AI-Enhanced Compliance: Navigating FDA and ISO Requirements for Pharma Manufacturers

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Introduction

The U.S. Food and Drug Administration (FDA) and International Organization for Standardization (ISO) guidelines for the pharmaceutical industry were developed to ensure that new therapies are manufactured according to the highest possible standards of quality, safety, and effectiveness. Experienced industry professionals can testify that it's challenging to fully understand and adhere to these stringent pharma regulatory compliance requirements. To help industry professionals understand the information they need to know to manufacture compliant, high-quality, safe, and effective products, this e-book offers overviews of the key FDA regulations and ISO standards that apply to pharma companies.

Simply understanding the rules of pharma regulatory compliance isn't enough, however. For many pharma manufacturers, the road to achieving and maintaining regulatory compliance is loaded with obstacles like inefficient manual processes, a lack of quality standardisation, and poor visibility into manufacturing operations. To empower you to overcome such challenges, this e-book also details the many ways that your compliance journey can be streamlined by using modern, AI-enhanced pharmaceutical compliance software solutions like MasterControl's quality management and manufacturing execution systems.

Your first step on the path to comprehensive pharma regulatory compliance starts here.

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21 CFR Part 11 Compliance Requirements

21 CFR Part 11 is a set of regulatory requirements enforced by the FDA that govern the use of electronic records and electronic signatures in companies whose products are FDA regulated. **21 CFR Part 11 guidelines** were enacted to ensure the authenticity, integrity, and reliability of electronic records and signatures used in pharma and other regulated industries while enabling quality and manufacturing professionals to embrace technological advancements such as purpose-built pharmaceutical compliance software.

Pharma quality and manufacturing professionals should be aware of the following key elements of 21 CFR Part 11 for which criteria have been established.

Electronic Records

21 CFR Part 11 guidelines define what constitutes an electronic record and set the requirements for their creation, maintenance, and archiving. They emphasise the need to ensure that electronic records are accurate, legible, and retrievable throughout their intended retention period.

Electronic Signatures

The criteria for electronic signatures, which are the digital equivalent of handwritten signatures, are outlined in FDA 21 CFR Part 11. These signatures are used to authenticate electronic records, and 21 CFR Part 11 compliance requires them to be unique to the individual, securely managed, and linked to corresponding records.

Audit Trails

21 CFR Part 11 compliance requires companies to implement secure and computer-generated audit trails for electronic records. Audit trails track any changes made to electronic records, allowing for a comprehensive view of the record's history, including when and by whom changes were made.

User Authentication and Authorisation

21 CFR Part 11 guidelines call for the establishment of procedures that ensure only authorised individuals have access to electronic records and can perform specific actions, such as creating, modifying, or approving records. User authentication processes must confirm user identity.

Training

21 CFR Part 11 guidelines require companies to provide adequate training to personnel who use electronic systems and maintain thorough electronic records that document their understanding of the regulatory requirements and proper procedures.

Validation

Any electronic system used for regulated activities must be validated to demonstrate that it performs as intended and meets 21 CFR Part 11 compliance requirements. Validation involves testing and documenting system functionality, security measures, and data integrity controls.

Data Integrity

The underlying principle of FDA 21 CFR Part 11 is the importance of maintaining the integrity of electronic records and signatures and ensuring they are accurate, reliable, and unaltered. To prevent unauthorised changes or deletions, it's critical to have adequate and appropriate controls in place.

Security

FDA 21 CFR Part 11 highlights the need for robust security measures that protect electronic records from unauthorised access, alteration, or destruction. These measures encompass both procedural safeguards (like access controls) and technical safeguards (such as encryption).

Record Retention and Retrieval

21 CFR Part 11 guidelines specify requirements for record retention periods and retrieval capabilities. Electronic records must be available for inspection, review, and copying throughout their retention period.

The Cost of 21 CFR Part 11 Compliance Failures

Noncompliance with Part 11 can result in tragic consequences, such as product recalls or legal actions. If your products are subject to FDA oversight, you must ensure your electronic record-keeping practices align with the 21 CFR Part 11 compliance guidelines devised to help uphold product quality. Read on to learn how modern digital tools facilitate compliance with 21 CFR Part 11.

