

Document Control and Archiving (DCA)



Spending too much time on document management?

- Eliminate and streamline work practices
- Reduce complexity of managing documents
- Embed knowledge of document management
- Entire document history viewable at a glance
- Effective and pending or related documents comparable side-by-side
- Electronic signatures for all user actions and complete audit trail of events
- Notifications and supervisory escalation for rapid response to change requests
- Powerful document search capability, including meta tags, fuzzy logic, and full text
- Recent documents window, allowing frequently used documents to be easily accessed
- Extensive reporting of real time metrics of key performance indicators
- Configurable document overlays for flexible controlled document design
- Microsoft .Net application built for secure document management, as well as simplified change management and validation

- Can be used standalone or bundled with other Syncade™ Smart Operations Management modules to maximize productivity

Introduction

Document Control and Archiving is a complete, off-the-shelf, electronic document management system.

Benefits

Complete Document Lifecycle Functionality.

DCA provides online document storage, single- and multi-document change control, automatic routing, document check-in and check-out, version management, archived records management, and printing.

Powerful Change Request Management.

Sophisticated change request management system offers flexibility with highly configurable change request workflows, including a conditional review option, serial and parallel review and approval, role and user-specific assignment feature, and delegation management of review and approval assignments. The Personalized Change Request pane displays all change requests requiring attention at a glance, helping to keep workload organized and consequently increasing productivity.

Easy Access. Document Kiosk for the production floor provides limited access to effective documents, which reduces the risk of procedure noncompliance. The Kiosk also frees document

management personnel from the rigors and enormous amounts of time spent on issuing controlled document copies. Multiple SOP binders are no longer necessary.

Streamlined Review and Approval. With DCA Change Request Workspace, document review and approval is easy, convenient and as close as your inbox. Workspace launches from a link via e-mail, and provides you all the benefits of the main DCA Change Request feature. Periodic and obsolescence review workflows take the aggravation out of annual document review and document retirement.

Simplify Validation and Commissioning. DCA is a true zero-client, web-based solution. You can quickly install, validate, and deploy the solution to all your users from a centralized server and begin to immediately realize the benefits. Whether tracking hundreds or tens of thousands of documents and change requests, you will be amazed at how quickly and easily you can ensure that all your document asset management and regulatory needs are met.

Product Description

DCA is a document management system for storing documents such as electronic work instructions, electronic batch records, formulations, material safety data sheets, and SOPs. With DCA, users can quickly find and instantly access the documents they need. DCA also makes the document review and approval process easy and efficient. Time spent on document and change request management, as well as the subsequent review and approval cycles, are dramatically reduced.

For industries under cGXP regulations, DCA is fully compliant with all relevant cGXP regulations, including 21CFR Part 11. DCA provides the functionality you need to make sure that your regulatory assets are safeguarded and proactively managed. The DCA intuitive, user-friendly interface makes it easy to quickly become productive in creating, revising, and securely managing all types of documents. As an integrated Microsoft .NET application, DCA provides unprecedented scalability for the largest enterprise needs, while allowing smaller companies to quickly leverage its advanced features.

When implemented together with the Training and Development module (TD), a complete closed-loop change management system ensures training on a

new or modified document. Document version training becomes automatic when DCA and TD are used together. TD recognizes Document Change requests in DCA that impact training requirements. Training administrators and users are notified of any document version training due, and they receive notifications of associated class schedules and training set to expire. The Self Certification feature in DCA allows a user to see all document-related training requirements in one convenient window. A user can instantly view any document that requires training and self-certify on the document version. In TD, the completed training is automatically updated in the employee's records.

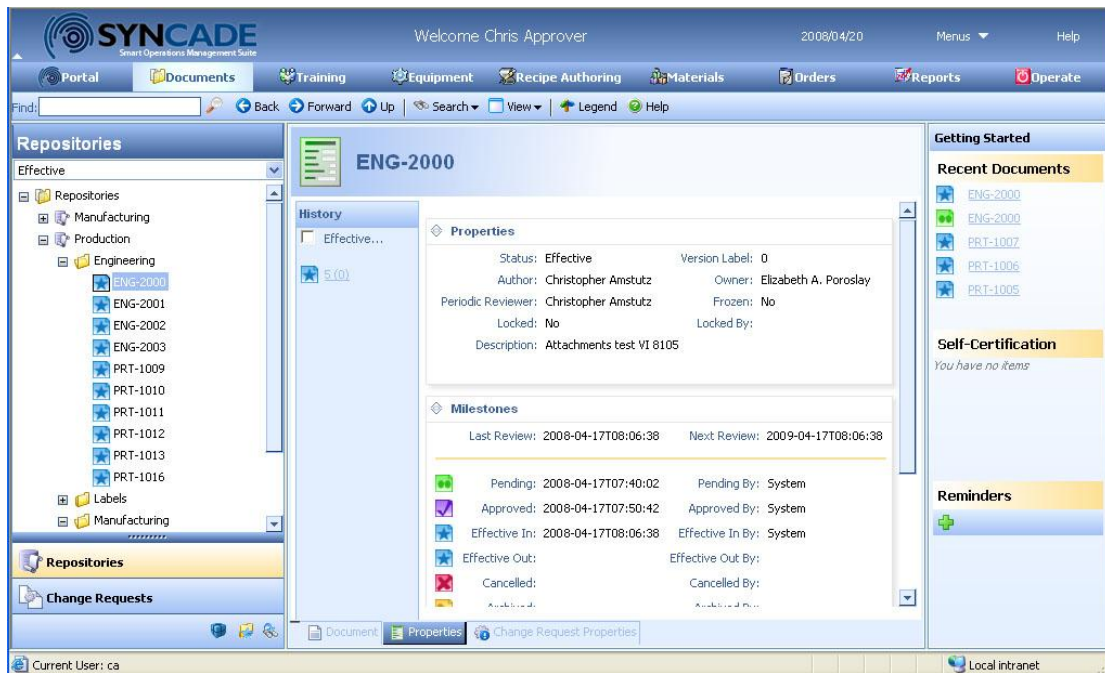
DCA can be used standalone or bundled with other Syncade software modules for maximum productivity.

