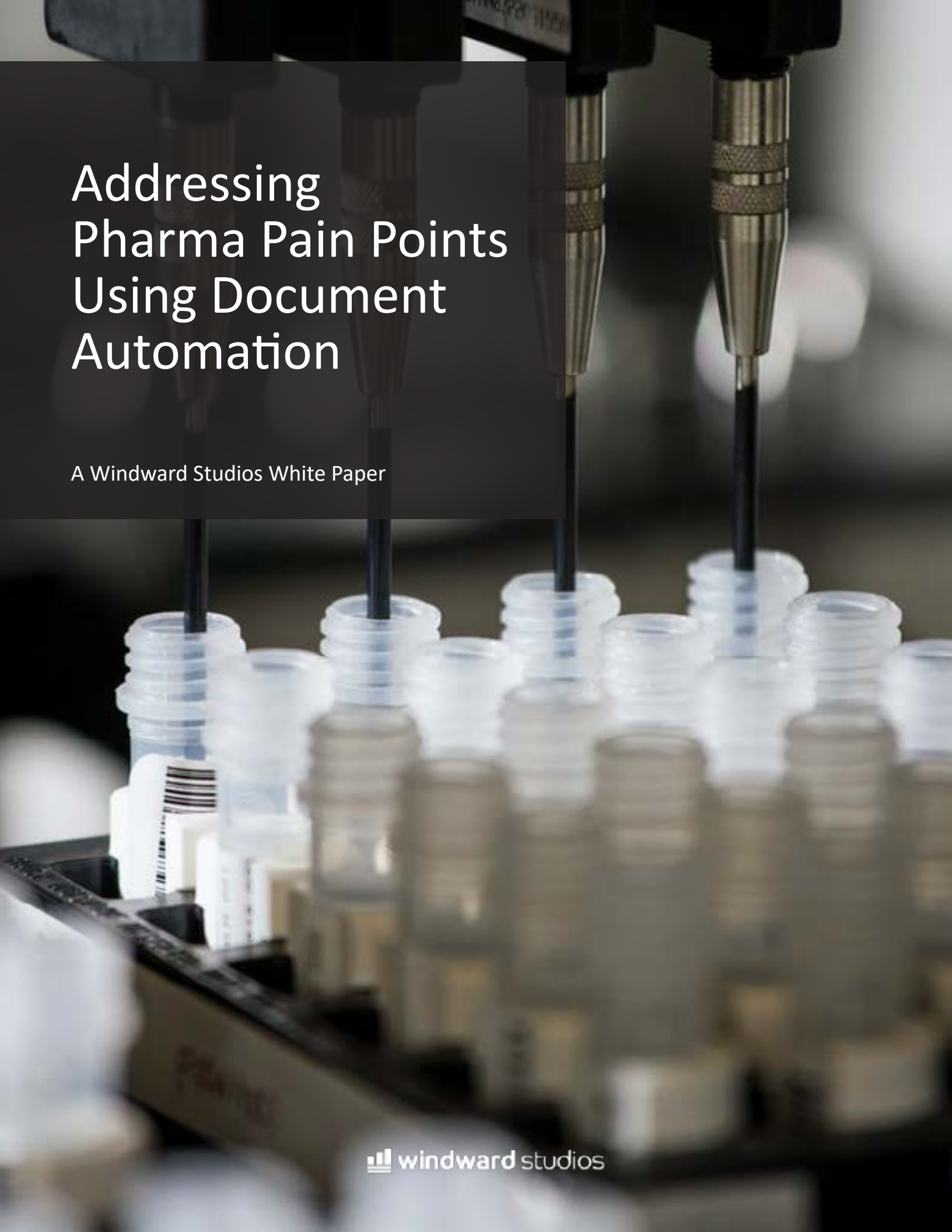

Addressing Pharma Pain Points Using Document Automation

A Windward Studios White Paper

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The FDA 483 letter is one of the most dreaded letters received by thousands of pharma companies. In 2018, 3,344 companies received this letter because they failed to comply with cGMP. Pharmaceutical companies need to understand the common compliance issues and address them before inspection but usually, it is not easy to address these issues and also work fast to get needed life-saving drugs to the market.

