Stem Cell & Exosome Facility

Controlled cell-processing and extracellular-vesicle production configured only after source, intended use and legal pathway are fixed.

Preliminary engineering range; excludes land, finance cost, taxes and import duty. Final scope and price are confirmed at the feasibility gate.

- Indicative CAPEX: USD 4.5–14M
- Delivery: 18–30 months to qualified facility and pilot process; clinical/product authorisation is separate.
- Capacity: Published only after cell source, batch scale, dose definition, recovery yield and intended use are fixed; a generic units/year figure would be misleading.

Process flow

Preliminary basis for zoning, equipment and validation.

- Qualified cell-bank receipt and quarantine
- Upstream culture and expansion
- Harvest, clarification and concentration
- Tangential-flow filtration, chromatography or ultracentrifugation as selected
- Sterile filling or controlled final packaging
- Identity, purity, potency, sterility and stability testing

Facility & clean environment

1,800–4,500 m² gross; 500–1,500 m² classified processing, typically Grade C/ISO 7 backgrounds with Grade A/ISO 5 critical manipulations where aseptic processing applies.

Critical open aseptic manipulations require ISO 5/Grade A protection with an appropriate Grade B/C background; closed processing may support a lower background after formal contamination-control assessment.

- High-reliability HVAC and backup power, clean gases, qualified water where applicable, cryogenic systems, monitored cold chain, bio-waste decontamination and robust electronic traceability.

Equipment architecture

Vendor-neutral equipment classes; final URS is issued at feasibility.

- Closed culture systems, incubators and biosafety cabinets
- TFF, chromatography or ultracentrifugation platforms
- Particle characterisation and analytical instruments
- Aseptic filling, cryostorage and monitored cold chain
- Environmental and microbiological monitoring systems

Capacity & programme

Published only after cell source, batch scale, dose definition, recovery yield and intended use are fixed; a generic units/year figure would be misleading.

18–30 months to qualified facility and pilot process; clinical/product authorisation is separate.

- Capacity assumes stated shifts, qualified inputs, maintenance and validated yield.

Quality & regulatory route

GMP or tissue/cell establishment pathway depends on intended use and claims; ISO 14644 qualification and country-specific biological-product or clinical-practice oversight.
Typical facility readiness: 15–24 months.

- Approval decisions remain with the competent independent authority.

Critical risks & staffing

Indicative 30–70 specialist FTE; 12–24 weeks training covering aseptic processing, analytical methods, deviation control and supervised engineering batches.

- Cell-bank contamination or identity loss
- Batch-to-batch potency variability
- Low recovery during isolation
- Adventitious-agent contamination
- Uncontrolled claims changing the regulatory classification

Feasibility gate

Operating economics are issued as a sensitivity model using local labour, utilities, materials, yield, utilisation and financing assumptions; they are not a guaranteed return.

Provide country, site, portfolio, capacity, budget, financing and target date.

- Project references disclosed only after intended-use alignment and client authorisation