

Incorporating Risk Management into the Outsourcing Relationship

Jim Miller

DCAT Risk Management Program

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Outsourcing highlights risk exposure

Perceived loss of control

- Someone else's shop
- More hand-offs to unrelated parties



Single point of sponsor responsibility

- Someone thinking about all the things that can go wrong

Financial implications are clear

- Costs not buried in budget line items
- Payments may continue despite cancellation or delay

Offending parties can be called out

- Assign blame without ruffling collegial ties

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Outsourcing risk implications are double-edged

Risk mitigating effects

- Reduced financial exposure
- Faster time to market
- Specialized expertise
- Performance improvement leverage
- Second sourcing

Risk-intensifying effects

- Reduced flexibility
- Variable quality of operations
- Other sponsors' products
- CMO strategy and financial performance
- Communication and coordination complexity
- IP protection

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Analyze true risk exposure

■ Knowledge is more powerful than fear

- Risks can often be estimated and scenarios worked out
- Major CMOs should have the data and experience to do this well
- Just the exercise improves understanding and can lead to risk reduction

■ What are the real risks of a blown batch?

- Worst case scenarios create contracting problems
- Six Sigma data should reveal probability and causes
- PAT will further limit, define exposure

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Use full range of risk management tactics

Mitigation tactic	Application
Avoidance	<ul style="list-style-type: none">■ Don't outsource■ Don't take the project
Prevention	<ul style="list-style-type: none">■ Validation■ Man-in-the plant■ EHS measures
Redundancy	<ul style="list-style-type: none">■ Second sourcing■ Back-up systems
Separation	<ul style="list-style-type: none">■ Smaller batches■ Split shipments■ Offsite storage
Transfer	<ul style="list-style-type: none">■ Insurance■ Joint ventures
Retention	<ul style="list-style-type: none">■ Indemnification■ Self-insurance

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Have realistic expectations of value and risk

- Risk management is part of sponsor's cost of doing business
 - Drug development and sales are inherently risky

- Can't load sponsor business risk on CMO
 - Not CMO business model
 - Margins can't support high levels of risk
 - Leads to protracted negotiations and relationship problems

- Limit CMO risk exposure to value-added
 - Operational performance
 - Regulatory performance
 - Schedule performance
 - Service performance

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Assign risk based on responsibility and reward

Market Risk	Technology Risk	Operational Risk
<ul style="list-style-type: none"> Product fails to achieve volume projections 	<ul style="list-style-type: none"> Adverse events/ no clinical efficacy 	<ul style="list-style-type: none"> Blown batch
<ul style="list-style-type: none"> Product exceeds volume projections 	<ul style="list-style-type: none"> Lack of process robustness 	<ul style="list-style-type: none"> Raw material shortages
<ul style="list-style-type: none"> Product priced below projections 		<ul style="list-style-type: none"> Regulatory violations

<ul style="list-style-type: none"> Shared responsibilities and risk
<ul style="list-style-type: none"> Sponsor sole responsibility
<ul style="list-style-type: none"> CMO sole responsibility

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Remember CMO strategy and financial risk

- Is company successful?
 - Profitability, growth
 - Is it financially stable?
 - Debt, credit history
 - Can company support its growth?
 - Cash flow, debt capacity
 - How dedicated to contract business?
 - What are owners intentions?
- Adverse business developments are more likely to be catastrophic than compliance or technical problems
 - Only 17% of sponsors review contractors financials annually

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Put contract conditions upfront in RFP process

- Risk management issues often more contentious and expensive than price

- Late negotiations reduce time for problem-solving
 - Contracts often take 6-12 months to negotiate
 - Switching costs are too high, timelines threatened

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Problem areas in contract negotiations

■ Problem situations

- Naïve clients
- High cost API
- Generics
- CMO insistence on own template

■ Contentious issues

- Blown batch/non-conforming products
- Indemnification
- Forecasts/schedule lock-in
- Exclusivity

■ Success comes from mutual understanding of needs

- Client education may be part of the process for CMOs
- Most terms are negotiable, underlying philosophy is not
- Willingness to refine, clarify overly-broad provisions
- Mutual hold-harmless for each other's negligence

Final thoughts

- Understanding sources of risk and who is responsible is critical in drug development
- CMOs play a role and bear certain share of the risk, but it is a small part of the overall
- Sponsors need to understand the full range of risk management tools available and apply them effectively
 - Contracts should not be the principal risk management tool