



MIDI's Quality 1st Development Process





GATE 0: STRATEGIC RESEARCH & ANALYSIS



GATE 1: **AGILE DEVELOPMENT: CONCEPT & FEASIBILITY**



GATE 2: **WATERFALL: DESIGN CONTROLLED DEVELOPMENT**



GATE 3: **DESIGN OUTPUT, MANUFACTURE, V&V**

Discovery Research

Identify and assess marketing, design, technology and regulatory facets to ensure minimal risk and maximum ROI through comprehensive Discovery Research.

Systems Analysis™

Formulate and prioritize data from Discovery Research, establishing a solid understanding of program requirements, strategic direction and associated risks.

Concept Innovation & Definition

Utilize Systems Analysis inputs for rapid concept development, fostering user-centric innovation and strategic program direction under concurrent engineering (DFX).

POC Feasibility Studies

Deploy iterative engineering, analysis, and early POC prototyping to rapidly verify feasibility, ensuring functionality, performance, and HFE/ user interface meet desired requirements.

Quality Planning & Control

Strategically plan device development to ensure effective progress, minimize risks, and maintain alignment with Design Controls, Risk Management and regulatory standards throughout development phases.

Design / Engineering Development

Create innovative, user-centric designs that meet market needs, integrating advanced engineering techniques with continuous efficacy and usability testing for optimal performance.

Prototype Build/Test

Ensure devices function as intended through rigorous Alpha/ Beta prototyping, manufacturing, formative Human Factors Engineering (HFE), and iterative early-stage device verification.

Design Output Refinement

Provide detailed specifications, drawings, and clear design outputs to ensure optimal, controlled manufacturing and adherence to regulatory standards.

Design Transfer & Manufacture

Select and manage suitable vendors, ensuring program communication, performance insight, adherence to deadlines, cost, quality, regulatory compliance and design transfer for a seamless transition into production.

Verification and Validation

Conduct thorough verification testing and design validation (summative usability studies) to ensure devices are safe, reliable, and meet the highest quality standards.

