Checklist

How to Implement AI in Life Sciences Quality: 5 Strategic Areas

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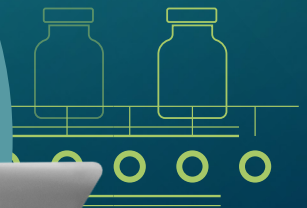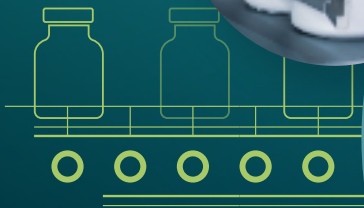
How to Implement AI in Life Sciences Quality: 5 Strategic Areas

As life sciences organizations face increasing complexity in quality management, artificial intelligence (AI) presents a transformative opportunity. According to McKinsey, AI can add $100 billion in value to life sciences,[1] with quality and manufacturing processes representing a significant portion of this opportunity. With successful implementation across functions and processes, organizations can see 30%-40% improvement in investigation effectiveness and potential to reduce time to market by 1-4 years through AI adoption.[2]

To see impactful value of AI, life sciences organizations must invest time and resources to align on the right strategic areas within their organizations to focus AI implementation to augment processes and help create efficiencies. Additionally, being in such highly regulated industries, life sciences manufacturers must also ensure safety, security, and compliance with their AI implementation. It's critical to identify appropriate use cases that are low risk to product or patients.

Checklist for AI Readiness for Life Sciences Organizations:

Workforce Readiness Assessment	
Benefit: Create an engaged, digitally enabled workforce that can effectively collaborate with AI tools while maintaining quality standards. **Example:** Today, only 6% of companies say they've upskilled their employees on AI. With Gen Z projected to make up 30%[3] of the workforce by 2030 and 85% already using AI tools at work,[4] organizations need to embrace this digital-native approach while maintaining quality oversight to evolve and keep up with a changing workforce.	☐ Evaluate current workforce AI literacy levels and opportunities for upskilling. ☐ Assess average employee tenure and turnover rates in quality roles. ☐ Review existing training programs for digital tool adoption. ☐ Gauge team openness to AI-assisted workflows. ☐ Map potential AI use cases to employee pain points. ☐ Develop change management strategies for different workforce segments.

Technology Infrastructure Assessment

Benefit: Ensure your technical foundation can support secure, validated AI implementations that enhance rather than disrupt existing processes.

Example: MasterControl's AI platform integrates purpose-built tools with existing quality management modules while maintaining security and validation requirements.

☐ Audit current software systems and digital capabilities.

☐ Evaluate data strategy and governance frameworks.

☐ Review integration capabilities between existing systems.

☐ Assess current automation levels in quality processes.

☐ Document data security and privacy requirements.

☐ Identify system validation requirements for AI tools.

Quality Process Optimization

Benefit: Target high-value opportunities where AI can reduce manual effort while improving accuracy and compliance.

Example: Deviation and CAPA management typically requires 4%-6% of a manufacturing site's resources.[5] AI-powered investigation tools can help research past events, identify root causes, and assess risk more quickly.

☐ Review current quality processes and identify bottlenecks.

☐ Have cross-functional employees document manual, time-intensive activities.

☐ Identify low-risk areas where AI can provide support for current manual tasks.

☐ List potential efficiency gains from AI implementation.

☐ Evaluate global regulatory compliance requirements.

☐ Prioritize processes for AI enhancement.

Skills & Capability Development

Benefit: Empower a workforce that can effectively leverage AI while maintaining critical quality oversight.

Example: Tools like MasterControl's Exam Generator can address common audit findings around training gaps. This AI tool can transform training processes beyond simple "Read and Understood" requirements, improving content comprehension on critical procedural documents.

☐ Map critical thinking and AI collaboration competencies.

☐ Plan upskilling programs and training curriculum for AI tool adoption.

☐ Identify domain experts who can guide implementation.

☐ Create frameworks for AI-human collaboration.

☐ Develop training materials for AI tools.

☐ Establish ongoing learning programs.

Implementation & Governance

Benefit: Ensure safe, compliant, and effective AI adoption that delivers measurable quality improvements.

Example: Starting with low-risk tools that optimize internal processes, like Document Translator from MasterControl, can easily show the value and ROI for AI implementation (time savings, cost savings compared to using third-party translation services, increased comprehension by providing global employees content in their native language, and more).

- ☐ Define realistic success metrics for AI adoption.
- ☐ Identify low-risk internal processes with opportunities for improvement with AI.
- ☐ Create change management and communication plans.
- ☐ Establish governance frameworks for AI tool usage.
- ☐ Plan pilot programs for initial deployment.
- ☐ Document validation and testing requirements.
- ☐ Create monitoring and maintenance procedures.

Next Steps:

Successful adoption of AI for life sciences companies starts with identifying low-risk opportunities to make meaningful change. Areas like internal quality processes represent safe AI usage where you can benefit from efficiency improvements and more by using AI to automate manual tasks, without risking to patient safety.

- ☐ Assess your organization's current state using this checklist.
- ☐ Identify priority areas for AI implementation.
- ☐ Connect with MasterControl to learn about purpose-built AI tools for life sciences quality management.
- ☐ Begin planning your AI adoption journey with a focus on compliance and validation requirements.

About MasterControl

With MasterControl quality management system (QMS) and manufacturing execution system (MES) software, you never have to sacrifice compliance to achieve efficiency. Our solutions are designed to ensure compliance with regulatory requirements while also increasing operational efficiency. By natively connecting quality and manufacturing data in one powerful digital tool, MasterControl enhances data connectivity and provides real-time visibility into processes across the entire life cycle of your life-changing products. Visit **www.mastercontrol.com** to learn how you can add efficiencies, embed quality into manufacturing operations, and bring your regulated products to market faster.

References

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3. "Gen Z In The Workplace: How Should Companies Adapt?" Johns Hopkins University, 18 April 2023.

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5. "Gen AI: A game changer for biopharma operations," McKinsey & Company. 28 January, 2025 Article.