Mastering Lab Compliance:
Innovative Solutions for Today's Challenges

WILEY

MilliporeSigma

Contents

Cover image: © Merck KGaA, Darmstadt, Germany

Imprint
© Wiley-VCH GmbH
Boschstr. 12, 69469 Weinheim,
Germany
Email: info@wiley-vch.de

Editors:
Dr. Cecilia Kruszynski de Assis &
Dr. Róisín Murtagh

Introduction

Lab Compliance Solutions

Enhancing Laboratory Compliance: Innovative Solutions for Seamless Operations

In today's dynamic and regulated landscape, laboratories across various industries face the critical challenge of maintaining compliance with ever-evolving regulations and standards. Non-compliance can result in severe consequences, from financial penalties to reputational damage. To address these challenges, cutting-edge lab compliance solutions have emerged, offering a comprehensive and streamlined approach to ensure adherence to regulatory requirements while optimizing operational efficiency [1].

To achieve maximum compliance, these solutions employ automation and machine learning algorithms. Automated workflows not only reduce the potential for human errors but also ensure that protocols and procedures are consistently followed. Additionally, machine learning algorithms analyze vast datasets to identify potential compliance issues, enabling proactive measures to be taken.

LANEXO® Inventory Management stands out as a leading solution in the realm of lab compliance, providing a comprehensive and efficient approach to managing laboratory inventory while ensuring adherence to regulatory standards. With its user-friendly interface and advanced features, LANEXO® enables laboratories to maintain accurate records of their supplies, chemicals, and equipment, facilitating compliance with strict storage and handling requirements. The system's real-time monitoring capabilities help prevent stockouts and expiry of critical materials, guaranteeing that laboratories operate smoothly and with minimal disruptions. Moreover, the system's built-in audit trail and data encryption features enhance data integrity, safeguarding sensitive information from unauthorized access. Now, laboratories can confidently navigate the complex landscape of compliance, ensuring precision and traceability, and ultimately, bolstering their commitment to excellence in research and development.

This eBook begins with an introduction to the Federal Food, Drug, and Cosmetic Act and Good Manufacturing Practice (CGMP) regulations. Drug firms organize activities into systems to ensure safe, high-quality drug production. The FDA outlines six systems: Quality, Facilities and Equipment, Materials, Production, Packaging and Labeling, and Laboratory Control. Then, we present a study that delves into corporate integrity culture, examining how a company's shared values and behaviors regarding compliance and ethics impact

its operations. The research highlights that upper management's consistent reinforcement of a culture of compliance and integrity is crucial to preventing its decay throughout the organization. The study focuses on the pharmaceutical sector, demonstrating connections between weak integrity culture, operational non-compliance (e.g., manufacturing violations), and financial non-compliance (e.g., restatements).

In conclusion, the ever-changing regulatory landscape demands that laboratories stay ahead of compliance challenges. Lab compliance solutions offer a comprehensive and proactive approach, integrating cutting-edge technologies, automation, and training to ensure seamless operations while upholding the highest standards of compliance. Embracing these innovative solutions not only safeguards the future of laboratories but also strengthens their position in the competitive global market.

Through the methods and applications presented in this eBook, we hope to educate researchers on new technologies and techniques for laboratory compliance solutions. For more information, we encourage you to visit lanexo.com to learn more and explore options to enhance your research.

Dr. Cecilia Kruszynski
Editor at Wiley Analytical Science

REFERENCES

[1] Valarmathi, S., et al. (2023). Textbook on Pharmaceutical Regulatory Affairs: Regulatory Affairs of Pharmaceuticals. Shashwat Publication.

Introduction to the Quality Systems Based Approach to CGMP Compliance

Adapted from Bliesner, D.M. 2020

OVERVIEW OF QUALITY SYSTEMS AND THE LABORATORY CONTROL SYSTEM

The US Food and Drug Administration (US FDA) mandates that a drug firm be operated in a state of control by employing conditions and practices that assure compliance with the intent of the Federal Food, Drug, and Cosmetic Act and portions of the Current Good Manufacturing Practice (CGMP) regulations that pertain to it.

