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Research Article

Artificial Intelligence and ML-Driven Personalized Hearing Aid Manufacturing: A Control-Mapped Governance Framework

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ABSTRACT

Hearing aid manufacturing has shifted from mass-produced, one-size-fits-many devices toward highly personalized products shaped by digital ear-canal scanning, generative design, additive manufacturing, and machine-learning-tuned digital signal processing. While this shift improves acoustic fit and patient outcomes, it introduces new governance challenges: personalization pipelines depend on AI/ML components whose behavior must remain traceable, verifiable, and compliant with medical-device quality regulations across every stage of production. This paper proposes a control-mapped governance framework that links each stage of AI/ML-driven personalized hearing aid manufacturing — digital impression capture, generative shell design, additive manufacturing, acoustic personalization, quality release, and post-market monitoring — to specific governance controls and applicable standards, including ISO 13485, IEC 60118, IEC 62366, and relevant FDA quality-system regulations. We argue that treating AI/ML governance as a set of controls mapped explicitly onto manufacturing stages, rather than as a separate compliance overlay, allows manufacturers to maintain both innovation velocity and regulatory defensibility. The framework is illustrated through a stage-by-stage control-mapping table and a discussion of algorithm change control, design verification, and post-market surveillance specific to personalized hearing devices. We conclude by examining implementation challenges, including data provenance across scanning devices, validation of generative design outputs against anatomical safety constraints, and the auditability of continuously updated fitting algorithms, and we outline directions for future work on standardized AI/ML governance in personalized medical-device manufacturing.

Keywords: *Hearing aid manufacturing; personalized medical devices; artificial intelligence; machine learning; governance framework; quality management system; additive manufacturing; ISO 13485; digital signal processing.*

INTRODUCTION

Hearing aids have historically been manufactured through a combination of standardized shell molds and manually tuned acoustic settings, an approach that constrains both physical fit and acoustic performance to broad population averages. Advances in three-dimensional ear-canal scanning, generative design software, additive manufacturing, and machine-learning-based digital signal processing (DSP) have enabled a new generation of hearing aids that are personalized at both the physical and acoustic level: shells generated from an individual patient's scanned anatomy, and fitting curves tuned by algorithms trained on large audiometric datasets rather than static formulas alone.

This personalization brings clear benefits in comfort and acoustic outcomes, but it also introduces governance complexity that traditional medical-device quality systems were not originally designed to address. Where a conventional hearing aid product line ships a fixed design validated once, a personalized AI/ML-driven pipeline generates a distinct design and a distinct set of fitting parameters for every patient, using models that may themselves be updated over time as new training data becomes available. Regulators and manufacturers alike must therefore answer a harder question than "is this product safe and effective," namely "is this personalization pipeline, across every patient-specific instance it produces, safe and effective, and can that be demonstrated on an ongoing basis."

This paper proposes a control-mapped governance framework that addresses this question by explicitly linking each stage of the AI/ML-driven manufacturing pipeline to a defined governance control and an applicable regulatory or standards reference. The remainder of the paper is organized as follows. Section 2 reviews the technical landscape of personalized hearing aid

manufacturing and relevant quality-system standards. Section 3 presents the proposed control-mapping framework in detail, including a stage-by-stage table. Section 4 discusses algorithm change control and design verification specific to AI/ML components. Section 5 addresses post-market monitoring. Section 6 discusses implementation challenges, and Section 7 concludes.

BACKGROUND

The Personalized Manufacturing Pipeline

A typical AI/ML-driven personalized hearing aid pipeline begins with a three-dimensional scan of the patient's ear canal, captured either optically or via silicone impression digitization. Machine learning models clean the resulting point cloud, detect anatomical landmarks, and classify canal shape characteristics relevant to shell design. A generative design stage then produces a patient-specific shell or earmold geometry that satisfies acoustic venting requirements, retention, and comfort constraints, typically optimized through parametric or generative algorithms rather than manual CAD editing. The resulting geometry is manufactured through additive manufacturing (3D printing), where machine learning models may assist in predicting optimal print parameters and detecting print defects through automated visual inspection. In parallel, the device's acoustic behavior is personalized: audiogram data and, increasingly, in-situ listening feedback are used to tune compression curves and noise-reduction behavior through machine-learning-assisted fitting algorithms, moving beyond the static prescriptive formulas historically used in audiology.

