



# Outsourcing, Technology Transfer & CMO-Client Relationships

*CMO Performance Management*

*Contract Manufacturing / Outsourcing  
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# Presentation Outline

Guiding Principles for Externalization

“Make” vs. “Buy” Options

External Supply Models

Integrated vs. Functional Services

Strategic vs. Collaborative Vendors

CMO Screening Process

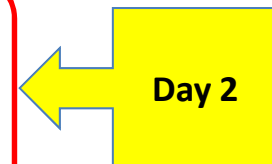
End-to-End mAb: from DNA to Phase 1 CTM

**CMO Selection – Interactive Exercise**

Vendor Management & Metrics

Managing Relationships with CxOs

CxO Scorecards



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# CxO-Client Relationships

## Purpose:

- Use the CxO Scorecard as a tool for managing strategic vendor relationships
  - Ensure ongoing communication for continuous improvement
  - Facilitate a 2-way feedback review session

## Team Objectives:

- Take existing CxO Scorecard program & evaluate against outsourcing needs
  - Continue to include Quality Risk Assessment
  - Continue to include Procurement for focus on cost/value
- There is no intention to force harmonization of all practices across work streams, but rather, select areas that make sense



# Strategic CxO Criteria

CxOs were selected based on the following criteria:

Criteria	Drug Substance	Drug Product	Analytical
Volume	2-3 batches / year	4-6 batches / year	15-20 new studies / year
Projects	1-2 projects / year	3-6 projects / year	8-12 projects / year
Cost	\$1M+ / year	\$1M+ / year	\$1M+ / year

Note: This does not exclude CxOs that may not fit the above criteria but are included based on other unique selection criteria



# CxO Scorecard Categories

## Account Support

- Evaluate the CxO on the basis of: RFPs, invoicing accuracy, timeliness and ease of completion of MSAs & CDAs, capabilities to handle electronic transfer of confidential information, responsiveness

## Project Management

- Evaluate the CxO on the basis of: project management support, communication, ability to deliver, turnover and stability with personnel, change communications, and flexibility

## Value

- Evaluate the CxO on the basis of: technical capability, quality of service being provided, competitiveness, timeliness and cost, continuous improvement / cycle time reduction efforts

## Quality

- Incorporates the evaluation performed by Quality Assurance under Quality Risk Rating of CxOs



# Account Support Survey Questions

How did they perform in returning RFPs/pricing in the requested time frame?

How compliant was the CxO when completing the RFP?

RFP revision process (i.e. ability to provide it RFT)

How did they perform in establishing or renewing MSAs in the requested time frame?

How did they perform in establishing or renewing CDAs in the requested time frame?

Does CxO follow instructions related to appropriate invoicing?

Limitation with IT (i.e., ability to share confidential information easily, large files, LIMS access, etc.)



# PM Survey Questions

Does CxO immediately notify us of changes to delivery timelines?  
Is CxO flexible in meeting demands and schedule changes requested?

How would you rate the weekly progress reports and/or meetings?

Are they effective in communicating when issues arise?

How was the availability of support when the primary contact was out of office?

Do they provide the appropriate level of project management to successfully manage the transfer of the project? (i.e. Project Plan, Gantt chart, etc)

Do they provide an appropriate communication plan to ensure SMEs are identified with our project SME counterparts? (i.e. Analytical SME, etc)

In cases with personnel turnover with the CxO, has the transition been managed well?

How did the CxO conform on appropriate shipping documents? This includes both shipping and receiving of materials, working with I/E, temperature excursions, etc.





# Value Survey Questions

Does CxO proactively solve technical issues?

Does CxO make effort to reduce overall lead time?

How have they demonstrated their broad technology capabilities?

How open are they to bringing in new technology and how well was it integrated into practice?

How well did the CxO proactively reduce cost over time?

Overall, how competitive was the supplier on price?

How well do they adhere to negotiated/RFP pricing?

How well did the CxO meet the quantity requirements?

Does the CxO deliver material/results on time?

Is the CxO's systems flexible to work with our system? (i.e. batch records, analytical procedures, receiving documents, etc)



# Category Weights

## Weight Distribution Across Categories

Survey Category	Survey Weighting
Account Support	15%
Project Management	35%
Value	35%
Quality Compliance	15%

\*Quality Compliance weighted low, since vendors with high quality risk are managed outside this process.

