Ensuring regulatory compliance is a top priority for organizations operating in FDA-regulated industries like **pharmaceuticals, biotechnology, and medical devices**. With strict requirements such as **21 CFR Part 11**, **Good Manufacturing Practices (GMP)**, and **Quality System Regulations (QSR)**, businesses must establish strong controls over electronic records, workflows, and system access.

**ServiceNow** provides a powerful platform to support compliance efforts, but out-of-the-box functionality needs to be carefully configured to align with regulatory requirements. Leveraging **Governance, Risk, and Compliance (GRC)** and **Integrated Risk Management (IRM)** capabilities within ServiceNow can significantly enhance compliance by automating key controls, improving audit readiness, and reducing operational risks.

This white paper explores the **best practices** for implementing **FDA compliance** in ServiceNow, outlines key controls needed across different modules, highlights common challenges, and provides a structured implementation plan with actionable steps.

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## Key FDA Compliance Requirements for ServiceNow

To meet **FDA regulations**, organizations must implement the following:

1. **Electronic Records & Signatures (21 CFR Part 11)**

   o   Enforce user authentication, audit trails, and system validation for regulated data.

   o   Implement **ServiceNow Approvals Engine** to ensure compliant digital signatures.

   o   Use **Audit Management in GRC** to track signature approvals and validation logs.

2. **Data Integrity & Security**

   o   Ensure data accuracy, prevent unauthorized access, and maintain traceability.

   o   Leverage **ServiceNow Security Incident Response (SIR)** to manage potential breaches.

   o   Use **GRC Policy and Compliance** to enforce regulatory security policies.

3. **Change & Configuration Management**

   o   Establish documented approvals and strict version control.

   o   Use **Change Management in ITSM** with mandatory **Risk Assessment workflows**.

   o   Implement **CMDB CI versioning** to maintain change history and compliance tracking.

4. **Incident & Problem Management**

   o   Use a risk-based approach for handling and resolving compliance-related issues.

   o   Integrate **Problem Management with GRC Risk Register** to assess potential FDA risks.

o   Automate escalation of high-risk compliance incidents through **IRM workflows**.

5.  **Validation & Qualification**

   o   Validate ServiceNow instances to confirm they meet FDA's intended use requirements.

   o   Leverage **GRC Continuous Monitoring** for ongoing validation tracking.

   o   Maintain validation records and system qualification documents in **ServiceNow Document Management**.

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## FDA Compliance Controls by ServiceNow Module

**1. Change Management (21 CFR Part 11, GMP)**

- Require **electronic approvals and signatures** for all system changes.
- Implement **workflow validation** to enforce structured review and approval processes.
- Maintain an **audit trail** capturing every change request, its rationale, and approvals.

**2. Configuration Management Database (CMDB) (GMP, QSR)**

- Ensure **full traceability** of IT assets and configurations tied to regulated systems.
- Implement role-based **access controls** to protect critical configuration data.
- Leverage **ServiceNow IRM to track configuration changes** and assess compliance risks.

**3. Incident & Problem Management (QSR, GMP)**

- Classify incidents based on regulatory risk levels.
- Enforce **root cause analysis (RCA)** and Corrective and Preventive Actions (CAPA).
- Set up **automated compliance alerts** within ServiceNow GRC to escalate high-risk issues.

**4. Access Control & Security (21 CFR Part 11, Data Integrity)**

- Enforce **multi-factor authentication (MFA)** for all privileged users.
- Configure **role-based access controls (RBAC)** to restrict sensitive records.
- Maintain detailed **audit logs** for all user activities and leverage **GRC for access governance**.

**5. Validation & Testing (21 CFR Part 11, GMP)**

- Develop and maintain a **Validation Master Plan (VMP)** within ServiceNow.
- Conduct periodic **user acceptance testing (UAT)** to confirm compliance alignment.
- Use **ServiceNow GRC for automated policy compliance tracking and validation records**.

Here's a revised and more detailed version with additional guidance:

## Challenges in Implementing FDA Compliance on ServiceNow

While **ServiceNow** provides a robust framework for **compliance management**, organizations in **FDA-regulated industries** often face challenges when aligning their instance with regulatory requirements. Successfully achieving and maintaining compliance requires overcoming the following obstacles:

### 1. Balancing Customization vs. Standardization

- **Challenge:** Excessive customization of ServiceNow can make validation efforts more complex and time-consuming, increasing the risk of non-compliance. Standardization, on the other hand, ensures easier maintenance but may not fully meet business needs.

- **Guidance:**

    o   Adopt **configuration over customization** to align with FDA requirements while minimizing validation complexity.

    o   Use **ServiceNow's Application Portfolio Management (APM)** and **IRM** to assess the impact of customizations before implementation.

    o   Implement **version control policies** to track changes and maintain regulatory consistency.

    o   Leverage **out-of-the-box (OOB) GRC/IRM capabilities** for policy management and regulatory workflows.

### 2. User Adoption & Training

- **Challenge:** Employees may find **FDA-compliant workflows** rigid and cumbersome, leading to workarounds that introduce compliance risks.

