



NAVIGATING THE PHARMA REGULATORY LANDSCAPE: UNLOCKING THE BENEFITS OF 21 CFR PART 11 AND ISO 27001 COMPLIANCE

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INTRODUCTION

Navigating a complex regulatory landscape is one of the biggest challenges that organizations face in the pharmaceutical industry. Regulatory compliance not only safeguards patients and consumers but plays a pivotal role in establishing and maintaining trust within the industry. Yet it also presents a myriad of challenges. The ever-evolving nature of regulations requires organizations to be vigilant and flexible, often requiring substantial investments in human and technological resources. And striking a balance between compliance and technological innovation can lead to security concerns and operational challenges, particularly as organizations become increasingly data-driven.

On the other hand, compliance with regulatory standards also presents some opportunities. For instance, adhering to 21 CFR Part 11 and ISO 27001 can help organizations boost operational efficiency, lower costs, improve quality control measures, and adopt more robust cybersecurity and data integrity measures.

In this whitepaper, we will explore Part 11 and ISO 27001 in more detail and discuss their implications for those operating within the pharmaceutical industry. We will also discuss some of the unique compliance and operational challenges that pharma organizations face and conclude with some ways that your organization can leverage these regulatory frameworks to improve operational efficiency and achieve compliance.





TITLE 21 CFR PART 11: AN OVERVIEW

Title 21 of the Code of Federal Regulations Part 11, commonly referred to as “Part 11,”¹ establishes the U.S. Food and Drug Administration (FDA) regulations on electronic records and electronic signatures in the pharmaceutical and healthcare industries. The FDA enacted Part 11 to ensure the reliability, integrity, and authenticity of electronic records. The guidelines have become increasingly important in the age of digitalization – providing a framework for the secure use of electronic systems, which enhances data integrity and reduces the risk of fraud and errors in critical processes.

Part 11 consists of three subparts. Subpart A includes the general provisions. Subpart B includes the criteria for electronic records. And Subpart C governs electronic signatures. Under Part 11, organizations must implement controls, including audits and audit trails, system validations, electronic signatures, and documentation for software and systems that they use to process electronic data.

- **Electronic Records.** Under Part 11, electronic records include any combination of text, graphics, data, audio, pictorial, or other information that is represented in digital form and stored in a computer or a similar device. These records must be maintained in a way that ensures their accuracy, reliability, and consistency throughout their lifecycle.
- **Electronic Signatures.** Electronic signatures are defined as a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be legally binding.
- **Security Controls.** Security controls are intended to ensure the integrity and confidentiality of electronic records. Part 11 requires the implementation of security controls, which include user authentication, access controls, and data encryption, among others. User authentication, such as passwords or biometrics, helps to prevent unauthorized access to the system. Access controls can limit which information a specific user can access. Data encryption protects data during both transmission and storage.
- **Audit Trails.** Under Part 11, organizations must create and maintain detailed audit trails. An audit trail is a chronological record of system activities that provides a secure and computer-generated time-stamped accounting. This helps to ensure transparency and traceability in the event of an investigation or audit.
- **Systems Validation.** Part 11 emphasizes the validation of systems to ensure that they are accurate, reliable, and consistent. Organizations must document that all hardware and software components that are used for the creation, modification, maintenance, archiving, retrieval, or transmission of electronic records operate in a controlled and reproducible manner.

¹<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application>

- **Record Retention.** Part 11 lists requirements for the retention and archiving of electronic records, including the duration and accessibility of records. These regulations are meant to prevent the loss of data, deterioration, or corruption over time, making sure that records remain intact and readable during the specified period.
- **Standard Operating Procedures.** Organizations must establish and maintain Standard Operating Procedures (SOPs). SOPs are written procedures for the use of electronic systems. They cover system validation, user access, audit trails, and other elements designed to ensure compliance with Part 11.

The application of Part 11 in the pharmaceutical industry is widespread – applying to different aspects of manufacturing, quality control, and document management. Some examples of electronic records governed by Part 11 include electronic data capture systems and batch records.



