

Drug Product, Tech. Transfer & CMOs

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18June2015



Connecting a World of
Pharmaceutical Knowledge

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



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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



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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?



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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)



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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



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CMO Selection Due Diligence - *Level 2*

- **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?



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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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Drug Product, Tech. Transfer & CMOs 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



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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

