

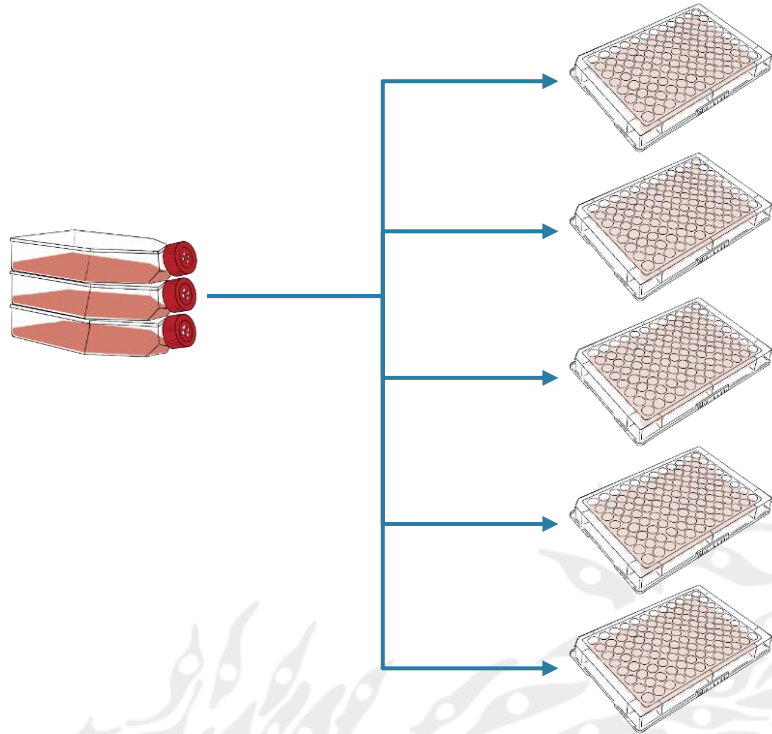


assay ready instaCELLs®
turning cells into reagents

continuous cell culture

inconsistent cell quality

THE CLASSICAL WAY OF CELL SUPPLY



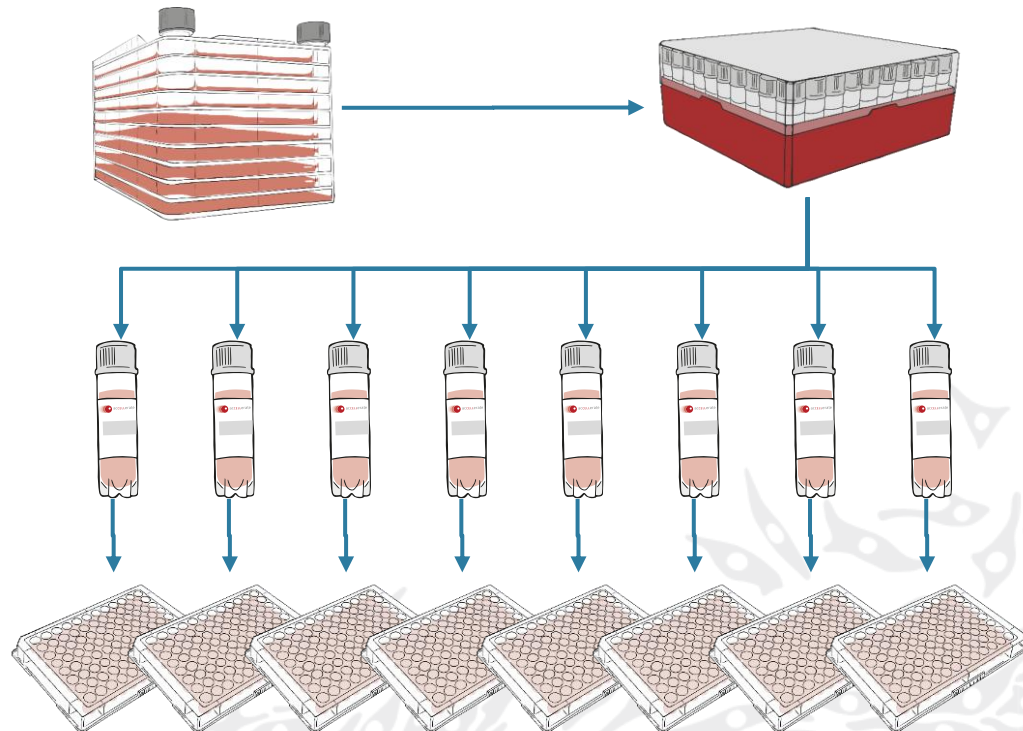
Cells are maintained and continuously passaged in small scale. The day before the assay the required number of cells are seeded into the assay plates while the rest is further cultivated.

