

Mastering HR Challenges in a Highly Regulated Industry

# Enhance HR Processes to Improve Shop-Floor Safety in the Life Sciences Industry





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# Summary

Consistent processes, quality control, and traceability are business critical in life sciences. Failure to validate and record training and comply with regulations can permanently damage company reputation and lead to substantial fines and penalties. With so much at stake, it is absolutely vital that employees and managers are regularly trained and fully certified. By bridging the gap between HR and core business processes, life sciences companies can ensure compliance, improve safety, and secure their future. The following pages explain how HR plays a key role in reaching these goals.

## What You Will Learn from This Guide

-  Which new skills are required in life sciences 3
-  How to improve worker safety on the shop floor 4
-  The importance of training validation 6
-  How to address HR challenges in life sciences 7



# The Life Sciences Workforce Requires New Digital Skills

According to Gartner, CIOs will “need to morph into chief HR officers” by 2021. Large-scale technological and transformational initiatives often fail because they do not sufficiently address the diverse needs of people within the organization. On the one hand, younger generations demand new technology such as mobile apps that enable more flexible work. On the other, the differing needs of more senior employees should not be neglected – after all, their experience is incredibly valuable.

**57%** of CEOs in pharmaceuticals and life sciences are finding it difficult to attract digital talent.

Source: PwC, 21st Annual Global CEO Survey

In life sciences, the race for talent is particularly competitive. Skilled consultants, researchers, scientists, and lab technicians are in high demand. But the necessary skillset is also changing as trends such as personalized medicine, blockchain-based track and trace, and digitized research and development come to the fore. This calls for new ways of training and reskilling employees – especially with regard to digital competencies.

## **Regulations Require Trained and Certified Employees**

But perhaps the greatest challenge is that of compliance and safety. All staff – from workers in the warehouse to laboratory heads – need to be fully trained and certified for their tasks. IT systems and processes must be validated. And administrative bodies like the FDA require life sciences companies to define and follow standard operating procedures (SOPs).

All of these challenges require closer connection between HR and core IT processes.

To ensure safety, employees at all levels must be certified and regularly trained. It's important that IT systems are closely linked to HR systems to simplify the necessary checks.



# Maximizing Shop-Floor Safety and Compliance

To keep workers safe and prevent heavy fines and expensive recalls, life sciences companies must follow compliant, validated procedures. Employees at all stages must be certified: from ordering raw materials and coordinating logistical and production processes, to quality assurance and delivery. HR is the common touchpoint for all of these processes.



**If a company does not check to ensure that there is a sufficient number of qualified staff to complete a task, certain processes, such as production or delivery, could be delayed.**

Regulations in the life sciences industry aim to ensure that all risks are as close to zero as possible. Due to the sensitive nature of the materials and products, the same high quality must be achieved according to SOCs, every time. In addition, some raw materials used in life sciences can be dangerous – and must be handled safely to prevent workplace accidents. Not only is full traceability required in every process, but companies also need to check the validity of their employees' certificates before they are allowed to conduct certain tasks.



