Increasing Risk Management Maturity in Lifesciences – taking the journey step by step

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Even the most carefully planned project can run into trouble.

No matter how well you plan, your project can always run into unexpected problems. Team members get sick or quit, resources that you were depending on turn out to be unavailable—even the weather can cause problems.

**BUT** the pharma industry has tended to neglect the importance of project risk management. This leads to unnecessary project failures and delays.
AGENDA

- Is this a journey we want to take?
  - Research findings & business needs
- Which way do we go?
  - Mapping the journey
- Taking the first steps
  - Walk before you run
- Potential pitfalls
  - Anticipating the banana skins
- Ready for the onward journey?
  - Gaining confidence & seeing results
- Managing risk in our Business
  - Case Studies and Best Practices
Is this a journey we want to take?

..responding to the lack of confidence in our ability to deliver Projects on time and to cost internally and from the Customer and the City....the Company has put a much greater focus on...how we manage our Projects and how we assess the Risks of delivering the Projects

Vision:
Improve our project time and cost performance...
Develop our Project Managers' competency (and confidence!) in Risk Management...
Demonstrate our professionalism to our customers...

Defining & enabling behaviours, embedding practices and stimulating the right attitudes
Enabling R&D strategy by focusing on Projects and Portfolios
Enhanced Time, Risk & Resource management
The journey for risk management – a need to change

- 2005/6
  - Gap analysis identified need to improve practice
    - Identification but little management of risk
    - Inconsistent reporting

- 2006
  - New R&D Chairman
  - Several late regulatory submissions
    - Lack of confidence in delivery
Research Shows That Different Factors are Critical For Different Measures of Performance.

1. Risk education.
2. Risk quantification.
3. Risk register.
4. Owners for all risks.
5. Up-to-date risk mgt plan.

1. Tight scope change control.
2. Integrity of performance measurement baseline.

Predictability Improves With Adequacy of Practices.

Time predictability
1. Is there company wide education on risk concepts?
2. Is there a visible risk register showing the impact and probability of each risk and other information?
3. Is there a formal process for identifying and quantifying risks?
4. Have all the risks that are to be managed had owners assigned?
5. Is the risk management plan up to date?

Q5: Adequacy of assigning risk owners
.. And Risk Management Impacts Different Aspects of Performance.

Data taken from an analysis (March 2007) of 339 sets of results in CfS Index, shows that Improved Risk Management correlates to improvements in:

- Benefits Realized.
- Efficiency.
- Effectiveness.

So, it’s pretty important!
Which way do we go?

- External cultivation or internal growth?
- Focus on training or capability development?
- PMs?
- Project Teams?
- Management?
- Governance?
# Training and Developing Project Managers

<table>
<thead>
<tr>
<th>External Cultivation</th>
<th>Internal Growth</th>
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<tbody>
<tr>
<td>+ Access to subject experts</td>
<td>+ Relates to company culture</td>
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<tr>
<td>+ Professional trainers</td>
<td>+ Integrated with company tools/systems</td>
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<tr>
<td>+ Resource ‘light’</td>
<td>+ Tailored to local vision</td>
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<tr>
<td>+ PMI accredited – PDUs</td>
<td>+ Departmental ownership</td>
</tr>
<tr>
<td>+ Central coordination (PMO)</td>
<td>+ Central coordination (PMO)</td>
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- Education not application
  - High cost
    - Cancellation fees

- Assumes local expertise
  - Resource intensive
    - Faculty
A new company in a new century – externally grown PMs

<table>
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<tr>
<th>Training Provision</th>
<th>Challenges</th>
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<tr>
<td>- Standard project management practice</td>
<td>- Changing company culture</td>
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<tr>
<td>- Limited Curriculum</td>
<td>- No customisation for GSK</td>
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<tr>
<td>- MS Project</td>
<td>- No linkage between courses</td>
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<tr>
<td>- Planning</td>
<td>- Unclear expectations for PMs</td>
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<tr>
<td>- Risk Management</td>
<td>- No PM community across R&amp;D functions inc Clinical</td>
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<tr>
<td>- Multiple external providers</td>
<td>- No central coordination</td>
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<tr>
<td>- Functional groups selected own providers</td>
<td>- Budget challenges in each group</td>
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<tr>
<td>- Internal Curriculum</td>
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<tr>
<td>- Drug Development</td>
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<td>- Conflict, Negotiation, etc</td>
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The journey for Risk Management 2002 – 2007