- Different operators cause different handling.
- Different quality of medium, serum and supplement lots.
- Different environment conditions, e.g. temperature, humidity, lab activity.
- Different culture conditions e.g. cell confluency or aggregation.
- Increased passage number (population doublings) over time.

assay ready instaCELLs

cells reagents in standardized quality

THE SMART WAY OF CELL SUPPLY



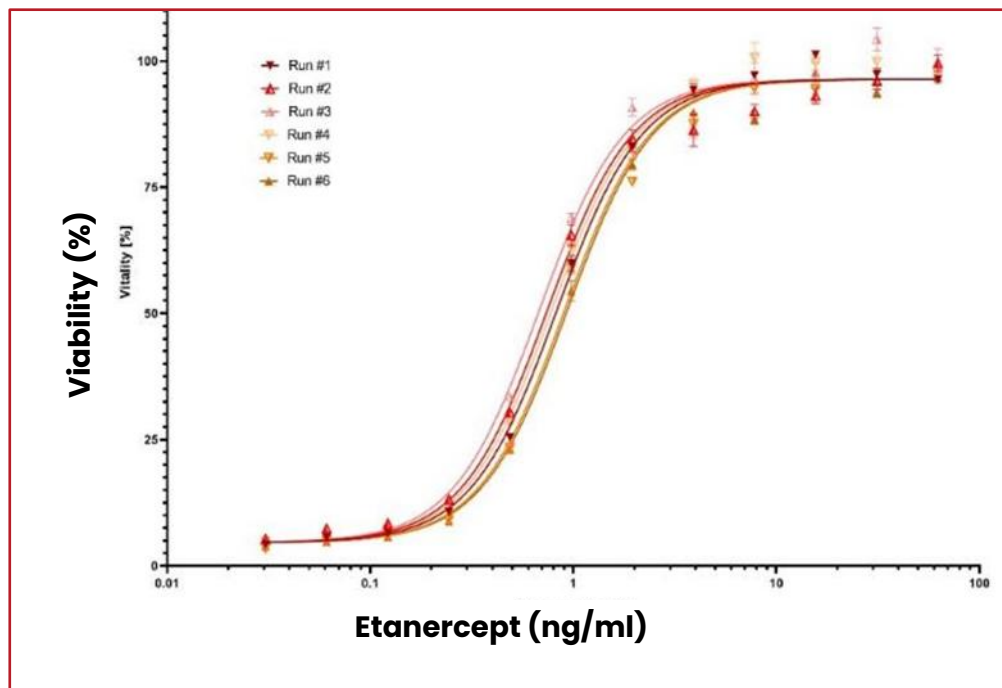
Cells are expanded to a large-scale, harvest as a homogenous batch, and cryopreserved in ready-to-use aliquots. For an assay, a single vial of prequalified cells is thawed and seeded directly into the assay plate.

