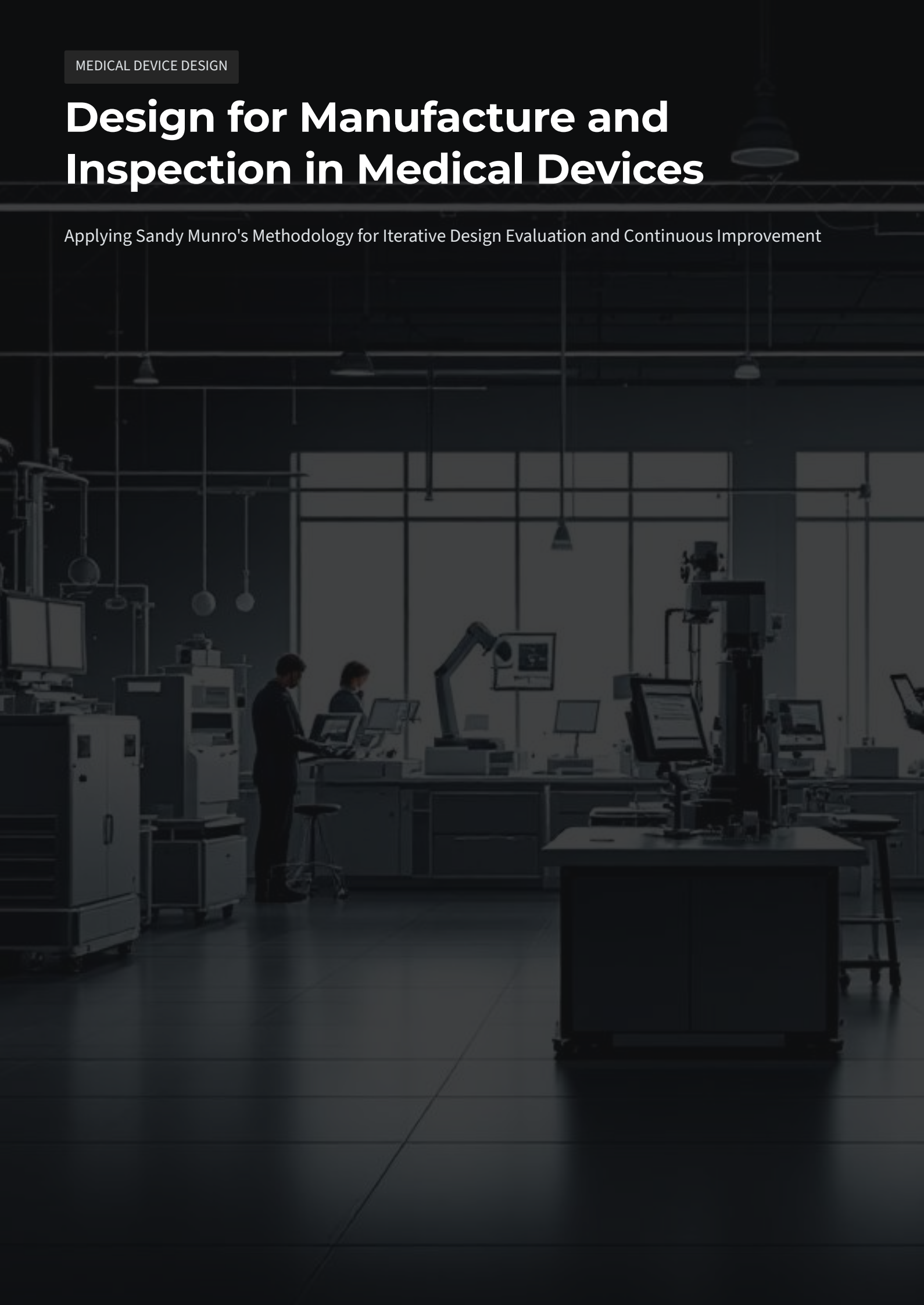
MEDICAL DEVICE DESIGN

Design for Manufacture and Inspection in Medical Devices

Applying Sandy Munro's Methodology for Iterative Design Evaluation and Continuous Improvement



Executive Summary

The medical device industry faces mounting pressure to deliver products that are safe, reliable, and cost-effective, while navigating an increasingly complex regulatory landscape. Engineers often focus on functional innovation, yet design manufacturability and inspectability—two of the most powerful cost and quality drivers—are addressed too late in development.

