



Johnson & Johnson
PHARMACEUTICAL RESEARCH
& DEVELOPMENT

Preclinical Development
Quality Assurance

Risk Management Documentation Template

| | |
|----------------|--|
| Project | |
| Date | |
| Team | |

| | |
|-------------------------|--|
| Author | |
| Document version | |

BACKGROUND

Regulations, SOPs, history, current approach

PURPOSE

Purpose of this project

APPLICABLE GROUPS

Global PDQA, PDQA Beerse, PDQA US, ...

RISK MANAGEMENT APPROACH

Reference to collected data (eg. MASC data, tables, graphs,...)

Reference to Risk management Excel template that can be added as attachment

PDQA MANAGEMENT APPROVAL

Date:

Signature:

Strategy Template - PDQA

Project:

Date:

Team:

| Points of attention | Clarification | Prioritization | | | | Required actions | | |
|--|---|--|--|--|--|------------------|-----|------|
| | | Compliance | Clients | PDQA | Other | What | Who | When |
| Main activities, current or future threats and opportunities | Break down complex items in manageable components | What is the impact on / importance for compliance? | What is the impact on the clients? E.g. Interference with critical path | What is the impact on PDQA? E.g. Workload, reputation | List any other important factors E.g. Urgency, Energy required for implementation | | | |
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Possible scores
H, M, L
1, 2, 3, 4, 5
↓, ↓↓, ↓↓↓ ↑, ↑↑, ↑↑↑

Risk Management Template - PDQA

Project:

Date:

Team:

OCC: Occurrence (How frequent is the cause likely to occur?)
 P: Probability (How likely is it to happen given all the factors?)
 I: Impact (If it happens, how painful will it be?)

Possible scores H, M, L
 1,2,3,4,5
 ↓, ↓↓, ↓↓↓ ↑, ↑↑, ↑↑↑

| Alternatives | Associated risks | Potential causes | O C C | Risk | | | PRO | CONTRA | Decision | Risk reducing controls | Residual Risk | | |
|-----------------------|--|--|-------------|---|--|---|---|--------------------------------------|--|------------------------|---------------|---|---|
| | | | | P | I | I | | | | | P | I | I |
| List all alternatives | What can go wrong with each alternative? | List all potential causes and their occurrence | | Assess probability & impact of the risk | What are the benefits of this alternative? | What are the drawbacks of this alternative? | Is the risk acceptable? What is the appropriate balance among benefits risks and resources? | What can be done to reduce the risk? | How big is the risk after implementing the risk reducing controls? | | | | |
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|--|---------------|
| Risk review | |
| Frequency | Process owner |
| Should be based upon the level of risk | |

| Risk communication & associated actions | | |
|---|-----|------|
| What | Who | When |
| | | |
| | | |
| | | |

Risk Management Template - PDQA

Project: Decrease in-life audits in Gentox department Date: 01-Dec-2006 Team: M.Y. SELF & A.N. OTHER

OCC: Occurrence (How frequent is the cause likely to occur?)
 P: Probability (How likely is it to happen given all the factors?)
 I: Impact (If it happens, how painful will it be?)

Possible scores H, M, L
 1,2,3,4,5
 ↓, ↓↓, ↓↓↓ ↑, ↑↑, ↑↑↑

| Alternatives | Associated risks | Potential causes | Risk | | | PRO | CONTRA | Decision | Risk reducing controls | Residual Risk | |
|---|--|---|---|---|---|--|---|---|--|--|---|
| | | | O | C | I | | | | | P | I |
| List all alternatives | What can go wrong with each alternative? | List all potential causes and their occurrence | Assess probability & impact of the risk | | | What are the benefits of this alternative | What are the drawbacks of this alternative? | Is the risk acceptable? What is the appropriate balance among benefits risks and resources? | What can be done to reduce or eliminate the risk? | How big is the risk after implementing the risk reducing controls? | |
| Switch to process-based instead of study specific in-life audits (allowed by OECD 14) | Approach not accepted by authorities | Authorities require at least 20 studies/year of same type before process based audits can be introduced | H | H | M | time-efficient | number of studies too low | NO GO | reconsider if number of studies increases | | |
| Stop performing in-life audits on post treatment activities | compliance decrease in Gentox department | less visits by PDQA leads to less quality | M | M | M | audits on post-treatment activities have low added value | | GO | Yearly study reconstructability system audits on each type of Gentox study | M | M |
| | lack of PDQA oversight | raw data in Gentox lab that is never audited | H | H | M | time-efficient | | | | | M |

| Risk review | |
|--|---------------|
| Frequency | Process owner |
| Should be based upon the level of risk | |
| yearly | M.Y. SELF |

| Risk communication & associated actions | | |
|---|------------|-----------|
| What | Who | When |
| propose new approach to PDC management | M.Y. SELF | 01-Jan-07 |
| communicate new approach within Gentox department | A.N. OTHER | 15-Jan-07 |
| communicate new approach at PDQA | M.Y. SELF | 20-Jan-07 |

Strategy Template - PDQA

Project: **In life audits** Date: **01-Nov-06** Team: **M.Y. SELF & A.N. OTHER**

| Points of attention | Clarification | | | Prioritization | | | Required actions | | |
|---|--|--|--|--|---|-----------|--------------------|--|--|
| | Compliance | Clients | PDQA | Other | What | Who | When | | |
| Main activities, current or future threats and opportunities | What is the impact on / importance for compliance? | What is the impact on the clients? E.g. Interference with critical path | What is the impact on PDQA? E.g. Workload, reputation | Just any other important factors E.g. Urgency, Energy required for implementation | | | | | |
| Change approach in life audit in Gentox department | 0 | ↓ | ↓ | L (energy for implementation) = quick win! | Risk assessment | Team A | 01-Dec-06 | | |
| Increasing number of observations during in-life audits in Bioanalysis department | H | M | 0 | H (urgency) | discuss with BAN management | M.Y. SELF | ASAP | | |
| | | | | | Inform auditors --> increased attention during in-life audits | M.Y. SELF | Next dept. Meeting | | |

Possible scores
 H, M, L
 1,2,3,4,5
 ↓, ↓↓, ↓↓↓ ↑, ↑↑, ↑↑↑