Drug Preparation & Packaging

GMP-oriented material dispensing, formulation, filling, packaging, inspection and quality-control capability for a defined dosage form.

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

- Indicative CAPEX: USD 8–30M
- Delivery: 20–36 months to facility qualification and engineering batches.
- Capacity: Cannot be stated responsibly until dosage form, pack, batch size and campaign strategy are fixed; feasibility publishes batch and annual tiers.

Process flow

Preliminary basis for zoning, equipment and validation.

- Material receipt, quarantine, sampling and dispensing
- Product-specific formulation or compounding
- Filtration/filling or solid-dose processing as selected
- Primary packaging and in-process controls
- Secondary packaging, coding and serialisation readiness
- Chemical, microbiological and stability release

Facility & clean environment

3,000–9,000 m² gross; 1,000–3,500 m² GMP production and support areas, grades determined by dosage form.

Grades are dosage-form and process specific. Non-sterile production commonly uses controlled Grade D/C-equivalent zones; sterile filling requires Grade A critical protection with appropriate background.

- Purified water and possibly WFI/clean steam, process gases, high-reliability HVAC, compressed air, dust/containment systems, backup power and waste treatment.

Equipment architecture

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

- Dispensing booths and contained transfer
- Product-specific mixers, granulators or solution vessels
- Filling, capping and inspection systems
- Blister, bottle, cartoning and coding lines
- QC, microbiology and stability chambers

Capacity & programme

Cannot be stated responsibly until dosage form, pack, batch size and campaign strategy are fixed; feasibility publishes batch and annual tiers.

20–36 months to facility qualification and engineering batches.

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

Quality & regulatory route

National GMP licence and product-registration pathway; EU-GMP readiness where contracted.
Typical facility qualification: 18–30 months; product approval is separate.

- Approval decisions remain with the competent independent authority.

Critical risks & staffing

Indicative 70–220 FTE depending on dosage form and shifts; 12–24 weeks GMP, process, QC and qualification training.

- Cross-contamination and mix-up
- Blend/formulation non-uniformity
- Fill-weight or seal failure
- Cleaning-validation failure
- Data-integrity and stability deviation

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.

- Pharmaceutical references supplied after dosage-form matching and client permission