Other Syncade Smart Operations Management Modules

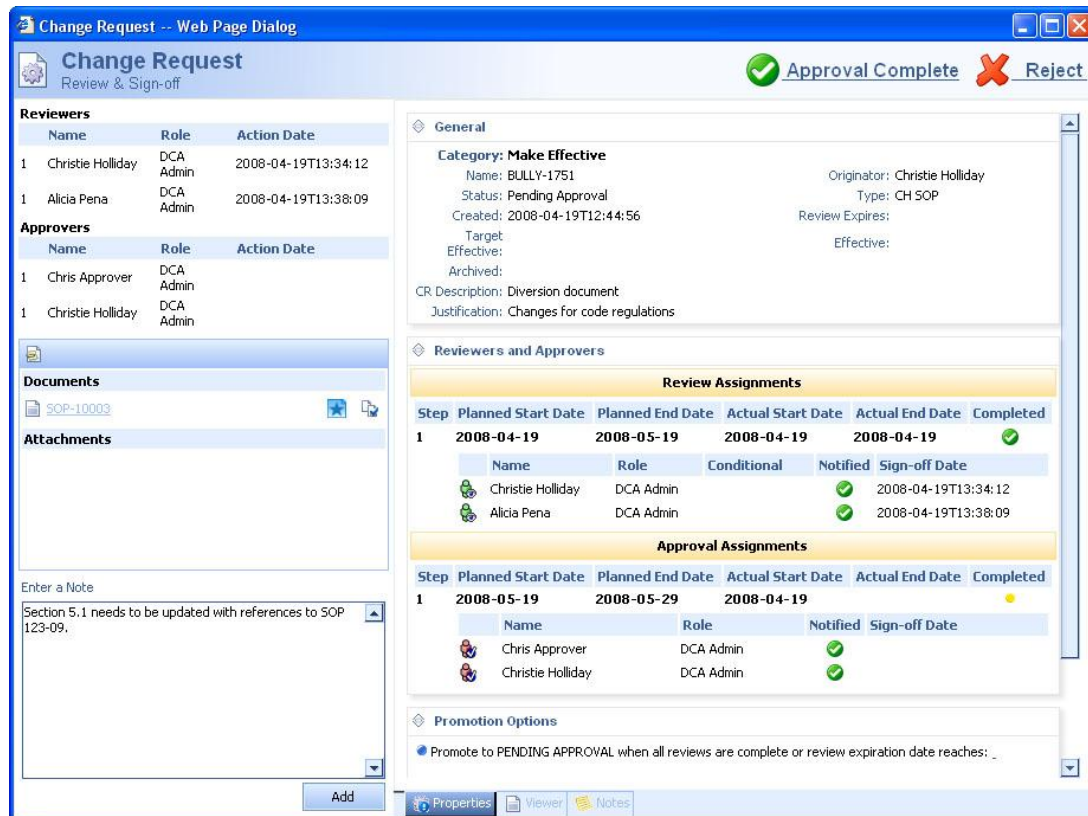
- Equipment Tracking (ET)
- Batch Production Records (BPR)
- Materials Management (MM)
- Weigh & Dispense (WD)
- Recipe Authoring (RA)
- Security & Audit (SA)
- Electronic Batch Record (EBR)
- Training & Development (TD)
- Manufacturing Information Portal (MIP)

