QUICKSTART | AI ENABLEMENT FOR REGULATED INDUSTRIES

DIGITAL & DATA READINESS

FRAME: 4-6 weeks
DELIVERY TEAM: AI Governance Lead, Compliance Analyst, Data/Systems Architect

BUILDING TRUSTWORTHY AI IN REGULATED ENVIRONMENTS

AI tools are flooding into regulated industries, but most organizations lack a consistent process to intake, evaluate, and adopt them safely. Without governance, organizations are at risk to accrue technical debt, miss value when POCs stall, and miss critical compliance requirements for audit and traceability. This QuickStart gives you a structured framework to govern AI adoption responsibly, enabling you to streamline intake, prioritize use cases, and prepare validation guardrails.

INDUSTRY CHALLENGES THIS SOLVES:

- No enterprise model for evaluating AI tool requests
- Compliance blind spots in AI deployment
- Fragmented intake of AI use cases with no prioritization or risk-based assessment
- Change management challenges with scientific and medical staff resistant to “black box” tools

SOLUTION OVERVIEW:

1. AI Governance Framework
   - Develop lightweight governance policies aligned to required regulations
   - Evaluation of data access controls, model data lineage, and AI-specific privacy safeguards, etc.
   - Recommend controls for explainability, traceability, and audit readiness
2. Technology Readiness
   - *Automation Readiness* – Assessment of infrastructure-as-code practices, MLOps pipeline maturity, and model deployment workflows
   - *AI Resilience & Continuity* – Review of failure recovery plans, model retraining protocols, and AI incident management readiness
   - *Technical Architecture & Integration* – integration capabilities and scalability of AI workloads
3. AI Use Case Intake Model
   - Build a standardized intake form and workflow for new AI tool requests
   - Define scoring criteria and risk tiers along with a prioritization rubric
4. Adoption Readiness Toolkit
   - Deliver validation templates and approval checklists for AI pilots
   - Define integration checkpoints with regulated systems
   - Provide a repeatable “go/no-go” decision framework for scaling tools

WHAT YOU GAIN:

- A governance + intake process tailored to AI adoption in regulated industries
- Risk-based scoring to prioritize AI pilots responsibly
- Validation templates and decision frameworks to guide safe adoption
- Faster, compliant intake process for new AI tools across R&D, regulatory, and commercial
- Detailed assessment report highlighting strengths/areas for improvement.
- Customized AI readiness roadmap with actionable recommendations.
- Executive summary presentation for stakeholders.
- Follow-up consultation to support implementation of recommendations.

WHY TURNBERRY:

We focus on frameworks, governance, and validation accelerators that enable clients to responsibly adopt AI tools within regulatory constraints—delivering clarity and structure in a fast, controlled QuickStart engagement.

REGULATORY CONSIDERATIONS:

We tailor governance, controls, and artifacts to your environment

QUICKSTART | OCM FOR AI AND WORKFORCE ENABLEMENT

BUSINESS & PEOPLE READINESS

FRAME: 4-8 weeks
DELIVERY TEAM: OCM Consultant, AI Governance SME, BA/Documentation

BUILDING TRUSTWORTHY AI IN REGULATED ENVIRONMENTS

AI only creates value when people change how they make decisions and do work. Without structured OCM and targeted enablement, POCs stall, technical debt grows, and regulatory risk increases. This QuickStart installs the people, process, and governance guardrails to move from pilot to production—safely and measurably.

INDUSTRY CHALLENGES THIS SOLVES:

- Immaturity of enterprise OCM playbook for AI adoption across business units
- Skill and trust gaps slow uptake; inconsistent training and communications
- Unclear decision rights (assist/augment/automate) and weak human-in-the-loop controls
- Limited measurement & auditability for AI-influenced work

SOLUTION OVERVIEW:

