

Carilion Clinic Innovation PROCESS WHITE PAPER



DRIVING MEDICAL DEVICE DEVELOPMENT

Carilion Clinic Innovation leverages partnerships across the Carilion healthcare system to create high-quality, early-stage medical device prototypes. Our goal is to validate working concepts and provide a roadmap to bring devices to market. To achieve results, we partner with Carilion's Human Factors team, the Center for Simulation, Research and Patient Safety, the Research and Development team, and clinical inventors.

INNOVATION FROM THE FRONTLINE

Innovation begins and ends with Carilion's medical providers. Ideas often originate from real-world challenges—a surgeon seeking to streamline surgery, a nurse frustrated with a tool, or a physical therapist noticing nearly every patient faces difficulties during treatment.

Regardless of the source, the next step is the same: submit an invention disclosure to Carilion Clinic Innovation. Once received, the Innovation team begins research. Our engineers enter the clinical setting to observe the problem firsthand, considering the environment, provider and patient needs, and desired outcomes. We frequently partner with Carilion's Human Factors team to map environments and processes, ensuring usability is a priority from the start.

In parallel, the Innovation team assesses the device's market potential by reviewing products, patents, and academic research to understand how the problem has been addressed in the past. Occasionally, existing solutions meet the need. More often, gaps between the goal and the capabilities of existing products remain. That's where development begins.

FROM OBSERVATION TO DESIGN

Initial development focuses on translating user needs into measurable objectives, or design inputs. We map every potential environment and user scenario to create a comprehensive view of how the device will be used. Planning includes requirements for each stage of the product lifecycle, from manufacturing to deployment support. We then develop a testing plan to guide design decisions, ensuring alignment with user needs.

Once the problem is fully understood and a solution plan is in place, prototyping begins. Ideation involves collaboration with the Human Factors team and clinical users. Sketches are created, concepts presented, and models built.

RAPID PROTOTYPING

Our lab features 3D printers, soldering and reflow stations, and machining tools. Guided by the philosophy of "Fail early, fail often, fail cheap", we iterate quickly. Clinical users provide input at every stage. Our unique placement in the Carilion Center for Simulation, Research and Patient Safety allows us to test prototypes in simulated clinical environments, accelerating development. An idea can evolve from a drawing to a low-fidelity model to a fully functional device in just weeks.

USER-FOCUSED TESTING

Functionality testing at Carilion Innovation begins early. Each iteration is held to increasingly rigorous requirements. As the design reaches completion, we implement a comprehensive testing plan that includes:

- » **Benchtop Testing:** Ensures reliability and repeatability in controlled settings.
- » **Simulation:** Replicates the unpredictability of clinical environments.
- » **Usability testing:** Aligns with regulatory standards for medical devices.

Quality is tracked with a rigorous, ISO13485-compliant Quality Management System (QMS). When a device fails, we revise the design and track changes.

Once all benchtop, simulation, and usability testing requirements are met, validation occurs in live clinical environments. We partner with Carilion Research and Development to design studies, ensure patient safety, and carry out clinical trials. While early testing verifies function, trials answer the question, "Does this device solve the original problem?" At the end of our process, we deliver a medical device supported by detailed documentation – problem, definition, user profiles, deployment plans, and test results. The final step is partnering to help bring the device to market.

PARTNER WITH US

Whether you're a startup or an established company, we collaborate to introduce innovative devices to the healthcare world. Interested in partnering with us? Reach out to innovation@carilionclinic.org to learn more about our pathway and projects.