Clinical Manufacturing Checklist

Check these off to streamline your path to clinic

Planning

- ◯ Realistic timelines for program
- ◯ Regulatory authority advice
- ◯ Manufacturing knowledge
- ◯ API properties
- ◯ Process complexity

Good development practices

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

Packaging

- ◯ Primary packaging options
- ◯ Sourcing and auditing
- ◯ Nonstandard packaging risks
- ◯ Device design for later phases
- ◯ Import/export for manufacture & trial

Process

- ◯ API amount needed
- ◯ Technical runs and/or placebos
- ◯ Visual inspection & labeling time
- ◯ Release testing & documentation
- ◯ Frozen formulation vs lyo development

Contracts

- ◯ Understanding of GMP quality requirements
- ◯ Formal quality audit resources
- ◯ Agreement on legal standards
- ◯ Adequate time for multiple partners

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

To learn how Vetter can streamline your path to clinic, contact David Brett at info@vetter-pharma.com.