**Workplace injuries and illnesses have a major impact on an employer's bottom line: almost \$1 billion per week.**

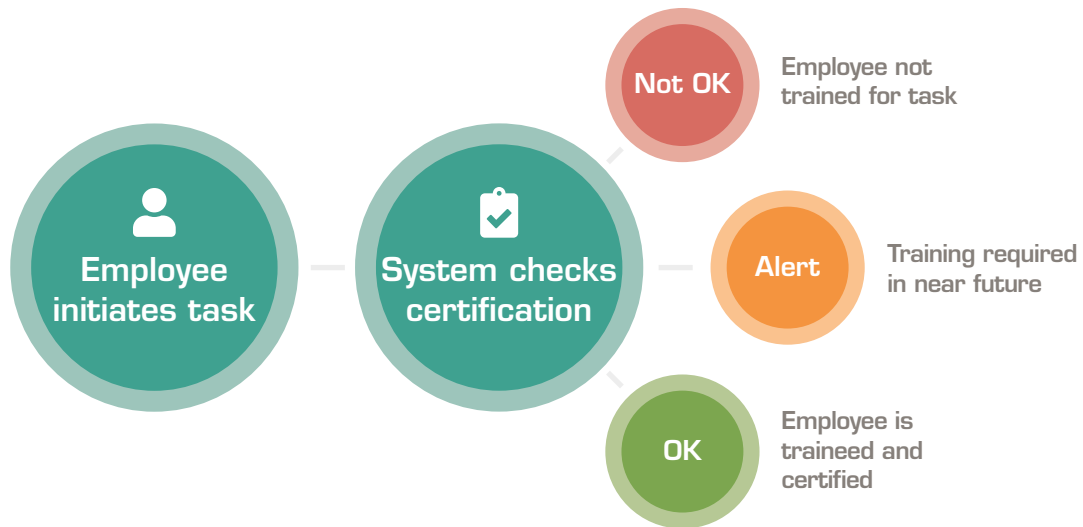
Source: United States Department of Labor

However, all too often, different business functions work with isolated IT systems. This fragmented approach makes compliance more complex. Without tight integration, it is nearly impossible to gain a full view of compliance.

## **Bringing HR into the Core Life Sciences Processes**

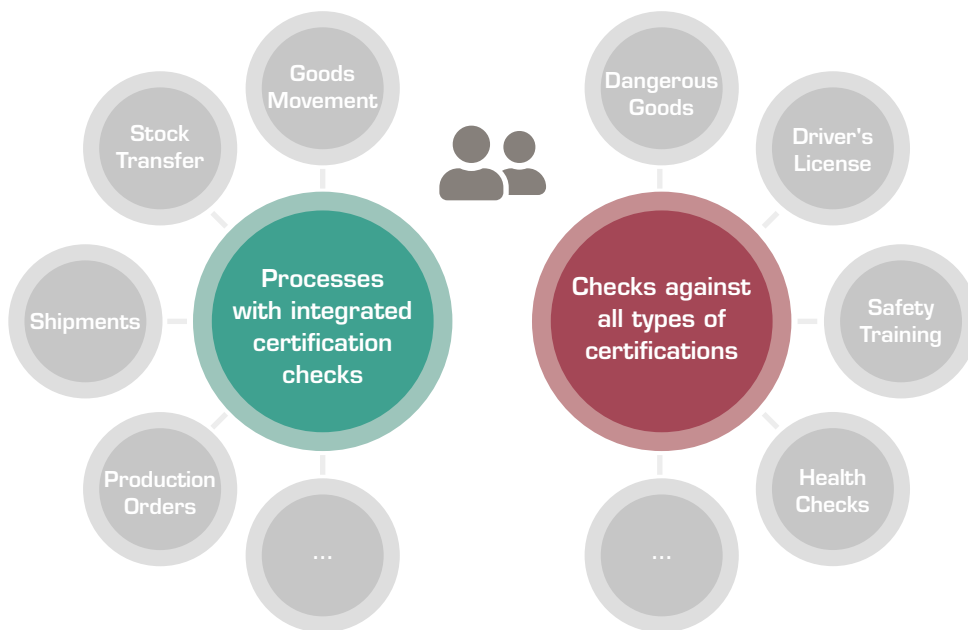
The lack of integration between HR data and core business processes is a problem plaguing many life sciences companies. Due to the disconnection between the two areas, companies are forced to turn to custom developments or manual checks to address the specific needs of life sciences. However, the former approach is often cumbersome and inefficient, while the latter can lead to compliance issues.

