White Paper



RFID FOR GMP/GLP ENVIRONMENTS

CONTACTLESS USER AUTHENTICATION, AUTHORIZATION AND ACCESS CONTROL IN THE CLEANROOM OR LABORATORY



Radio-frequency identification (RFID) is widely used across industries for physical access control, print security and single sign-on (SSO) access to computer systems and files. And it's easy to see why—RFID enables secure, contactless user authentication with the wave of an ID badge, token or smartphone. But most RFID readers are not designed for use in laboratory or cleanroom applications. Here's what you need to know about implementing RFID or BLE/NFC for user authentication in regulated GMP or GLP environments.

User authentication is the ability to correctly identify an individual user and match their information to the device, equipment or systems they are using.

Access control is the ability to ensure that only authorized users are able to gain access to a device, asset or system.

USER AUTHENTICATION AND ACCESS CONTROL IN LIFE SCIENCES

When working in a regulated laboratory or manufacturing environment, security is essential. Companies in the life sciences industry must ensure that only the right people have access to physical premises, supply cabinets, machines and equipment, printers and computer systems. User authentication and access control help companies:

- + Protect intellectual property.
- + Protect the physical security of staff, equipment and facilities.
- + Meet Good Laboratory Practice (GLP) and/or Good Manufacturing Practice (GMP) regulations for information security and custody.

User authentication and access control solutions are used for both physical security and information security in a laboratory or cleanroom environment. An RFID solution can be used for: When computer and network security is compromised, organizations may face:

- + Physical access control for secured laboratory and cleanroom premises.
- + Single sign-on (SSO) to computer systems, networks and printers.
- + Electronic signature authentication for Manufacturing Execution Systems (MES) or Laboratory Information Management Systems (LIMS)
- + Operation of machinery and equipment.
- + Access to supplies and controlled substances.

Implementing user authentication and access control within the context of a GLP or GMP environment presents extra challenges and requirements. The system must:

- + Meet GLP and GMP regulations and security standards, such as 21 CFR Part 11.
- + Be able to be cleaned and sanitized in accordance with GMP protocols.
- + Be easy, convenient and hygienic for laboratory staff.

RFID FOR LABORATORY INFORMATION SECURITY

Information management is critical in a GLP laboratory environment. 21 CFR Part 11 (in the US) and similar global standards require strong 2-factor user authentication systems for login to lab management software and systems and secure electronic signatures for lab documentation. Maintaining information security and handling electronic signatures in accordance with 21 CFR Part 11 and other regulations can be time-consuming and frustrating for both IT and laboratory staff.

RFID is a simple and secure solution for user authentication and access control within a GLP or GMP environment. RFID (or smartphone-based Bluetooth Low Energy (BLE) or Near-field Communication (NFC) systems) rely on something laboratory personnel already carry with them: their company ID badge or smartphone (if allowed).

For environments that require 2-factor authentication, RFID can be used in conjunction with either biometric or password systems. Two-factor authentication requires users to provide a secondary method of authentication along with the RFID badge or smartphone credential.

- + Password systems must be implemented using best practices to ensure proper security. This requires using a strong, unique password (with a minimum of 8-12 characters not forming a recognizable word or phrase and incorporating upper- and lower-case letters, numbers and special characters), changing that password at least every 90 days, and keeping the password secret. This may be onerous for users to maintain. Password systems also create more work for IT because passwords are often forgotten or compromised. These problems can put the facility out of compliance and put sensitive data and laboratory systems at risk.
- + A biometric system combined with RFID allows password-free 2-factor authentication, which is easier for both users and IT. There is nothing for users to remember and there are fewer problems for IT to manage. A biometric solution such as the Nymi band allows users to authenticate biometrically once per shift and remain authenticated until the band is removed, enabling seamless authentication for systems as they move through their day.

THE ADVANTAGES OF RFID/NFC IN A GLP/GMP ENVIRONMENT

RFID offers a number of advantages for GLP/GMP environments. Users get fast, secure and contactless access to everything they need in the laboratory or manufacturing facility, from cleanroom entrance to secured equipment to Manufacturing Execution Systems (MES) and laboratory information management systems (LIMS). RFID supports high levels of security—including advanced encryption—making cards or tokens very difficult to hack or compromise. This provides a high degree of certainty that users are properly identified and authenticated for lab and equipment access and electronic signature management within the MES or LIMS.

