Stakeholders’ identification: key success factor for the implementation of Electronic Document Management Systems

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Presentation outline

- Factors influencing Electronic Document Management Systems (EDMS) implementations
- Case Study 1 – Project “A”
- Case Study 2 – Project “B”

Factors influencing implementations

- Before system go-live:
  - Stakeholder Identification and Participation
  - Commitment and Leadership
  - Scope management
- After system go-live:
  - User perception of system need
  - Time, rewards and incentives
  - Technology / people / processes
  - Training and end-user support
Stakeholder identification & participation

• Users must become "stakeholders"
  • Give them the opportunity to participate in decisions concerning the system
  • When individuals "buy-in", they possess "ownership" of the idea and become facilitators in making the implementation successful

Commitment and Leadership

• Commitment must be displayed by individuals involved in the implementation at all levels
  Should be identified as Stakeholders
  • Leadership support is key to successful systems’ implementations
**Scope management**

- "scope creep" - can be minimised by:
  - Stakeholder identification
  - Clear scope changes
    - **escalation procedures**
      - changes prioritisation (GxP/Non-GxP)
      - Steering Committee approval

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**User perception of system need**

- Technology should not be adopted for its own sake - a genuine need must exist
- Users will use technology once they understand how it can make them more productive

- Users are stakeholders. A **communication plan** to stakeholders needs to be established.
- User representatives (per function) should also be part of the project team
Time, rewards and incentives

- Mastering technology requires time
- Users have very little time (and patience) for experimenting with new technologies
- Creative ways to provide time for users to play with new technology:
  - Encouraged through the use of rewards and incentives
  - Formal recognition of their technology endeavours

Technology / people / processes
Training and end user support

- Users must feel confident in the operation of the technology and their own ability to integrate it into daily processes
- Train, train and re-train
- User support can be divided into layers:

Case Study 1 – Project “A”

- Project Specifications
- Factors influencing the implementation
### Project Specifications (1)

<table>
<thead>
<tr>
<th>System</th>
<th>EDMS implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal</td>
<td>Deliver a local database for Regulatory Affairs to create, store and archive documents and interface with an electronic Publishing tool.</td>
</tr>
<tr>
<td>Use</td>
<td>Use:</td>
</tr>
<tr>
<td></td>
<td>– Regulatory Affairs, Clinical Development</td>
</tr>
<tr>
<td></td>
<td>– approximately 20 users</td>
</tr>
<tr>
<td>Location</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– 1 US location</td>
</tr>
</tbody>
</table>

### Project Specifications (2)

<table>
<thead>
<tr>
<th>Time</th>
<th>4 months (in 2002)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budget</td>
<td>Fixed budget</td>
</tr>
<tr>
<td>Constraints</td>
<td>Validation required:</td>
</tr>
<tr>
<td></td>
<td>– 21 CFR Part 11</td>
</tr>
<tr>
<td></td>
<td>– ICH guidelines</td>
</tr>
<tr>
<td>Project Team</td>
<td>5 team members:</td>
</tr>
<tr>
<td></td>
<td>– Validation Lead – from vendor</td>
</tr>
<tr>
<td></td>
<td>– Quality Assurance – from vendor</td>
</tr>
<tr>
<td></td>
<td>– Sponsor – from Regulatory Affairs</td>
</tr>
<tr>
<td></td>
<td>– Project Manager – from Document Management</td>
</tr>
<tr>
<td></td>
<td>– Technical support – from Information Services</td>
</tr>
</tbody>
</table>
Factors influencing implementations

- Before system go-live:
  - Stakeholder Identification and Participation
  - Commitment and Leadership
  - Scope management

- After system go-live:
  - User perception of system need
  - Time, rewards and incentives
  - Technology / people / processes
  - Training and end-user support

Case Study 2 – Project “B”

- Project Specifications
- Project Team
- Factors influencing the implementation
### Project Specifications (1)

<table>
<thead>
<tr>
<th>System</th>
<th>EDMS Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal</td>
<td>Deliver a single regional (US/EU) database for all key documents (intended for Regulatory Submissions)</td>
</tr>
</tbody>
</table>
| Use          | Multi-functional use:  
|              | – Regulatory Affairs, Quality Assurance, Project Management, Clinical Development, Development Research, Biostatistics & Data Operations,  
|              | – Translational Medicine & Clinical Pharmacology,  
|              | – Medical and Technical Writing, etc. |
| International locations: |  
|              | – Europe 2 locations, USA 2 locations |

### Project Specifications (2)

<table>
<thead>
<tr>
<th>Time</th>
<th>9 months (2007-2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budget</td>
<td>Fixed budget</td>
</tr>
</tbody>
</table>
| Constraints   | Validation required:  
|              | – 21 CFR Part 11  
|              | – ICH guidelines  
| Project Team  | Remote Project Management:  
|              | – Project Manager in the UK  
|              | – Project Team in the US (same US location)  
|              | Multi-cultural implementation team from:  
|              | – America, Spain, China and India |

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Factors influencing the implementation

Before system go-live (1):

✅ Stakeholders’ identification and participation:

- Identification:
  - Departments involved identified by Business Owner(s)
  - Departmental representation identified by Management

- Communication plan in Project Charter:
  - Weekly (+ad hoc) Validation Team meetings
  - Monthly meetings with Functional Liaisons
  - Functional Liaisons responsible for departmental communication
  - Monthly Status report sent to Steering Committee
  - Meetings with vendors as needed

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Factors influencing the implementation

Before system go-live (2):

✔ Commitment and Leadership
  – Steering Committee approach

✔ Scope management
  • Scope changes rejected – some would be implemented as Change Controls after system “go-live”.

Factors influencing the implementation

After system go-live:

✔ User perception of system need

✔ Time, rewards and incentives
  • Part of employees objectives

✔ Technology / people / processes
  • Updated company procedures

✔ Training and end-user support
  • Content Management training
  • Functional Liaisons / Content Management support
  • IT Help Desk / System Administrator
Projects Comparison

<table>
<thead>
<tr>
<th>Case Study 1 – Project “A”</th>
<th>Case Study 2 – Project “B”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single document type</td>
<td>Pre-defined document types</td>
</tr>
<tr>
<td>• Difficult to search</td>
<td>• Search capability improved per</td>
</tr>
<tr>
<td>• No document specific attributes</td>
<td>document type and attributes</td>
</tr>
<tr>
<td>• Unlimited scope for document type</td>
<td>• Attributes specific to document type</td>
</tr>
<tr>
<td>Freedom of classification</td>
<td>Pre-defined classification based on</td>
</tr>
<tr>
<td>• Users unable to find documentation</td>
<td>document type</td>
</tr>
<tr>
<td>20 users</td>
<td>200 users</td>
</tr>
<tr>
<td>Electronic signatures</td>
<td></td>
</tr>
<tr>
<td>~100,000 documents in repositories</td>
<td>&gt;250,000 documents in repository</td>
</tr>
</tbody>
</table>

Lessons Learned

• Stakeholders involvement can make the difference between success and failure:
  – Identify Stakeholders
  – Prepare a Stakeholders’ communication plan based on level of prioritisation
  – Involve Stakeholders’ to participate in the project before go-live and after go-live
Thank you