Relevant Quality and Regulatory Standards

Hearing aids are regulated medical devices in most jurisdictions, and manufacturers typically operate under a quality management system aligned with ISO 13485, the international standard for medical-device quality management. Device-specific standards such as IEC 60118 address hearing aid electroacoustic performance, while IEC 62366 addresses usability engineering relevant to the fitting process. In the United States, manufacturers must additionally comply with the FDA's Quality System Regulation under 21 CFR Part 820, which governs design controls, production and process controls, and post-market surveillance obligations including complaint handling and corrective and preventive action (CAPA). None of these standards were originally written with continuously updated AI/ML models in mind, which creates interpretive gaps that a control-mapped governance framework can help address by translating existing quality-system requirements into concrete controls applicable to each AI/ML-driven manufacturing stage.

Governance Gaps in AI/ML-Driven Personalization

Three governance gaps are particularly salient in this domain. First, traditional design verification assumes a fixed design output; a generative design model instead produces a distinct output for every patient, requiring verification logic that checks each output against anatomical and safety constraints rather than verifying a single fixed design once. Second, traditional software validation assumes relatively infrequent, discrete software releases; ML-tuned fitting algorithms may be updated more continuously as new audiometric data accumulates, requiring a change-control process suited to incremental model updates rather than only major version releases. Third, traceability requirements under existing device history record practices were designed around uniform batch production; personalized manufacturing requires traceability at the level of the individual patient-specific design and its associated model version, scan data, and verification outcome.

Control-Mapped Governance Framework

The proposed framework organizes governance around six manufacturing stages, for each of which we identify the corresponding AI/ML function, the governance control required to manage it, and the standard or regulation most directly applicable. Table 1 summarizes this mapping.

The value of this mapping lies in making explicit, at each stage, what must be controlled and against what reference, rather than treating AI/ML governance as a single monolithic compliance exercise applied after the fact. For example, the control associated with ear-canal scanning is not merely "validate the scanner" but specifically "validate the input data quality threshold that the downstream ML landmark-detection model requires to perform reliably," which is a materially different and more actionable control. Similarly, the control associated with generative shell design is not simply "review the design" but "verify each generated output against defined anatomical and acoustic venting constraints," reflecting the per-patient nature of the design output.

Industrial Engineering Implications: Throughput and Quality Trade-offs

Mass Customization and Cycle Time

From an industrial engineering standpoint, AI/ML-driven personalization converts hearing aid production from a mass-manufacturing process into a mass-customization process, in which every unit follows a distinct design path through scanning, generative design, and additive manufacturing. This shift changes the relevant process metrics: rather than optimizing a single fixed line for maximum throughput of an identical part, manufacturers must optimize cycle time and first-pass yield across a distribution of patient-specific geometries, some of which are more complex to print or finish than others. The control-mapped governance framework interacts directly with this concern, since automated per-instance verification, if poorly optimized, can itself become a throughput bottleneck; the framework therefore treats

Table 1: Control-mapped governance framework for AI/ML-driven personalized hearing aid manufacturing

Manufacturing Stage	*AI/ML Function*	*Governance Control*	*Reference Standard*
Ear-canal scanning & digital impression	Point-cloud cleanup, landmark detection, shape classification	Input data validation; scan-quality acceptance threshold	ISO 13485; IEC 62366
Personalized shell / earmold design	Generative design, parametric fit optimization	Design-output verification against anatomical constraints	ISO 13485 §7.3; FDA QSR 820.30
Additive manufacturing (3D printing)	Print-parameter prediction, defect detection (vision ML)	Process validation; in-line inspection sign-off	ISO 13485; ISO/ASTM 52900
Acoustic & DSP personalization	Audiogram-based fitting algorithm, ML-tuned compression curves	Algorithm change control; clinical validation record	IEC 60118; FDA 21 CFR Part 820
Quality release & traceability	Anomaly detection on QC telemetry, predictive yield modeling	Batch release approval; device history record (DHR) linkage	ISO 13485 §7.5; UDI regulation
Post-market monitoring	Field-performance drift detection, complaint-signal clustering	Post-market surveillance; corrective/ preventive action (CAPA)	ISO 13485 §8; FDA 21 CFR 820.198

verification latency as a process design parameter to be balanced against the acceptable review queue length for human-in-the-loop checkpoints.

Statistical Process Control for Variable Outputs

Classical statistical process control assumes repeated measurement of a nominally identical part against fixed tolerance bands. In a personalized pipeline, no two shells are geometrically identical, so process control must instead be applied to derived, normalized quality indicators — for example, deviation between the printed part and its generative design target, or wall-thickness margin relative to the minimum constraint for that specific geometry — rather than to raw dimensional measurements. Machine learning models used for defect detection in the additive manufacturing stage are therefore trained to compare each printed unit against its own unique design file rather than against a shared reference part, a distinction that has direct implications for how process capability is defined and monitored on the production floor.