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Simplifying 21 CFR Part 11 Compliance With With Modern, AI-Enabled Digital Tools

To meet 21 CFR Part 11 guidelines, a digital document and process management system is essential. Modern tools like MasterControl's specialised, intelligent solutions have been designed to simplify 21 CFR Part 11 compliance for today's quality and manufacturing professionals. For pharmaceutical companies that have embraced compliance software — especially solutions with embedded AI tools — 100% compliant processes and documentation isn't aspirational, it's achievable. Software built for 21 CFR Part 11 compliance can unify the goals of your quality and manufacturing departments and turn regulatory compliance into a business accelerator by providing efficiencies and benefits that include those listed below.

Controlled, Audit-Ready Records

Digitisation helps quality and manufacturing departments ensure that documentation is complete, compliant, and readily available. Modern 21 CFR Part 11 compliance software protects all electronic records within a secure document repository accessible only to authorised users. Based on rights, users can search for and immediately retrieve records identified as permissible.

Reliable Electronic Signatures

A robust pharmaceutical compliance software solution will provide fields for all the information required for FDA 21 CFR Part 11-compliant signatures, including name, date/time of signing, and meaning of signature. Also, the solution should automatically link every signature to a specified record.

Automated Audit Trail Capture

The FDA expects electronic record users to have a system in place to capture secure, computer-generated, and time-stamped audit trails to independently record the date and time of entries and actions involved in creating, modifying, or deleting. Modern digital tools are designed to automatically capture and maintain this information and export it in human-readable format.

User Authentication/Authorisation Enforcement

A robust 21 CFR Part 11 compliance software solution will offer multiple levels of security to ensure the authenticity of each user, document, and electronic signature in the system. Users should only be able to gain access using a unique ID and login password that cannot be duplicated or transferred. Separate, unique IDs and passwords may be required for approvals.

Comprehensive Training and Training Records

Digital solutions facilitate the creation and deployment of simple or extensive required training courses for compliance. Furthermore, using AI to streamline tasks like exam creation ensures users remain competent without wasting resources. Trainees can be automatically tasked when essential documents change and new training becomes necessary. Modern software also automates the follow-up and escalation of past-due training and creates audit trails for all training data and records.

Accelerated Validation

To alleviate the validation burdens faced by any company seeking 21 CFR Part 11 compliance, providers of proven software solutions have developed pioneering and patented tools that allow their customers to dramatically accelerate validation time. A robust solution will also ensure that all audit trails are revalidated with each update.

Sustained Data Integrity

A reliable digital system reduces the risk of data loss, tampering, or unauthorised modification. Using purpose-built software ensures the integrity of the data in your electronic records and establishes a secure foundation for advancements in AI-powered tools. Proven solutions promote the reliability and accuracy of data throughout your records' entire life cycles.

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21 CFR 210 and 211 Compliance Requirements

21 CFR Part 210 and 21 CFR Part 211 are two related federal regulations pertaining to the quality, safety, and efficacy of pharmaceutical products manufactured and distributed within the U.S. Part 210 clarifies the scope, applicability, and key terms related to minimum current good manufacturing practices (**cGMP**) for pharmaceuticals. Part 211 outlines cGMPs and controls to assure the integrity of finished pharmaceuticals. Together they provide the pharma regulatory compliance framework that manufacturers and quality professionals must use to develop detailed processes and controls to produce and market drugs in the U.S. Noncompliance with these regulations can lead to regulatory actions and sanctions by the FDA. The main points are summarised below.

Organisation and Personnel

Manufacturers must have a clear organisational structure and an adequate number of regularly trained personnel responsible for various aspects of drug production. This includes a quality control unit responsible for approving or rejecting drug products.

Written Procedures

All responsibilities and procedures relating to any pharmaceutical manufacturing practice and quality control must be in writing and followed, including training, facilities and equipment maintenance, storage, packaging, etc. Deviations must be justified and recorded, including time limitations when appropriate.

Buildings and Facilities

Manufacturers' facilities must be a suitable size, cleaned, maintained, and facilitate orderly operations. Plumbing and environmental conditions must be maintained to preserve drug integrity and prevent contamination.

Equipment

Equipment design, size, and location must be suitable for intended use and uniquely identified. Equipment must be regularly cleaned, sanitised, maintained, and calibrated as necessary. Usage and cleaning logs must be maintained. Contact surfaces must not alter drug integrity. Automated equipment, including computers, must be regularly validated to assure performance.

Components, Drug Product Containers, and Closures

Manufacturers must handle raw materials, components, and closures properly to ensure drug quality and prevent contamination and mix-ups. They must be stored off the floor and spaced to permit cleaning and inspection. Sampling and testing protocols and responsibilities must be specified. Status must be identified and oldest stock used first.