ISO 27001: AN OVERVIEW

ISO 27001 is a globally recognized standard for information security management systems (ISMS).² The standard provides a systematic risk-based approach to identifying, managing, and mitigating information security risks, ensuring the confidentiality, availability, and integrity of data. Some of the key elements of ISO 27001 include conducting a risk assessment, establishing a set of information security policies, implementing security controls, and having a system in place to continuously monitor and improve the organization's ISMS.

Some of the ways that ISO 27001 benefits pharmaceutical organizations include:

- **Robust Risk Management.** ISO 27001 provides a structured and systematic approach to identifying, assessing, and mitigating information security risks. This framework allows organizations to proactively address vulnerabilities and threats.
- **Improved Confidentiality, Integrity, and Availability.** The standard's holistic approach, which emphasizes the confidentiality, integrity, and availability of data helps organizations to maintain the trust of stakeholders and customers.
- **Legal and Regulatory Compliance.** ISO 27001 compliance helps organizations meet complex and dynamic regulatory requirements.
- **Continuous Improvement.** Organizations that adopt ISO 27001 are committed to regularly reviewing and improving their information security measures. This commitment to continuous improvement better positions the organization to deal with evolving threats and technological innovations.
- **Competitive Edge.** ISO 27001 certification shows that an organization is committed to maintaining information security best practices, helping to instill confidence among clients and partners, and setting the company apart from competitors.

One of the largest obstacles for pharmaceutical organizations is harmonizing ISO 27001 with existing quality management systems and quality standards such as Good Manufacturing Practice or Good Laboratory Practice, which is necessary to ensure a unified approach to risk management, compliance, and continued improvement.

²<https://www.iso.org/standard/27001>

PHARMACEUTICAL INDUSTRY COMPLIANCE CHALLENGES

The pharmaceutical industry faces a unique mix of challenges that are largely attributable to complex regulations, evolving standards, and the rapid adoption of new technologies. Some of the most significant compliance challenges that pharmaceutical organizations face include:

Regulatory Complexity

Pharmaceutical organizations operate within a complex regulatory landscape with multiple agencies and global standards. For instance, in addition to Part 11, pharma organizations operating within the U.S. may also be subject to:

- Current Good Manufacturing Practice (cGMP) regulations as provided in 21 CFR Part 210 and 211.
- Drug Enforcement Administration (DEA) regulations.
- New Drug Application (NDA) regulations as provided in 21 CFR Part 314.
- Good Clinical Practice (GCP) regulations as provided in 21 CFR Part 312.
- Pharmacovigilance requirements.
- Health Insurance Portability and Accountability Act (HIPAA) regulations.
- Drug Supply Chain Security Act (DSCSA) regulations.

Keeping pace with these and other evolving requirements requires organizations to invest substantial time and effort, although new digital technologies with regulatory compliance features can streamline many compliance processes.

“The number and complexity of regulatory requirements has increased substantially over recent years and this trend is set to continue in the near term. Responding to this increasingly complex regulatory environment is extremely challenging, especially as non-compliance can have a profound effect on cost, corporate reputations and, ultimately, patients’ lives.”

– Deloitte, The Challenge of Compliance in Life Sciences: Moving from Cost to Value³

³<https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/lshc-challenge-of-compliance.pdf>



Data Integrity and Security

Ensuring that electronic records and sensitive data are secure is a constant challenge. This is especially true given that more and more organizations are transitioning to electronic records systems and the rapid adoption of new technologies can lead to vulnerabilities.

Sensitive data is an obvious target of increasingly sophisticated cyber-attacks. A single breach can be devastating, leading to the loss of sales, trust, irreparable brand damage, and serious liability. Moreover, improper use of consumer data can lead to actions by state and federal authorities. In addition to implementing adequate cybersecurity measures, organizations need to stay up to date on the latest data protection regulations and determine which apply to them. For example, organizations transacting business in Europe may be subject to the General Data Protection Regulation (GDPR), while those that sell to customers in California and meet certain revenue or data handling thresholds may be subject to the California Consumer Privacy Act (CCPA).

