

Contracted Manufacturing for Cell therapy

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Disclosure

- Consulting fee from KM Pharmaceutical Consulting LLC as President and Founder.

Drug/Biologics Development



Basic Research

POC studies

<GLP studies>

- Toxicology / Safety
- Biodistribution (cell fate)

Clinical Trials



Research

Process
Development

GMP setting

Manufacturing clinical lots



Pre Pre-IND meeting

Pre-IND meeting

IND-Filing

What do you need to do before IND?

Research

Process Development

GMP setting

Optimize product
using screening system

Source controls
Control of Raw Materials Quality
Manufacturing Process Controls
Detailed Product Characterization

Optimize process

- Stability test
- In-process and final product release testing development
- Final product packaging and delivery study
- GMP documentation

- Biologics manufacturing is technologically complex, high regulated process in comparison to small molecule manufacturing
- A product is defined by process

Options for manufacturing

- Own manufacturing facility
- Not own manufacturing facilities
 - **Commercial Contracted manufacturers (CMOs)**
 - Academic facilities

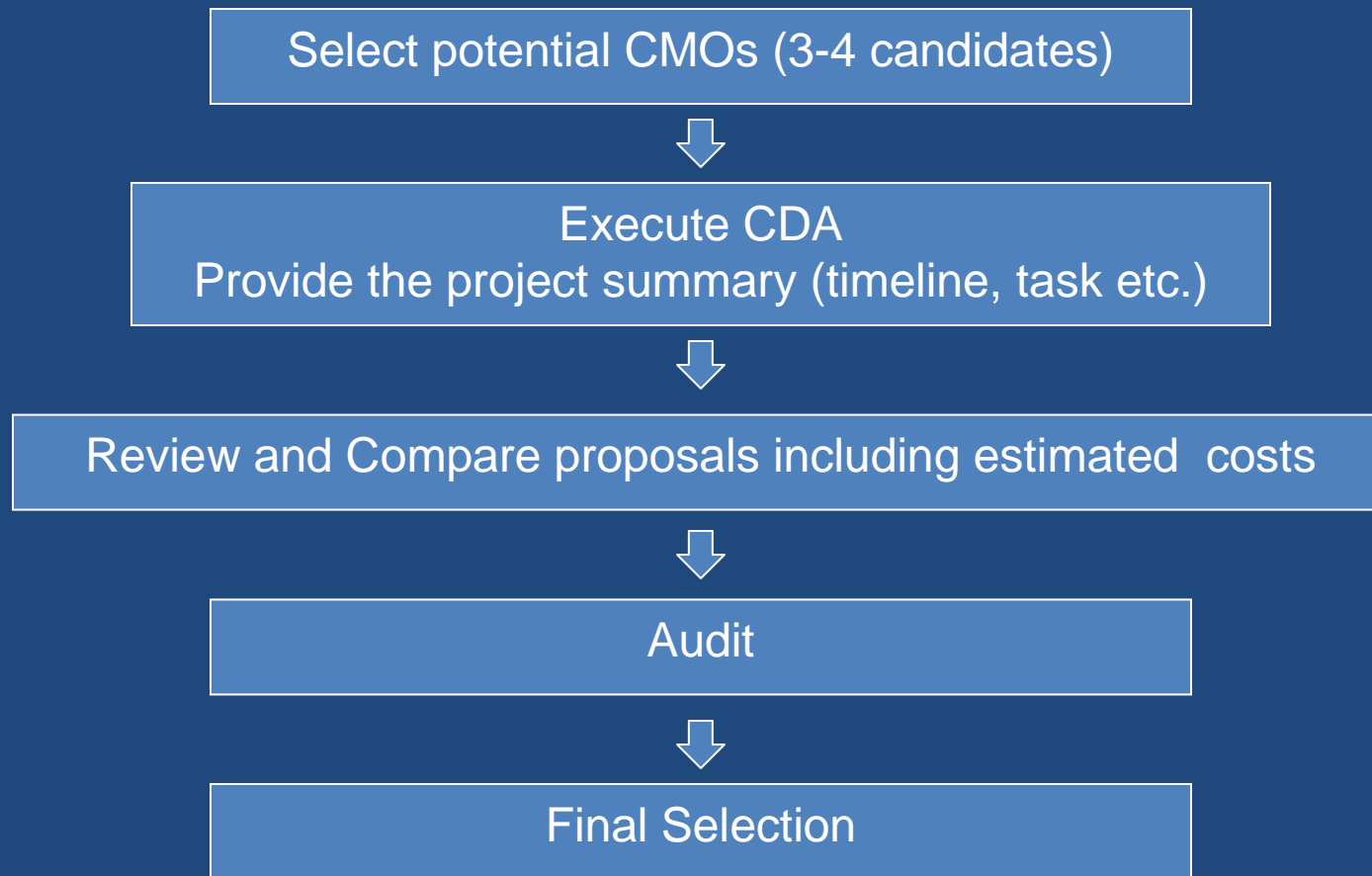
Advantage of CMOs

- You can use the expertise CMO already established for particular kind of product (cell product, gene therapy, antibody etc.).
- You don't need to invest to build your own full manufacturing facility for your product (especially in early development stage).

Cost, Resource and Time saving

Process for CMO selection

< Example >



Key Factors to select CMOs (1)

- What stage are your product at?
- What kind of task do you need to contract out?
 - Simple Tech transfer?
 - Include process development?
 - Up to commercial product?
- What is your requirement?
 - Timeline
 - Cost

Key Factors to select CMOs (2)

- Does CMO have Capability to meet your requirement?
 - Extensive technical expertise and technology platform
 - Experience and track record
 - Facility (meet all requirement)
 - SOPs
 - Dedicated, Experienced Project Management
 - Resource and turnover
 - Financial security

Audit for CMO selection

The audits should be conducted in order to evaluate the facilities, critical systems and controls with regards to compliance with cGMP for manufacturing.

- Facility Design, Construction, Access and Flow
- HVAC System/Air Classification/Pressure Differentials
- HEPA Filter Preventative Maintenance/Recertification
- Environmental Monitoring
- Facility Cleaning
- Material Control
- Deviations, Corrective and Preventive Action (CAPA)
- Personnel Training
- Document Control
- Facility and Equipment Validation etc.

How to work with CMOs

Need to work as team

- Share the goal and timeline (from each task to whole development plan)
- Share the information
- Good communication

Conclusion

Biologics-focused CMO is one of good options for Pharma/bio-tech companies especially in early stage development.

Need to select the CMO carefully to meet your requirement and goal



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Presenter Disclosure

Minako Koga

The following relationships exist related to this presentation:

**KM Pharmaceutical Consulting LLC,
Consulting Fee, President/co-founder**