



Selecting, Sourcing and Auditing of Overseas GMP Operations

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The Five C's of CMO Selection

- Capability
 - ▶ Technical knowledge and competence
- Capacity
 - ▶ Equipment and facilities
 - ▶ Resources
- Compliance
 - ▶ Quality system
 - ▶ Inspection history
- Cost
 - ▶ Total cost
- Customer focus
 - ▶ Project management
 - ▶ Flexibility
 - ▶ Communication



Capability

Capability Attribute	Molecule Type	North America/ Europe	China/ India
Core technical expertise	Small Molecules	Excellent	Excellent
	Biologics	Excellent	Good
Technical planning	Small Molecules	Detailed step-by-step	Variable
	Biologics	Detailed, per unit operation	Variable
Technical Execution	Small Molecules	Slow and defined but usually successful	Highly variable
	Biologics		High variability expected
Quality of Work Product	Small Molecules	Good	Variable
	Biologics	Good	Variability expected



Capacity

Capacity Attribute	Molecule Type	North America/ Europe	China/ India
Human Resources	Small Molecules	Good	Excellent
	Biologics	Good/ Excellent	Fair/Good
Equipment	Small Molecules	Excellent	Good to excellent
	Biologics	Excellent	Variable
Technical Execution	Small Molecules	Slow and defined but usually successful	Variable
	Biologics		High variability expected
Quality of Work Product	Small Molecules	Varies	Variability
	Biologics	Good	Variability expected



Compliance Points to Consider

China/ India versus US/ EU

Strengths

- Hunger to do better
 - ▶ Quick to learn and get involved strategically
- Solid scientific training
 - ▶ More highly qualified pool available
- Greater flexibility
 - ▶ Willing to go the extra mile
- Solid experience from small molecule generics
 - ▶ 20% of all generics manufactured in India, 10-15% in China

Concerns

- Emphasis on compliance relatively recent
 - ▶ Increased outsourcing from developed world
 - ▶ Ambition to supply drugs worldwide
 - ▶ Addition of biologics to the portfolio
- Unclear local regulatory environment
- Cultural differences
 - ▶ Hierarchical society structure
 - ▶ Straightforward talk not considered polite
- Infrastructure differences
 - ▶ More complicated logistics



What to Focus during Audits

- Pick an area and follow the whole story
 - ▶ Ask “20 Questions” to get a full picture
 - ▶ Look for inconsistencies when asked the question a couple of different ways
- Tour the Facility
 - ▶ First-hand observation of the vintage & quality of equipment & facilities
 - ▶ People on the floor are usually more candid
 - ▶ We were taken to a site 40-50 miles away from the supposed manufacturing site during an audit of an important SM intermediate in China
- Ask them to walk you through a Batch Record or an SOP



Summarizing...

- Indian and Chinese companies are eager to become “mainstream”
- Many US-trained Indians and Chinese Executives and Scientists have moved back to provide strategic leadership
 - ▶ Setting up solid quality systems and business processes
 - ▶ Enhancing regulatory compliance
- US/ European and local companies have established significant operations
 - ▶ Lonza’s investment in the Genome Valley near Hyderabad
 - ▶ Boehringer Ingelheim & Kenwell to build operations in Bangalore
 - ▶ Bharat Biotech manufacturing Hib vaccine for Pfizer (Wyeth)
 - ▶ Novartis manufacturing Rabies vaccine in Ankleshwar plant
 - ▶ Autekbio (Chinese Govt supported) setting up Biologics manufacturing in Beijing
 - ▶ Biocon, Dr. Reddy’s, Intas....
- Outsourcing of Biologics to India and China is bound to increase