Compliance with Part 11 and ISO 27001 standards can help organizations ensure that there are adequate measures in place to safeguard systems and information.

Supply Chain Compliance

Managing compliance across complex pharmaceutical supply chains that involve potentially many stakeholders presents a significant challenge. For example, the Drug Supply Chain Security Act (DSCSA) was enacted to enhance the security of pharma supply chains and reduce the distribution of counterfeit drugs. The Act establishes a system for tracing and tracking prescription drugs throughout the entire supply chain, from manufacturers to wholesalers, distributors, and dispensers. Technologies with data management and analytics capabilities, blockchain technology, and barcodes, and radio-frequency identification (RFID) can all play a role in managing supply chain compliance.



Finding Talent and Training

Much like other industries, pharma faces a significant talent shortage. For example, according to a McKinsey report,⁴ 80% of pharma-manufacturing organizations report a skills mismatch, leading to a decrease in productivity and innovation. Moreover, given that organizations struggle to find qualified workers, it is crucial to have programs in place to upskill staff and ensure that they are continuously updated on evolving regulations and best practices.

Risk Management

Given the significant data security challenges that pharmaceutical organizations face, it is critical to implement effective risk management strategies. Standards like ISO 27001 provide a comprehensive framework for adopting a risk-based approach to information security. And through continuous improvement, organizations can refine their information security measures to respond to new threats.

Risk management, however, extends beyond information security. Organizations must ensure the quality and safety of products through robust quality control measures, product testing, and adhering to the standards set by regulatory bodies. They must prepare for potential supply chain disruptions, such as material shortages, transportation issues, or geopolitical events. Effective risk management involves assessing these supply chain risks and mitigating them to ensure a consistent and reliable flow of critical materials.

Some other areas where risk management strategies are needed include reputation management, market competition, and environmental and security concerns. In terms of reputation management, any negative publicity related to issues such as defective products or recalls can result in a loss of business or trust, as well as stiff regulatory fines and potential lawsuits.

Achieving compliance in the pharmaceutical industry requires a multifaceted approach, which regulations like Part 11 and standards like ISO 27001 help lay the groundwork for. Let's explore some ways that your organization can be better prepared to overcome these and other challenges.

⁴<https://www.mckinsey.com/industries/life-sciences/our-insights/pharma-operations-creating-the-workforce-of-the-future>



OVERCOMING COMPLIANCE CHALLENGES IN THE PHARMACEUTICAL INDUSTRY

Successfully navigating compliance challenges in the pharma industry requires a proactive and strategic approach. The following are some ways that you can help your organization to become and stay compliant.



STAY UP TO DATE ON THE LATEST REGULATIONS

As we discussed above, regulations in the pharma industry are vast and can change often. It is important to regularly monitor local, national, and international regulations and standards that impact the industry. Selecting a compliance solution that is regularly updated by industry experts to comply with the latest regulations can help ensure that you remain up to date.



BUILD RESILIENT SUPPLY CHAINS

Establish relationships with reliable suppliers and adopt strategies to make your supply chains more resilient. For instance, developing contingency plans for disruptions. In addition, new digital technologies can make it easy to streamline time-consuming and tedious traceability tasks.



CONDUCT ROUTINE AUDITS

Regular internal audits and assessments help ensure that your processes are effective and align with regulatory requirements. They also help identify potential areas of improvement and take corrective action to mitigate compliance risks. If your organization is ISO 27001 certified, conducting routine audits is a requirement to keep your certification.



TRAIN AND EDUCATE EMPLOYEES

Ensure that employees receive routine comprehensive compliance training to ensure that they are up to date on the latest data protection, safety protocols, and any regulations that apply specifically to their roles. Invest in upskilling and retaining staff to mitigate ongoing talent shortages.



IMPLEMENT ROBUST DATA PROTECTION MEASURES

Develop comprehensive data protection policies to ensure that all sensitive data is kept private and secure. Some examples of effective data protection measures include data encryption, access controls, and vulnerability checks to minimize the risk of data breaches.