This paper presents a structured approach to Design for Manufacture (DFM) and Design for Inspection (DFI), drawing from Sandy Munro's teardown-based methodology. By embedding manufacturability and inspection considerations early and iteratively evaluating designs against production realities, organizations can dramatically reduce cost, risk, and time-to-market—without compromising performance or compliance.

Introduction: The Manufacturing Challenge in Medical Devices

Medical devices operate under some of the world's most demanding design constraints. Engineers must balance:

Precision Components

Precision component interfaces and biocompatible materials

Regulatory Control

Stringent documentation, validation, and regulatory control (ISO 13485, FDA QSR, MDR)

Economic Efficiency

Economic pressures for efficiency and scalability

Yet, manufacturability and inspection are too often treated as post-design activities addressed only when a prototype struggles to scale or fails quality inspection. This reactive model increases design churn, delays launches, and escalates costs.

A proactive, iterative DFM/DFI approach, informed by Munro's proven manufacturing philosophy, reverses this sequence making manufacturability a design input, not an afterthought.

Munro's Methodology: Learning from Design Reality

The Munro Philosophy

Sandy Munro's methodology, grounded in decades of automotive and aerospace teardown analysis, centers on understanding how design choices directly influence cost and manufacturability. His Design for Manufacturability (DFM) and Design for Assembly (DFA) frameworks measure the efficiency of a product's architecture by analyzing:

Part Count Analysis

Part count and function consolidation

Assembly Efficiency

Assembly motion efficiency and sequence simplicity

Process Selection

Process choices relative to material and tolerance needs

Cost Modeling

"Should-cost" modeling versus realized cost

This data-driven teardown and scoring system yields a quantitative assessment of design maturity highlighting where redesign can deliver the greatest gains in cost, assembly time, or quality.

Translating Munro to Medical Devices

Munro's automotive-based framework transfers seamlessly to Medical Devices. A ventilator manifold, prosthetic joint, or catheter handle can all be decomposed into functionally redundant, over-toleranced, or inspection-intensive elements.

Applying Munro's system allows engineers to:

- Benchmark competitor or legacy devices through structured teardown
- Score each assembly's manufacturability
- Set "should-cost" targets aligned with validated manufacturing processes (e.g., injection molding, CNC, additive)

In a regulated environment, the benefit is not just efficiency, it's repeatable quality through simplification.

Design for Manufacture (DFM) in Medical Devices

Principles Under Regulation

Design for Manufacture in Med Device demands precision without overconstraint. Key principles include:

- **Geometry simplification:** Minimize intricate undercuts or overhangs that raise tooling cost and defect risk
- **Tolerance realism:** Use process capability data (Cpk/Ppk) rather than arbitrary precision
- **Validated materials:** Choose biocompatible materials with established manufacturing histories (e.g., ISO 10993, USP Class VI)
- **Process-driven design:** Match design features to stable, validated fabrication methods such as laser welding for microjoints or insert molding for multi-material components

Early Cross-Functional Engagement

DFM maturity depends on early collaboration among design, manufacturing, quality, and supplier engineering. Incorporating supplier DFM feedback into CAD reviews—particularly regarding moldability, bonding, or assembly jigs can eliminate months of iteration downstream.

Integrating pilot build data into the design cycle (yield rates, dimensional Cpk trends) transforms DFM from theoretical to empirical, aligning the design team's metrics with production performance.

Design for Inspection (DFI): Embedding Verifiability in Design

Inspection as a Design Input

In medical manufacturing, if it can't be measured, it can't be validated. DFI ensures every critical feature can be inspected efficiently and unambiguously. Key strategies include:

01

GD&T Structure

Explicit GD&T and datum structure aligned with inspection access

02

Measurement Intent

Designing with measurement intent: Adding reference bosses, optical features, or datums for coordinate metrology

03

Inspection Workflow

Considering inspection workflow: Can the part be fixtured easily? Can high-throughput automation measure key features inline?

Munro's "Build and Break" Applied to Inspection

Munro advocates a "build and break" approach prototyping fast, testing to failure, and learning from the results. Applied to inspection, this translates into prototyping metrology early. By validating inspection techniques (CMM, optical, CT scanning) in tandem with prototype builds, teams discover tolerance stack issues and measurement errors before design freeze.

Embedding digital inspection simulation using CAD-to-metrology digital twins helps ensure that design changes remain measurable and verifiable throughout iterations.