- **Guidance:**

    o   Provide **role-specific training** to ensure employees understand compliance responsibilities.

    o   Use **ServiceNow HR Service Delivery (HRSD)** for structured training plans and policy acknowledgments.

    o   Implement **inline guidance and tooltips** within ServiceNow to educate users during their workflows.

    o   Set up **automated reminders** for compliance-related tasks using **ServiceNow Flow Designer** to reinforce best practices.

### 3. Data Governance & Integrity

- **Challenge:** Maintaining accurate, validated data across multiple ServiceNow modules can be difficult, especially when integrating with external systems.

- **Guidance:**

  - Implement **data validation rules** and **automated reconciliation processes** to ensure integrity.

  - Use **ServiceNow CMDB** with **Configuration Compliance** to track regulated IT assets and maintain accurate metadata.

  - Set up **audit logs** and enforce **electronic signature requirements** for data changes using **IRM and GRC controls**.

  - Regularly review **data retention policies** to comply with FDA regulations while optimizing performance.

## 4. Audit Readiness & Evidence Management

- **Challenge:** Maintaining continuous compliance and keeping up with documentation requirements is **time-intensive** and prone to human error.

- **Guidance:**

  - Utilize **ServiceNow GRC's Policy and Compliance Management module** to automate regulatory documentation tracking.

  - Implement **real-time compliance monitoring dashboards** to assess readiness for audits.

  - Use **ServiceNow's Document Intelligence and AI-driven categorization** to efficiently manage compliance-related evidence.

  - Schedule **automated audit logs and reporting** using **Performance Analytics** to proactively address gaps.

## 5. Enforcing Change Management Controls

- **Challenge:** FDA regulations require **strict change control processes**, including documented approvals and electronic signatures. However, users often resist these additional steps, viewing them as administrative burdens.

- **Guidance:**

  - Configure **ServiceNow Change Management** to require **multi-level approvals** for regulated systems.

  - Use **IRM's Continuous Authorization Monitoring (CAM)** to enforce policy-based approvals.

  - Automate **change risk assessments** to categorize changes based on FDA impact.

      o    Implement **ServiceNow DevOps Change Acceleration** to integrate compliance-driven controls without slowing innovation.

By leveraging **ServiceNow IRM and GRC**, organizations can **streamline compliance workflows, enforce policies in real-time, and generate automated compliance reports**, reducing manual effort while ensuring **continuous audit readiness**.

Would you like any additional areas explored in more depth?

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## FDA Compliance Implementation Plan for ServiceNow

**Phase 1: Assessment & Planning**

- Identify all ServiceNow modules handling FDA-regulated data.

- Conduct a **gap analysis** to evaluate current processes against FDA requirements.

- Define a **compliance governance framework** using ServiceNow GRC.

**Phase 2: Configuration & Control Implementation**

- Configure **electronic approvals & audit trails** in Change Management.

- Implement **role-based access controls (RBAC)** across ServiceNow.

- Enforce **incident classification based on compliance risk**.

- Utilize **ServiceNow GRC for compliance automation**.

**Phase 3: Validation & Documentation**

- Develop a **Validation Master Plan (VMP)** and document validation procedures.

- Perform **system validation and user acceptance testing (UAT)**.

- Establish ongoing **monitoring and audit capabilities** within ServiceNow IRM.

**Phase 4: Training & Continuous Compliance**

- Provide **compliance training** to employees.

- Conduct **regular compliance audits** using automated reporting from GRC.

- Monitor **emerging FDA regulations** and update controls as needed.

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## Checklist for Ensuring FDA Compliance in ServiceNow

- ✓ User authentication and multi-factor security controls are in place.
- ✓ Change Management requires electronic approvals with an audit trail.
- ✓ CMDB maintains accurate, validated configuration data.

✓ Incident Management classifies issues based on compliance risk.
✓ Access controls enforce least privilege and role-based restrictions.
✓ Validation processes align with **21 CFR Part 11** and **GMP** guidelines.
✓ A governance team oversees ongoing FDA compliance within ServiceNow.
✓ **ServiceNow GRC/IRM is utilized for continuous compliance monitoring and automation**.

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## Conclusion

Successfully applying **FDA compliance** to a **ServiceNow instance** requires thoughtful planning, the right system controls, and a proactive approach to enforcement. Organizations must strike a balance between **functionality and compliance**, ensuring that ServiceNow enhances efficiency rather than creating additional barriers.

By leveraging **ServiceNow GRC and IRM**, businesses can automate compliance processes, enforce critical controls, and maintain audit readiness with greater ease. A well-configured ServiceNow instance ensures not just compliance, but also operational efficiency and long-term sustainability in FDA-regulated industries.

**Need help implementing FDA compliance in ServiceNow?** Contact our team for expert guidance on best practices and tailored solutions.

## About Mana'o Pili ↘

Mana'o Pili is a Hawai'i based technology consulting firm specializing in business automation through ServiceNow. Mana'o Pili provides its customers with individualized solutions. We reject the notion of one-size-fits-all solutions. Instead, we partner with you to craft a tailored plan that aligns with your unique needs, budget, and objectives. Our approach focuses on optimizing your existing platform while minimizing customization and reducing technical debt.

Here at Mana'o Pili, we treat our customers as 'ohana (family), listen closely to your challenges and deliver tailored attention with exceptional service.