Drug Product, Tech. Transfer & CMOs

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Drug Product, Tech. Transfer & CMOs

• Documentation & Process Knowledge Management

• CMO Selection Due Diligence
  - Level 1
  - Level 2

• Summary
Technical Transfer & CMOs
Documents & Process Knowledge Management

- Confidential Disclosure Agreement
- CMO Questionnaire
- Quotes/Statement of Work/Purchase Orders
- Clinical or Commercial Supply Agreement
- Quality Agreement (Clinical - EU & Canada)
- Regulatory Documentation
- Process Flow Diagram & Description/Batch Records
- Analytical Methods Transfer & Qualification/CoA
- Cold Chain & Shipping Management/Logistics

CMO Selection
Due Diligence - Level 1

- CMO’s Capabilities & Experience (must haves)
  - Drug Product Critical Quality Attributes
  - Scale of Process and Capacity
  - Analytical Methods both IPC & Release Testing

- CMO’s Pharmaceutical Elegance
  - Overall visual cleanliness and organization
CMO Selection
Due Diligence - Level 1

- **Clinical vs. Commercial** (not many do both all that well)
  - Clinical programs (Phase 1 & 2) need tactical attributes
  - Commercial programs need strategic partner

- **Location, Location, Location**
  - Direct flights? Flight duration? Day trips?
  - How are the Hotels & Restaurants near the CMO?

CMO Selection
Due Diligence - Level 1

- **CMO SOPs Look Great** (they all do, large quantities too)

- **During the Quality Audits Review, Review, Review**
  - **Quality** (Prosecution of deviations/exceptions/investigations)
  - **Metrology** (Instrument/equipment ranges and frequency)
  - **Validations** (Manufacturing and utility equipment)
  - **Media Fills** (Frequency/intervention updates/presentations)
  - **Visual Inspection** (Manual vs automated, qualification)
  - **Equipment/Facility Maintenance** (Records & visual)
  - **Environmental Monitoring** (Trending Reports)
CMO Selection
Due Diligence - Level 2

• CMO’s Business Scope
  – Manufacturing their own products
  – Competing demands for resources

• CMO’s Business Goal
  – Committed to long term growth and innovation
  – Basis of staff & management bonuses
  – Managing only the margin
  – Cars in the parking lot

• Manufacturing Centric Business Process & Discipline
  – Do they utilize Manufacturing Sciences? TQM, SPC, Six Sigma, 5S
  – Do they have KPIs?
  – Do all the employees know how their CMO makes money?
  – Enterprise System? But can they get the info out?
  – How many shifts per day?
CMO Selection
Due Diligence - Level 2

- Quality of CMO’s Technical Team
  - Any SMEs? Extent of knowledge/experience?
  - How deep is the bench?
  - Automation technical support on staff? Contractor support?
  - CMO staff turnover rate? Number of open positions?
  - Recruitment challenges? Nice place to live?

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Summary 1

- A Solid Supply Agreement - Priceless
  - Legal support may be required when unintended events occur

- CMO’s Capabilities & Experience – Like a Glove
  - Minimize risk and maintain drug product’s CQAs

- Quality Audits – It’s All in the Details
  - Provides insight into the CMO’s values & culture
Drug Product, Tech. Transfer & CMOs
Summary 2

• CMO’s Business Model & IQ – Managing Beyond Margins
  — Manufacturing centric approach saves resources

• CMO’s Technical Team – More SMEs the Better
  — A short bench increases risk on many fronts

• Managing any CMO - Trust But Verify
  — The knowledge level of the staff & SMEs is a solid indicator of how much directing and oversight will be required