Design and Artificial Intelligence

Agentic AI for Change Management: A Case Study of the AI Change Management Process Assessment for Medical Device Manufacturers

--Manuscript Draft--

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Abstract:	Medical device manufacturers are rapidly integrating Artificial Intelligence (AI) into software-as-a-medical-device (SaMD) and AI-enabled devices (AIeMD), which amplifies regulatory, safety and governance obligations. This paper demonstrates how an agentic AI system can autonomously execute the AI Change Management Process (CMP) Assessment. The AI-CMP assessment is an integrated, 35-section change assessment that spans medical device identification, risk classification, software safety classification and incorporates requirements from software lifecycle (IEC 62304), AI governance, data management (IEC PAS 63621), model development and testing (BS 30440 and IEC 63450-draft), product and software risk management (ISO 14971, ISO 24971-2 and PD IEC TR 80002-1), cybersecurity (IEC 81001-5-1), EU AI Act Articles 9–15 (2024/1689), and post-market monitoring (ISO 13485). Using a case study of a new-start manufacturer (MemoryTell), we propose that an agentic AI reduces assessment time by 68%, raises documentation completeness from 62% to 98%, and achieves full traceability from hazards to controls and verification. The system preserves human oversight for clinical and regulatory decisions, aligning with the EU AI Act's transparency and oversight provisions. The study suggests agentic AI functions as a force-multiplier for quality and regulatory teams, improving safety, consistency and audit readiness while maintaining manufacturer accountability. A mixed methods and design research approach is taken to develop a State-of-the-Art change assessment tool that can be utilised for AI Agent adoption. Real-world use case demonstrates validity of the AI-CMP tool using qualitative and quantitative data analysis by large and small medical device manufacturers supporting adoption readiness and potential for development of an AI-agent.
Additional Information:	
Question	**Response**

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Abstract

Medical device manufacturers are rapidly integrating Artificial Intelligence (AI) into software-as-a-medical-device (SaMD) and AI-enabled devices (AIeMD), which amplifies regulatory, safety and governance obligations. This paper demonstrates how an agentic AI system can autonomously execute the AI Change Management Process (CMP) Assessment. The AI-CMP assessment is an integrated, 35-section change assessment that spans medical device identification, risk classification, software safety classification and incorporates requirements from software lifecycle (IEC 62304), AI governance, data management (IEC PAS 63621), model development and testing (BS 30440 and IEC 63450-draft), product and software risk management (ISO 14971, ISO 24971-2 and PD IEC TR 80002-1), cybersecurity (IEC 81001-5-1), EU AI Act Articles 9–15 (2024/1689), and post-market monitoring (ISO 13485). Using a case study of a new-start manufacturer (MemoryTell), we propose that an agentic AI reduces assessment time by 68%, raises documentation completeness from 62% to 98%, and achieves full traceability from hazards to controls and verification. The system preserves human oversight for clinical and regulatory decisions, aligning with the EU AI Act's transparency and oversight provisions. The study suggests agentic AI functions as a force-multiplier for quality and regulatory teams, improving safety, consistency and audit readiness while maintaining manufacturer accountability. A mixed methods and design research approach is taken to develop a State-of-the-Art change assessment tool that can be utilised for AI Agent adoption. Real-world use case demonstrates validity of the AI-CMP tool using qualitative and quantitative data analysis by large and small medical device manufacturers supporting adoption readiness and potential for development of an AI-agent.

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Declaration of interests

☒ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☒ The author Niamh St John Lynch is not employer or perform any other purpose for Design and AI and was not involved in the editorial review or the decision to publish this article.

☒The authors declare the following financial interests: funding by Research Ireland under the Regulatory Compliance Framework for Trustworthy AI Medical Device Software (Reg-Fr-AIMs) project, ID 21/FFP-A/9255) as a PhD candidate and member of the Reg-Fr-AIMs team. Personal relationships which may be considered as potential competing interests:

The author is a member of several Technical Committees for Healthcare International Standards, and Chair of TC10 Medical Equipment, Systems and Software. Technical Committees expert membership is held under IEC TC 62 and CEN-CENELEC including Software Network Artificial Intelligence Group (SNAIG) and SNAG Task 2 (Artificial Intelligence) members with insight into medical device and healthcare standards development. This does not negatively impact the quality of research or act in conflict with policies and procedures as a researcher.

Cover Letter for Submission to Design and AI

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Editor-in-Chief
Design and AI

Dear Editor,

I am pleased to submit our abstract for forthcoming manuscript entitled:

'Agentic AI for Change Management: A Case Study of the AI Change Management Process Assessment for Medical Device Manufacturers'

for consideration in the Design and AI Special Issue on Agentic AI.

This paper presents the first integrated, agentic-AI–driven approach to the AI Change Management Process (CMP) Assessment for medical device manufacturers. Using a real-world case study (MemoryTell), we demonstrate a State-of-the-Art Change Management System for AI-enabled Medical Devices that can be automated as an AI agent. The opportunities this brings with it can reduce assessment execution time by up to 68%, increase documentation completeness from 62% to 98%, and achieve full traceability from hazards to controls and verification.

The manuscript is highly aligned with the aims of Design and AI, providing a design-research-led methodology for implementing agentic AI systems within regulated environments, particularly across e-QMS and SDLC workflows.

We confirm the manuscript is original, not under review elsewhere, and all authors approve its submission. We further confirm that no conflicts of interest exist and all disclosures are transparently reported.

We appreciate your consideration and look forward to your response.

Sincerely,
Niamh St John Lynch
Corresponding Author & PhD Candidate with DkIT

Highlights

- Introduces an agentic AI system that autonomously completes a comprehensive AI Change Management and Planning (CMP) Assessment across 35 sections.
- Demonstrates end-to-end execution for a realistic medical device manufacturer case (MemoryTell) including PTM evaluation, risk propagation and EU AI Act alignment.
- Theoretical quantified benefits: 68% reduction in assessment lead time, 36-point uplift in documentation completeness, 100% risk traceability coverage, and 68% fewer reviewer hours.
- Demonstrates how agentic AI acts as a co-creative regulatory partner while preserving manufacturer accountability, human oversight and auditability.
- Maps CMP sections to specialised agents and provides implementation guidance for integration into existing e-QMS and SDLC workflows.
- Demonstrates manufacturer readiness for AI Agent adoption to improve and reduce resource burden from existing regulatory requirements.