INFINITY IVD / CAPITAL PROJECT SERIES

Stem Cell & Exosome Processing Facility

Investor technical brief for cell-bank control, closed culture expansion, harvest, extracellular-vesicle isolation, aseptic handling, analytical release and qualified cold-chain operations.

INDICATIVE CAPEX

USD 4.5-14M

Excludes land, tax, duty and finance

DELIVERY

18-30 months

Design basis to qualified pilot process

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01 / CAPITAL DECISION

The facility in one investment view

A preliminary basis for intended-use alignment, site screening, financing and formal feasibility commissioning.

CAPITAL BAND

USD 4.5-14M

Equipment + controlled environment + qualification

GROSS FOOTPRINT

1,800-4,500 m2

500-1,500 m2 classified processing

DELIVERY

18-30 months

Qualified facility and pilot process

CRITICAL ZONES

ISO 5 / ISO 7

Open aseptic step and background as assessed

A

Facility output

Controlled cell processing and extracellular-vesicle material produced under a defined source, intended use and release strategy.

B

Capacity rule

Published only after batch scale, dose definition, recovery yield, release cycle and intended use are fixed.

C

Regulatory boundary

Facility readiness does not itself authorise a clinical claim, medicinal product, tissue service or market placement.

02 / CLASSIFICATION FIRST

The intended use changes the entire project

Clinical service, research material, cosmetic ingredient and biological medicinal product pathways require different facility, evidence and authority strategies.

R&D / RUO

Research workflows; no patient-treatment or unapproved therapeutic claims.

TISSUE / CELL SERVICE

Country-specific establishment, donor, traceability and clinical-practice oversight.

COSMETIC INGREDIENT

Ingredient manufacture, safety substantiation and market-specific cosmetic rules.

BIOLOGICAL MEDICINAL PRODUCT

GMP, clinical-development, comparability, potency and authority-approved dossier pathway.

AUTOLOGOUS SERVICE

Patient-specific chain of identity/custody and local clinical authorisation.

ALLOGENEIC PLATFORM

Master/working cell bank, donor eligibility, adventitious-agent and comparability controls.

03 / PROCESS FLOW

From qualified cell bank to characterised final material

01

Bank and quarantine

Identity, source, documentation, release status and controlled storage.

02

Culture expansion

Closed vessels, incubators or bioreactors with defined media and passage controls.

03

Harvest and clarify

Cell removal, prefiltration and time/temperature-controlled transfer.

04

Concentrate and purify

TFF, chromatography or ultracentrifugation selected from product-quality targets.

05

Formulate and fill

Sterile filtration where applicable, aseptic filling or controlled final packaging.

06

Characterise and release

Identity, purity, potency, sterility, particle profile and stability evidence.

CONTROL PRINCIPLE: SOURCE TRACEABILITY + CLOSED PROCESSING + RECOVERY CONTROL + ASEPTIC PROTECTION + ORTHOGONAL CHARACTERISATION

04 / ZONING

One-way flow protects the cell bank and the final product

RECEIVING / QUARANTINE
Status-controlled materials and cell-bank receipt.

CLOSED CULTURE
Grade C / ISO 7 basis, subject to process closure and risk.

CRITICAL ASEPTIC STEP
Grade A / ISO 5 protection with appropriate background.

DOWNSTREAM SUITE
Clarification, TFF and purification with segregated flow.

QC / MICROBIOLOGY
Identity, purity, potency, sterility and particle characterisation.