Activities found in drug firms can be organized into systems. Control of all systems helps to ensure the firm will produce safe drugs, have the proper identity and strength, and meet the quality and purity characteristics as intended [1–3].

For drug firms, the FDA has outlined the following general scheme of systems that affect the manufacture of drugs and drug products:

(1) *Quality System:* assures overall compliance with CGMPs and internal procedures and specifications. The system includes the quality control (QC) unit and all its review and approval duties. It also includes all product defect evaluations and evaluations of returned and salvaged drug products.

(2) *Facilities and Equipment System:* includes the measures and activities that provide an appropriate physical environment and resources used in the production of the drugs or drug products. It includes:

  (a) Buildings and facilities along with maintenance.

  (b) Equipment qualifications, calibration, and preventative maintenance; cleaning and validation of cleaning processes.

  (c) Utilities such as heating, ventilation, air-conditioning, compressed gases, steam, and water systems.

(3) *Materials System:* includes measures and activities to control finished products and components including water or gases that are incorporated into the product, containers, and closures. It includes validation of computerized inventory control processes, drug storage, distribution controls, and records.

(4) *Production System:* includes measures and activities to control the manufacture of drugs and drug products including batch compounding, dosage form production, in-process sampling and testing, and process validation. It also includes establishing, following, and documenting the performance of approved manufacturing procedures.

(5) *Packaging and Labeling System:* includes measures and activities that control the packaging and labeling of drugs and drug products. It includes written procedures, label examination and usage, label storage and issuance, packaging and labeling operations controls, and validation of these operations.

(6) *Laboratory Control System:* includes measures and activities related to laboratory procedures, testing, analytical method development, validation and/or qualification/verification, and the stability program.

According to FDA, "The Quality System provides the foundation for the manufacturing systems that are linked and function within it." This approach is commonly referred to as the six-system model and is still used today by FDA to conduct inspections of good manufacturing practice (GMP) facilities.

As stated in (6) earlier, FDA considers a firm's Laboratory Control System (LCS) to be a key element in CGMP compliance. Within the LCS are at least 10 additional sub-systems or sub-elements, which may include:

- Laboratory Managerial and Administrative Systems (MS)
- Laboratory Documentation Practices and Standard Operating Procedures (OP)
- Laboratory Equipment (LE)
- Laboratory Facilities (LF)
- Method Validation and Method Transfer (MV)
- Laboratory Computer Systems (LC)
- Laboratory Investigations (LI)
- Data Governance and Data Integrity (DI)
- Stability Program (SB)
- General Laboratory Compliance Practices (CP)

These 10 sub-elements of the LCS have been created to promote the establishment and maintenance of Quality Systems and sub-systems, which demonstrate you are in control of your laboratory operations and thus in compliance with the CGMP regulations.

REGULATIONS AND REGULATORY BODIES

The primary, globally significant regulations related to the manufacturing, processing, packing, or holding of drugs include:

- 21 Code of US Federal Regulations Part 210 and 211 Current Good Manufacturing Practice Regulations
- EudraLex – Volume 4 – Good Manufacturing Practice (GMP) guidelines

The major regulatory bodies or organizations that enforce the regulations or assist in harmonizing international regulatory efforts include:

- US Food and Drug Administration (US FDA, United States)
- European Medicines Agency (EMA, European Union)
- Medicines and Healthcare Products Regulatory Agency (MHRA, United Kingdom)
- Health Canada (Canada)
- Brazilian Health Regulatory Agency (ANVISA, Brazil)
- Pharmaceuticals and Medical Devices Agency (PMDA, Japan)
- Therapeutic Goods Administration (TGA, Australia)
- World Health Organization (WHO-International)
- Central Drugs Standard Control Organization (CDSCO, India)
- The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH-International)
- Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) (PIC/S-International)

There are numerous other country-specific bodies, which enforce their own laws related to the manufacturing, processing, packing, or holding of drugs. The reader is encouraged to consult the requirements of their own country's laws and regulations regarding the manufacture of pharmaceuticals.

