

# **NDA & FDA Compliance Requirements: How Document Automation Software Can Help**

White Paper



### Introduction

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The innovation of new drugs and vaccines and their introduction into the market sees the generation of a large volume of documents. Pharmaceutical companies need ways to keep track of and efficiently manage these documents.

Windward can help automate the document generation process.

FDA regulations compliance has become a necessary and lengthy aspect within the industry as it's aimed at only promoting high quality, safe, and efficient drugs in the market (the application to the drug approval process by the FDA can take anywhere [between 12-15 years](#)). The fact that only around [10% of the drug applications](#) got approved in the last three years and the average cost of introducing a new drug into the market was around [\\$2.8 billion \(in 2013\)](#) makes a serious case for getting it right the first time.

To ensure improved productivity and compliance with these regulations, pharmaceutical companies can take advantage of document automation systems like Windward.

[Windward](#) can help generate thousands of documents in just a few clicks: fast and flawless!



### Stages of Drug and Vaccine Development

Before any new drug can be released into the market, pharmaceutical companies must ensure the [following steps](#) are adhered to after the discovery and development step:

#### Preclinical Stage

Researchers looking to innovate new drugs spend considerable time in [this step](#). Here, processes are chiefly interdisciplinary with contributions from biologists, chemists, and pharmacologists playing key roles. The result of this interdisciplinary consultation is then submitted to the necessary governmental and where applicable global authorities such as the Food and Drug Administration (FDA) to be reviewed.

For the research to be considered legitimate it needs to be supported by a series of corresponding documents. Missing or inconsistent documentation is grounds for





dismissal for any drug by the FDA. Among the key documents that need to be submitted for the review process include those referring to the study reports, quality assurance documents, and related operating procedure documents, chemical composition, and structure reports as well as its possible side effects.

### **Document Automation is Key — Breaking Barriers and Building Bridges with Windward**

Given the high load of documents that need to be properly recorded and processed and given all the different aspects that go into this step of developing a new drug, automation of document generation is a smart choice. Switching to [document automation software like Windward](#) offers pharmaceutical companies an incredible opportunity to improve their efficiency in document creation and get rid of human errors (making it easier for them to meet conditions meted out by regulatory bodies). The best part about Windward is it makes template creation super simple, as there's no need for coding. So even an individual researcher in your pharma company can come up with templates right in popular platforms like MS Office. Once the templates are created, the software will populate it with data based on the parameters and logic conditions set by the user. It can create documents in a [wide range of output formats](#) including PDF, HTML, DOCX, and more.

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### **Clinical Trial Stage**

This is the step within which human trials are carried out and only [25% of drugs](#) get past [phase 3](#) in this stage. The initial trials are often on a smaller scale. As the trial process progresses, the number of people involved in [this phase](#) increases and can shoot into thousands in the form of brochures, safety reports, adverse reaction reports, quality compliance documents, and more. The documentation and review processes must be in adherence to the set FDA regulations. These documents also play a critical role in the tracking of clinical trial results.

Documents generated during this phase can reach up to half a million pages (and Windward can make it at a rate of knots)!



This is undoubtedly a high amount of documentation that needs proper management. The information included in these documents is also sensitive as it includes patients' details. The safety of such information is, therefore, imperative.

Manual system for handling such a heavy volume of documents not only exposes the process to multiple human errors but increases the chances of creating information gaps in the event hard copies go missing or are misplaced (another downside is the time-intensive nature of such processes).



### **Automating the Document Generation Process for Clinical Trials Can Make a Huge Difference in Presenting Substantial Evidence to the FDA**

[Document automation](#) offers a quick and powerful solution to these above challenges. It can generate thousands of documents error-free in just a few clicks. This translates to the general ease of pharma regulation compliance. There will be no more significant

delays resulting in your new drugs getting into the market (as FDA can get their hands and eyes on documents with [‘substantial evidence’](#)).

### **NDA Approval & Post-Market Stage**

[This phase](#) follows the successful completion of the clinical trial phase and you begin to sell the drugs or vaccines in the market after the NDA (New Drug Application) approval. While pharmaceutical companies have the green light to take their product into the market, they are not exempted from rigorous documentation processes. Reports on any side effects (adverse reactions), quality control measures (just to mention a few) are still necessary and vital.

### **Automate Document Creation for Continued Compliance**

Windward's [document automation](#) during this phase is pivotal as it helps you to maintain pharmacovigilance and regulatory compliance. It also eases the process of reacting to emerging information through its feedback loops and reduces the time taken to convey information to the necessary channels and authorities.

### **Busting the Challenges of Regulatory Compliance**

Poorly managed documents can mean failure of regulatory standards, which causes setbacks in the approval process. The fines imposed on companies failing to meet



the necessary regulatory standards coupled with the cost of remedying the situation can cripple a company ([as figures show millions of dollars](#) are involved in the drug-development process).

### **Capture Key Data and Generate Reliable Documents & Reports with Windward**

Document creation with the help of [Windward](#) makes it easy to create the necessary clinical trial documents and compliance reports. It eventually makes decision making and approvals an easy task since all relevant parties can easily access the necessary information (error-free). The process of innovating, developing and marketing a new drug, as a result, becomes reliable, transparent, time-saving, and cost-effective.