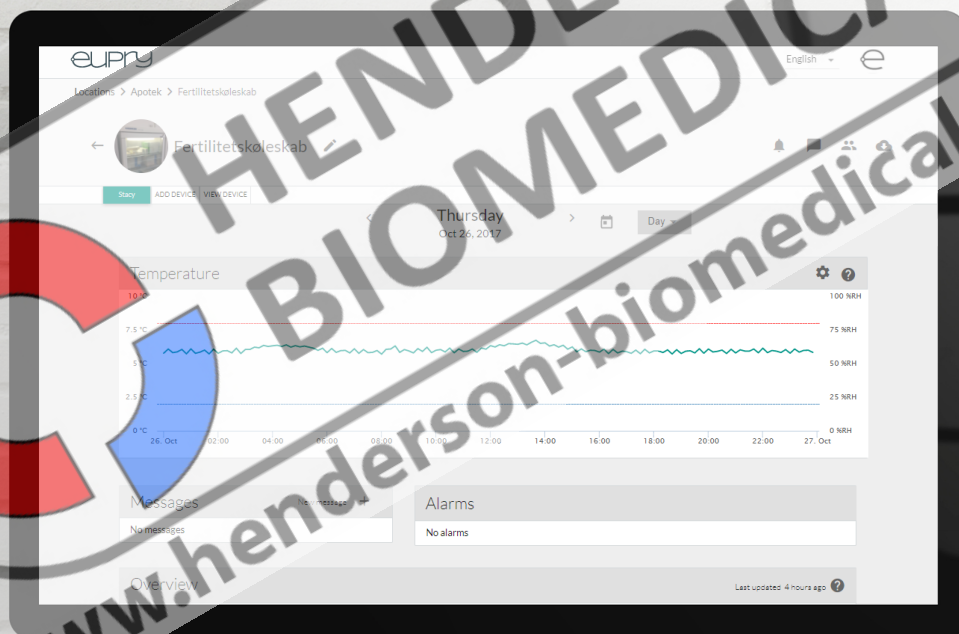




## FDA 21 CFR Part 11 Compliance Package



## What is FDA 21 CFR Part 11?

FDA 21 CFR Part 11 refers to the regulations set forth by the FDA regarding electronic records and electronic signatures. The purpose of the regulation is to ensure that electronic records and digital signatures can be trusted in the same way that handwritten records and subsequent signatures on paper are trusted.

## How Does it Work?

### 1. The FDA 21 CFR Part 11 Module is enabled in the Eupry System

By enabling the 21 CFR Part 11 module to the service plan of the organisation, extra functionality will be added and the system will hereby comply with the regulation.

### 2. Follow Eupry's Compliance Protocol

There are some procedures that your organisation must do internally to comply with the regulation, like authenticating the identity of users and notifying the FDA of the intention of using an electronic system as a replacement for paper records. By following our complete compliance protocol, you can ensure that your internal procedures comply with the regulation.

## Our Service:



#### **The Most Cost Effective Solution on the Market**

Eupry provide a modern, flexible solution which is ready for large and small customers.



#### **Simple & Implementation**

Preparing your system for FDA approval is straightforward using Eupry's 2-step solution.



#### **Data Validation**

The data within our system is verified and trusted.



#### **Automated & Secure Backup**

Our documentation is accurate, backed up and always available to you.



#### **Audit Log**

Export an exhaustive list of all changes that have been made in the system for an audit.



#### **Easy Electronic Signatures**

Sign and confirm changes within the system using a PIN code.



#### **Highly Experienced Quality & Regulations Team**

Eupry are specialists in helping you get an FDA approval.