REGULATORY GUIDANCE

Traditionally, regulatory agencies themselves have provided limited insight and assistance into how organizations operating within the pharmaceutical industry can comply with the regulations. However, over time, regulatory guidance and other instruments have arisen and evolved and today consist of a large body of knowledge, which can be used by organizations to aid in compliance with the CGMPs.

When it comes to regulatory guidance for QC Laboratories, the following documents may be helpful:

- US FDA Compliance Programs to FDA staff, Chapter 56: Drug Quality Assurance 7366.002 Drug Manufacturing Inspections
- US FDA Guidance for Industry, Quality Systems Approach to Pharmaceutical CGMP Regulations
- ICH Harmonized Tripartite Guideline, Q1A to Q1F Stability
- ICH Harmonized Tripartite Guideline, Q2 Analytical Validation
- ICH Harmonized Tripartite Guideline, Q3A to Q3D Impurities

- ICH Harmonized Tripartite Guideline, Q4 to Q4B Pharmacopoeias
- ICH Harmonized Tripartite Guideline, Q6A to Q6B Specifications
- ICH Harmonized Tripartite Guideline, Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
- ICH Harmonized Tripartite Guideline, Q8 Pharmaceutical Development
- ICH Harmonized Tripartite Guideline, Q9 Quality Risk Management
- ICH Harmonized Tripartite Guideline, Q10 Pharmaceutical Quality System
- ICH Harmonized Tripartite Guideline, Q12 Lifecycle Management
- ICH Harmonized Tripartite Guideline, Q14 Analytical Procedure Development
- WHO Annex 2: Good Manufacturing Practices for Pharmaceutical Products: Main Principles
- FDA Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations, September 2006

It should be noted that although not legally binding, violations of the principles of the ICH Harmonized Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7, are sometimes documented as findings by FDA.

REFERENCES

[1] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211.

[2] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.1.

[3] US FDA (2017). Compliance Programs to FDA staff, Chapter 56: Drug Quality Assurance 7356.002 Drug Manufacturing Inspections.

Corporate Integrity Culture and Compliance: A Study of the Pharmaceutical Industry

Adapted from Altamuro, J.L.M. et al. 2022

This study examines corporate integrity culture—a firm's shared values and behaviors related to compliance, trustworthiness, and ethics. The results indicate that top management must consistently reinforce a culture of compliance and integrity, lest it decay throughout the organization.

INTRODUCTION

Organizational culture is a system of shared values and norms, which shapes attitudes and behaviors [1]. Evaluating this type of culture across diverse functions of a corporation is complex.

We explored integrity culture, a survey-identified aspect, by scrutinizing compliance in two functions: manufacturing and finance. Our sample includes publicly traded pharmaceutical companies that comply with regulations set by the United States Securities and Exchange Commission (US SEC) and the Food and Drug Administration (FDA). Restatements signify financial non-compliance and adverse FDA outcomes as operational non-compliance.

Initially unrelated, plant-level Good Manufacturing Practices (GMP) breaches and financial reporting issues seem unrelated. In the same way, we expected accounting misapplication not to drive plant compliance issues.

A firm likely has a weak integrity culture if (i) internal control probability is below the industry median but ineffective controls are reported or (ii) "tone at the top" issues are reported. We then linked this to operational and financial non-compliance.

Our pharmaceutical sample spans 1,209 firm-years (2003-2016) with 140 restatements and 78 control weaknesses.

HYPOTHESIS DEVELOPMENT

Culture guides challenging areas like ethical choices [2], affecting action evaluation via engendered norms [3]. Neglecting integrity culture may increase non-compliance [4].