With RFID—used alone or in combination with biometrics for a 2-factor solution—compliance with information management regulations is faster, easier and less onerous for both end-users and IT.

For the end-users:

- + Reduces the password fatigue and frustration linked to the need to remember different combinations of passwords.
- + Reduces the time spent entering the same password for the same account.
- + Is fast, convenient and contactless.

For the IT department:

- + Provides higher levels of security and is less likely to be compromised than password systems.
- + Reduces the time spent in IT support for forgotten passwords,
- + Centralizes the authentication systems for easier management.
- + Provides the ability to secure all entry/exit /access levels to systems without multiple user requests.
- + Centralizes access control information for compliance tests with the various standards.

An RFID solution enables a faster release with simultaneous security. Instead of entering passwords, all that is required is the creation of a passport, which can be in a card, wristband or key fob, for example. The transmission does not start until the transponder is within a few centimeters of the reader. No battery or additional power source is needed, as passive transponders are powered by the electromagnetic field of the RFID reader

HOW RFID WORKS

RFID cards have two main components:

- + an integrated circuit that can store and process information
- + an antenna to transmit or receive a signal

Each RFID card stores a unique data set such as a number—that serves to identify the card and, by extension, the person carrying it. When a card with an embedded RFID tag is in close proximity with an RFID reader, the reader transmits a radio signal to interrogate the tag. The radio signal activates the tag, which then uses the power in the radio signal to respond to the reader with its unique ID.

BLE AND NFC

Bluetooth[®] Low Energy (BLE) and Near-field Communication (NFC) are both contactless data exchange technologies. Their main difference from RFID is that the information carriers (e.g., a smartphone) are active radio transmitters (beacons) and require a power source.

- NFC operates in near-field ranges (<20 cm) and is based on high-frequency RFID technology (13.56 MHz).
- BLE is a short-range radio technology for distances up to 10 meters operating at a frequency of 2.4 GHz.

When smartphones are used for user authentication and access control, they act as card emulators, sending a unique user ID to the reader.

CHALLENGES IN IMPLEMENTING RFID IN CLEANROOM ENVIRONMENTS

There are some specific challenges in implementing RFID/NFC within life sciences, food and pharmaceutical manufacturing, and other industries requiring cleanroom conditions. These environments require:

- + The ability to clean and sanitize the reader in accordance with GMP requirements.
- + High levels of security so the system cannot be compromised.

In addition, companies implementing RFID in the life sciences must consider all of the challenges common to implementing RFID across all industries, including support for multiple technologies and evolving technology and security requirements. When selecting an RFID reader for cleanroom applications, it is important to select one that will meet all of your needs—now and in the future.

+ CHALLENGE: SANITATION

The special demands of GMP environments are often overlooked. Built into plastic housings, conventional devices cannot be regularly treated with disinfectants or aggressive cleaning agents, as they are not resistant to aggressive substances and many cleaning cycles.

SOLUTION: CONNECT BOX WITH INTEGRATED ELATEC READER

Systec & Solutions designed and created a housing implementing the RFID solution of its partner ELATEC. The CONNECT BOX houses the reader within stainless steel and glass, which are commonly used for GMP applications. These materials can withstand the rigors of cleaning and

sanitation in a GMP environment. The reader is located safely under a cleanroom-compliant and easy-to-clean glass pane. The CONNECT BOX has smooth surfaces and is designed without beads, edges or open connections. The enclosure meets protection class IP65 (protection against low-pressure water jets from any direction, as well as condensation and water spray). The closed design and selected materials make the CONNECT BOX particularly suitable for use in the regulated environment of the life science industry and wherever hygiene is the top priority. From the clean rooms of the pharmaceutical industry to food production and the cosmetics industry, it represents an RFID/NFC reader that is easy and quick to clean.



+ CHALLENGE: LAB SECURITY REQUIREMENTS

Lab and cleanroom environments require high security to control access to physical premises as well as computer networks and software systems. That means that the reader must be resistant to both physical tampering and hacking.

