



nyimi™

| SOLUTION BRIEF

Connected Workers in the Passwordless Smart Factory

A wearable smart authentication solution that delivers all-access convergence and e-signatures in GxP-validated environments



The pharmaceutical and biopharmaceutical sectors encounter distinct obstacles when it comes to integrating digital transformation strategies into their manufacturing operations. Rigorous regulatory standards designed to safeguard vital medications also challenge innovation. Nevertheless, fostering new technologies and improving processes are crucial for advancing patient care. To optimize pharmaceutical production, digital transformation initiatives often focus on enhancing operational efficiency, ensuring data integrity, and promoting worker satisfaction. A shared pain point that impacts each of these areas is authentication.

The Password Pain Point in Manufacturing

In drug manufacturing, quality and compliance regulations necessitate extensive documentation. While digitalization efforts like ERP, MES, EBR, LIMS, and other industrial platforms have automated many shop floor processes, operators still shoulder the burden of repetitive authentications within these systems.

For example, electronic signatures (e-signatures) that require username and password entries can exceed 100 instances in an operator's shift. Furthermore, the pervasive password problem at large has prompted stricter IT policies that require frequent password changes and increased character complexity. As a result, operators are uniquely at risk for password

fatigue, productivity slowdowns, and security vulnerabilities. In addition, the immediate challenges from password authentication can have greater downstream consequences.

How Password Authentication Challenges Affect the Enterprise

- Password fatigue and workarounds
→ *Quality and compliance issue*
- Productivity slowdowns
→ *Increases time and cost*
- Cybersecurity attacks
→ *Threaten IT and OT networks*

The Adoption of Biometric Authentication

Biometric authentication has emerged as a promising solution that tackles the unique password pain point in the pharmaceutical industry. Successful biometric authentication in this context requires GxP-validation, strong security measures, and user-friendly functionality that specifically serves the needs of active workers. These criteria aim to enhance efficiency in authentication processes, ensure data integrity, and ease the overall operator experience by removing manual password entries.

While various solutions exist today, such as biometric mouses, iris scanners, and facial recognition readers, beware of critical limitations that can hinder effectiveness in manufacturing environments.

Critical Considerations for Active Workers Using Biometric Authentication Solutions

Is it designed for use on communal devices?

Traditional biometric authentication methods are best designed for single-user devices like personal computers. Here the user needs to enroll their biometrics once and they can be securely stored on the device. In manufacturing settings with shared devices, users must either enroll their biometrics on multiple devices, which is cumbersome and makes data deletion challenging, or biometric data can be stored centrally. While the latter is common, centralized storage of biometric data compromises data security and user privacy.

How does centralized PII storage affect the enterprise and its end-users?

Centralized storage of personally identifiable information (PII), as related to communal device designs, exposes it to cybersecurity threats and removes user ownership. The biometric data becomes the property of the enterprise and becomes vulnerable to cybersecurity attacks, which occur at an increasing rate. In critical environments, offline functionality becomes another crucial consideration. Centralized approaches can work with data replication, but this further spreads sensitive data, akin to the importance of not duplicating private keys in public key systems.

Can it work with PPE?

The use of Personal Protective Equipment (PPE) is standard practice in many manufacturing areas and strictly required in sterile environments. Cleanroom compatibility adds a layer of complexity in evaluating a biometric authentication solution. While different solutions can be deployed in different areas, this increases the IT sprawl for managing and scaling technologies in the long-run.

Smart Authentication: A Future of Connected Workers

Nymi revolutionized authentication in the pharmaceutical industry with an innovative operator-centric approach. Unlike traditional methods focused on system authentication, the Nymi connected worker solution enables continuous authentication at the person-level, facilitating uninterrupted workflows across applications, systems, and networks.

By leveraging industry-leading security protocols, Privacy by Design principles, and emphasizing the user experience, the Nymi connected worker solution digitally empowers operators to authenticate a single time to their wearable device, the Nymi Band™, and seamlessly continue their work in passwordless, contactless, and handsfree workflows.

The “connected worker” is a transformative smart authentication solution that combines biometrics, presence, and persistent identity to deliver across intersecting priorities desired in regulated manufacturing industries: time savings, enhanced productivity, better data integrity, and strong security that is easy to use – even in GxP-validated environments.



The Nymi Connected Worker Solution

Wearable Device + Platform

Nymi connects people to multiple applications, systems, and networks in a single authentication to their Nymi Band™. A Nymi connected worker is digitally empowered with passwordless, contactless, and handsfree authentication-based workflows, such as for app sign-in, e-signatures, physical access, and more.