We explored firm-level culture's influence on compliance across functions. Compliance needs steady reinforcement due to employee focus on measurable aspects [5]. Manufacturing staff's compliance largely hinges on plant management driven by upper management's influence.

Culture shapes compliance via internal control. Internal control, per the Committee of Sponsoring Organizations (COSO) [6], assures objectives. Top management's integrity culture, part of internal control, affects functions through interactions and incentives. Thus, we propose:

H1: Weak integrity culture in ineffective control links to financial and operational non-compliance.

In H2: We analyzed cross-function non-compliance correlation, reflecting subtle cultural aspects beyond internal control. Shared attitudes across functions signal similar norms at a time. Thus, we propose:

H2: Financial and operational non-compliance correlate, after controlling for the integrity culture reflected in the internal control environment.

COSO highlights boards shaping internal control importance. Strong governance could induce compliance emphasis, spurring similar norms. Hence, we propose:

H3: Weak integrity culture does not cor-relate with strong shareholder governance.

DATA AND RESEARCH DESIGN

Measures of operational non-compliance and financial non-compliance

The FDA checks manufacturing compliance with GMPs to ensure products meet requirements. GMP violations involve procedural lapses, complaint handling, or validation issues. FDA inspections result in an establishment inspection report (EIR), reviewed along with Form 483 for action decision. Outcomes are official, voluntary, or no action, forming Form 483 and district decision.

For operational non-compliance, we use a scoring system from Gray et al. [7] with scores ranging from 0 to 3.5 for each inspection outcome. Higher scores indicate severe non-compliance. We apply this to FDA inspections, aggregating inspection scores for a fiscal year to get operational non-compliance values (OPNON).

Financial non-compliance (FINON) is measured through restatements, capturing errors and manipulations, both tied to Graham et al.'s culture integrity attribute [8]. We use an indicator variable for each firm-year, marking restatements.

Creation of culture measure and test of H1

We employed a probit model (A1) to predict internal control weaknesses (ICW) in the firms. ICW is 1 for firm-year with internal weakness, signaled by SOX 404 or 302, or in Rice et al. [9]'s ICW sample. It is also 1 for a restated fiscal year if initial reports show strength but later reveal weakness.

We label low predicted probability firms below the industry median as having weak integrity culture (WEAK_CULTURE_PRED = 1). WEAK_CULTURE_PRED positively relates to „tone at the top" (TONE), suggesting shared unexplained aspects.

A firm-year indicates weak integrity culture (WEAK_CULTURE_IC = 1) if disclosing „tone at the top" (TONE = 1) or WEAK_CULTURE_PRED = 1.

FINON is 1 for restated financial statements. OPNON is the average FDA inspection score per firm-year, showing GMP violations. As WEAK_CULTURE_IC = 1 subset of ICW = 1, coefficient on WEAK_CULTURE_IC reflects incremental culture-compliance connection beyond other ICWs (ICW = 1, WEAK_CULTURE_IC = 0).

Test of H2

We deployed a model to test weak integrity culture's effect on financial and operational non-compliance, beyond the internal control environment. It adds OPNON after supervision of the internal control environment. We use financial and operational non-compliance's positive link as a weak integrity culture indicator. We control for integrity culture in internal control, operations, complexity, growth, performance, and past restatements.

Test of H3

We assess H3 through two tests mirroring corporate integrity culture tests. For shareholder governance strength, we follow Gompers et al. [10] and Bebchuk et al [11]. This test, involving a few weak-culture firms in our pharmaceutical sample without FDA data, employs broader Compustat data. WEAK_CULTURE_IC is 1 if „tone at the top" (TONE = 1) or WEAK_CULTURE_PRED = 1. To match firm traits, we focused on predicted probability-based internal control assessments.

EMPIRICAL DESCRIPTIVE RESULTS

Statistics

We observe a significant positive correlation between WEAK_CULTURE_IC and both operational and financial non-compliance. Noteworthy, correlations were present between operational non-compliance, restatements, sales volatility, and auditor reputation.