General System Requirements

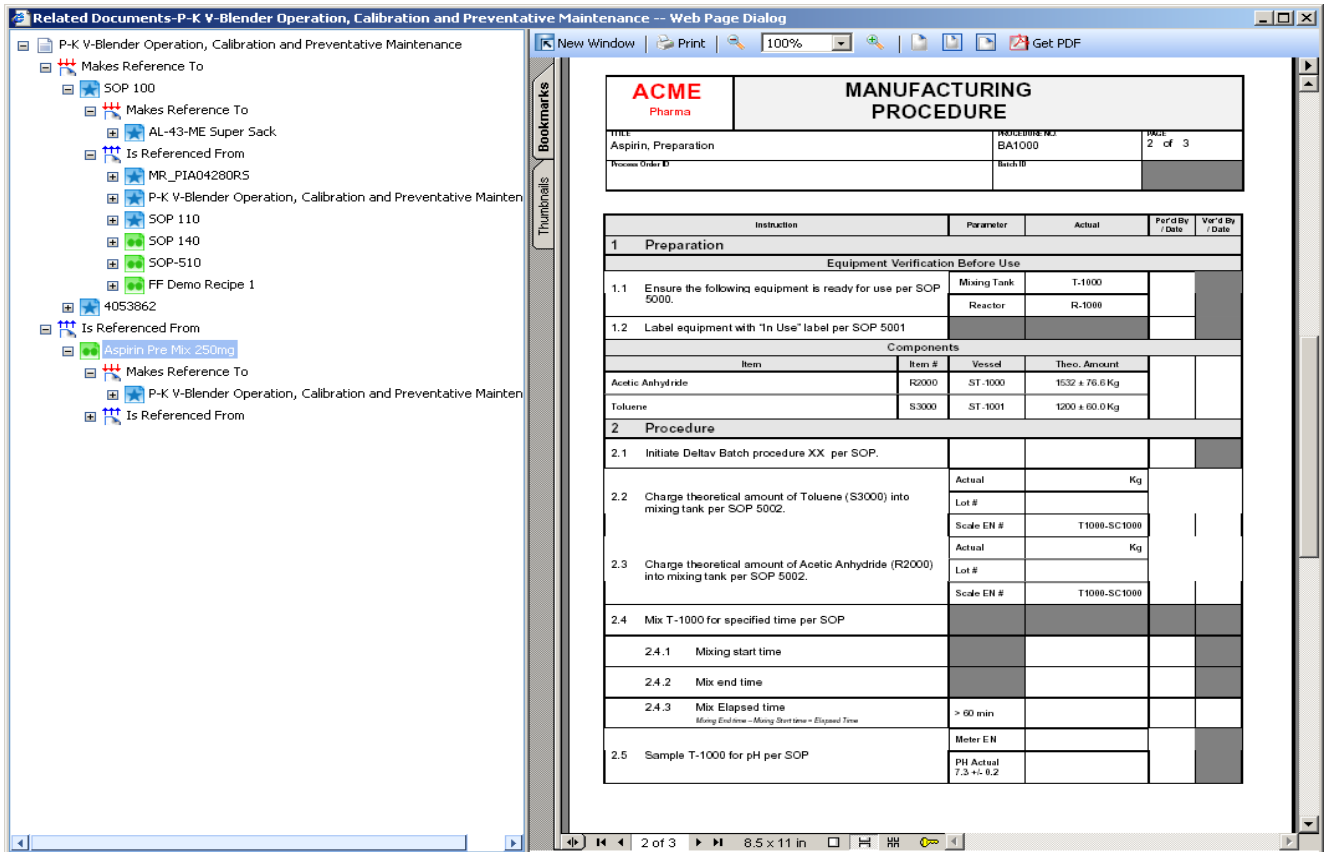
A server class PC with Internet Explorer is needed to support the Syncade solution. Microsoft SQL Server is the underlying database. For client access, a PC with Internet Explorer is needed. Please consult the factory for further details regarding hardware requirements and software versions.



The DCA document repository provides a complete view of a document's history.



Reviewing and completing a change request is easy.



ACME Pharma

MANUFACTURING PROCEDURE

Aspirin, Preparation

Process Order ID: BA1000

Batch ID: [blank]

Page: 2 of 3

Instruction	Parameter	Actual	Per'd By / Date	Ver'd By / Date
1 Preparation				
Equipment Verification Before Use				
1.1	Ensure the following equipment is ready for use per SOP 5000.	Mixing Tank	T-1000	
		Reactor	R-1000	
1.2	Label equipment with "In Use" label per SOP 5001			
Components				
Item	Item #	Vessel	Theo. Amount	
Acetic Anhydride	R2000	ST-1000	1532 ± 76.6 Kg	
Toluene	S3000	ST-1001	1200 ± 60.0 Kg	
2 Procedure				
2.1	Initiate Deltav Batch procedure XX per SOP.			
2.2	Charge theoretical amount of Toluene (S3000) into mixing tank per SOP 5002.	Actual		Kg
		Lot #		
		Scale EN #	T1000-SC1000	
2.3	Charge theoretical amount of Acetic Anhydride (R2000) into mixing tank per SOP 5002.	Actual		Kg
		Lot #		
		Scale EN #	T1000-SC1000	
2.4	Mix T-1000 for specified time per SOP			
2.4.1	Mixing start time			
2.4.2	Mix end time			
2.4.3	Mix Elapsed time <i>Mixing End time - Mixing Start time = Elapsed Time</i>	> 60 min		
2.5	Sample T-1000 for pH per SOP	Meter EN		
		pH Actual	7.3 ± 0.2	

Reference documents can be easily accessed.

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