- Ready to use like a reagent. No cultivation required.
- Increased assay precision by using homogeneous prequalified cell banks.
- Instant availability at any time and at a consistent quality.
- Convenient to use for an easy assay transfer to affiliates and CDMOs

assay ready instaCELLs

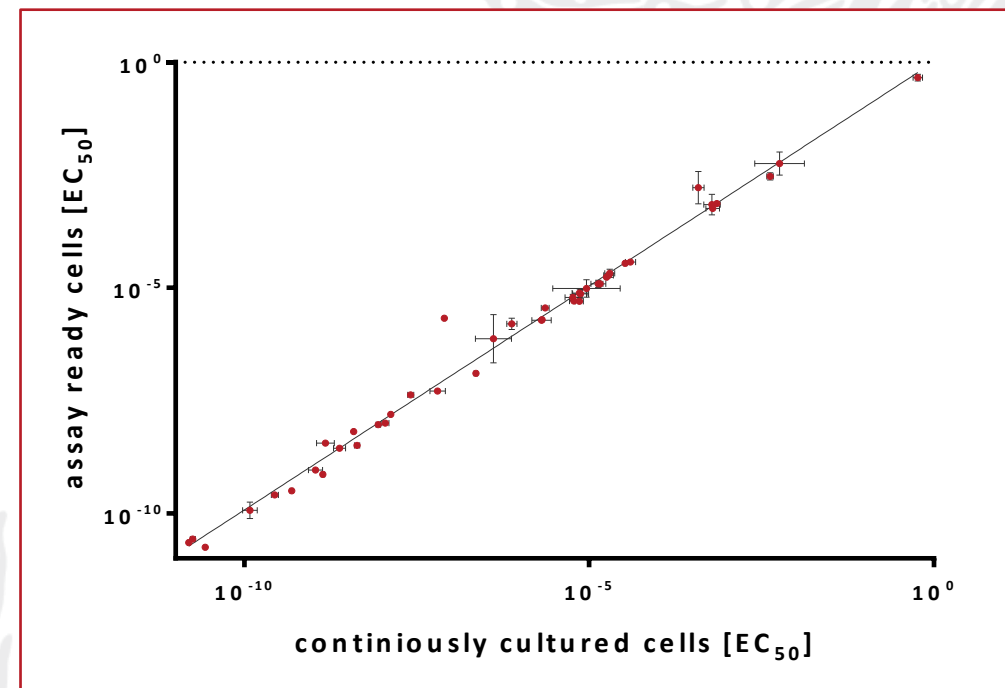
precise & accurate

ASSAY PRECISION



L-929 assay ready instaCELLs were thawed and directly seeded into a 96 well plate. Serial dilutions of TNF- α neutralizing antibody Etanercept were added to the cells before they had been challenged with TNF α . In six independent experiments L-929 Assay Ready Cells very precisely determine the potency of Etanercept.

ASSAY ACCURACY



Potency assays addressing different target groups and end points from 45 projects have been analyzed. The potency (EC₅₀ [M]) measured with assay ready instaCELLs very much correlates with the potency in assays performed with cells from a continuously passaged culture.

instaCELLs in GMP bioassay

simplified assay documentation

CONTINUOUS CELL CULTURE

- thaw cells from a WCB
- passage cells in culture
- harvest / detach cells
- count the cells
- seed cells into assay plates
- run the bioassay

ASSAY READY instaCELLs

- thaw a vial of assay ready instaCELLs
- seed cells into assay plates
- run the bioassay

instaCELLs in GMP bioassay

qualification critical reagents

CONTINUOUS CELL CULTURE

- culture medium
- FBS & supplements
- culture vessels
- assay medium
- assay plates
- controls & assay reagents