- Principles of Risk Management
- Broad education of principles and methodologies
- All PMs attended (but not clinical PMs)
- No embedding of practice following training
- No tool selected for R&D use
- No clear development expectations for PMs
- No supporting culture
  - No expectations for team members
  - No mandated training across the matrix
Taking the first steps

- Instigate a Change Project & set targets
- Acknowledge time commitment
- Realistic timeframe for adoption
- Develop local experts
- Provide facilitators
- Communicate, communicate, communicate
- Celebrate & reward
The journey for risk management – first steps

- 2007 – 2009
  - Maturity model established
  - Practical workshop launched
    - Simple Excel risk register
    - Education across R&D
    - Central funding for training
  - Clear expectations for PMs, teams and governance
Potential pitfalls

- Excessive organisational change
- Baseline data
- Lack of integration
- Great process but…..
- Governance reinforcement
Masses of models & tools available, yet...

...Many of the issues are behavioural:

- Failure to follow well structured process
- Risks identified but not managed
- Poor KM – little learning from experience

...And there is significant risk from failure in other PM disciplines:

- Poor estimating
- Failure to control scope
- Inadequate resourcing

Poor project management!
Practice gap – Approach rarely matches reality
Risk Management Approach vs. Deployment

Corporate Practices - Risk

Pharma
Key role for Governance in reinforcement of behaviour

Metrics easily gathered from minutes

- Risk registers logged pre meeting
  - Team *adopting*
- Key risks presented
  - PL/PM *integrating*
- Discussion within the meeting
  - Governance *understanding*
The journey for risk management – continued work with our partners

2009–11

- Integration of maturity model with other practices
- Updated Excel register to ‘match’ future Planisware format
- 3rd Level Kirkpatrick review
- Training course updated accordingly
- Expert clinics
- Project Team Resource centre created
Ready for the onward journey?

- Was it all sorted? – No

- Essential to maintain your belief & commitment
  - Measure success

- Continuous improvements are vital
  - Integration into other practices
  - Practice development
  - Tool development
  - Training development
  - Support development
The journey for risk management – Business as usual

- 2011 onwards
  - Planisware risk management functionality roll
  - Project Team Resource centre updated
  - Project team health checks
  - Training course adopted into new Academy plans
  - Expert clinics continued
  - Closure of Change Programme in 2012

‘Risk management has become part of the way we work, which means increased confidence in our project plans’
Project Capability Benchmarking
Managing Risk in our Business
Risk Management is universal

- Company
  - Strategic Risks
    - Competitor Advantage
  - Operational Risks
    - Company Viability
  - Financial Risks
    - Stakeholder Harm
  - Compliance Risks
    - Patient Harm
Tool Considerations

- A formal risk management tool is not essential. However, they can be very valuable in the right circumstances.
- No single tool or method can be applied to all situations.
- All tools require a good understanding of the process under review.
- The team provides a range of expertise and various perspectives to enhance the tool.

More important than any tool:

The right people having the right conversation at the right time!
## Tool Comparison

Not all tools assess all risks / not all risks are failures

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<tr>
<th>Tool</th>
<th>Acronym</th>
<th>Common Uses</th>
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<tbody>
<tr>
<td>Failure Modes &amp; Effects Analysis</td>
<td>FMEA</td>
<td>Evaluate equipment &amp; facilities</td>
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<td>Quantitative Uses data based on scientific understanding to determine probability &amp; impact</td>
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<tr>
<td>Fault Tree Analysis</td>
<td>FTA</td>
<td>Investigate product complaints</td>
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<td>Quantitative/Qualitative Evaluates system failures one at a time</td>
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<tr>
<td>Hazard Analysis &amp; Critical Control Points</td>
<td>HACCP</td>
<td>Preventive applications</td>
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<td></td>
<td>Qualitative Bottom up approach to prevent hazards occurring</td>
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<tr>
<td>Hazard Operability Analysis</td>
<td>HAZOP</td>
<td>Evaluate process safety hazards</td>
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<tr>
<td></td>
<td></td>
<td>Qualitative Identifies potential deviations from norm</td>
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FMEA – Failure Modes & Effects Analysis

- Prospective tool to quantify risks involved in different stages of a process
- Scoring method to identify points of greatest risk
- Prioritises areas for attention/resources
- Developed in aerospace industry – 1940–60s
- Increasingly used in healthcare
  - Clinical trials
  - Drug prescribing
Will good risk management prevent issues occurring?