Iterative Design Evaluation: Closing the Feedback Loop

The Evaluation Cycle

The core of Munro's success and the essence of effective DFM/DFI is iteration. Each cycle of design, prototype, and test should be evaluated against manufacturability metrics:

Plan

Define target cost, tolerance limits, and assembly time

Prototype

Build and test using representative processes

Measure

Collect dimensional, process, and inspection data

Validate

Repeat under pilot or production conditions

Redesign

Simplify, consolidate, and correct based on data

Quantitative Evaluation Tools

Use structured evaluation tools to guide decisions:

Scoring Matrices

DFM/DFA scoring matrices (Munro-style weighted factors)

Trade-off Analysis

Pugh charts for design trade-offs

Statistical Metrics

Statistical metrics such as yield, Cpk/Ppk, and inspection time

Plotting these over iterations creates a maturity curve, where diminishing returns signal readiness for scale-up. This makes design decisions traceable, auditable, and defensible critical in regulatory submissions and design history files (DHF).

Case Example: Surgical End-Effector Design

A design team developing a minimally invasive surgical end-effector applied Munro's DFM/DFI principles to evaluate manufacturability and inspection readiness during the early prototype phase.

Initial Prototype

The first iteration prioritized mechanical precision and articulation range. The end-effector assembly consisted of 22 discrete components, including linkages, pivot pins, bushings, and laser-welded joints. While functional testing met all clinical performance criteria, the prototype exhibited:

- → High assembly variability due to tight alignment tolerances across multiple sub-joints
- → Difficult inspection access, especially for internal weld seams and rotational clearances
- → Excessive reliance on manual fitting and operator skill, driving yield variability

DFM and DFI Evaluation

Using a structured teardown and scoring process inspired by Sandy Munro's DFM/DFA analysis, the team benchmarked part count, assembly time, and inspection burden. The review revealed:

- Redundant pivot hardware that could be consolidated via integrated flexure components
- Overly complex machined geometries that could be converted to MIM (metal injection molding) with post-machining only on critical datums
- Inconsistent datum structures that made CMM inspection and fixture alignment inefficient

A manufacturability matrix assigned weighted scores for assembly ease, process repeatability, and inspection accessibility. The original design scored 64/100, indicating high functional performance but low manufacturing robustness.

Redesign and Validation

The redesign focused on part consolidation and inspection visibility:

- Reduced component count from 22 to 15 through subassembly integration
- Replaced multiple fasteners with a snap-fit interface compatible with automated assembly
- Modified the linkage geometry to allow line-of-sight CMM measurement and incorporated
- Validated manufacturability using pilot production runs and in-process dimensional

Implementation Roadmap

Stage Gate Integration

1

Integrate DFM/DFI into Stage Gates: Require manufacturability and inspectability reviews before design freeze

2

Cross-Functional Teams

Empower Cross-Functional Teams: Create collaborative design-review templates that include supplier input

Teardown Database

3

Leverage Teardowns: Build an internal database of competitive and legacy product teardowns scored by Munro-style metrics

4

Training Program

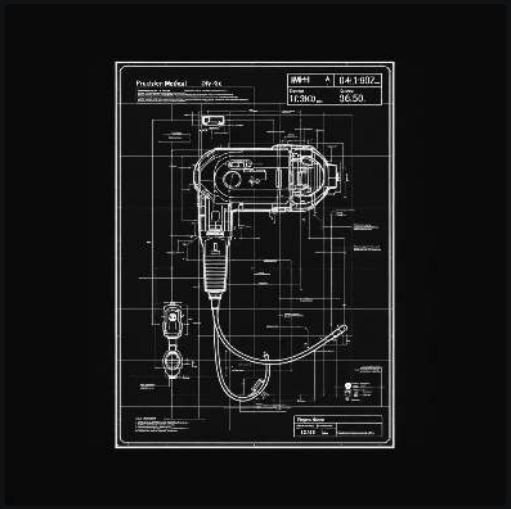
Train for DFM Thinking: Equip engineers with structured teardown and assembly analysis skills

QMS Integration

5

Link DFM/DFI to QMS: Feed manufacturability metrics directly into design control and CAPA systems

Conclusion



Design for Manufacture and Inspection is more than cost control, it is risk management through simplicity.

By integrating Sandy Munro's teardown methodology into the medical device lifecycle, teams can quantify design maturity, expose hidden inefficiencies, and evolve products through structured iteration.

The most manufacturable medical devices are not just simpler they are safer, more compliant, and more scalable. Iterative, data-driven design evaluation ensures that manufacturability and inspection precision are not end-stage hurdles, but foundational elements of innovation.