Production and Process Controls

In-process controls, tests, and/or examinations must be conducted on appropriate samples of each batch to assure uniformity and integrity of drug products. Measures and yields of components and products must be accounted for throughout the manufacturing process.

Labels and Packaging

Manufacturers must develop and follow procedures to prevent contamination and mix-ups. Labels must match the master production record specs and clearly identify the strength, quantity, lot, and control number of drug products. Excess labeling must be destroyed.

Distribution, Complaint Handling, and Reviews

Manufacturers must document and follow procedures for proper distribution and handling of complaints about drug products. Quality control reviews should be conducted at least annually.

Records and Reports

Comprehensive documentation, including production records and quality control reports, must be maintained to demonstrate compliance with cGMP. Records should be maintained for one year after expiration date and must be readily available for authorised inspections.

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Simplifying 21 CFR 210 and 211 Compliance With With Modern, AI-Enabled Digital Tools

Digitisation plays a significant role in helping companies adhere to the **guidelines set forth in 21 CFR Parts 210 and 211**. It lets manufacturers modernise their operations, improve efficiency, and produce consistently higher-quality products. Those benefits can be extended even further with the aid of digital, intelligent, and natively connected pharmaceutical compliance software solutions that support integration. Some of the compliance-related benefits of advanced digital tools like MasterControl's purpose-built solutions are outlined below.

Document Control and Management

Manufacturers that transition from paper-based documentation to electronic document management systems can ensure that documents, including standard operating procedures (SOPs), batch records, and specifications, are centrally stored, easily accessible, version-controlled, and searchable. Changes and approvals can be tracked and verified electronically.

Data Integrity and Traceability

Digital systems provide robust audit trail capabilities, ensuring the integrity and traceability of data. This aligns with the requirement to maintain accurate and complete records. Electronic forms reduce errors by their very nature. Electronic signatures and user authentication enhance data security and accountability.

Change Management

Changes to procedures, equipment, or processes can be documented, reviewed, and approved electronically. Automated workflows can ensure that changes follow proper approval routes and are implemented consistently, reducing the risk of noncompliance. Automatically generated audit trails and time stamps fulfill documentation requirements.

Training Management

Training materials can be stored, tracked, and assigned based on roles. Automated reminders ensure that personnel stay up to date with required training. Electronic enforcement mechanisms prevent unqualified personnel from violating requirements and AI features allow for streamlining exam creation to ensure competency and compliance.

CAPA Management and Root Cause Analysis

Companies can electronically record and track any quality event, including deviations and nonconformances. Automating and routing corrective action/preventive action (CAPA) processes facilitates root cause analysis, corrective action planning, and preventive action implementation.

Data Analytics and Reporting

Better utilisation of data through reporting and predictive analytics tools is a crucial efficiency and provides a competitive edge. Specialised, intelligent solutions make it possible to proactively identify trends, monitor key performance indicators (KPIs), and make data-driven decisions to improve processes, reduce variability, and enhance product quality.

Supplier and Audit Management

Digital systems allow companies to maintain electronic records of supplier qualifications, audits, and communications. Solutions geared toward supplier and audit management help to ensure the quality of raw materials and components, efficiently maintain partnerships, and verify compliance efforts both internally and externally.

Risk Management

Digital platforms aid significantly in risk assessment and management by incorporating systematic risk identification, analysis, and mitigation into operations. Companies using purpose-built digital tools are better suited to prioritise risks and effectively implement controls.

Validation and Compliance

Digitised systems must be validated (and revalidated when necessary) to ensure they perform as intended and meet regulatory requirements. Reputable software vendors offer validation tools for use with their products that streamline validation efforts and facilitate more frequent upgrades.

Remote Monitoring and Collaboration

Digitisation enables remote monitoring of critical processes, equipment, and data. This degree of connectivity is being leveraged more for remote inspections and is especially important when remote work or social distancing is required. Cloud-based systems offer the added benefit of being simultaneously available to multiple stakeholders in different locations, 24/7.

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ISO 9001 Compliance Requirements

ISO 9001 is a globally recognised standard for quality management systems (QMS) that provides a framework to help organisations ensure the consistent delivery of products and services that meet customer and regulatory requirements. The **ISO 9001 quality management system standard** gives companies a systematic approach for enhancing their processes, improving customer satisfaction, and driving continuous improvement. It empowers organisations to create a culture of quality that permeates every aspect of their operations, leading to long-term success and sustainability. The standard can be adapted to various industries and organisational sizes, and it emphasises a process-oriented approach to quality management that focuses on well-defined processes, clear responsibilities, and a commitment to continuous improvement.

