

Strategic Compliance Solutions for a Dynamic GxP World.

Reduce compliance deviations by up to 45%
and achieve significant training cost savings
with tailored solutions that go beyond
workflow integration.



KaDo Consulting



Overview

▶▶▶	The KaDo Consulting Approach	03
▶▶▶	The KaDo Philosophy	05
▶▶▶	Building Sustainable Compliance	06
▶▶▶	Cost of inadequate Training	09
▶▶▶	Learning beyond Static SOPs	10
▶▶▶	Decision Enabler Knowledge Mgmt	12
▶▶▶	3 use cases	14
▶▶▶	Why KaDo Consulting	17



The KaDo Consulting approach

Our Perspective:

- Despite decades of advancements in technology and regulatory frameworks, persistent GxP issues in quality compliance highlight the need for a paradigm shift. KaDo Consulting adopts a holistic approach where Training, Knowledge Management, and Change Management work together to tackle these root causes effectively.

We do it better:

- Transforming compliance from a cost to a competitive advantage.
- AI-driven learning, dynamic knowledge, and adaptable training.
- 45% reduction in compliance deviations and 40% lower training costs.

**up to 45% Reduction in
Compliance Deviations**
(Deloitte 2023)



**Empowering your teams for lasting
compliance success.**

Hi, I'm Raik Knieknecht, founder of KaDo Consulting, with 20+ years of experience in GxP Training & Change Management.

KADO CONSULTING KEY ADVANTAGES

Industry-leading time-to-compliance

- **33%** faster issue resolution vs. traditional approaches.
- Workflow-embedded learning reduces training time by **40-50%**, with documented cost savings of **15-30%**.

Sustainable knowledge retention

- **62%** reduction in repeat errors through AI-powered knowledge systems.
- **28%** improvement in process accuracy with workflow-embedded learning, and **40%** reduction in unintentional compliance violations.

Change-resilient teams

- Workflow-embedded learning boosts SOP adoption and triples training completion rates, with **2x higher** satisfaction.
- **18-month** ROI from reduced training costs and compliance violations post-KM implementation.

With KaDo Consulting, compliance becomes a strategic asset – enhancing business agility and driving sustainable growth.

The KaDo Consulting PHILOSOPHY

For 20 years, inspection findings have remained largely unchanged. By aligning training, knowledge, and change management, KaDo Consulting not only ensures regulatory compliance but also achieves a 28% improvement in process accuracy and a 40-50% reduction in training time—addressing root causes rather than symptoms.

KaDo's integrated approach to Training, Knowledge, and Change Management creates a dynamic, adaptable compliance process.

This holistic strategy covers all aspects of compliance—from initial training to sustained knowledge retention and behavioral change.



20 Years of GCP Inspections: Time for a Paradigm Shift

KaDo Consulting: Transforming Compliance Challenges into Sustainable Solutions.

Persistent Findings*



- Protocol deviations
- Data integrity issues
- Inadequate informed consents
- Lack of sponsor oversight

Root Causes



- Training treated as a checkbox exercise
- Limited integration of Knowledge Management
- Resistance to cultural change

The KaDo Approach



Task-Specific Training: Focused on real-world applications, drives immediate behavioral change



Sustainable Knowledge Management: Makes insights actionable and fosters continuous improvement



Change Management: Embeds compliance as part of culture, enabling proactive adaptation

*An analysis of GCP inspection findings over the past 20 years reveals a striking consistency: the same critical issues—protocol deviations, data integrity problems, inadequate informed consents, and sponsor oversight failures—continue to dominate. This highlights a persistent industry-wide struggle to address root causes, despite advancements in technology and regulatory frameworks.

Building Sustainable Compliance Through Capability & Knowledge

Is your staff truly qualified?

By integrating innovative learning and sustainable knowledge management, KaDo empowers GxP staff to excel.

Our unified compliance framework not only ensures regulatory adherence but builds a culture of capability. Through aligned training, knowledge, and change management, we equip teams with the skills and adaptability to meet regulatory demands and drive organizational growth.