ASSAY READY instaCELLs

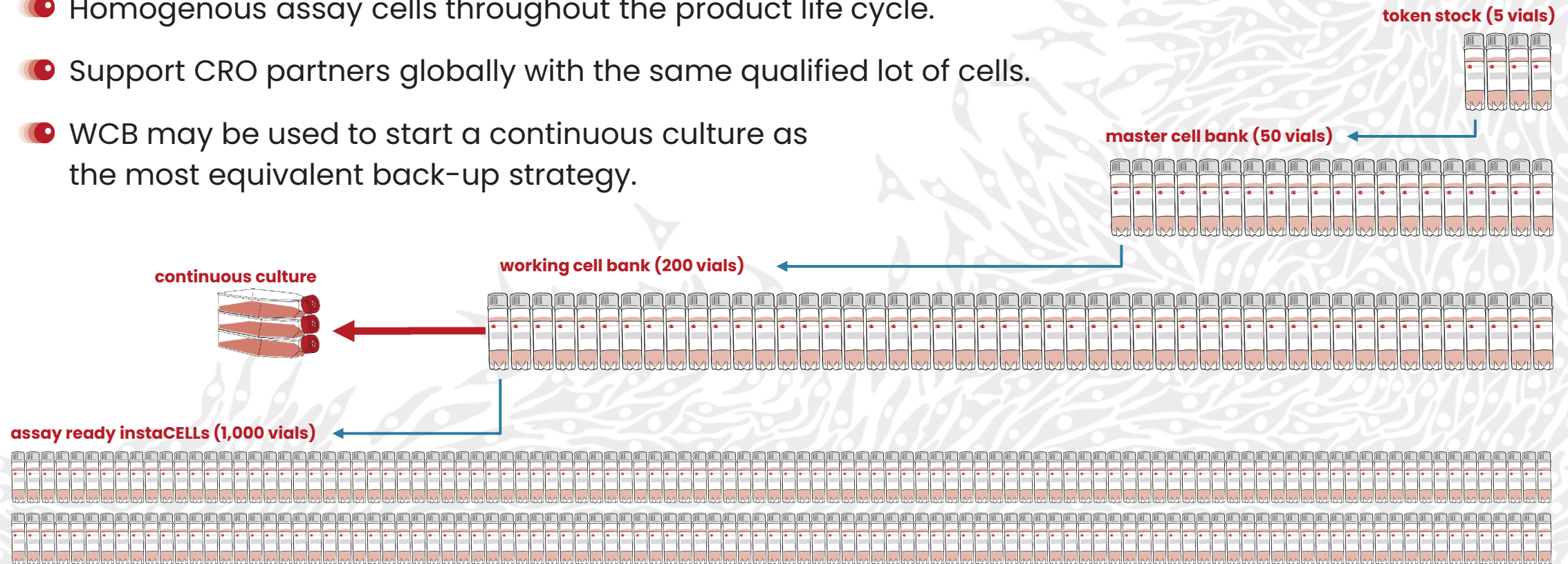
- assay ready instaCELLs
- assay medium
- assay plates
- controls & assay reagents