SOLUTION: RUGGED HOUSING, ENCRYPTION AND 2-FACTOR AUTHENTICATION

Both the HMI and desktop versions of the CONNECT BOX have a front made of glass and are embedded in a cleanroom-compatible IP65 stainless steel housing. For the integrated solution for the wall or the control cabinet, there is a choice between flush mounting or installation with a stainless steel frame. The ELATEC reader supports advanced encryption suitable for highsecurity laboratory or manufacturing environments. Encrypted RFID or BLE/NFC signals are very difficult to intercept or counterfeit. For even higher security, the CONNECT BOX is compatible with biometrics (Nymi Band) for two-factor authentication.



+ CHALLENGE: MANAGING MULTIPLE TECHNOLOGIES

There are dozens of RFID card technologies in use around the world, each with its own data formats, communication frequencies and security capabilities. Cards can be broadly separated into high frequency (HF) and low frequency (LF), depending on the radio frequency band range they use to communicate. However, within these categories, cards by different manufacturers have their own unique formats. Businesses with multiple locations, or that have expanded through mergers and acquisitions, may end up with multiple card technologies used within a single company. In addition, some labs and manufacturers are moving towards smartphone authentication using Bluetooth[®] Low Energy (BLE) or Near-field Communication (NFC) technology.

SOLUTION: ELATEC READERS ARE UNIVERSAL

The CONNECT BOX is available as an RFID, NFC, BLE and smartcard reader. ELATEC RFID readers are "universal"; some can read more than 60 card technologies, including HF and LF RFID as well as NFC and BLE. They are also certified for use in as many as 110 countries. The reader is also compatible with the Nymi Band, a biometric solution for fast and secure authentication.



+ CHALLENGE: ERGONOMICS

Confirmations have to be made numerous times a day in a regulated industry. An ergonomically suitable solution for the corresponding workstation should not be neglected.

SOLUTION: MULTIPLE HOUSING CONFIGURATIONS

The CONNECT BOX is available in three different versions and thus covers a wide range of spatial and ergonomic requirements. It can be mounted on the side of an HMI system, set up on a table or integrated into the wall or in a control cabinet.



+ CHALLENGE: CHANGING SOFTWARE REQUIREMENTS

There are several reasons why RFID readers may need to be updated or reconfigured. End-users may adopt a new card technology. Emerging security threats may prompt device manufacturers or organizations to enable advanced encryption, two-factor authentication or other security features for identity management. Or software developers may make changes in operating systems that require reconfiguration of the reader. Opening the housing to physically remove and update each device, or replacing outdated devices, is both expensive and time-consuming for organizations with dozens of installed readers throughout the lab or manufacturing facility.

SOLUTION: ELATEC READERS ARE "FUTURE PROOF"

ELATEC readers have a robust open API that makes them highly adaptable and practically "future proof." The readers can be programmed to enable unique functionality, such as integration with MES/LIMS software or two-factor authentication. They can also support a variety of encryption formats for high-security applications. The API is powerful and flexible, so organizations will be able to upgrade their existing readers to address new opportunities and requirements in the future that have not yet been imagined. This vastly increases the shelf life of both installed systems and inventory. And since the readers can be easily reconfigured after installation (via contactless configuration card or remote configuration over a network), the CONNECT BOX is certain to meet the needs of users for a long time to come.

THE CONNECT BOX AT A GLANCE:

- + Designed for cleanroom and GMP environments
- + Particularly easy to clean
- + Complies with IP65
- + Smooth surfaces made of stainless steel and shatterproof glass
- + Can be combined with Systec & Solutions hardware or used as a stand-alone solution via a USB cable
- + Easy to retrofit
- + Can be used as RFID, BLE, NFC and smart card reader
- + Compatible with Nymi Band for biometric authentication

elatec.com

EMEA Puchheim, Germany +49 89 552 9961 0 sales-rfid@elatec.com AMERICAS Palm City, Florida, USA +1 772 210 2263 americas-info@elatec.com ASIA PACIFIC Shenzhen, China +86 158 1759 1668 apac-info@elatec.com JAPAN Tokyo, Japan + 81 90 1846 6900 japan-info@elatec.com