Industry Pain Points

- **Training Gaps:** complex Learning Matrix, Surface-level training, outdated formats, limited modern tools.
- **Knowledge Deficits:** Poor retention, lack of integration with training.
- **Adaptation Challenges:** Difficulty adapting to new regulations, skill gaps.
- **Compliance Culture:** Reactive approach, misalignment with real-world application.
- **Resource Constraints:** High turnover, insufficient change support, challenges in measuring training impact.
- **Over-Reliance on SOPs:** Static SOPs as primary training tools.

Quantifiable Results with KaDo Consulting

Achieve sustainable compliance through integrated training and knowledge management
– proven to drive measurable impact.



Reduction in Compliance Violations

Studies show that combining training with knowledge management reduces compliance breaches by **45%**, while workflow-embedded learning improves process accuracy by **28%** and reduces training time by **40-50%**. (Deloitte, 2023; LinkedIn Learning, 2022; ATD, 2021)



Faster Problem Resolution

23% faster onboarding time and up to **30%** faster process implementation. Workflow-embedded learning enables quicker issue identification and resolution, helping organizations remain agile and responsive. (ATD, 2021)



Reduced Repeat Errors

20-25% fewer errors in process execution, with 30% higher accuracy in documentation. Structured knowledge management reduces compliance errors by making critical knowledge accessible and accurate. (LinkedIn Learning, ATD, 2021)



Cost Savings and ROI

Cost Savings and ROI
ROI achieved within **18 months**, with efficiencies reducing search & training time by **40-50%**. Investments in integrated training and KM systems yield quick payoffs by reducing compliance costs and streamlining processes. (LinkedIn Learning, KPMG, 2022)

Quantifiable Impact and ROI with KaDo's Integrated Compliance Approach

35-45%

Compliance Violations
Reduced

18 month

ROI for KM realized

30%

reduction of compliance
costs

40%

reduction in
training time

KaDo's integrated compliance solutions deliver swift, measurable impact—reducing compliance violations by up to **45%**, lowering compliance costs by **30%**, and achieving ROI within **18 months**.

Workflow-embedded learning also reduces training time by **40%**, ensuring sustainable compliance.

The cost of inadequate training

Compliance training is more than a requirement—it's a vital safeguard against costly risks in today's regulated world.

The Reality

Inadequate training leads to **costly errors**, **non-compliance**, and **reputational damage**. Poorly trained teams can expose companies to **financial losses worth millions**.



Case Example

The 2021 vaccine contamination case* highlights how a single **training gap** led to production delays, recalls, and losses estimated at **\$500 million to \$1 billion**. Effective training is more than compliance—it's essential risk mitigation.



Takeaway

Effective training, knowledge, and change management help prevent these risks, protecting your business from **catastrophic financial and reputational consequences**.



*<https://www.fda.gov/media/151710/download>

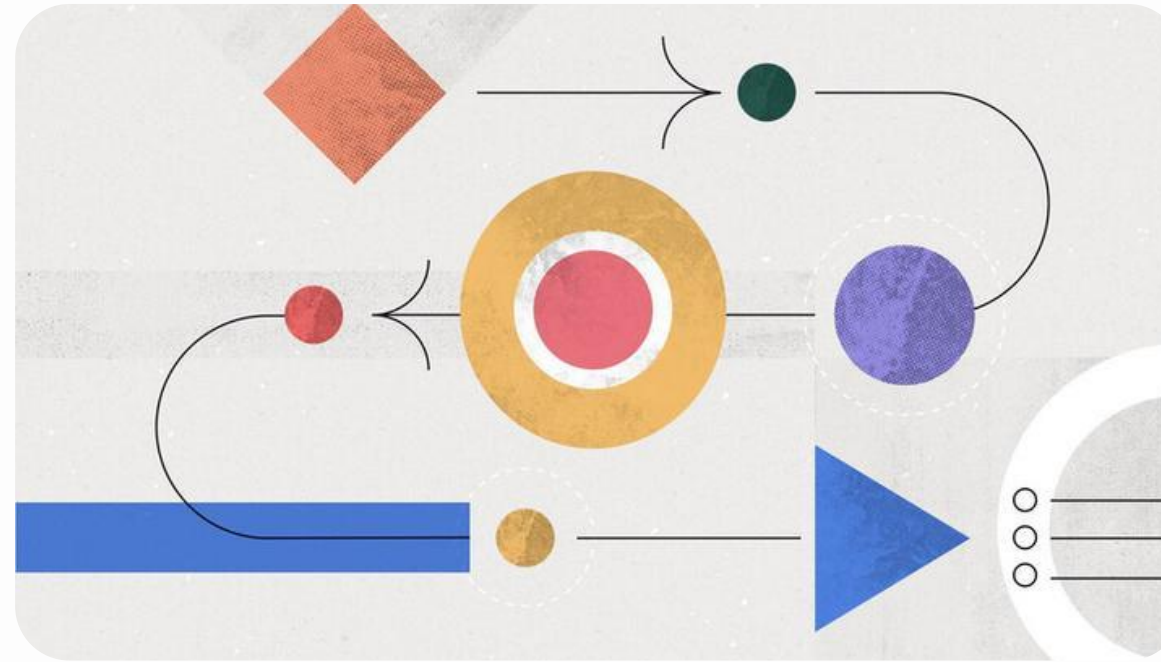
Beyond Static SOPs: Advancing Training and Knowledge Management in GxP