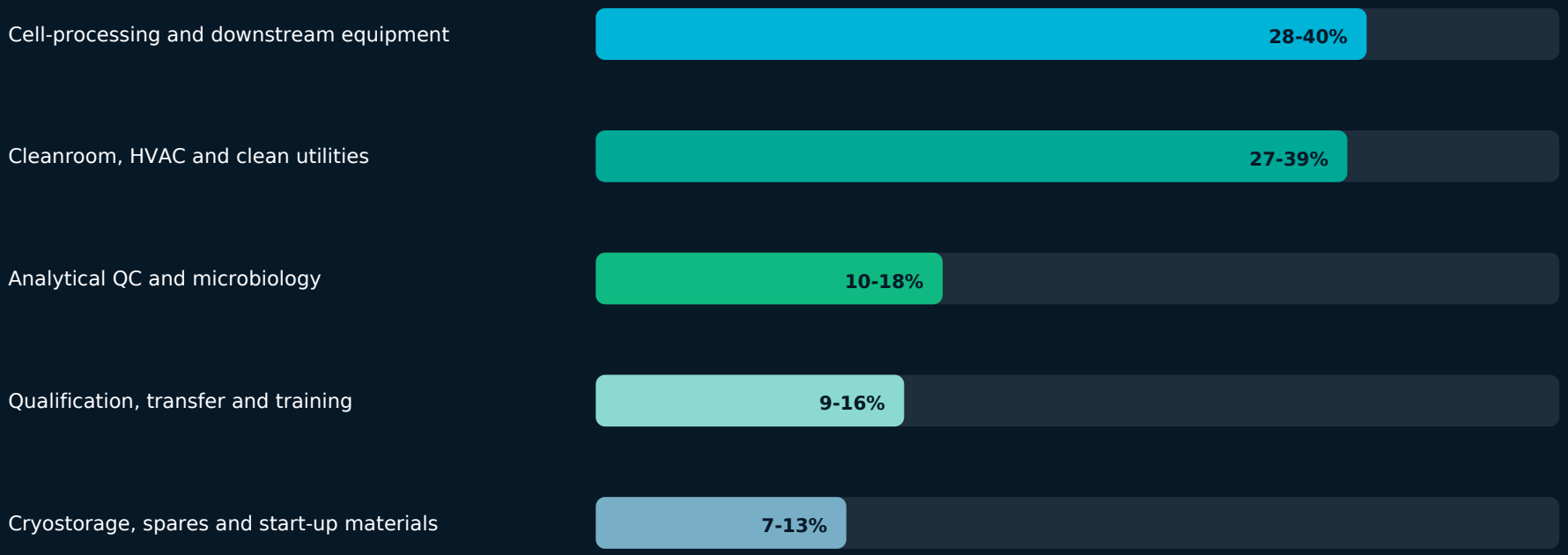
CRYO / COLD CHAIN
Mapped cryogenic, frozen and 2-8 C storage with backup.

Indicative gross footprint: 1,800-4,500 m2, including 500-1,500 m2 classified processing. Final grades follow intended use, open/closed steps and contamination-control strategy.

05 / CAPEX CONTROL

What the USD 4.5-14M band includes

Indicative allocation envelope only. Final values follow intended use, URS, site survey, batch scale and supplier quotations.



Excludes land, financing, tax, duty, clinical development, authority fees, working capital and off-site utility reinforcement unless contracted.

06 / SCALE BASIS

Capacity is a batch-yield model, not a machine nameplate

PILOT

Development scale

Small closed-culture trains; method development, engineering batches and limited pilot output.

MODULAR

Parallel batch scale

Multiple incubator/bioreactor modules, dedicated downstream train and expanded analytical release.

COMMERCIAL

Campaign scale

Defined bioreactor strategy, redundant downstream capacity, campaign scheduling and validated hold times.

Feasibility calculation inputs

- Cell source and seed-train design
- Culture vessel and working volume
- Harvest frequency and viable-cell performance
- Isolation recovery at each downstream step
- Dose or release-unit definition
- QC cycle, failure rate and stability inventory
- Shift, campaign and maintenance assumptions

07 / CELL EXPANSION

The seed train controls identity, consistency and contamination risk

A

Cell bank

Master/working bank, quarantine, identity and traceability.

B

Thaw and recovery

Defined recovery, viability, passage and acceptance criteria.

C

Expansion

Flasks, multilayer vessels, closed bags or bioreactors as selected.

D

Media strategy

Qualified inputs, preparation, filtration, hold time and cold chain.

E

In-process control

Viability, morphology, density, contamination and passage limits.

F

Harvest readiness

Defined culture endpoint linked to downstream timing and capacity.

08 / ISOLATION STRATEGY

Recovery, purity and scalability must be balanced

The platform is selected against critical-quality attributes; no single isolation method is universally appropriate.

CLARIFICATION

Centrifugation and depth/membrane filtration remove cells and debris.

TFF

Scalable concentration and diafiltration with shear and membrane-fouling controls.

CHROMATOGRAPHY

Size-exclusion, affinity or ion-exchange polishing where process development supports it.

ULTRACENTRIFUGATION

Useful for selected scales; throughput, operator dependence and recovery must be evaluated.

STERILE FILTRATION

Compatibility and product-loss risk assessed before inclusion.

FORMULATION

Buffer, concentration, container and hold-time strategy linked to stability.