The ISO 9001 standard specifies various requirements organsations like pharma companies must meet for its QMS to be effective. These requirements are broadly categorised into the key areas listed below.

Scope

An organisation seeking ISO 9001 compliance must define the scope of its quality management system, specifying its boundaries and applicability.

Normative References

ISO 9001 refers to other standards and documents that provide guidance for the implementation of a QMS.

Terms and Definitions

The ISO 9001 standard defines key terms that pharma companies seeking compliance must know.

Context of the Organisation

ISO 9001 calls for the identification of the internal and external issues relevant to an organisation's purpose and strategic direction. This includes identifying the needs and expectations of interested parties (i.e., customers, regulators, employees, etc.).

Leadership

ISO 9001 requires organisations to demonstrate that they have the proper leadership for and commitment to the QMS. Leadership must establish a quality policy and ensure it is communicated and understood and that responsibilities and authorities are properly assigned.

Planning

To achieve ISO 9001 compliance, organisations must establish quality objectives that are measurable and consistent with the quality policy. They should also plan actions to address risks and opportunities.

Support

Organisations must be prepared to dedicate sufficient resources to an ISO 9001-compliant quality management system, including competent personnel, infrastructure, and suitable work environments. This entails ensuring the awareness and competence of employees. The standard also requires documents to be appropriately controlled and maintained as needed for the QMS.

Operation

Processes must be implemented to meet quality objectives and requirements. Compliant operations also entail properly addressing customer communications, determining requirements, and monitoring customer satisfaction. ISO 9001's process-oriented approach calls for organisations to define and manage their key processes, identify interactions between these processes, and continually refine them for improved efficiency and effectiveness.

Performance Evaluation

A QMS' performance must be continually monitored, measured, analysed, and evaluated. Conducting internal audits and management reviews helps the organisation assess the ongoing effectiveness of its QMS.

Improvement

To meet 9001's requirements, ISO compliance management calls for organisations to take actions to address nonconformities and continually improve the effectiveness of its QMS. This entails the use of corrective actions/ preventive actions (CAPAs) to prevent issues from recurring.

These are the high-level regulatory requirements outlined in ISO 9001:2015, the most recent version of the standard. The standard provides detailed guidelines for each of these areas, and organisations seeking ISO 9001 certification must comply with these requirements and demonstrate their implementation to a certification body.

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Simplifying ISO 9001 Compliance With Modern, AI-Enabled Digital Tools

The ISO 9001 standard serves as a comprehensive framework that helps companies like those in the pharma industry establish and maintain a QMS that drives customer satisfaction, process efficiency, and continuous improvement. But compliance isn't achievable if your company doesn't have a system that's up to the task. By implementing specialised regulatory compliance software that simplifies ISO 9001 compliance, pharma companies can improve their competitive positioning, build stronger customer relationships, and confidently navigate the complexities of today's regulatory environments. The following are just a few of the many benefits an ISO 9001-compliant intelligent, electronic quality management system (eQMS) like the one offered by MasterControl can provide to companies in the pharma industry.

Enhanced Process Efficiency

ISO 9001 requires organisations to document and improve their processes, with the intent of increasing efficiency, reducing errors, and better utilising resources. Modern eQMS solutions leverage automation and AI to streamline quality processes, enabling organisations to integrate the management of documents, quality events, change control, audits, and training within one centralised, intelligent platform.

Faster, Better Decision-Making

The ISO 9001 standard's emphasis on evidence-based decision-making is aimed at helping organisations make informed choices backed by data and analysis. With the advanced analytics, AI, and predictive reporting capabilities built into modern QMS software solutions, appropriate personnel have easy access to the information they need to make informed decisions quickly.

Comprehensive Risk Management

The applicable ISO guidelines for pharmaceutical industry are intended to help organisations identify and mitigate risks and avoid costly mistakes. An eQMS that unifies and enhances visibility into all risk-related activities can give a company an accurate, up-to-date, and more complete picture of the risk landscape across products, processes, and business units.

Expanded Market Access

ISO 9001 certification provides a competitive edge, as it demonstrates a commitment to quality and customer satisfaction. It also makes it easier to enter new markets and attract potential customers. Certification and customer satisfaction are much easier to obtain with a robust digital system that connects data and provides instant access to compliance-critical documentation.

Culture of Continuous Improvement

ISO 9001 encourages organisations to adopt a culture of continuous improvement, driving innovation and adaptation to changing market conditions. An eQMS not only provides an infrastructure for ISO compliance management but it also gives pharma companies better visibility into quality data and activities, which fuels the continuous improvement of quality management processes, business performance, and products.