cell banking strategy

support the product life cycle

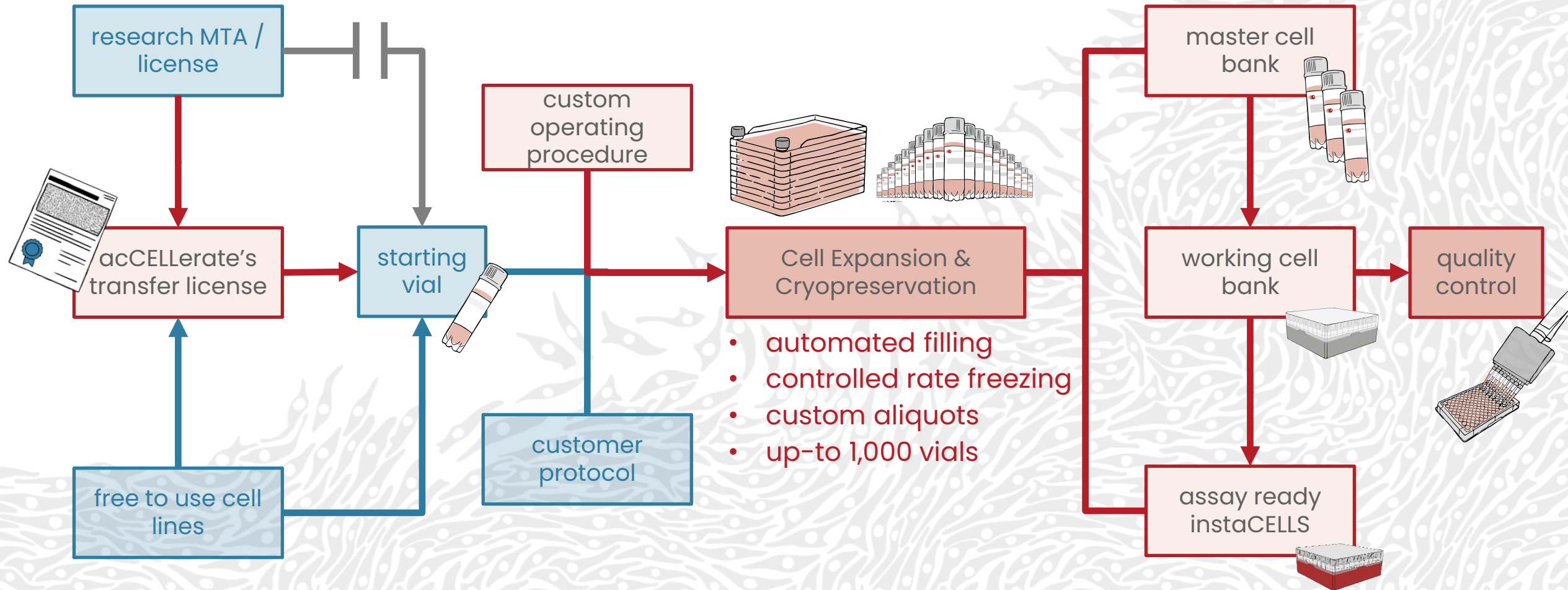
4-TIER CELL BANKING

- Same level of cell bank from assay development to commercial QC.
- Homogenous assay cells throughout the product life cycle.
- Support CRO partners globally with the same qualified lot of cells.
- WCB may be used to start a continuous culture as the most equivalent back-up strategy.



we make the cells
custom cell banks

PROJECT WORKFLOW



qualification to meet assay performance

CELL BANK QUALITY

- cell count per vial¹
- cell bank homogeneity
- cell viability & debris
- viability after 24h
- cell recovery
- doubling time²
- morphology²

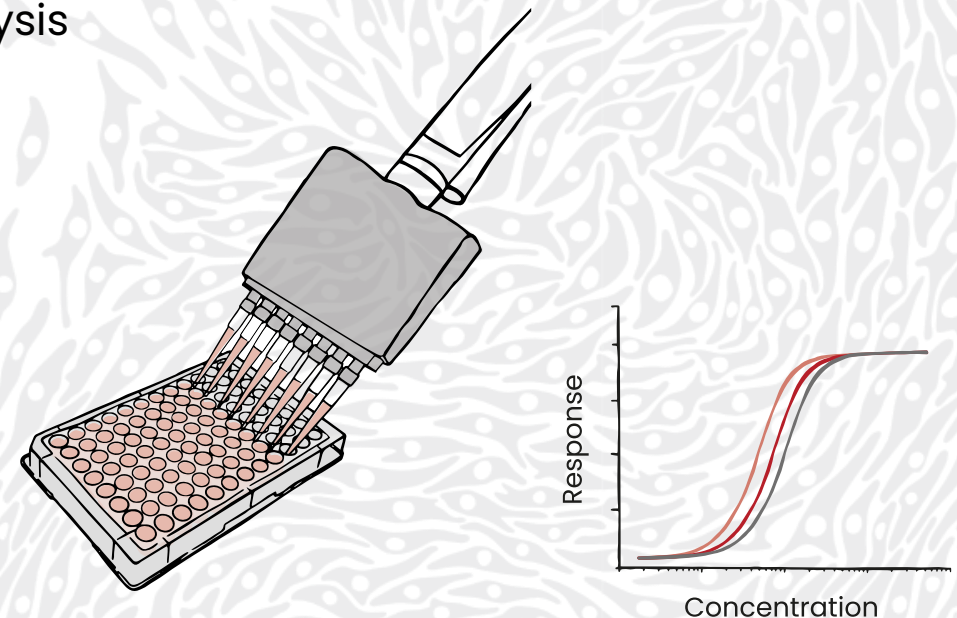
PURITY & IDENTITY

- sterility (yeast, fungi, bacteria)
- test for mycoplasma
- test for adventitious viruses³
- cell identity by STR analysis
- species identity

ASSAY PERFORMANCE

- stability of markers protein²
by Flow Cytometry or qPCR
- functional assay performance²
e.g. reporter gene assay, proliferation, htrf ...