At KaDo Consulting, we advocate for TASK-specific training that transforms behaviors by addressing real-world challenges. Unlike static, role-based training, task-specific approaches adapt dynamically to evolving regulatory demands, driving immediate and measurable impact.



Challenging Tradition

Traditional PDF SOPs can't keep up with today's fast-paced, agile environments. We move beyond static documents to foster **real-time, workflow-embedded learning**.



The Solution

We help clients transition from static SOPs to dynamic, **workflow-embedded training** and knowledge solutions that integrate seamlessly into daily tasks.



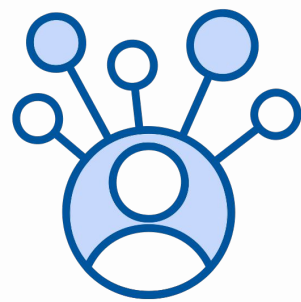
Value

Real-time access to critical knowledge ensures staff are empowered and compliant, enabling better decision-making and agility.



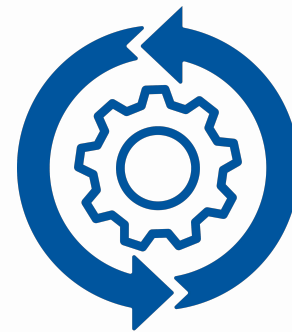
Workflow Learning

In today's dynamic GxP environments, traditional training methods fall short. Workflow learning and targeted automation provide a proactive approach to compliance by embedding knowledge directly into daily tasks, reducing the need for reactive oversight.



Modernizing Compliance

Automation and workflow learning enable proactive compliance management, reducing dependency on reactive audits and inspections.



How it works

Embedding training and SOPs into workflows creates a seamless learning environment that maintains staff qualification without disrupting operations.



Outcome

Enhanced efficiency and a forward-looking compliance culture.



Decision Enabler: Knowledge Management

In regulated industries, knowledge is only valuable when it's **accessible** and **actionable**. Sustainable knowledge management does more than store information; it **empowers teams** to make informed, compliant decisions at every step.

Integrating KM with training transforms knowledge into an **adaptive, strategic** resource rather than a static archive.

01

Sustainable Knowledge Management transcends static documentation by making insights actionable. At KaDo, we empower teams to use this knowledge to fuel innovation, adapt dynamically to evolving regulatory frameworks, and prevent recurring GxP findings.

02

Use Case: In GCP, a KM system that captures lessons learned from previous trials helps prevent costly mistakes in future studies. Integrated with training, KM drives continuous improvement.

03

KM fosters both compliance and operational excellence by transforming insights into actionable knowledge and driving proactive decision-making.



KaDo Consulting: Integrating Training, Knowledge, and Change for Lasting Compliance

KaDo Consulting combines training, knowledge, and change management into a comprehensive compliance framework that empowers your team to achieve lasting, proactive compliance.

Four core use cases to explore:

- **Knowledge Management Ecosystem** for Clinical Development – Ensures accessible, actionable insights.
- **GxP Learning Automation** – Streamlines compliance training through intelligent automation.
- **Bite-Sized Learning Factory** – Delivers modular, easily digestible training units.
- **GCP Virtual Instructor** – Provides AI-powered, real-time GCP guidance tailored to specific roles and regions.

