IV Solution Manufacturing

Sterile parenteral solution production from pharmaceutical water and compounding through filling, sterilisation and microbiological release.

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

- Indicative CAPEX: USD 18–55M
- Delivery: 24–40 months to qualified facility and process-validation batches.
- Capacity: Tier 1: 8–20M units/year; Tier 2: 30–70M units/year; container size, cycle time and shifts dependent.

Process flow

Preliminary basis for zoning, equipment and validation.

- Purified water/WFI generation and distribution
- Raw-material dispensing and solution compounding
- Sterile filtration where applicable
- Bottle or flexible-bag forming/filling/sealing
- Terminal sterilisation or aseptic processing
- Visual inspection, container closure integrity, sterility and release

Facility & clean environment

5,000–14,000 m² gross; 1,500–5,000 m² GMP production/support with Grade A–D areas according to container and process.

Terminally sterilised filling commonly uses Grade C/D backgrounds subject to risk assessment; aseptic filling requires Grade A with Grade B background. Utility and component preparation grades are separately defined.

- High-capacity PW/WFI, clean steam, plant steam, chilled water, compressed gases, redundant power, HVAC, wastewater treatment and microbiological monitoring.

Equipment architecture

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

- PW/WFI, clean steam and distribution loops
- Jacketed compounding vessels and transfer systems
- BFS/FFS or bottle/bag filling lines
- Autoclaves and visual inspection
- Sterility, endotoxin, chemistry and microbiology QC

Capacity & programme

Tier 1: 8–20M units/year; Tier 2: 30–70M units/year; container size, cycle time and shifts dependent.

24–40 months to qualified facility and process-validation batches.

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

Quality & regulatory route

National GMP and sterile-product registration; EU-GMP readiness where scoped.
Facility/process readiness typically 24–36 months; authority approval separate.

- Approval decisions remain with the competent independent authority.

Critical risks & staffing

Indicative 100–280 FTE; 16–28 weeks sterile GMP, utilities, aseptic/terminal process and microbiology training.

- Bioburden/endotoxin excursion
- WFI loop contamination
- Fill-volume or seal-integrity failure
- Sterilisation lethality deviation
- Visible/particulate contamination

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.

- IV solution project details disclosed only with client authorisation