NO!

- Not all risks can be completely mitigated or avoided
- Not all risks can be identified – stuff happens!
- The issue list is transient as they are identified and resolved but they may lead to changes for the project
Case Study 1 – Preclinical Data
Risk Management can save money

- Project team brainstormed potential risks for completing a phase 2 clinical programme as scheduled.
- Multi disciplinary team contribution with ‘invited’ facilitator.
- Clinical study potentially impacted by outcome of a high risk toxicology study.
- Review of the critical path by the PM identified float so study could be delayed until after the tox results were available without impacting the regulatory submission date.

- Outcome: negative tox study results and project terminated. Saving to company of not starting the clinical study ~£1 million pounds
Case Study 2 – Audits

FDA Warning Letter / French Authority observation

- ‘Your firm failed to review all aspects of the risk assessment process to determine if other components were lacking, review other risk assessments for similar shortcomings and evaluate related procedures and subsystems to determine if they also needed to be addressed in a similar manner. In addition, your firm did not provide evidence of implementation of all the planned actions.’

- ‘There is no risk assessment procedure to evaluate risks related to the products manufactured in the plant (e.g. toxicity, design of facilities…) the equipment used, the qualification/validation needs or related to judgement when initiating new projects’
Measures can be captured for each participating site and for the study overall. Unusually high deviations from an observed study benchmark can be flagged and a “site quality risk level” assigned for each site for the given measure.

- In this example, the overall Adverse Event rate for the study is 8.7 AEs per subject–year. The given site in the study currently has an AE rate of 5.6 AEs per subject–year, which places it in the “yellow” or elevated quality risk level for this measure.

Depending on the nature of the identified issue, potential follow–up actions may include the following:

- Increasing the percentage of Source Document Verification required at the site;
- Delivering additional guidance and training on specific aspects of the protocol;
- Planning additional on–site visits to more closely monitor certain aspects of the site’s study conduct.
Rituximab – biological, systemic therapy licensed for non-Hodgkins Lymphoma & rheumatoid arthritis.

Four risk factors
- Therapeutic risk
- Complex dose calculation
- Part or multiple vials to be added to infusion bags
- Pump requires frequent setting adjustments

FMEA used as a proactive approach to managing the risks
- Focus groups identified failure modes in each stage of the process
- For each mode the cause & effects were identified and scored to produce the RPN.
- Highest RPN modes affecting patients were investigated for modifications that could lower the risk e.g.
  - Failure mode – wrong body surface area calculated – RPN – 600
  - Cause – incorrect data for height & weight on prescription

Risk reduction strategies are being put in place including:
- Routine weighing of patients before prescriptions are written

FMEA: a new approach to manage high risk medicines
S Williamson, N Wake, G Donovan (Northumbria Healthcare Trust)
Case Study 5 – Team resistance
It's not what you call it it’s what you do that matters

- Project team didn’t have time to ‘naval gaze’ they were ‘too busy’ dealing with the issues to assess risks.
- PM introduced an assessment of the future issues
- Team adopted a Future Issues Log
- Outcome: 18th months later recognised as the team with the best risk management practice!
Poor reporting of risk

- Impatience or Over confidence
  - We’ll cross that bridge when we come to it
  - We’ll fix that later

- Vested interest
  - I’m determined to see my project through regardless
  - Once it’s an issue I can get rewarded for solving the problem

- Secrecy or ‘your problem’
  - It’ll be seen as excuses for failure
  - I don’t have a solution
  - We don’t want their interference

- Messenger Syndrome
  - Blame culture
  - Bearers of bad news get punished
Communicating risks

- In failed projects the PM is often unaware the ‘big hammer’ that was about to hit them. Frequently someone on the team actually did see that hammer, but didn't inform the PM.
  - If you don't want this to happen in your project, you better pay attention to risk communication.

- Consistently include risk communication in what you do. If you have a team meeting, make project risks part of the default agenda (and not the final item on the list!).
  - This shows risks are important and gives team members a "natural moment" to discuss them and report new ones.

- Communication is key between the PM and project sponsor or principal. Focus your communication on the big risks here.
  - Make sure you don't surprise the boss or the customer!
Summary
Effective risk management is consistently shown to be positively correlated with on time delivery.

Failure to manage project risk leads to project issues.

If you don’t manage risk you had better be exceptional at issue management!
Thank You

Questions?

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