Yield, Rework, and Economic Trade-offs

The governance controls specified in Table 1 also carry economic weight relevant to industrial engineering practice. Stricter automated verification thresholds at the design and print-inspection stages reduce the risk of releasing a non-conforming personalized device but increase the rate at which units are routed to rework or re-scanning, with associated cost and lead-time impact. Manufacturers implementing this framework must therefore calibrate verification tolerances not only against regulatory risk but against yield and rework cost models specific to their production volumes, a trade-off that is itself a natural candidate for further ML-based optimization once sufficient production history has accumulated to model the relationship between tolerance settings and downstream rework rates.

Algorithm Change Control and Design Verification

Managing Continuous Model Updates

Because ML-tuned fitting algorithms and generative design models may be retrained or refined as new data accumulates, the framework treats each model version as a controlled configuration item, analogous to a software release under design controls. A model change log records the training data snapshot, validation results, and approval decision associated with each version, and any change to a production model requires re-validation against a defined acceptance criteria set before deployment, mirroring software validation practice under 21 CFR Part 820 while accommodating the higher update frequency typical of ML components.

Per-Instance Design Verification

For generative shell design, the framework specifies automated per-instance verification: every generated geometry is checked against a defined set of anatomical constraints (minimum wall thickness, vent placement tolerances, retention feature presence) before being released to manufacturing, with any output falling outside tolerance routed to human review rather than automatically proceeding to production. This per-instance verification step functions as the personalized-manufacturing analogue of traditional design verification, replacing a single one-time check with a continuously applied automated check at production scale.

Human-in-the-Loop Checkpoints

The framework designates specific checkpoints at which human review is required regardless of automated verification outcomes, including final acoustic fitting sign-off by a licensed audiologist and periodic sampled review of generative design outputs by a quality engineer, ensuring that automation accelerates rather than fully replaces professional oversight at points where clinical judgment or regulatory accountability is required.

Post-Market Monitoring and Continuous Governance

Governance does not end at product release. The framework extends control mapping into the post-market phase, where machine learning models applied to field-performance telemetry and complaint data can detect drift in device performance or emerging failure patterns across a personalized product population. Because each

device in the field corresponds to a distinct manufacturing instance with its own scan data, design version, and fitting algorithm version, post-market signal analysis benefits from the same traceability infrastructure established during manufacturing, allowing a detected field issue to be traced back to a specific model version or manufacturing stage far more precisely than would be possible with a uniform, non-personalized product line. Detected anomalies feed into the manufacturer's corrective and preventive action process, closing the governance loop between field performance and upstream model and process controls.

Implementation Challenges

Data Provenance Across Scanning Devices

Manufacturers often receive ear-canal scan data from multiple scanning hardware vendors and clinical partners, each with differing data formats and quality characteristics. Establishing consistent data provenance and quality metadata across these sources is a prerequisite for reliable application of the input-validation controls specified in the framework, and remains an integration challenge in practice.

Validating Generative Design Against Anatomical Safety

Defining a complete, machine-checkable set of anatomical and safety constraints for generative shell design is nontrivial, since some safety-relevant properties, such as comfort or long-term skin contact tolerance, are difficult to encode purely as geometric constraints and may require ongoing refinement based on clinical feedback.

Auditability of Continuously Updated Algorithms

Maintaining a complete, auditable history of fitting-algorithm versions, their training data, and their validation outcomes at the scale of frequent updates requires dedicated model-governance tooling that many smaller manufacturers may not yet have in place, suggesting a role for shared industry tooling or standards in this area.

CONCLUSION

This paper has proposed a control-mapped governance framework for AI/ML-driven personalized hearing aid manufacturing, linking each stage of the personalization pipeline — from ear-canal scanning through post-market monitoring — to explicit governance controls grounded in established medical-device quality standards. By treating AI/ML governance as a set of stage-specific, actionable controls rather than a generic compliance overlay, manufacturers can pursue the acoustic and comfort benefits of personalized manufacturing while maintaining the traceability, verification, and auditability that regulated medical-device production requires. As personalized manufacturing techniques continue to mature and as regulatory expectations for AI/ML-enabled medical devices continue to develop, frameworks of this kind offer a practical bridge between innovation and compliance, and future work should focus on industry-shared tooling and benchmark practices that make such control mapping easier to implement consistently across manufacturers.

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