1) using a qualified counting method
2) with reference to the token or master stock
3) token or master stock only



GMO-like documentation to meet authority requirements

COP – Custom Operating Procedure

- material to be used
- detailed handling instructions
- Documentation requirements
- quality specification

BR – Manufacturing Batch Record

- material which has been used
- documentation of each passage
- documentation of harvest and freezing

QR – Quality Report

- description of QC tests
- documentation of QC results

CoC – Certificate of Conformity

- alignment with COP
- OOS statement

CoA – Certificate of Analysis

- alignment with specification
- OOS statement

business models

prepared to support every stage

instaCELLS MADE-TO-ORDER

for early assay development

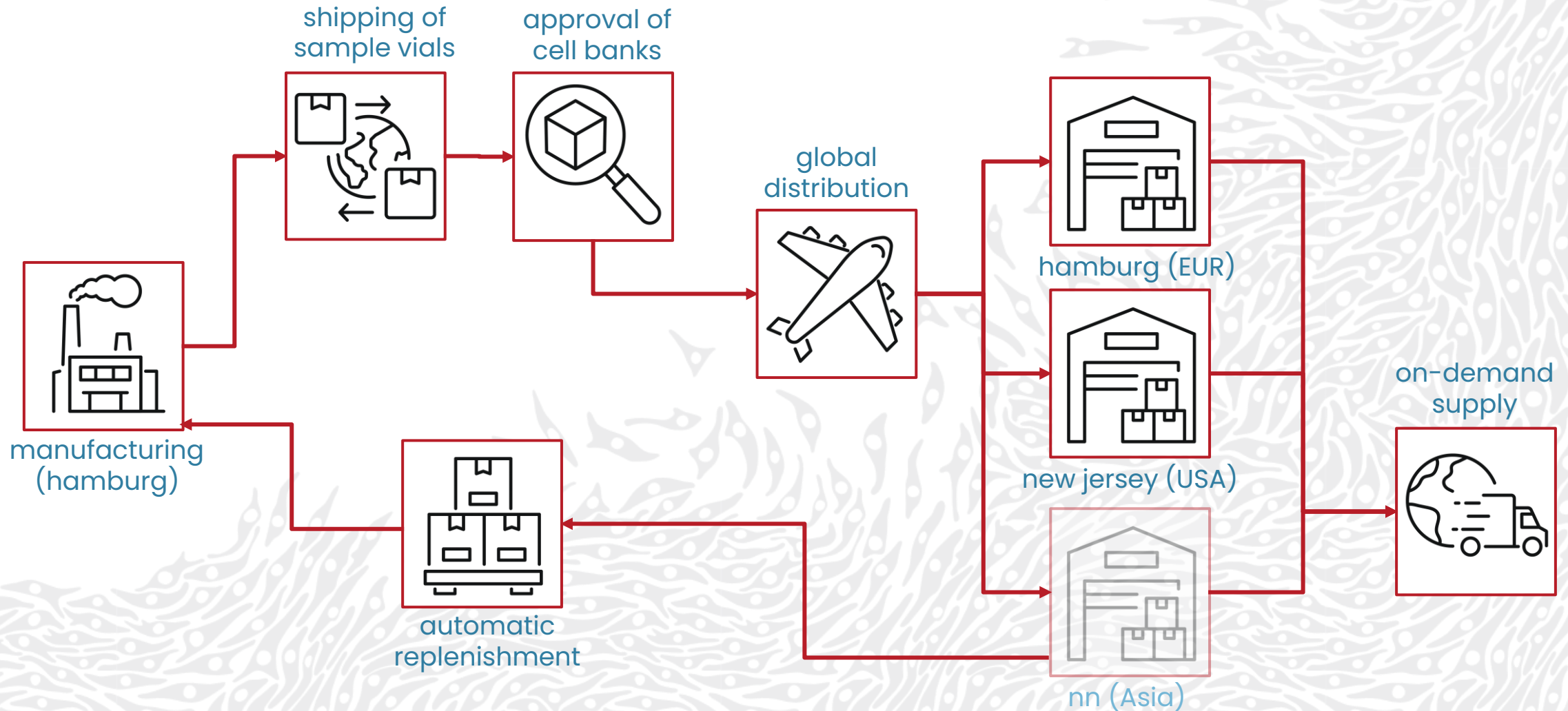
- production starts upon PO arrival
- lead time between 4-8 weeks
- invoice for entire order immediately
- separate charges on storage

