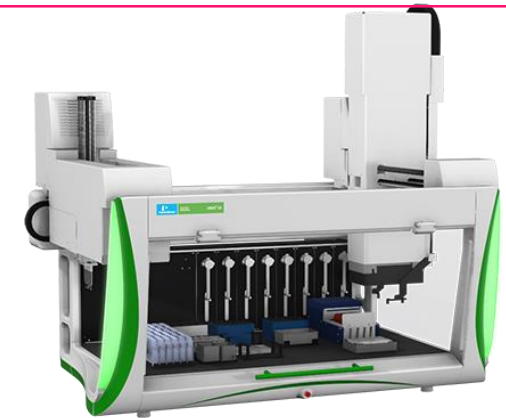
Äkta avant



Äkta Pilot



2xÄkta Flux



Janus robot

## FILL AND FINISH

Semi-automatic  
aseptic filling of liquids

**up to 3000  
vials**

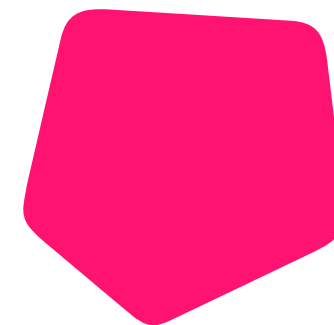
Compliance with

**FDA & EMA standards**

**>300** Fill & Finish  
campaigns

**Labelling,  
packaging  
and storage**

of clinical test samples





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# FACILITIES



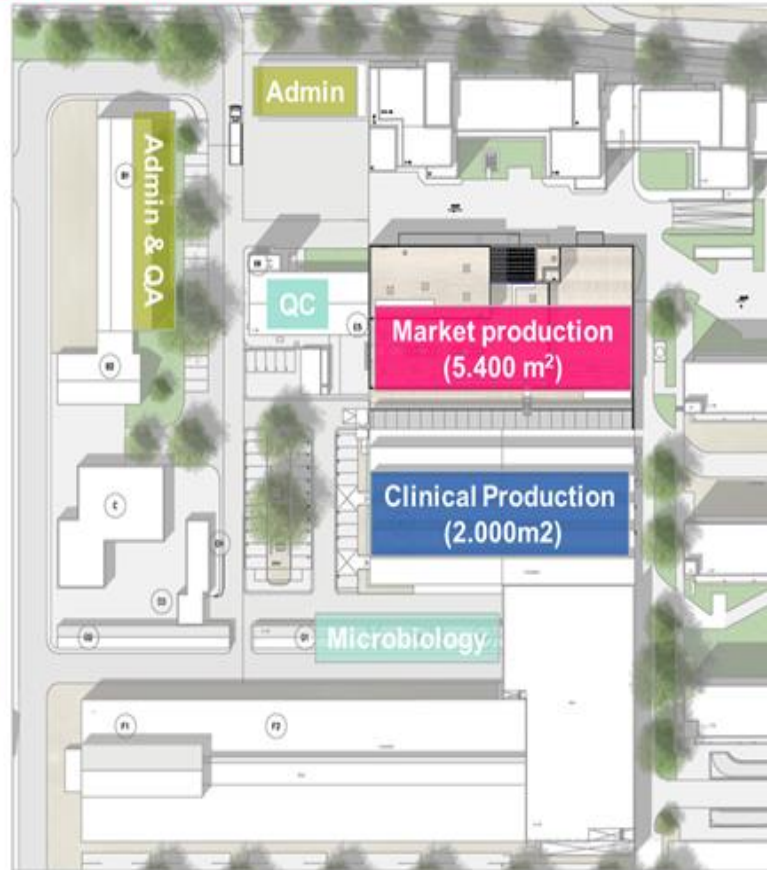
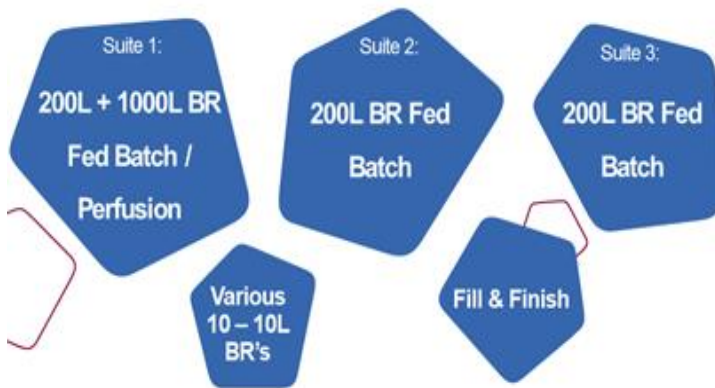
# CELONIC HEIDELBERG: MODULAR EXPANDABLE FACILITY

## CELONIC COMMERCIAL & CLINICAL PRODUCTION FACILITIES

### Commercial facility



### Clinical production facility



### Fully Integrated CDMO Services for Biologics, Cell Therapies & Gene Vectors

- Clinical (In Operation):
  - 1000L Bioreactor FB/Perfusion
  - 3x 200L Bioreactor FB/Perfusion
  - Various 10L Bioreactors
- Commercial (In Operation since Apr. '21):
  - 1 Line, 3x 200 plus 3x 2000L Bioreactor FB
  - 1 Line, 3x 200 plus 3x 2000L Bioreactor FB
  - 1x 1000L Bioreactor Perfusion 1x 200L Bioreactor Perfusion

# TOTAL QUALITY MANAGEMENT SYSTEM

## Assured product quality

- **Internationally authorized and inspected**  
Swissmedic, RHI (Basel)  
RPI Tübingen (Heidelberg)  
FDA (Heidelberg)
- **Pharmaceutical development**  
Quality by Design (QbD)  
over the product lifecycle

## Fulfilled Expectation

- **Design control approach**  
know and meet customer expectation
- **Service delivery**  
holistic process landscape  
ISO 9001 certified
- **Customer orientation**  
targeted processes and service attitude

*EMPATHY EXCELLENCE EFFICIENCY*

*Excellent organizations consistently deliver outstanding achievements that meet or exceed the expectations of all their stakeholders.*

*EFQM Excellence Model 2013*

## Celonic's principles for Business Excellence

- **Business Process Management**
- **Culture and corporate values**
- **Continuous Improvement**
- **Total quality management**

## Trackwise Digital QMS:

Quality events & CAPA - Documentation management - Training management

## LIMS:

Lab Information and Management / Documentation

# Stein Facility : A World Class ATMP Production Site



## Highlights

- State of the art manufacturing building
  - Flexible space usage
  - Connected to full site infrastructure
- Multi-usage free space of app. 5'900 sqm available
  - Partially separated from main tenant
  - Private logistics bay feasible incl. truck ramp
  - Work stations included
- Co-tenant to Novartis business units:
  - Cell & Gene Therapy
  - Solids manufacturing
- State-of-the-art infrastructure (clean & black utilities)



# CELONIC IS: ROOTED IN QUALITY, NIMBLE, AMBITIOUS WE ASPIRE TO GROW WITH YOU



Experience &  
Expertise



Cell Line Development  
Innovative Platforms



Flexible Business  
Models



JRS Umbrella



Perfusion & Fed-  
Batch Processes



Discovery to  
Market Supply