Are your teams ready to thrive in today's fast-evolving regulatory landscape?

Use Case 1 – Knowledge Management Ecosystem for Clinical Development

Objective: Support Clinical Development teams in transitioning to agile methodologies while managing vast volumes of critical knowledge across 50 countries.

Challenge: Consolidate multi-source knowledge (50+ SharePoints) into one central KM system for 6,000 employees, providing each employee with the right information at the right moment to make informed decisions effectively.

Solution: KaDo Consulting implements a Knowledge Management platform using Appian to centralize knowledge and support continuous learning cycles.

Success Factors:

Just-in-time Learning

Contextualized Knowledge Delivery

Accessible Knowledge Base for Real-Time Application



30% faster issue identification enabled by real-time knowledge access and streamlined data consolidation through integrated KM systems (Deloitte, 2023).

Studies indicate that knowledge management systems can reduce employee search time by an average of **40-50%**, depending on the implementation and system maturity level.

Use Case 2 – GxP Learning Automation

Objective: Optimize GxP training management and reduce manual workload for Learning Admins.

Challenge: Eliminate repetitive administrative tasks by integrating robotic process automation (RPA) and supporting role-based learning.

Solution: KaDo Consulting deploys RPA solutions with Automation Anywhere to manage recurring tasks and streamline learning matrix administration.

Success Factors:

Automated Compliance Checks

Continuous Updates of Learning Content

Role-Based, Targeted Learning Paths



62% reduction in repeated errors

thanks to structured KM and automated processes (KPMG, 2022)

Reduction in FTE Studies indicate that automation typically reduces full-time equivalent (FTE) requirements by 30-40%, with some companies achieving up to 50% in exceptional cases.

Use Case 3 – Bite-Sized Learning Factory

Objective: In the context of GxP compliance, bite-sized, task-specific learning modules address persistent issues by embedding practical, actionable knowledge into daily workflows. This approach fosters immediate behavioral change and reduces repeat findings.

Challenge: Move away from static, long-form training to concise, highly targeted learning modules.

