

Pharmaceutical, Biomedical and Consumer Products Leader

Worldwide Safety Portal — A Documentum/Plumtree Solution

The Organization

This integrated consumer packaged goods, pharmaceutical, biomedical, and animal health product manufacturer serves global markets from operations located across more than 25 countries. It markets leading brands in all categories and businesses where it participates, ranging from confectionaries, to over the counter treatments, prescription drugs, and animal health products. With over 85,000 employees worldwide, the firm enjoys annual revenues in excess of \$90 billion.

The Business Challenge

Safety - in holistic a sense - is a "religion" at this world-class enterprise - and no safety category is more important than the new drug development process. To that end, the firm has chartered an elite worldwide safety organization to compose and monitor uniform safety standards and procedures. However, working on a worldwide basis presents considerable challenges, particularly from the standpoints of collaboration, information currency, and acknowledgement.

The Burntsand Solution

Burntsand designed and built a secure worldwide Safety Portal powered by Plumtree and Documentum featuring time-based information tracking and email notification services. This portal is a subset of the company's overall enterprise portal that is exclusive to its worldwide safety community. It ensures that named users receive and respond to highly controlled safety policies, directives, and key Standard Operating Procedures (SOPs), as well as facilitating the controlled collaborative processes used to author them.

Project Background

This integrated consumer packaged goods, pharmaceutical, biomedical, and animal health product manufacturer employs over 85,000 people and generates in excess of \$90 billion in annual revenues. The markets it serves are global and its operations, ranging from research to manufacturing and sales sites, are located across dozens of countries encompassing some 25 local languages in total. Its product portfolio, numbering in the hundreds, includes leading brands in all respective categories - from confectionaries and over the counter treatments – to prescription drugs and health products for animals.

For all businesses and product lines, safety is a core company value and high-priority business objective. In fact, safety has an integral and direct relationship to the market success and financial performance of its brands. One of the most important aspects of safety is the authoring, approval and dissemination of Standard Operating Procedures (SOPs) that deal directly with adverse event reporting and other safety-related issues surrounding the new drug development process.

To accomplish this, the firm has chartered an elite worldwide safety organization to set and monitor uniform standards and procedures across all business units and divisions. However, working on a global scale presents the organization with considerable timing, accuracy and cost challenges. This is particularly true from the standpoints of collaboration, information currency, and the timely acknowledgement that critical SOPs are received and implemented. This Portal ensures that only the most recently approved version of any SOP is published, that all worldwide safety personnel are notified, and that each member of staff performs required reviews according to his or her role.

Safety Portal

Burntsand has designed a secure portal complete with a tightly coupled Web content management system. On the consumption side, the portal allows named users worldwide to view SOPs, notifying them by email when new items become "Effective."

On the creation side, it enables domain experts, authors, and editors to create SOPs—including the collection of inputs from outside sources—across their entire lifecycle.

To insure proper reach and security, the portal also integrates a personnel database (including temporary employees as needed) and directory services. It profiles and tracks individuals by role, access privileges, and acknowledgement requirements. This last requirement, "acknowledgement," means that all targeted users must take some time-limited action for each SOP they are assigned, either on the creation or the consumption side.

ABOUT BURNTSAND

Burntsand is a technology consulting firm specializing in integrating content, processes and data. For more than a decade, Burntsand has been a respected EMC Documentum partner with proven expertise in Enterprise Content Management. Leading organizations have trusted Burntsand to deliver results-oriented business solutions including document management and scanning, digital asset management, web and portal publishing, publications automation, and records retention. Burntsand delivers optimum time to value and unrivaled customer experience whether delivering an Enterprise Content Management Roadmap, complex integration or product installation. Our consultants work hard to ensure that accountability, leadership, teamwork and trust are the guiding principles of every engagement. With additional expertise in .NET development, Burntsand can help you create intelligent solutions that integrate seamlessly with your business.

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Accurate Content – Proactive Participation

The product safety mission has two demands: 1) Trusted, accurate procedures, and 2) Proactive participation and use of those procedures. The safety portal addresses both - accuracy side, via authoring and approval workflows; and on the participation and use side, through email notification and audits.

Only a highly select and controlled group of users can participate in the new or revised SOP approval process. Yet, even among them, none can alter a source file. Instead, a read-only version is rendered in the Adobe Portable Document Format (PDF) and circulated among approvers, who can then annotate them with comments and suggested modifications.

These must be returned to the author, who is the only individual authorized to execute changes. And, before a draft SOP can be forwarded to a final approver – the manager empowered to grant Effective Status, a consensus must be reached among all approvers. The SOPs are automatically watermarked when printed to ensure proper identification and quality.

Thus a universe of named users, beginning on the consumption side and then moving upstream through the creation and approval process, traverses five key roles:

- **Consumers** - The portal's general audience, these users have access to all Effective SOPs published to the site via read-only PDF files. Consumers who are targeted and required to read and acknowledge a particular SOP are notified by email. These events trigger a timer and SOP consumers who do not access that SOP within a specified period are sent reminder emails. Sophisticated tracking reports enable management audits of this process.
- **Authors** - Those users primarily responsible for creating new Standard Operating Procedures and / or drafting new versions of current Effective procedures and who, in general, have unlimited access and modification privileges to all draft or "in-process" items. An array of common desktop authoring and creation tools is supported and available for use. At checkout of a work-in-progress item, the correct tool is automatically launched for them.
- **Reviewers** - A team explicitly assigned to each in-process SOP who are able to annotate drafts (using text notes) routed to them in PDF format. These individuals must then take one of three actions: 1) annotate and return, 2) review without comment, or 3) decline to review. All reviewer annotations are available to all authors and other reviewers. Reviewers use the portal to access SOP drafts in the review workflow cycle via a customized inbox and then are given a specific timeframe to complete their task.
- **Approvers** - These users, assigned as a team to a specific procedure under review, have all the rights and privileges of a Reviewer, but in addition can - upon unanimous agreement - nominate a draft SOP for effective Status. Like Reviewers, the Approver teams are distributed and use the portal to participate in the approval cycle via inbox customizations - and again; email prompts keep the process on schedule.
- **Final Approvers** -The SOP Final Approver is a single user empowered to convey final approval to a new or updated procedure once it has been vetted by an appropriate team of Approvers; thus elevating that SOP to Effective Status.



The Solution

By combining a powerful and highly disciplined Documentum Web content management system with Plumtree's market-leading portal technology, implementing company-specific customizations and a tight integration with directory services and email, Burntsand has addressed this firm's mission critical safety needs for the control and distribution of Standard Operating Procedures. The solution is both user friendly and thoroughly auditable - essential attributes in an environment where the distribution of information alone does not satisfy strict operational requirements.

Business Benefits

- Faster creation and approval cycles
- Easier and more secure access to mission critical content
- More timely uptake of new standards and procedures
- Improved reporting and managerial controls