Greater Employee Engagement

When employees are involved in the quality management process, it fosters a greater sense of ownership, empowerment, and commitment to the organisation's success. With modern pharmaceutical compliance software, personnel stay connected to the information they need to drive success. A proven eQMS automates the development and execution of training programmes to ensure employees are competent and regulatory training requirements are met.

Improved Customer Satisfaction

By focusing on understanding and meeting customer needs, organisations can enhance customer satisfaction and loyalty, leading to an increase in repeat business and positive referrals. A modern eQMS that integrates the processes involved in managing CAPAs, customer complaints, and quality events, positions pharma companies to delight customers with consistently high-quality products. QMS digitisation also enhances collaboration effectiveness, which helps streamline supplier management and ultimately improves the quality of pharmaceutical products.

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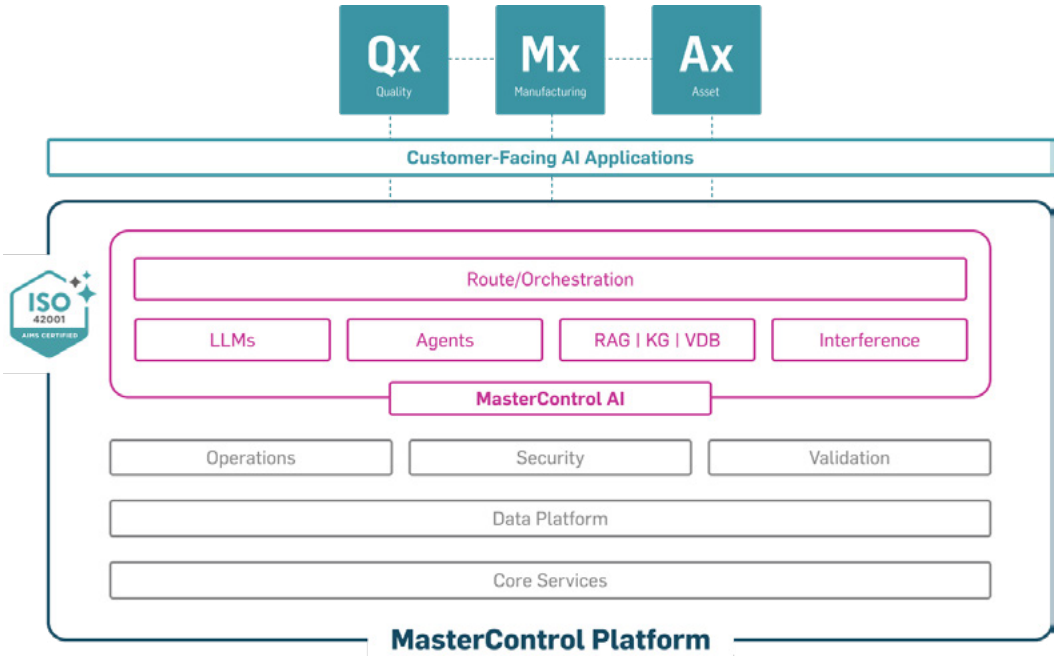
Building an Intelligent Digital Foundation: Unifying Quality, Manufacturing, and Asset Management

The perception that introducing a new QMS, MES, or asset management system can cost too much or disrupt operations too much shouldn't stop organisations from taking steps to achieve a digital transformation that can dramatically reduce compliance burdens. It doesn't have to be a daunting undertaking that's done all at once. The key to success with digitally mature compliance processes is taking an iterative approach and having departments in lockstep in each phase. Connected data is a foundational part of this approach.

Small steps toward digital maturity are easier to take when you have seamless integration between quality and manufacturing solutions. Having a common platform that unites quality and manufacturing teams enables them to work together to streamline digitalisation across their shared processes, shared workflows, shared data visibility, shared training platform for compliance, and much more.



About MasterControl

MasterControl Solutions Inc. is a leading provider of cloud-based quality, manufacturing, and asset management software for life sciences and other regulated industries. For three decades, our mission has been the same as that of our customers – to bring life-changing products to more people sooner. MasterControl helps organisations digitise, automate, and connect quality, manufacturing, and asset management processes and has a proven track record of improving product quality, reducing costs, and accelerating time to market. Over 1,100 companies worldwide use MasterControl to streamline operations, maintain compliance, manage critical assets and equipment, easily analyse and interpret large amounts of data, and visualise business insights in real time.

For more information, visit **www.mastercontrol.com**.