Clinical manufacturing checklist

Check off these steps to streamline your product's path to the clinic.

Step 1

Preliminary planning

- [ ] Realistic timelines
- [ ] Regulatory authority advice
- [ ] Manufacturing knowledge
- [ ] API and formulation properties
- [ ] Supply chain complexity

Step 2

Primary packaging, API, & materials

- [ ] Primary packaging options
- [ ] Sourcing and auditing
- [ ] Nonstandard materials risks
- [ ] Later-stage injection device design
- [ ] Import/export for manufacturing & trial

Step 3

Contracts

- [ ] Necessary suppliers
- [ ] Scope of work/quotation
- [ ] Formal audit resources
- [ ] Quality agreements
- [ ] Service contracts

Step 4

Good development practices & analytics

- [ ] ICH Q8/Q9/Q10
- [ ] Understanding of CQAs & CPPs
- [ ] Scale-up issues
- [ ] Data sharing with your CDMO
- [ ] Robust SOPs for analytical methods

Step 5

Process

- [ ] API amount needed
- [ ] Technical runs and/or placebos
- [ ] Product stability testing & CDMO cycle times
- [ ] Release testing & documentation
- [ ] Frozen formulations vs. lyo development

Step 6

CDMO selection

- [ ] Safe handling of API
- [ ] Experience with high-value API
- [ ] Quality audit system alignment
- [ ] Experience with similar compounds & packaging
- [ ] Test method equipment & experience
- [ ] Available fill slots
- [ ] Realistic timelines

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