OPNON's positive coefficient is significant, implying that operational non-compliance can trigger financial non-compliance, even after accounting for „tone at the top." Adjusting for weak culture measures and firm traits retains a positive link, albeit with reduced magnitude.

H3 test results focused on weak integrity culture and shareholder governance. We found no evidence of any governance measure associated with firm culture, consistent with Guiso et al. [12] In CEO turnover's influence on culture, we explored CEO turnover after financial non-

compliance as per Hennes et al. [13] The findings demonstrate a noteworthy correlation between CEO turnover and accounting restatements, as well as operational non-compliance, with particular emphasis on their interrelation.

We further probe post-CEO turnover culture shifts, examining measures of weak integrity culture in and beyond the internal control environment. It was found a drop in the internal control environment's weak culture measure and a marginal reduction in financial-operational non-compliance link post-CEO turnover, indicating CEO turnover's potential to alter integrity culture.

CONCLUSION

We explored the organizational weak integrity culture's role in cross-functional non-compliance. In a pharmaceutical sample with FDA-inspected plants, we linked operational and financial non-compliance. Our weak culture measure uses internal control data, revealing links to FDA inspection failures and restatements. Operational non-compliance was associated with financial non-compliance after internal control.

Weak culture's internal control reflection lacks significant shareholder rights association, but the link between operational and financial non-compliances strengthens in weaker rights cases.

Market reactions showed worse restatement impact for firms with FDA weaknesses. CEO turnover inclination rises for restating firms with severe operational non-compliance.

Our evidence suggests cross-functional non-compliance may stem from integrity culture. It signals compliance concerns go beyond business functions. Firms with weak cultures face shareholder value drops.

Limitations include small weak culture subsample and culture's intangibility. Nevertheless, our findings offer managerial and regulatory insights. Root cause investigations should transcend functions. Regulators might predict non-compliance via other agency records. We envision a future where cultural insights guide effective regulation and firm management.

We have shown positive cross-functional non-compliance links, likely culture-driven. As culture measurement advances, regulators and stakeholders could use it to comprehend and act on compliance dynamics. Our study contributes toward this future.

REFERENCES

[1] O'Reilly, C. and Chatman, J. (1996). Culture and social control: Corporations, cult and commitment. *Research in Organizational Behavior.*

[2] Graham, J.R. et al. (2022). Corporate culture: Evidence from the field. *Journal of Financial Economics.* DOI: 10.1016/j.jfineco.2022.07.008.

[3] Fischer, P. and Huddart, S. (2008). Optimal Contracting with Endogenous Social Norms. *American Economic Review.* DOI: 10.1257/aer.98.4.1459.

[4] Anand, G. et al. (2012). Decay, Shock, and Renewal: Operational Routines and Process Entropy in the Pharmaceutical Industry. *Organization Science.* DOI: 10.1287/orsc.1110.0709.

[5] Holmstrom, B. and Milgrom, P. (1994). The Firm as an Incentive System. *The American Economic Review.*

[6] PricewaterhouseCoopers (Firm) and Everson, M.E. (2013). Internal Control: Integrated Framework.

[7] Gray, J. V. et al. (2011). Quality risk in offshore manufacturing: Evidence from the pharmaceutical industry. *Journal of Operations Management.* DOI: 10.1016/j.jom.2011.06.004.

[8] Graham, J.R. et al. (2016). Corporate Culture: The Interview Evidence. *SSRN Electronic Journal.* DOI: 10.2139/ssrn.2842823.

[9] Rice, S.C. et al. (2015). Does SOX 404 Have Teeth? Consequences of the Failure to Report Existing Internal Control Weaknesses. *The Accounting Review.* DOI: 10.2308/accr-50974.

[10] Gompers, P. et al. (2003). Corporate Governance and Equity Prices. *The Quarterly Journal of Economics.* DOI: 10.1162/00335530360535162.

