

# DocXamine for the Pharmaceutical Industry:

## *Expediting Electronic Submissions*

This scenario shows how a pharmaceutical firm can use DocXamine to dramatically expedite the preparation of the myriad documents required for an electronic submission.

### **Adding DocXamine to your Electronic Submission Workflow Process**

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#### **The Challenge**

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Electronic submissions to the FDA — a process which involves compiling a complex set of documents and producing them in Adobe Acrobat® PDF format — may streamline the process toward time-to-market, but most pharmaceutical companies are discovering a host of potential problems in their e-submission “supply chain”.

Document flaws that remained hidden in ordinary editing and printing can cause costly errors as you render the resulting PDF. Even perfectly good documents may have features — such as tracked revisions, improper choice of fonts, inconsistently inserted symbols, or errors in cross-referencing — which print to paper correctly, but expose themselves as navigation and submission problems when output to PDF.

Some documents may not render at all, but worse are the documents that do render and expose one or more of the following inconsistencies:

- Large blank sections where text dropped out
- Missing or incorrect symbols
- Inappropriate or excessive font choices
- Invalid hyperlinks and bookmarks
- File sizes greater than accepted guidelines

While it is troublesome enough to determine such issues in one document, or even a handful of documents, deciphering the problem and its resolution from the Acrobat file can be a maddening challenge for even the most knowledgeable document creation professional. When compiling the hundreds of documents or more used in a single NDA, these problems can derail a timely submission, delaying your return on the development investment you’ve made.

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## The DocXamine Solution

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Whether you are using a “home grown” solution or third party product such as Core Dossier, as you gather documents used as the source for any electronic submission, add this one important step to your traditional workflow: analyze them with DocXamine.

DocXamine probes your baseline documents for properties that are potential failure points. Since formatting requirements can be unique by document collection, DocXamine’s customizable *rules* focus the analysis to better align the current work product to the generation of reliable and conforming PDF results.

DocXamine’s reporting capabilities provide document analysis by collection summary or individual document detail. A document task list report can be produced to identify problems within specific documents. Long before the submission deadline, your staff can prioritize and repair problems in an orderly fashion without last-minute pressure or surprises.

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## The benefits

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The addition of DocXamine in your process flow means:

- Reducing administrative time to submission
- Meeting internal and external submission deadlines
- Identifying flawed source documents which produce flawed electronic output
- Minimizing the labor-intensive steps of checking source documents
- Evolving your process flow to improve authoring and submission cycles in the future

## The DocXamine Solution — Step-by-Step

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### Step 1: Define or select the rules for analysis.

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What document properties do you want to analyze? Typically, business rules are established in your initial set-up and then reused in later projects. Microsystems has predefined the most common categories and rules within those categories, but you can customize and add to the existing set by simple drag and drop techniques.

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### Step 2. Gather the files you want to work on.

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In DocXamine, you begin by *creating a project*, then adding one or more *collections* of files into the project. Whether you use the Window’s Explorer file system, or a document management system, you can search and select these documents using a familiar interface.

By grouping the files in collections, you can isolate segments of the submission for baseline review and compliance. These same collections can be re-evaluated later in the process to ensure that all identified issues have been resolved.

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### Step 3. Run the files through DocXamine.

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Once your project is defined, and collections of documents are assembled, DocXamine goes to work probing each document seeking the properties and rule results.

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**Step 4. View the reports and print the tear sheets.**

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DocXamine provides two types of reports:

- Summary reports, which assess the overall collection quality and provide a comprehensive view of the general condition of the submission.
- Detailed reports, which include document-by-document itemization of triggered rules, can be used as a work list to guide the individual corrections necessary to stabilize the overall submission.

Reports can be viewed on-screen, or printed, and are hyperlinked directly to the documents.

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**Step 5. Fix the problems.**

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DocXamine's clear diagnoses have equally clear remedies — we help you understand not only what's broken, but also the best way to fix it. In many cases, your own automation tools coupled with our DocXstyles or DocXtools add-ins can quickly remedy most problems.

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**Step 6. Do midstream reassessments.**

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DocXamine is also a powerful reassessment tool. Run a document collection through DocXamine *after* initial corrections have been made and you can make sure that what was targeted to be fixed was indeed corrected, and identify any final issues. (You may even get a heads-up on important issues for your next in-house training class.)

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**Step 7. Generate the submission with confidence.**

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In the final stage of work, you can focus on FDA e-submissions, not Microsoft Word - PDF troubleshooting.

## For more information on DocXamine

For more information about DocXamine, consult our Web site at:

<http://www.microsystems.com/docxamine.htm>

Call us at (630) 261-0111, or email us at:

<mailto:info@microsystems.com>.

Need a document analyzed or corrected:

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