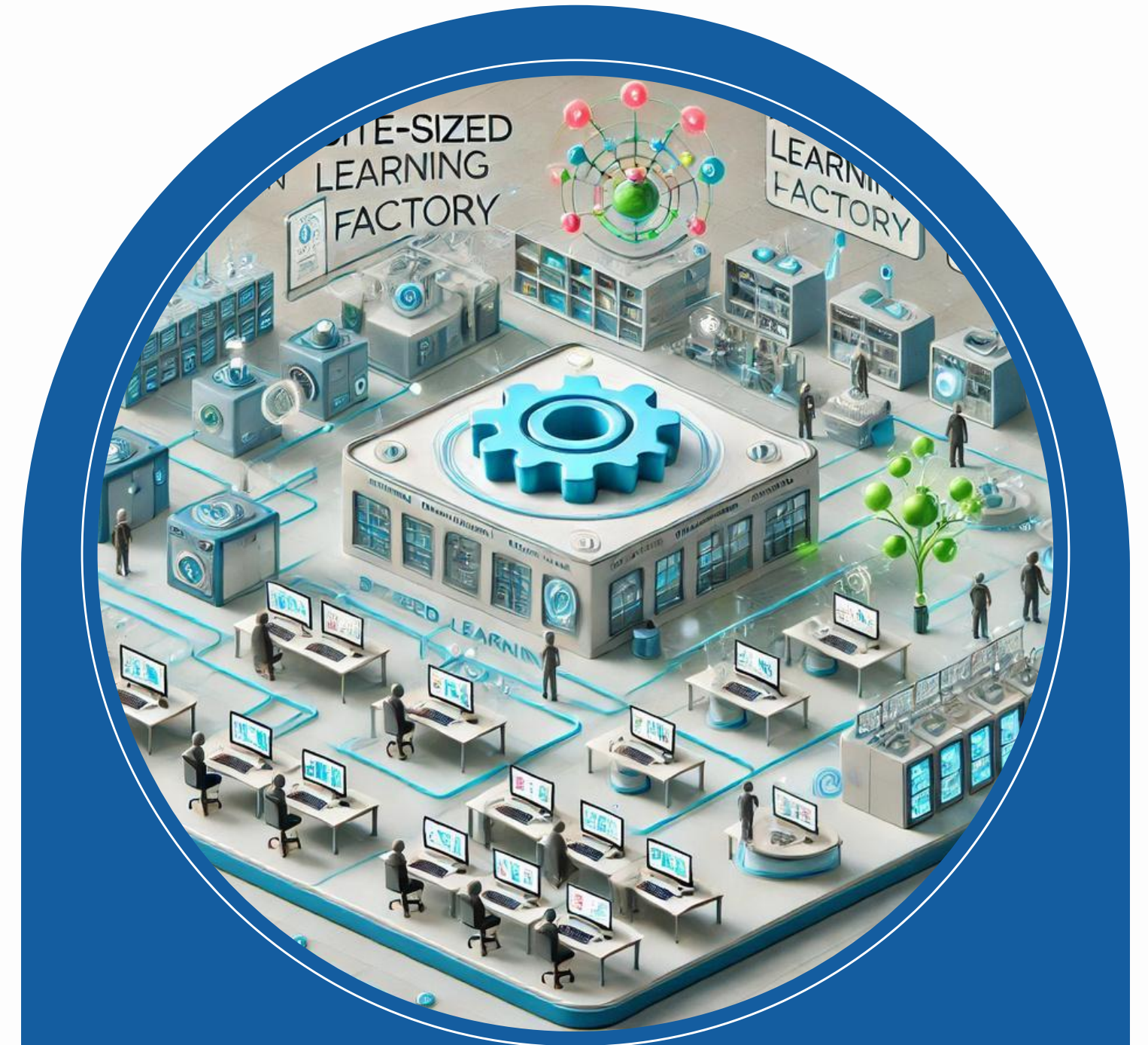
Solution: KaDo Consulting establishes a 'Bite-Sized Learning Factory,' defining a skill framework to identify and develop both personnel and technical resources, with the primary goal of acting as an internal advisor for tailored learning solutions. This factory not only delivers short, adaptive training units designed to meet specific task requirements and regulatory standards but also focuses on advancing the capabilities of Training Managers.

Success Factors:

Task-Based, Modular Learning

Real-Time, Adaptive Training Updates

User-Friendly, Engaging Format



40% reduction in compliance violations through the implementation of targeted, adaptive learning solutions and **55%** improvement in employee awareness due to continuous, accessible training modules and interactive learning (Harvard, 2023).

Use Case 4 – GCP Virtual Instructor

Objective: Provide an AI-powered virtual GCP instructor for real-time support and continuous learning in clinical research.

Challenge: The complexity of GCP makes real-world application difficult. Professionals need a **24/7 virtual coach** for on-demand guidance, critical answers, and flexible, task-specific training—ensuring compliance anytime, anywhere.

Solution: KaDo Consulting developed the GCP Virtual Instructor—a free, AI-driven learning and knowledge management tool that offers tailored, role- and region-specific GCP insights to clinical research professionals.

Key Success Factors:

- Role- and Region-Specific Adaptation
- Real-Time Knowledge Support
- Multilingual Capabilities



Outcomes:

- **Improved Compliance:** Continuous, instantly available GCP guidance enhances regulatory adherence.
- **Increased Efficiency:** Reduces time spent searching for information, allowing teams to focus on critical tasks.
- **Fosters a Learning Culture:** Supports continuous learning and improvement within organizations.

WHY CHOOSE KADO CONSULTING FOR SUSTAINABLE COMPLIANCE?



Integrated Change, Training, and Knowledge Management to drive real, lasting improvements in compliance behavior.



Strategic Compliance Solutions tailored for dynamic, regulated environments.



Data-driven, research-backed results that enhance compliance and operational efficiency.

With KaDo Consulting, compliance becomes an embedded, proactive element of your organization—empowering your team to confidently navigate complex regulatory challenges.



Ready to revolutionize your GCP compliance strategy?

KaDo Consulting offers the expertise and tools to turn compliance challenges into strategic opportunities.

👉 **Let's start the conversation today!**

Contact us to explore tailored solutions for your organization's needs.



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