[11] Bebchuk, L. et al. (2009). What Matters in Corporate Governance? *Review of Financial Studies.* DOI: 10.1093/rfs/hhn099.

[12] Guiso, L. et al. (2015). The value of corporate culture. *Journal of Financial Economics.* DOI: 10.1016/j.jfineco.2014.05.010.

[13] Hennes, K.M. et al. (2008). The Importance of Distinguishing Errors from Irregularities in Restatement Research: The Case of Restatements and CEO/CFO Turnover. *The Accounting Review.* DOI: 10.2308/accr.2008.83.6.1487.

Staying Compliant in Today's Lab Environment

Insights on industry trends, customer needs, and lab compliance solutions

In this interview, we sit down with the team behind LANEXO® Inventory Manager, a cutting-edge software solution tailored for regulated analytical and QC laboratories. They share valuable insights on how they stay informed about industry trends, their strategies for identifying customer needs and developing product solutions, and why compliance is crucial in today's lab environment. Discover the challenges labs face in maintaining compliance and learn how LANEXO®'s innovative features address the need for adherence to safety, regulatory, and quality standards. From capturing consumables data digitally at the point of use to ensuring data traceability and reliability, LANEXO® is revolutionizing lab inventory management, making it more efficient, safer, and fully compliant with industry regulations.

How do you stay informed about new products and trends in the industry?

There are a variety of things that we are doing to stay informed about new products and trends in the industry. By having conversations and collaborations with industry peers and cross-functional teams, e.g., sales and marketing, who share their insights and experience, reading industry blogs, conducting market research, and attending conferences and events. All these efforts contribute to staying informed about the latest trends and new products.

What strategies do you use to identify customer needs and develop product solutions?

Conducting market research, creating personas, and collecting customer feedback are the main strategies that are used to identify our customer's needs. Understanding customers' main points and creating personas are essential to developing a product solution that will help to enhance the customer's daily work life. Once the customer needs are identified, you can focus on developing a product roadmap that will address them with short- and long-term goals. It is always important to get customer feedback even before implementing a product solution to understand if the solution will address their needs and solve or reduce their challenges.

Why is compliance so important in today's lab environment?

It is important that labs adhere to their own and state-regulated compliance as failing to do that will have consequences from a safety, regulatory, and quality perspective. Compliance helps to establish safety protocols, which reduce the risk of accidents and injuries to lab personnel. Following regulatory requirements is necessary to avoid legal penalties, fines, and reputational damage. Having lab standards and procedures set in place is critical to ensure the reliability and accuracy of laboratory results. All these compliance aspects help to maintain the integrity of laboratory processes and ensure that results are trustworthy and actionable.

What challenges do labs face today when it comes to compliance?

Regulations encompassing industry-specific standards, as well as those established by federal and state entities, present a significant level of complexity. For lab personnel, it is difficult to stay up-to-date with new regulations or changes and ensure that all requirements are being met. Furthermore, training laboratory personnel poses significant challenges as they need comprehensive instruction in regulatory compliance, laboratory procedures, and safety protocols. The bigger your lab, the more challenging it is to ensure that everyone is trained correctly.

What is LANEXO®?

The LANEXO® Inventory Manager is a software solution specifically designed for regulated analytical and QC laboratories. With our solution, we allow customers to digitally capture consumables data at the point of use in the lab. We help customers to manage their lab inventory more efficiently and safely, saving customers up to 70% of the time they spend on inventory tasks and making consumable storage safer and more compliant with regulations by providing information about the storage of incompatible chemicals. Using an Android or IOS app, customers can register consumables through RFID,enabling quick registrations, relocation and full traceability displayed in the audit trail, which can be exported. Customers can also connect other systems, e.g., LIMS, ELN, and ERP systems via the available open-end APIs, ensuring the interconnectivity of software solutions within their lab.

How does LANEXO® address the need for compliance in labs today?

