Case Study

**SoluSoft
i2Scan**

Document Scanning Solution

Introduction

If a pharmaceutical firm anywhere from the world, wants to market a drug or pharmaceutical compound to the United States, Europe, Japan or one of the other regulated markets, they need to submit the documentation regarding the drug in a pre-defined format that is being recommended by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

The Common Technical Document (CTD), which describes the predefined format for the preparation of a well-structured CTD, is used by pharmaceutical companies for submission to regulatory authorities. In addition, the ICH has facilitated international electronic communication through the provision of Electronic Standards for the Transfer of Regulatory Information (ESTRI) that meet the requirements of both the pharmaceutical companies and regulatory authorities. A result of this has been the Electronic Common Technical Document (eCTD) that allows for the electronic submission of the Common Technical Document (CTD) from applicant to regulator.

ICH is a joint initiative involving both regulators and research-based industry representatives of the European Union, Japan and the USA in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality and efficacy of medicines.
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The submissions have to be in computer readable format with Table of Contents and have the following modules:

1. Administrative and prescribing information
2. Overview and summary
3. Quality (pharmaceutical documentation)
4. Safety (toxicology studies)
5. Efficacy (clinical studies)

During these submissions, voluminous amounts of paper documents are generated.

Key Challenges

An International Pharmaceutical Company before working with SoluSoft had a cumbersome and manually intensive process they were using during the assembly of CTD submissions. Documents in CTD submissions have to be maintained in a particular format. In order to market a drug, a Marketing Authorization Application has to be submitted to regulatory bodies in the form of dossiers.

A voluminous amount of documents are created during this process. At times it may be several boxes full of papers or even an entire truckload of paper. While shifting to an electronic CTD submission (eCTD), documents with data were being photocopied on pre-defined document templates to apply the appropriate headers and footers. Subsequently the resulting documents were then scanned into designated folders. The scanned images were then dragged and dropped into appropriate eCTD module folders for submission. On an average the team spent about one week to format a submission.
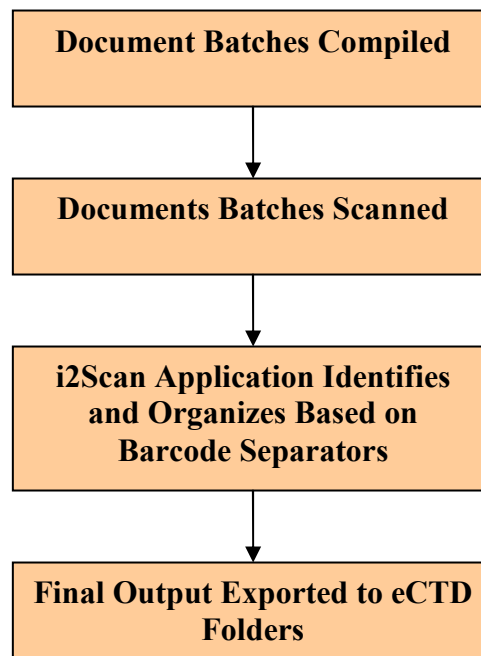
The key challenges faced during this process were:
- Handling of voluminous amount of paper
- Human and mechanical errors during document scanning, copying and printing
- The entire process had to be repeated in the case of errors
- The process was tedious, time consuming and error prone

Solution

SoluSoft analyzed the process of CTD submission and suggested they implement i2Scan developed by SoluSoft Technologies Pvt. Ltd. Submissions are now put together into batches for scanning. Barcode document separators are used to identify separate documents and batches. Option of using OCR, Barcode and blank pages is available for separation as well.

SoluSoft's application i2Scan scans the document batches and separates them. i2Scan reads the barcode on separators and identifies their destination folders and exports them automatically to the corresponding location. The destination folders are created as per eCTD module submission structure.

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┌──────────────────────────────────┐
│   Document Batches Compiled       │
└──────────────────────────────────┘
                 │
                 ▼
┌──────────────────────────────────┐
│   Documents Batches Scanned       │
└──────────────────────────────────┘
                 │
                 ▼
┌──────────────────────────────────┐
│   i2Scan Application Identifies    │
│   and Organizes Based on           │
│   Barcode Separators               │
└──────────────────────────────────┘
                 │
                 ▼
┌──────────────────────────────────┐
│   Final Output Exported to eCTD   │
│   Folders                          │
└──────────────────────────────────┘
```

The QA department compiles the paper documents for submission, in a batch. Document separators are then inserted to differentiate documents and batches. The team uses barcode as separators to automatically organize documents and batches. The end result is that as documents are scanned the are immediately stored in the desired location for retrieval and dissemination.

While configuring the application for scanning, appropriate headers and footers are selected. The headers and footers can be in the form of text or images. The content defined for the

header and footer is superimposed on the scanned images. The final image contains the actual scanned documents along with the header and footer superimposed. Completed documents can be exported in PDF format which is a part of the regulatory requirements, when the output is exported to create the eCTD folders.

The eCTD submission has been made easy to create and simple to submit with the i2Scan implementation. The QA department can now complete all the submissions in one pass. Even if there is an error, the entire process need no longer be repeated, only the relative document can be rescanned and replaced. The documentation process which occupied so much of their time before is now completed in hours.

Summary

A customer with a complex and painful process manually constructing a dossier for submission to regulatory agencies turns to SoluSoft seeking a solution. We were able help them by providing the expertise and i2Scan software to automate the document capture process and streamline their operation. The customer was also able to reduce the number of steps and amount of time required to create the submission Dossier in a single operation. Now with less effort and a minimal investment the customer is achieving faster and better results and is able to respond to changes and issues much more quickly.

Business Benefits

- Lower initial investment
- Streamlined business process
- Manual submission process eliminated
- Single application for Scan, QC, PDF conversion and submission
- Ease in complying with regulatory Agencies
- Lower operating cost
- Substantial reduction in man-hours
- Optimal use of resources
- Users can now spend more time on core business activities
- Ease of use reduces time to configure and operate
- Processing cost is economical
- Highest functionality at the lowest ongoing cost of ownership
- Cost savings enable a fast return on your investment

Contact Us

SoluSoft Inc. 300, Willow Street South North Andover, MA 01845 Tel: (978) 681-6600 Fax: (978) 688-4884 http://www.solu-soft.com	**SoluSoft Technologies Pvt. Ltd.** A-704/705, Shapath IV, Opp. Karnavati Club, S.G. Highway, Ahmedabad-380051, Gujarat, India. Tel: (91) 79-30073211/12 http://solusofttech.com