ESTABLISH A COMPLIANCE CULTURE

Foster a culture of compliance by emphasizing and thoroughly explaining its importance at all levels. Develop processes to encourage open communication to report potential compliance issues and ensure that employees understand the consequences of non-compliance.



PRIORITIZE QUALITY CONTROL

Implement robust and stringent quality control measures throughout the production process. Ensure that you regularly test products for compliance with applicable safety and quality standards. Address any issues that arise to prevent potential regulatory violations.



SEEK LEGAL AND REGULATORY ASSISTANCE

Consult with legal and regulatory experts to receive guidance on which regulations apply to your organization, what those regulations require, and the measures that you can implement to ensure continued compliance.



MONITOR AND EVALUATE PERFORMANCE

Identify and adopt key performance indicators (KPIs) to help you routinely monitor and evaluate compliance performance. For example, you could track the percentage of employees who have received compliance training. Use these metrics to identify trends, measure the effectiveness of your compliance initiatives, and make continuous improvements.



INVEST IN TECHNOLOGY

In many ways, the decision to invest in the right digital technologies is the most important step that your organization can take toward becoming and remaining compliant. These solutions can streamline time-consuming tasks while eliminating the occurrence of costly errors. For instance, with the right solutions you can streamline reporting processes, improve data accuracy, monitor key compliance metrics, and implement proactive maintenance strategies to ensure that equipment is always performing at an optimal level.

“Regulatory flexibility is not about dropping standards or compromising [good manufacturing practice] compliance, but rather improving synergies with better collaboration between regulators and manufacturing companies, while incorporating risk-based approaches. The future of quality in the pharmaceutical industry could be more innovative and efficient than ever, with digitalization and collaboration with regulatory agencies.”

– Pharmaceutical Technology⁵

⁵<https://www.pharmaceutical-technology.com/sponsored/regulatory-approval-in-the-covid-era-how-the-pandemic-changed-drug-development/>



HOW WE CAN HELP

Accruent provides a comprehensive suite of products and solutions that are specifically designed to help pharmaceutical manufacturers overcome the challenges they face and achieve their business goals. These products and solutions help manufacturers to achieve compliance with the latest regulations and standards, streamline document management processes, improve asset maintenance and management to boost productivity and product quality, and improve company-wide visibility and collaboration.

These solutions include:



Maintenance Connection is an industry-leading CMMS solution that helps pharmaceutical organizations analyze, manage, and track their assets throughout all stages of the lifecycle. This helps to save time, streamline maintenance tasks, improve maintenance care, lower costs, and ensure that you can continue to deliver safe and high-quality products.



Meridian is a best-in-class engineering document management system is backed by over 20 years of unmatched industry expertise and can help your organization to gain complete control and visibility over all critical assets and project files via a secure centralized repository. Meridian ensures that your employees always have access to up-to-date documentation and streamlines collaboration across all departments.



Observe enables manufacturers to connect, monitor, predict, and control multiple equipment types across their facilities. This real-time visibility empowers them to optimize maintenance and energy efficiency, improve air quality, and maximize employee wellness.

THE ACCRUENT AND KINSMEN GROUP PARTNERSHIP

Accruent and Kinsmen Group share a common mission: simplifying complex information management and building a more connected future through specialized solutions. Kinsmen Group leverages its deep experience in engineering, operations, and maintenance to transform data into high-value insights, driving digital success for asset-intensive industries worldwide. Their holistic and cost-effective approach, supported by technology partnerships and an agile delivery methodology, accelerates digital transformation.

Similarly, Accruent, as the global leader in workplace and asset management software, empowers pharmaceutical manufacturers by unifying people, systems, and data. Their solutions not only deliver operational excellence but also reveal new growth opportunities. With world-class expertise and professional services, Accruent helps companies maximize investments in people and assets to drive business growth and innovation. Together, these organizations provide a comprehensive, transformative roadmap for achieving digital mastery in the most demanding industries.

Get in touch today to learn more about how our industry-leading solutions can help transform your organization.

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