The LANEXO® Inventory Manager is a validated software that supports laboratory compliance with FDA 21 CFR Part 11 and EU GMP Annex 11 because of several essential features such as using access cards that provide a unique digital signature for each user, user authentication requirements, and time-stamped audit trails. By capturing the data electronically via RFID labels, we ensure data traceability, reliability, and integrity. The risk of human error during data transcription gets eliminated; digital records can be found easily as every consumable registered to the system is immediately available. Additionally, we allow customers to set up user permissions according to your laboratory's setup and approval processes.

How does LANEXO® stand out from other products on the market?

We are currently the only company who provides an inventory management solution by using RFID labels and a smartphone, which captures consumables data at point of use in the lab. We have a vendor-neutral solution as the RFID labels can be used on any type of consumable. In addition to Identifier and Location labels, we offer RFID Smart Seal labels, which have sensors that detect when consumables are opened and then automatically calculate their expiry dates. From a safety perspective, the application will alert customers when incompatible materials are stored together in a location. All actions within the app are captured in an audit trail (e.g., consumable volumes, used by whom, when, and for what) and can be exported. Finally, it is easy to use and can be simply integrated into our customer's existing workflows with an intuitive user interface.

How cost-effective is the process compared to the former techniques?

The goal of the LANEXO® Inventory Manager is to automate our customer's daily inventory tasks in a compliant and safe way. This will be done by capturing, monitoring, and finding consumable information in a fast way. We have created a survey to help us understand how much time our customers are spending on manual repetitive tasks (e.g., registering consumables, locating consumables for an experiment, relocating consumables, opening consumables, calculating the expiry date, identifying expired stock, and more). Based on the survey, we have found that it takes an average of 500 minutes for a customer to go through all these manual repetitive tasks. By using the LANEXO® Inventory Manager, and digitalizing these tasks, it will only take an average of 30 minutes to go through these repetitive tasks, reducing the time spent on inventory tasks and effectively increasing the time for our customers' lab personnel to focus on their primary function – being scientists.

This interview was conducted by Dr. Cecilia Kruszynski, *Editor* of Wiley Analytical Science.

Paul Podlech

Paul Podlech is a product manager for the LANEXO® System Merck's Digital Chemistry program.

He joined Merck in 2017 and LANEXO® in 2020 and worked across different roles including marketing, quality, product ownership, and product management. His passion is to combine the skills he learned during his Business-Informatics studies with Life-Science to digitalize life in the lab.

Chemical waste - the true cost of inefficient waste management

Chemical inventories are essential for safety, good management and compliance. A recent C&EN survey uncovered key trends and challenges in using a chemical inventory.

The survey:

Commissioned from C&EN by MilliporeSigma

Over **1,000** professional respondents

In-depth interviews with selected respondents

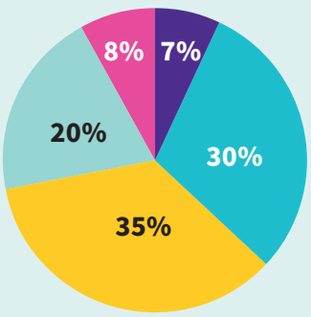
84% of respondents based in North America

How are chemical inventories used now?

Impact of pandemic:

Remote access to real-time chemical inventories more important

11% of respondents said pandemic had changed their perspective



Satisfaction with current CIMS

- very satisfied
- satisfied
- neutral
- somewhat dissatisfied
- not at all satisfied

Which systems are used?

41% chemical inventory management system (CIMS)

39% laboratory information management system (LIMS)

31% electronic lab notebooks (ELN)

29% None of these

8% other

What are the common problems with CIMS?

An inefficient inventory system causes inefficiency, higher costs and greater risks.