Nymi Band™

The Nymi Band is a workplace wearable that is enrolled by an individual and afterwards biometrically authenticated via fingerprint for continuous use.

The Nymi Band applies a Zero Trust framework to identity by combining biometric authentication, continuous Always-On Authentication™, and Multi-Factor Authentication (MFA) in an easy-to-use wearable device.

In addition to strong identity assurance, the band is equipped with presence, activity, and other physiological systems, making it a next-generation smart authentication device that utilizes a powerful combination of functions beyond identity alone.



The Nymi Band is also purpose-built to meet the unique demands of manufacturing and cleanroom environments:

Durability:

The Nymi Band is built to withstand the challenges of industrial environments, offering ruggedness and longevity for sustained operations.

- IP66/IP67 Ingress Ratings
- Polycarbonate TPU straps
- 3+ day battery life

Cleanroom Compatibility:

Designed to meet strict cleanroom standards, the Nymi Band minimizes contamination risks and adheres to cleanroom protocols.

GxP Validation:

The Nymi Band undergoes comprehensive validation processes to comply with Good Practice (GxP) standards, guaranteeing reliability, security, and integrity. Nymi also supports customers through the GAMP5 validation process with templates.

- FDA 21 CFR Part 11
- EU Annex 1
- GAMP5

Regulatory Compliance:

Aligned with industry regulations and guidelines, the Nymi Band ensures adherence to data protection, privacy, and security requirements.

- FCC: USA
- IC: Canada
- CE: EU, Switzerland
- UKCA: UK
- MIC: Japan
- SRRC: China
- IMDA: Singapore
- KC: Korea

HOW IT WORKS



1.

One-Time Enrollment with Admin



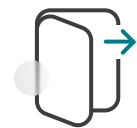
2.

Single Daily Authentication



3.

Use for All-Access and E-Signatures Across Systems



4.

Instant De-Authentication When Unworn

Nymi Connected Worker Platform

The Nymi Connected Worker Platform is deployed on-premise and connects to the enterprise Active Directory. It manages the biometric security and privacy of Nymi Band users and connects people to a growing ecosystem of applications and devices through technology integrations and standards.

Core Use Cases in the Pharmaceutical and Biotechnology Industry

All-Access Convergence

Logical systems

- Passwordless Login
- Nymi Lock Control™

Physical access systems

IT/OT networks

E-Signatures

Additional Use Cases (Bespoke Examples from Customers)

- Occupancy management
- Geofencing
- Visitor and contract management
- Access management with LMS
- Social distancing and contact tracing



Nymi-Ready Integrations on the Connected Worker Platform

SOFTWARE

R&D LABS

LIMS

- LabWare
- LabVantage

ELN

- PerkinElmer

MANUFACTURING/QC LABS

ERP

- SAP (via bioLock)

VLMS

- Kneat
- ValGenesis

MES/EBR

- POMSnet
- Koerber PAS-X
- Emerson Syncade
- FactoryTalk®PharmaSuite®
- Siemens OpCenter EXPH
- MasterControl
- Tulip
- Apprentice

Industrial

- Aspentech
- Rockwell Automation
ThinManager
- Citrix

SSO

- Evidian
Authentication
Manager
- Okta
- Ping Identity
- Duo Security

HMI/SCADA

- Siemens WinCC
- GE iFix
- Rockwell PanelView
- Rockwell FactoryTalk

Corporate IT

- Windows 10
- Microsoft Azure AD

DCS

- Emerson DeltaV
- ABB 800xA
- Siemens SIMATIC PCS 7

HARDWARE

CLEANROOM GRADE MONITORS, TABLETS, AND TERMINALS



GENERAL ENDPOINT DEVICES



PHYSICAL ACCESS SYSTEMS (PACS)



STANDARDS



Looking to a Digitally Empowered Future in Pharma

As innovation continues to digitalize the workplace, operators now have the opportunity to interact with their shop floor systems through a digitally empowered, secure, and smart authentication process.

Nymi is dedicated to forging enduring partnerships and has built a platform solution designed to adapt, scale, and grow alongside their customer's digital transformation journeys. This commitment ensures that customers can navigate an unknown future and gain ongoing returns by investing in their connected workforce.

About Nymi

Nymi connects people to their digital world in a single authentication to their Nymi Band. We are delivering connected workers to regulated industries with our innovative solution that enables tap-to-access with a compliant wearable wristband. With Nymi, organizations can simultaneously upgrade their security and employee experience to unlock the true value of digital transformation, one that includes the connected workforce.

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