



# What Does “Used For Regulatory Purposes” Really Mean?

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**T**his article will define, interpret and apply what “Used For Regulatory Purposes” really means and how it can impact an organization. The author will share a practical example of a system and give some advantages of knowing what “Used For Regulatory Purposes” means and the positive impact it could have on a company. In contrast, the author will communicate some disadvantages of not knowing what “Used For Regulatory Purposes” means and the negative impact it could have on a company.

## Definition of “Used for Regulatory Purposes”

The definition, interpretation and application of “Used for Regulatory Purposes” vary much like the Food and Drug Administration’s (FDA’s) Code of Federal Regulations does for many of us. The author’s definition of “Used for Regulatory Purposes” is the following:

Systems, which includes people, business processes and electronic systems that are used to either satisfy predicate rule requirements, make a decision related to predicate rule requirements, or used to submit data to a regulatory authority such as the FDA.

This definition cannot only help you and your organization determine what is “Used for Regulatory Purposes,” but appropriately interpret and apply the

definition to minimize the compliance risk and better manage the costs associated with being in compliance.

The author has been fortunate enough to have been active in the regulated industry for over 20 years and has found the “Used for Regulatory Purposes” model is an excellent approach to determining what is and what is not “Used for Regulatory Purposes,” as it has an impact to an organization regardless of what the company’s outcome is.

## Systems

As mentioned previously, a system is comprised of people, business processes and electronic systems. Let us dissect a bit further. Business processes are often and should be well documented in a policy, standard operation procedure (SOP), and/or a work instruction (WI). Electronic systems can range from electronic systems used to track adverse events, manage clinical trial data, manage company documentation, manage business processes themselves (continuous batching systems or deviation systems), or even financial systems. Lastly, people are a part of a system no matter if it is a business process or an electronic system, as there is always a human interface associated with a business process or a human machine interface (HMI) with an electronic system.

## System Example

Let us examine a computerized system since the uses of different technologies are increasingly used to not only assist in bringing drugs and devices to the market faster, but also streamline business processes in order for companies to achieve maximum efficiency. For the sake of this article, the author will use an electronic system used to manage company documentation. Of course, there are several systems that can achieve this objective, both on a small or large scale. However, what we will focus on is whether or not the electronic system used to manage company documentation is “Used for Regulatory Purposes.” How does one determine whether or not an electronic system used to manage company documentation is “Used for Regulatory Purposes?” Let us go back to the definition of the “Used for Regulatory Purposes:”

Systems, which include people, business processes, and electronic systems that are used to either satisfy predicate rule requirements,



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make a decision related to predicate rule requirements, or used to submit data to a regulatory authority such as FDA.

Let us assume this system is managing an organization's policies, SOPs and WIs. Let us take a few examples of the predicate rule requirements to help determine whether or not the system is "Used for Regulatory Purposes." Predicate rule 21 CFR Part 211, Sec. 211.100 Written procedures; deviations, requires the following:

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.<sup>1</sup>

In this instance, it is required by the FDA Code of Federal Regulations to have written procedures in place that shall be maintained to reflect current work practices. If these procedures are maintained and stored in a company's electronic documentation management system, then the system is "Used for Regulatory Purposes" because the predicate rule, 21 CFR Part 211, requires companies to establish and maintain such records.

Take another example from the predicate rules to further the point. Predicate Rule 21 CFR Part 820, Sec. 820.40 Document controls, states,

Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following: (a) Docu-

ment approval and distribution. Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part. The approval, including the date and signature of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use. (b) Document changes. Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be communicated to the appropriate personnel in a timely manner. Each manufacturer shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective."<sup>2</sup> Key words in this predicate rule are, "shall establish and maintain procedures to control all documents that are required by this part."<sup>3</sup>

In this example, because this predicate rule requires a company to establish and maintain all records required in this part and your organization is using an electronic documentation management system to maintain these records, then a system is "Used for Regulatory Purposes." Furthermore, documents such

as the Design History Record (DHR) and the Design Master Record (DMR), which are required to be established and maintained by this predicate rule, are also used in submission to FDA for approval to market and sell their respective medical device. However, please note that providing this information to FDA in a submission is dependent on the class of the medical device an organization is producing.

The author points this out, as this example could potentially satisfy another requirement of the definition of "Used for Regulatory Purposes," which is, if data from a system is used for submission to a regulatory authority such as FDA, the data is therefore "Used for Regulatory Purposes." As one can see, using the definition of "Used for Regulatory Purposes" and assessing one's systems against what is required by the predicate rules is advantageous and can significantly minimize the organization's compliance risk. However, there are also disadvantages associated with not applying the "Used for Regulatory Purposes" model.

## Advantages and Disadvantages

There are most certainly advantages with applying the "Used for Regulatory Purposes" model as well as disadvantages when not applying the "Used for Regulatory Purposes" model.

The advantages with applying the "Used for Regulatory Purposes" model are many. First, one can minimize the organization's compliance risk, therefore, decreasing the chances of receiving a FDA Form 483 Citation, FDA Warning Letter, or an Untitled Letter. Secondly, one strengthens the company's compliance knowledge by exposing them to the applicable predicate rules. By doing so, the company can begin to build a compliance strategy from a solid foundation.

Along with advantages, there are almost always disadvantages.

The disadvantages with not applying the “Used for Regulatory Purposes” model are also copious, and can be damaging to a company. First, the organization is potentially increasing its compliance risk and therefore increasing the chances of receiving FDA Form 483 Citations, FDA Warning Letters, or Untitled Letters. If the company is unfortunate enough to receive any of the aforementioned FDA documents, the results can have a detrimental effect on the company’s reputation to consumers, stakeholders and shareholders alike. Furthermore, there can be significant financial loss as a result of the company stock decreasing based on the news that a FDA Warning Letter was issued. In addition, an organization must also commit to investing and allocating money and resources towards addressing and resolving the violations in order to satisfy FDA enough for the agency to lift the company from the FDA Warning Letter status.

## Conclusion

In this article, the author used predicate rules that required various documents to be established and maintained. Furthermore, an example of an electronic system was used to manage company documentation for the purposes of providing practical examples of apply the “Used for Regulatory Purposes” model.

**If the company is unfortunate enough to receive any of the aforementioned FDA documents, the results can have a detrimental effect on the company’s reputation to consumers, stakeholders and shareholders alike.**

Whether the company is establishing and maintaining records required by the respective predicate rules by way of a manual business process or an automated process such as an electronic documentation management system, the author recommends one apply the “Used for Regulatory Purposes” model in order to minimize the compliance risk, build a solid compliance strategy and avoid FDA Warning Letters similar to the Letter Sandstone Medical Technologies, LLC received on May 30, 2008: Warning Letter No. 2008-NOL-11 Birmingham, AL cited:

Specifically, your firm has no documented quality system procedures for the manufacturing and distribution of the laser systems, which would include device master records, device history records, and acceptance activity records. Furthermore, your

firm has not established procedures for performing quality audits, identifying training needs, design control, document control, purchasing controls, change control, process controls, labeling controls, finished device marketing and distribution, and control and disposition of non-conforming product or complaint handling.<sup>4</sup>

In conclusion, whether the respective system is manual or automated, it is imperative to apply the “Used for Regulatory Purposes” model. ▲

1 Available at <http://library.compliancegurus.com/Default.aspx>.

2 Available at <http://library.compliancegurus.com/Default.aspx>.

3 Available at <http://library.compliancegurus.com/Default.aspx>.

4 Sandstone Medical Technologies, LLC Warning Letter No. 2008-NOL-11 Birmingham, AL available at <https://library.compliancegurus.com/Default.aspx>.