Most important issues in chemical inventory management:

97% finding data when you need it

95% easy access to data when you need it

87% automated data capture from instruments

74% relating data from different brands of instruments

62% data accessibility from any device

56% open-source data analysis software

Biggest challenges in chemical inventory management:

66% relating data from different brands of instruments

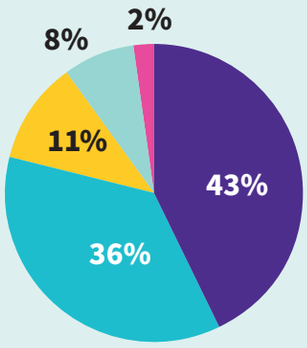
60% finding data when you need it

58% data accessibility from any device

56% easy access to data when you need it

53% open-source data analysis software

49% automated data capture from instruments



How often are inventory levels of chemicals and reagents checked?

- less than weekly
- weekly
- several times a week
- daily
- several times a day

Biggest pain points in managing chemical inventory

70% real time information and auto-updates

32% expired chemicals, waste disposal

17% training and support

16% finding chemicals when needed

15% need a CIMS

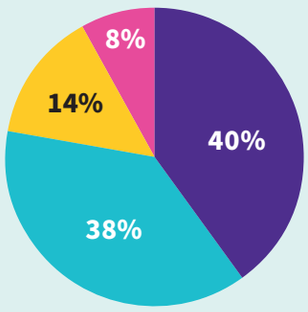
14% ordering and reordering

12% inventory descriptions

12% ease of use

11% compliance and regulation

11% chemical storage and safety



How prepared would you be for an unannounced chemical audit?

- prepared
- somewhat prepared
- very prepared
- largely or completely unprepared

25% of respondents said lack of materials meant:

Being unable to conduct an experiment at least 10% of the time

More than 3 work days were lost each month

17% of respondents lost 10% or more of their inventory each month due to spoilage or expiry

On average expired and hazardous waste disposal cost over $7,000 per month

How do CIMS assist compliance?

Lab safety and regulatory compliance were key aspects of managing a chemical inventory; **81%** of respondents follow at least 1 set of regulations.

Top 10 challenges in regulatory compliance:

- **28%** documentation and reporting
- **26%** keeping up with changing regulations
- **21%** disposal of expired chemicals and chemical waste
- **14%** training and support
- **13%** chemical storage and safety
- **12%** real time information and auto updates
- **12%** time spent
- **12%** SDS, CoAs
- **9%** audits and certifications
- **9%** interpreting regulations

Top 10 pain points regarding lab safety:

- **47%** training and support
- **34%** chemical storage and safety
- **33%** enforcing compliance
- **21%** facility, equipment, space
- **14%** expired chemicals and waste disposal
- **7%** labels, RFID tags etcdisposal
- **5%** need a CIMS
- **5%** real-time information, auto updates
- **5%** time spent
- **5%** keeping current on regulations

Better CIMS is a smart investment

CIMS are essential to productivity and safety for companies that work with chemicals. A weak system leads to considerable cost in the form of lost productivity and wasted resources.

28% of respondents were dissatisfied with their current CIMS

A CIMS should:

- Allow multiple users
- Detail location and amount of chemicals
- Provide reliable real-time information
- Track expired chemicals

The LANEXO® Lab Inventory, Safety and Compliance Management System uses RFID tags and a mobile app to:

- Reduce time wastage through better monitoring
- Manage compliance and safety risks through automation
- Avoid errors through easy specification and identity checks

WILEY

MilliporeSigma

CASE STUDY: THE LANEXO® INVENTORY MANAGER AND LABORATORIO FARMACEUTICO S.I.T.

The LANEXO® Inventory Manager transformed the inventory management process at Laboratorio Farmaceutico S.I.T. in Mede, Italy. Before implementing LANEXO®, they managed their inventory manually using Excel, which was time-consuming and prone to errors. With LANEXO®, they streamlined their inventory management, reducing reagent registration time and gaining better control over their stock. Analysts praised the system's efficiency and ease of use, particularly the location labels. While exact metrics weren't calculated, it's estimated that LANEXO® saved them approximately 250 hours per year.

Access the full case study at
www.lanexo.com/resources/blog