Figure 1: Integration Simplifies Certification and Training Checks



Integrating HR data into core business processes makes it significantly easier to validate whether an employee is qualified to perform a certain task. For example, before an employee begins a task involving hazardous materials, the HR system will check their data to verify that they have the necessary certification. It can also provide warnings when certification is about to expire and an employee needs to be retrained. This ensures shop-floor safety and compliance, and prevents the risk of costly accidents and production delays due to lack of skilled resources.

Figure 2: Many Life Sciences Processes Require Certification and Validation





## Validating and Documenting Every Training Activity

In highly regulated industries like life sciences, it is not only necessary to train all employees – companies must also be able to verify that training. This requires a system that can capture, store, and report on training data, as well as supporting audit processes and GxP (good practice) guidelines. Not only that, but the system itself must be validated to prove that it can do what it says it can do. Due to the strict, complex regulations in the life sciences industry, the costs and time involved in validation are difficult to predict and can quickly rise. In order to prevent costs from skyrocketing, an integrated IT infrastructure and extensive knowledge is required.



Process validation is defined as the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality products.

Source: U.S. Food & Drug Administration

Validation and documentation can take between three and six months to complete. This means that software with quarterly release updates is not suitable for life sciences, as companies require time to meet their validation requirements. Some solutions, such as SAP SuccessFactors Learning, offer slower release cadences to cater to this need, as well as additional validation reporting features.

The costs and time involved in validation are difficult to predict and can quickly rise. This is because the strict regulations in life sciences are complex.

# 30% – 40%

**of the costs associated with IT validation are avoidable.**

Stephan Limberg, Head of Center of Excellence for the Process Industry, itelligence AG

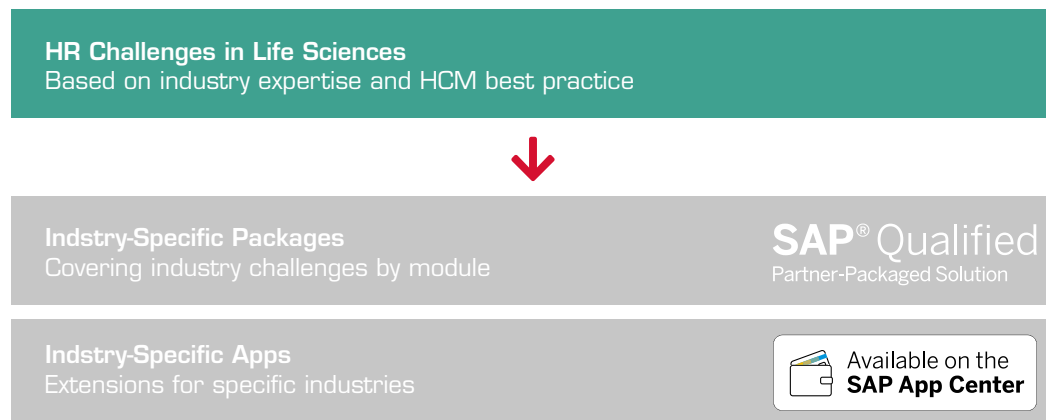


# The Two-Layer Approach to Industry-Specific Business Challenges

HR processes are different in every industry. Standard solutions will not always cover your specific demands. That's why itelligence has developed a two-layer approach to extend and enhance standard HCM software with functionality relevant to your industry. Our approach leverages the existing capabilities of solutions such as SAP S/4HANA and SAP SuccessFactors – SAP's cloud HCM software – and adds only the functions you need.

We offer a solution with integrated functionality for the life sciences industry, including proof of delivery, lot control and traceability, and regulatory compliance and validation. In addition, we can deliver industry-specific packages, preconfigured to suit your needs. With these extensions to your SAP SuccessFactors solution, you can integrate HR data into your core business processes and increase the impact of your company's most important asset: your people.

Figure 3: itelligence Fills in the Gaps with the Functionality for Your Industry Demands



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Get in touch with our expert  
Jan Ammann

» [jan.ammann@itelligence.de](mailto:jan.ammann@itelligence.de)