# Quality Risk Rating of CxO

Risk Elements	Description	● = Low    ● = Medium    ● = High	Risk Rating
cGMP Compliance History	Regulatory and audit history	●	●
Quality System Processes	Number of deviations, batch reworks	●	●
Complaints	Clinical complaints / vendor involvement	●	●
Investigations	Timeliness, Root Cause Analysis, Thoroughness	●	●
Change Management	Communications on Changes / Change Control	●	●
Quality Agreement	Acceptability of QAA / Deviations of the Agreement / in place & effective	●	●
Technical Capabilities	Age of facility / Technical Capabilities	●	●
Quality and Risk Culture	Risk Assessment & Continuous Improvement / RFT / Vendor QA Oversight	●	●
Materials Assurance	Identity testing, supplier assessment, testing & vendor qualification programs	●	●
Communications	Notification of Deviations / Changes / Ability to contact & visit	●	●
Product Risk	Type of product (sterile)	●	●
Business Risk	Financially stable, clinical studies, vendor location	●	●
Supply Chain	Supply of API and Excipients	●	●
<b>OVERALL RATING: MEDIUM QUALITY &amp; BUSINESS RISK</b>			●



# Survey Category Weights

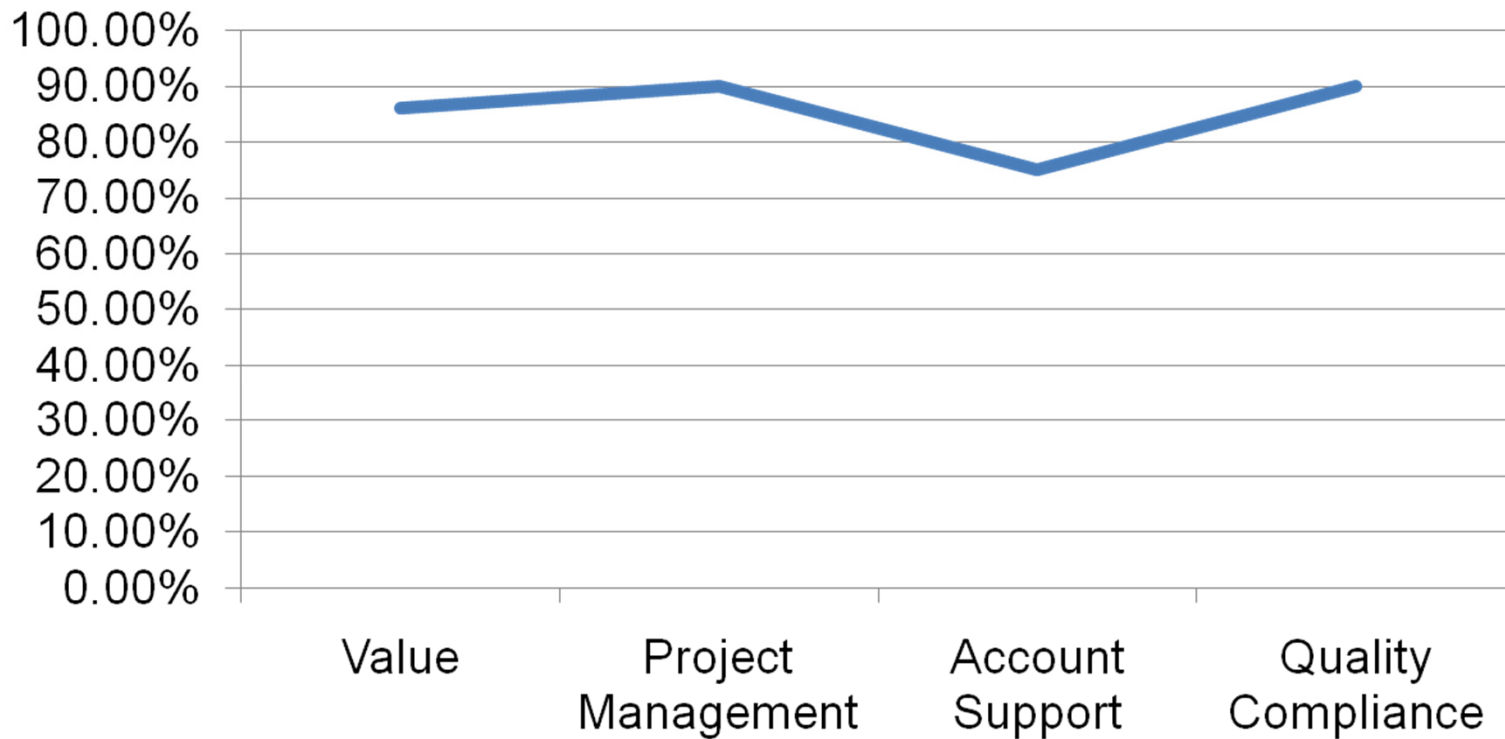
## Other Data Collected

Survey Question					
On a scale of 1-5, how would you rate your overall experience with the CxO?	I would rather be in Siberia eating popsicles in the middle of winter than to return to work with this CxO again.	I would work with them again but need wholesale management changes and infusion of capital investments.	The CxO meets the needs but could benefit from continuous improvement.	Yes, they are the CxO of choice for this project.	I would rather work there than here.
Why was this CxO selected for this project?	strategic (in-licensing)	technical capability	timeliness	cost effective	re-load batch



# Scorecard Example

Overall Score 88.62%



High

Low

# Conclusions

- ❖ CxO selection process is the most critical step in outsourcing.
- ❖ CxO-Client relationship is a two-way street; ensure ongoing communication and feedback, for continuous improvement.
- ❖ There is no PERFECT CxO. This is a myth!





# Acknowledgement



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