Agaram TECHNOLOGIES

# How Logilab SDMS helps Laboratories to enable Eudralex Annex 11 Compliance

White Paper

**Part 1**

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# INTRODUCTION

## About Eudralex Annex 11 and its importance

Eudralex is the collection of rules and regulations governing medicinal products (for human use as well as for veterinary use) in European Union (EU). Eudralex consists of 10 volumes, of which only Volume 1 (concerning medicinal products for human use) and Volume 5 (concerning medicinal products for veterinary use) present official legislation. The basic legislation is supported by a series of guidelines that are published within the other eight volumes.

Eudralex Volume 4 consists of three Parts and a series of nineteen Annexes. Within Part 1, guidelines pertaining to Documentation are presented in Chapter 4. Moreover, Annex 11 included guidelines for the use of computerized systems within GMP-regulated activities. When used in conjunction with Chapter 4, Annex 11 provides guidance for the use of electronic documents (electronic records and electronic signatures) within the GMP environment.

## Background

Similar to US FDA's 21 CFR Part 11, groups within the European pharmaceutical industry came together alongside the Commission of the European Committees in 1991 to adopt 2 new directives. These directives would lay the principles and guidelines for good manufacturing practice for the production and distribution of medicinal products in Europe.

Annex 11 is part of Volume 4 and specifically refers to computer systems. In 1991, the Pharmaceutical Inspection Co-oP (PIC) created a document defining their requirements for computer systems that would later be given the name Annex 5, and even later renamed as Annex 11 to become part of the EU GMP Guidelines. In 1992 it became part of the GLP and GCP requirements for Europe, unifying the requirements for the management of electronic records and signatures in pharmaceutical companies.

As computerized systems increased in complexity and sophistication, the core and initial guidance outlined in the original Annex 11 started to become unsuitable to meet the needs of the European pharmaceutical organizations. This out-of-date guidance led to a new version of Annex 11 being released in January 2011, with additional information provided around documentation that came into effect in June of that year.

## How it will apply to the organizations?

Looking into the guidelines provided under Chapter 4 Annex 11, it can be noticed that it only really applies to the production and distribution of medicinal products and not medical devices. Although this may seem inadequate thus far, medical device organizations who want to stay ahead of the curve may choose to adopt the guidance and align their activities anyway. No doubt that when the EU gets round to it, it will mould and apply this guidance to more regulated areas, including devices.

In a nutshell, if we are uncertain about which standards to align the organization processes right now, complying with Annex 11 is not a bad idea. Working to apply these guidelines in the organization will most definitely help those (medical device organizations) now and in future when more relevant guidance is released.

## How Eudralex Annex 11 helps to ensure compliance and ease of use?

By introducing Annex 11 in the organization, the ability to streamline business processes can be effectively ensured. It will reduce turnaround time and costs, all by establishing criteria for the use of electronic records and signatures. If it were not for guidelines such as Annex 11 and rules such as 21 CFR Part 11, we would be unable to manage records and other electronic content in a compliant way. The benefits of managing this content electronically are unparalleled, significantly reducing the risk of human errors, reducing operational costs and speeding up time-to-market.

# PRIMARY FOCUS AREAS OF EUDRALEX ANNEX 11

The following are the key areas in which regulated organizations must look at as primary areas of focus when dealing with Annex 11:

## 1. The features of the computerised system

There is a range of features that are required by Annex 11 when implementing a computer system to manage electronic records. the organizations must research well to align with these requirements.

## 2. Standard Operating Procedures (SOP)

As with all regulated industries, the companies that operate within them are governed internally by the Standard Operating Procedures they use. It may vary according the industry and its business processes followed. The following SOPs can be prepared by the organization which will help them to assure compliance and improve the quality.

1. System Administration and Maintenance
2. Physical Security
3. Logical Security
4. Incident and Issue/Problem Management
5. System Change Control
6. Configuration Management
7. Disaster Recovery
8. Electronic Signature Policy
9. Backup and Restoration

## 3. System Validation

When implementing an electronic system for the use in regulated activities, it is necessary to ensure that the documented evidence is available, and that the electronic system is fit for its intended use. In other words, we need to demonstrate that the system does what it should do. There must be controls in place that allow to identify when the system does not function as per its intended use.

In **Part 1**, we have understood the fundamental concepts of Eudralex Annex 11 and its vital requirements as applicable to Computerized systems in the regulated food and medical products industry.

In **Part 2**, we shall look into the overview of Logilab SDMS and its importance in Eudralex Annex 11 as applicable to Computerized systems

In **Part 3**, we shall look into how Logilab SDMS fulfils the requirements of Eudralex Annex 11

(To be continued in Part – 2)