09 / PROCUREMENT BOUNDARY

Vendor-neutral bioprocess equipment architecture

A

Cell bank and culture

Cryostorage, incubators, biosafety cabinets, closed vessels and bioreactors.

B

Harvest

Closed transfer, centrifugation, clarification and depth-filtration systems.

C

Concentration

TFF skid, pumps, single-use flow paths and integrity testing.

D

Purification

Chromatography or ultracentrifugation selected from the process basis.

E

Aseptic finish

Isolator or LAF protection, filtration and controlled filling/packaging.

F

Analytical QC

Particle, protein, identity, potency, sterility and stability platforms.

10 / SITE READINESS

Reliability is part of product protection

POWER

Redundant supply, UPS and generator transfer for incubators, monitoring and cryostorage.

HVAC

Pressure cascade, filtration, recovery and temperature/humidity control.

CLEAN GASES

Qualified CO2 and process gases with monitoring and backup.

WATER

Purified-water or higher-grade basis only where the defined process requires it.

CRYOGENICS

Ventilation, oxygen-depletion alarms, inventory and emergency response.

BIO-WASTE

Validated decontamination, segregation, effluent and disposal pathway.

DATA

Electronic genealogy, alarms, audit trails, backup and access control.

COLD CHAIN

Mapped 2-8 C, frozen and cryogenic storage plus qualified transport.

11 / CRITICAL QUALITY ATTRIBUTES

Orthogonal methods support a defensible release decision

Exact methods and limits are product- and intended-use-specific and are established during development and validation.

IDENTITY

Cell markers or vesicle-associated marker strategy

PARTICLE PROFILE

Concentration and size distribution

PURITY

Protein, lipid, nucleic-acid and impurity profile

POTENCY

Mechanism-linked biological or functional assay

SAFETY

Sterility, mycoplasma, endotoxin and adventitious-agent controls

STABILITY

Real-time, in-use, shipping and freeze-thaw programme

12 / CCS

Facility, process and behaviour form one contamination-control system

Material flow

Quarantine, status segregation, disinfection and one-way transfer.

Personnel flow

Gowning qualification, airlocks and controlled interventions.

Open operations

Grade A / ISO 5 protection and validated aseptic practice where required.

Closed systems

Connection strategy, integrity, hold time and single-use controls.

Monitoring

Viable/non-viable programme, trending, alerts and investigations.

Cleaning

Validated agents, rotation, residues and equipment/room coverage.

Utilities

Gas, water and HVAC qualification with excursion response.

Data review

Batch, environmental and equipment evidence reviewed together.

13 / PEOPLE AND KNOW-HOW

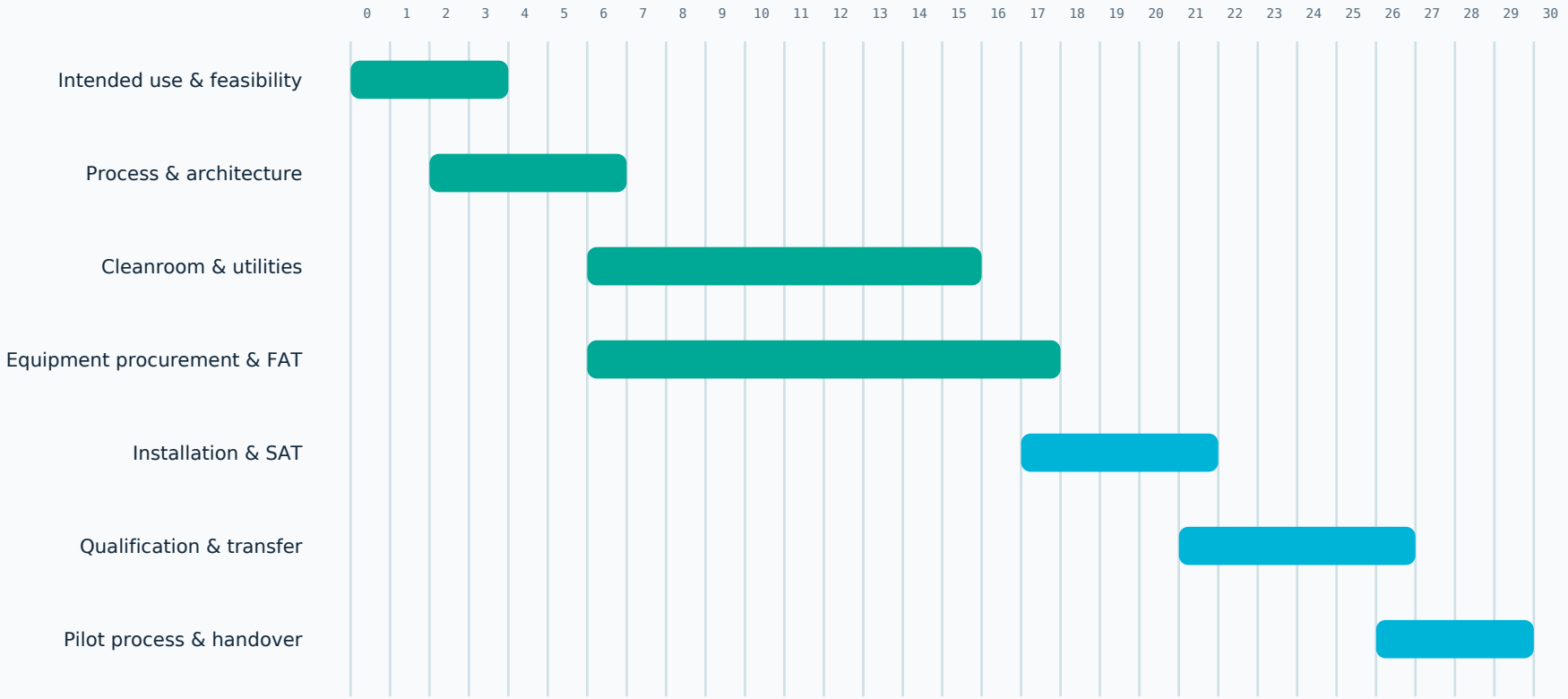
Indicative staffing: 30-70 specialist FTE