instaCELLS MADE-TO-STOCK

for late-stage development and batch release

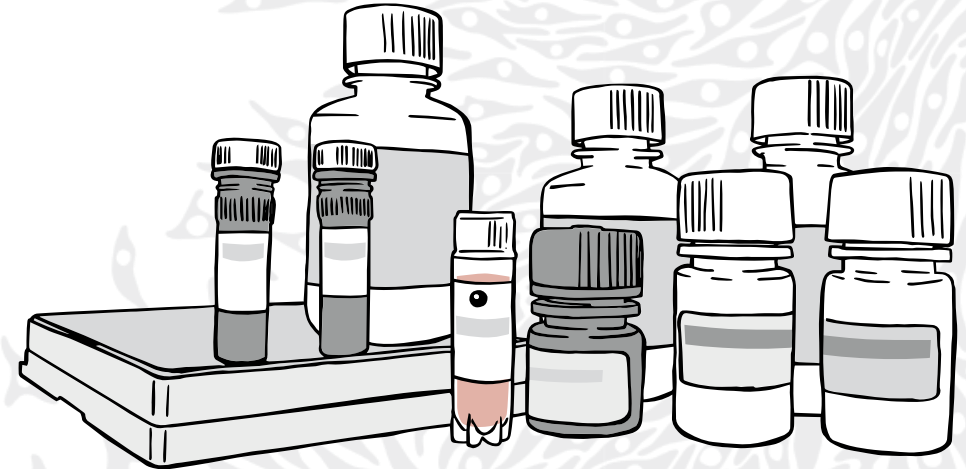
- manufactured at the maximal lot size
- automatic stock replenishment
- order on-demand from local warehouse
 - > no pre-ordering, no bound capital
 - > frees internal storage capacities
- no storage costs
- global distribution to affiliate sites & CDMOs
 - > all sites work with the same lot of cells
- custom kiting

global cell supply manufacturing, storage, & distribution



POTENCY ASSAYS FOR BATCH RELEASE

- **instaCELL TNF- α neutralization assay kit**
 - L-929 instaCELLs (murine fibroblasts)
 - cytotoxicity assay
- **instaCELL GM-CSF potency assay kit**
 - TF-1 instaCELLs (human erythroblasts)
 - proliferation assay
- **instaCELL G-CSF potency assay kit**
 - NFS-60 instaCELLs (murine hematopoietic cells)
 - proliferation assay
- **instaCELL IL-2 potency assay kit**
 - CTLL-2 instaCELLs (human hematopoietic cells)
 - proliferation assay



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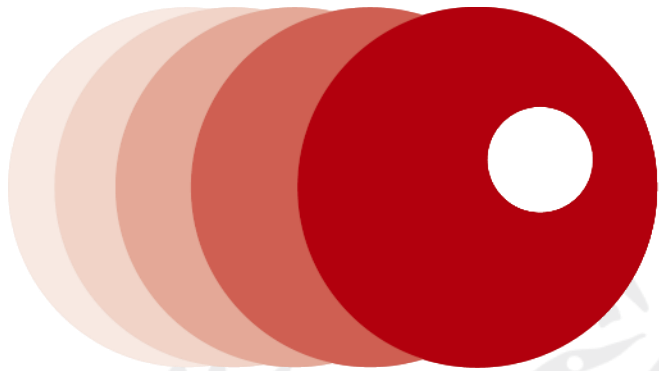
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THANK YOU!



acCELLerate

we make your cells