Record keeping is the most common compliance headache for industry players and it is understandable since scientists would like to concentrate on science and not administration. However, the two cannot be separated since records and reports play a big role in determining safety, ensuring consistent results as well as replicating processes among other benefits like pharmacovigilance. Document automation has significantly helped scientists get on with their work and still keep accurate records that comply with regulations.

Let’s take a look at some of the pain points that are addressed by this technology:

Inability to Create Collaborative SOP Documents

When the FDA carries out investigations, they usually check to see if the SOP documents are complete and contain guidelines that include input from the quality control unit, leadership, and employees input. This requires that the company maintains a living document that can be accessed and contributed to by everyone involved. It is hard to have such constant collaboration between different departments since the document versions get mixed up and at times no one is in charge of incorporating the changes to a document. Collaboration can become a time-waster and create confusion.

When document automation software is used, on the other hand, it is designed to improve collaboration. While a company sets up SOPs, every department can be involved and everyone can contribute towards the document. The different versions of a document are the worry of the automated system and not individuals so nothing gets mixed up. Once a final document is approved, it can be circulated digitally to the different signatories to add their signatures.
It also allows for feedback to be added to the document in case certain procedures need to be adjusted.stays productive.

Providing Written Procedures

Regulatory bodies issue citations to pharma companies that are unable to provide written procedures detailing production and process controls. These are necessary to confirm that a drug has a purported identity, purity, and quality. This requires that the company provides written information that identifies the drug and all the properties it contains in specific quantities as well as the quality of whatever is added. This information is reviewed by the FDA when determining the efficacy and safety of a drug. The time it takes to ramp up all these SOPs can create major delays for the scientists and many may try to skip this step and end up with citations.

The solution to this is having standard automated document templates that will guide the scientists throughout the process. By simply entering certain data into the template, the software will do the rest to produce a detailed procedure document with every detail included. There is no need to start from scratch every time you need to have a compliance document generated. Document automation software can source information from other preexisting documents as well as from databases that have been linked to the system. It is a quick and painless process that allows the company to focus on the core activity of making drugs.

Document Translation

Pharmaceutical companies collaborate with scientists from different parts of the world. While this is a great thing for science since they can share different developments in medical research, for some companies this has resulted in citations because documents like quality guidelines and disclosure agreements may not be understood by everyone. This requires that on top of creating the required documents, the companies have to find a translator to translate the documents into the language their partners understand. This process takes up a lot of time and at times the translation may not be perfect. The translation may also be an added cost of production.

With the right kind of software, translation can be done automatically, this ensures that everyone participating in the research is on the same page and no time, effort, or money is wasted on a physical translator. The translation may go further than just interpreting words and include converting measurements to what is commonly used in another country, for example converting ounces to grams or Fahrenheit to Centigrade. Collaboration with foreign scientists becomes much easier.

Adverse Event Reporting and Product Complaints

The release of a new drug into the market is just the beginning of a new range of documents that need to be compiled. First of all, the pharmaceutical company needs to collect every report of adverse events involving the drug. This could range from minor reactions to major possible fatal reactions. Every report needs to be recorded and included in a report. The data may come in from different sources and in different formats (phone, email, text) it is a pain trying to capture every report and entering it into a centralized database. Product complaints may also be reported right from complaints about packaging to questions about the efficacy of the drug. Regulatory guidelines require that the report is made and the action taken is also indicated. For example, recalling a batch of drugs or changing the labeling.

What might be a tiresome job for humans and a recipe for error, is a simple everyday task for document automation software. The necessary documents can be generated based on data entered into the system and the accuracy of the documents can be trusted. Automation software can capture data from emails, scanned paper documents as well as data entered manually and it will determine what should be included in the final document.

Final Thoughts

Non-compliance is a major source of trouble for pharmaceutical companies and it is not out of willful rebellion. Different circumstances related to human error can result in failure to comply with requirements. Where documents are concerned, technology will help such companies comply with all the guidelines. With set procedures and predesigned document templates, documenting becomes a simple background process that scientists can be sure they are doing right the first time.