

Case Study

Jumpstarting Document Management Efficiency & Scalability

Satish Kumar, MBB, Head of Process Improvement

We are committed to ongoing innovation and optimization, illustrated by our recent project that transformed our document management process into a highly organized, efficient, and scalable system. We have achieved significant enhancements by adopting the ASSO (Accumulate, Sort, Standardize, Optimize) methodology. Key improvements include a remarkable 95% reduction in search times, ensuring that folders, solution pages, and log sheets are readily accessible. This streamlined approach boosts productivity and fortifies our compliance posture. The standardized process established by this project sets a new benchmark for future initiatives, positioning our organization at the forefront of operational excellence.

Procedural Challenges

The document management process in our organization is always under scrutiny to ensure that we consistently deliver exceptional services. In performing continuous innovation, we surveyed for areas that could be improved and noted the following:

1

Dispersed Storage

Folders were not 100% centralized, requiring extra time and resources.

2

Lack of Standardization

Various methods for organizing, labeling, or archiving folders existed.

3

Noncompliance

The additional time needed to locate critical documents could have resulted in noncompliance risks.

Objectives

- Reduce folder search times to under five minutes
- Create a centralized, organized document inventory
- Ensure compliance by archiving completed studies promptly
- Implement a standardized process for long-term sustainability

Our strategy when tackling the objectives involved:

- An emphasis on waste reduction
- Process standardization
- Data-driven analysis
- Focused training and collaboration
- Engaged feedback
- Value creation



2

4

Initiatives & Solutions via the ASSO Approach

The ASSO approach was a cornerstone of this transformation where we took the following actions:

Accumulate: Gathered all folders, log sheets, and solution pages from various locations.

Sort: Categorized and organized documents based on relevance, study type, and usage.

Standardize: Implemented consistent naming conventions, labeling, and a two-step sign-in/out process.

Optimize: Streamlined the physical setup and integrated a digital inventory system for seamless access and tracking.

Our strategy successfully established the following solutions:

Workplace Organization

We utilized Sort, Set in order, and Sustain principles by creating a controlled document room capable of meeting our standards of excellence. We also created an alphabetized, labeled cabinet system to underscore clarity for improved physical access and minimized search times.

Electronic Integration

We developed and deployed an electronic inventory tool to enable real-time tracking, reduce manual effort, and support remote access to document information.

Process Standardization

Our team established a two-step sign-in and out procedure to create transparency and accountability in folder handling. The procedure ensured complete traceability and compliance with organizational standards.

Training & Change Management

We proactively delivered structured training programs aligned with the new standard operating procedures to ensure 100% employee compliance and understanding. We also created a detailed business guideline document to formalize and institutionalize the process for current and future reference.

5 Compliance Reinforcement

We planned to conduct regular process audits and compliance checks to verify adherence to the new system and identify opportunities for continuous improvement.

Outcomes & Lessons Learned

Following our strategic approach, we successfully achieved scalable improvement outcomes across our documentation protocols, which involved forming a central repository and bolstering physical document safety assurances. Our efforts resulted in the following improvements:

| Metrics | Improvement Percentage |
|---|------------------------|
| Average time spent searching | 95% |
| Ability to locate folders in 3-5 minutes | 54% |
| Ability to locate folders in less than 1 hour | 100% |
| Loose folder reduction | 100% |
| Staff trained | 100% |

Our optimization journey provided us with several key lessons learned, including:

- Scope Clarity: Clear goal setting at the start is essential for optimized solutions.
- End-to-End Understanding: Archiving, a key step, was underestimated initially. Comprehensive process mapping is critical.
- Cultural Change Management: Adopting new processes takes time, and we proactively deployed change management strategies for the adaptation period.
- Sustainability: Regular audits and adherence to standardized processes are necessary to maintain long-term benefits.

Ensuring Ongoing Engagement & Staff Support

We took the following actions to ensure that the streamlined operations from our project remained actively utilized across the company:

| Control | Control Type | Responsibility | Action | Frequency |
|----------------------------------|------------------|-------------------------|-------------------------------------|-----------|
| Folder Organization | Visual Check | Department Head | Perform spot checks on folder order | Monthly |
| Digital Inventory Updates | System Review | Implementation Owner | Cross-check inventory with folders | Weekly |
| Two-Step Sign- In/Out Process | Process Audit | Department Head | Verify sign-in/out logs | Weekly |
| Staff Training | Training Records | Process Owner | Conduct refresher sessions | Annually |
| Process Adherence | Compliance Audit | Implementation Owner | Perform detailed audits | Quarterly |

The New Worldwide Standard

We have established a new benchmark for document management within our organization. We have created a highly streamlined, compliant, and efficient process by embracing the ASSO approach. The success of this initiative highlights the power of strategic planning, robust implementation, and a commitment to continuous improvement. We're excited to extend this cutting-edge model to other operational areas and invite potential sponsors to be part of this journey towards excellence and innovation.



"Efficiency isn't just about doing things faster; it's about creating a system where excellence becomes the standard. This recent project is a testament to that."

Satish Kumar, MBB Head of Process Improvement

Contact us today to learn more about how our capabilities can benefit your unique needs in your upcoming clinical trials.



Staff Response

"We have significantly decreased the time spent searching for folders and log sheets. Maintenance and compliance are critical to continue this success."

"The organization of folders in a single location has tremendously cut back on time spent searching."

"This project has mitigated major compliance risks and improved efficiency — a true success!"

References

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