1. OCM Strategy & Adoption Governance
   - Build a clear narrative, multi-channel communications, and manager toolkits
   - Define decision modes, escalation, and human-in-the-loop gates for high-risk use cases
   - Risk-tiered adoption criteria aligned to your policies & regulations
   - Stakeholder & impact mapping; establish a change network
2. Role-Based Workforce Enablement
   - Skills blueprint by persona
   - Training assets: AI fluency, responsible use & privacy, prompt playbooks, SOP/job-aid updates
   - Hands-on Prompt Labs and “pair-with-bot” sessions embedded in daily workflows
3. Pilot Activation & Change Execution
   - Adoption plans for 1–2 priority use cases
   - Communications calendar & messaging, champion program, floor support/office hours
   - Live feedback loop into a change backlog
4. Measurement, Readiness & Sustainment
   - Adoption & value scorecards: utilization, quality/consistency, cycle time, error rates, CSAT/NPS, override rates, risk incidents
   - Readiness checkpoints and go/no-go for scale; audit-ready artifacts
   - 30/60/90-day sustainment plan with owners, cadence, KPIs

WHAT YOU GAIN:

- An enterprise OCM playbook for AI (decision rights, governance, human-in-the-loop)
- Modern LMS to accelerate learning and collaboration
- Role-based curricula and reusable training assets (fluency, safety, prompts, job aids)
- Pilot adoption plans & comms that drive measurable behavior change
- Manager coaching model and champion network to scale wins quickly
- Adoption & value dashboards plus an executive readout and 90-day roadmap

WHY TURNBERRY:

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REGULATORY CONSIDERATIONS:

We tailor governance, controls, and artifacts to your environment

QUICKSTART | COMPLIANCE AUTOMATION & AI MVP

Powered by Cmpli.ai, a Turnberry AI product

FRAME: 4-6 weeks
DELIVERY TEAM: Regulatory SME, Validation Analyst, Cmpli.ai Configurator, Cloud Architect

ACCELERATING COMPLIANCE IN A COMPLEX REGULATORY LANDSCAPE

Life sciences organizations face growing regulatory pressure (PCCP, Annex 11, MDR/IVDR, promotional material review, IRA/340B). Traditional validation and documentation processes are manual, slow, and resource-heavy. This QuickStart delivers a working MVP of Cmpli.ai in the client's environment, configured with pre-built templates to accelerate compliance tasks.

COMMON USE CASES FOR CMPLI.AI IN LIFE SCIENCES

- Biopharma – Drafting and validating regulatory submission sections; promotional material compliance review
- MedTech – Generating design history file (DHF) and device risk management documentation under MDR/IVDR
- CROs – Automating site monitoring reports and trial master file (TMF) compliance documentation
- CDMOs / Manufacturing – Automating GMP validation documentation and DSCSA batch record reporting

SOLUTION OVERVIEW:

1. Use Case Identification & Prioritization
   - Facilitate intake and prioritization of candidate compliance use cases
   - Select 1 high-value use case
2. Lightweight Readiness Assessment
   - Assess chosen use case against 8 key readiness components (governance, process, data, audit readiness, integration, scalability, OCM)
   - Identify strengths, gaps, and automation opportunities
3. MVP Delivery (Configured in Client Environment)
   - Configure Cmpli.ai with tailored templates for the selected use case
   - Enable citation-backed outputs for validation and audit traceability
   - Demonstrate automation running in the client's secure environment
4. Use Case Roadmap for Scale
   - Deliver a roadmap for expanding automation to additional use cases
   - Provide a maturity scorecard and prioritized next steps
   - Package findings in an executive briefing for alignment and investment planning

WHAT YOU GAIN:

- A live MVP of compliance automation running in your environment in 4–6 weeks
- Structured evaluation of compliance readiness across 8 key components
- Reusable templates tailored to Biopharma and MedTech
- A readiness roadmap to guide scaling automation responsibly

WHY TURNBERRY:

Turnberry combines deep regulatory and validation expertise with a plug-and-play and compliance-ready AI platform, Cmpli.ai. Together, we deliver fast, working automation solutions that prove value quickly and establish a clear, governed path to scale.

REGULATORY CONSIDERATIONS:

We tailor governance, controls, and artifacts to your environment (e.g. NDA, CFR Part 11, GCP, etc.).