Cell processing	10-24 FTE	Bank, culture, harvest and controlled transfers
Downstream	5-12 FTE	TFF, purification, formulation and filling
Analytical QC	6-14 FTE	Identity, purity, potency, safety and stability
QA & Regulatory	4-9 FTE	QMS, batch review, validation and dossiers
Engineering	3-7 FTE	HVAC, cryogenic, calibration and maintenance

Transfer package: 12-24 weeks role-based aseptic, bioprocess, analytical, deviation and equipment training plus supervised engineering batches.

14 / EXECUTION

18-30 months to qualified facility and pilot process



MONTH 0 = APPROVED INTENDED-USE AND DESIGN BASIS. CLINICAL OR PRODUCT AUTHORISATION IS OUTSIDE THIS FACILITY PROGRAMME.

15 / INVESTMENT RISK

Failure modes that must be designed out

Cell-bank contamination or identity loss	Qualified source, segregation, genealogy, testing and controlled access.
Batch-to-batch potency variability	Defined culture limits, CPP/CQA linkage, comparability and trend review.
Low downstream recovery	Mass balance, membrane/resin selection, hold-time and scale-down development.
Adventitious-agent contamination	Raw-material qualification, closed processing, monitoring and safety testing.
Uncontrolled intended-use claims	Governance of claims, classification and change control before design decisions.
Cryogenic or power failure	Redundancy, alarms, emergency response and validated backup capacity.

16 / DELIVERABLES

The handover is a controlled operating platform

The contracted scope is converted into an indexed engineering, quality and technology-transfer dossier for client ownership and audit readiness.

ENGINEERING

- Design basis and URS
- Process flow and zoning
- Room data sheets
- Utility and equipment loads

QUALIFICATION

- DQ / FAT / SAT
- IQ / OQ protocols
- Calibration register
- Facility qualification plan

QUALITY

- QMS and SOP set
- Batch and QC records
- CCS and risk files
- Deviation / CAPA system

TRANSFER

- Process instructions
- Analytical-method transfer
- Training and competency
- Supervised pilot batches

17 / NEXT DECISION

Commission the stem-cell and exosome feasibility study

This brief is an indicative engineering envelope. The feasibility gate produces the location-, intended-use- and process-specific investment case.

- Country, city and intended site
- Cell source and intended use
- Upstream batch scale
- Exosome isolation strategy
- Release and potency concept
- Budget and financing source
- Target operational date
- Regulatory and clinical-development route

REQUEST A FACILITY-SPECIFIC STUDY

Start the project feasibility gate.

Submit the intended use, cell source, process concept, site condition, budget and schedule through the secure investor project desk.

infinityivd.com/start-project

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