



WHITEPAPER

## The Qt Company's Offering for the Medical Industry

By Roger Mazzella  
Senior Product Manager, The Qt Company

Time, resources, cost.

The three items that keep any C-Level executive, vice president, project or program manager up at night when considering the go-to-market strategy of their medical devices.

This white paper explains how Qt not only reduces your total costs of ownership (TCO) and time-to-market, but also effortlessly scales to any type of hardware you are developing for.

You will learn about Qt's core functionalities, widely used and adopted key product add-ons for medical device manufacturers, as well as how Qt fits and supports the medical regulatory environment.

Finally, you will find out how Qt has positioned itself as a medical thought leader, influencing the future of the medical device industry as a member of industry professional organizations and participant in various medical device working groups.


# Introduction

First developed in 1994, Qt is the leading independent technology for cross-platform development. Over 70 industries are developing Qt-based products for desktop, embedded, and mobile operating systems. The foremost global companies create medical, in-vehicle systems, and industrial automation devices with Qt. Its history in the medical industry dates back over 20 years. One of the first devices built with Qt was an ultrasound machine in the mid-1990s.


Today's digital health products require an ever faster and more intuitive user experience (UX) along with a more modern, reliable, and responsive user interface (UI). Expectations are high as millions of people across the world have gotten used to the high UI/UX benchmark set by their smartphones. Digital health and wellness apps must function on a mobile device as seamlessly as any other application on that machine. For a device which contains embedded software, the touchscreen UI/UX must be as intuitive, responsive, and reliable as the UI/UX on one's smartphone or it is not good enough.


Achieving a high-performing, universally adopted UX is not trivial. Medical devices themselves can be very intricate, with complex functionality and algorithms built on a wide variety of hardware platforms and upon a number of different operating systems (OS). Bringing a medical device to market takes a significant monetary, resource, and time investment. A 2010 Stanford University study claimed that the average cost of bringing a U.S. Food and Drug Administration (FDA) 510(k)-medical product from inception to release was \$31 Million USD. For high-risk, novel medical products requiring premarket approval (PMA), the cost would run at \$94 Million USD, according to the same study<sup>1</sup>. The average time-to-market for a medical device is anywhere between three to seven years. A project of such a scale requires various internal and external teams within software engineering, hardware engineering, product management, regulatory affairs, quality, marketing and, and other fields.

Time, resources, and costs can easily get out of hand for such a project. Qt's flexibility, multi-platform support and many other benefits can minimize your overhead.

 **Reduced time-to-market:** Two key factors that affect the go-to-market time for medical devices are actual product development time and regulatory/compliance timeframes. If you are familiar with Qt, you most likely know of the various libraries and toolsets which allow your software team to develop faster. Developers can focus on creating the best user experiences instead of coding what is already been coded for you. The cycle of Prototyping – Development – Testing – Deployment is faster and more efficient with Qt.

Qt also supports your regulatory and compliance efforts through our internal resources or our industry-leading partner network.

 **Scaleable Solution:** Qt is a cross-platform framework, compatible with a multitude of operating systems and hardware. All you need is to write your source code once and have the capability to deploy it anywhere you need it. You do not need teams of developers coding specifically for different hardware architectures and/or operating systems.

 **Lower total cost of ownership (TCO):** Fewer resources needed and quicker time to market means a lower total cost of ownership and faster revenue recognition.

In the following pages, you will learn how Qt fits in the medical industry and why it is the leading solution of its kind among medical device manufacturers. We will elaborate on Qt's core functionalities, widely used and adopted key product add-ons for medical device manufacturers, as well as how Qt fits and supports the medical regulatory environment. Finally, you will find out how Qt has positioned itself as a medical thought leader, influencing the future of the medical device industry as a member of industry professional organizations and participant in various medical device working groups.



## Highlighted Product Functionality

### Reference Stack and Core Libraries

#### Boot to Qt

The Boot to Qt software stack is a light-weight, Qt-optimized, full software stack for embedded Linux systems installed on the target device. Boot to Qt is ready to run with embedded Linux operating system, hardware drivers, and Qt itself.

Boot to Qt is ideal for both evaluating Qt on real embedded environments. Use one of the pre-built reference images to quickly get the embedded development environment up and running. Now, you can debug directly on the target medical device – a much simpler and faster process. Deployment to the embedded target device literally takes one click. Later, the stack can be customized to production by building embedded Linux images.

The ease and speed gained from prototyping and debugging directly on your chosen medical device hardware is just one advantage of Boot to Qt. If there is a change in design and/or hardware, deploying to another

target hardware is still as easy as just one click thanks to Qt's cross-platform compatibility. Boot to Qt is a key feature which enables very quick and efficient human factors testing.

#### Qt Lite

Qt Lite is a configuration system allowing software developers to define, in detail, which modules they need within the Qt software stack without having to include any unnecessary libraries, tools, or features. Developers can start out with the minimum deployable Qt configuration and add features as they are needed. With Qt Lite, a developer can create a more than 60% smaller binary, which frees up memory and processing power.

Medical devices are developed on a wide range of embedded operating systems and hardware. The IoMT (Internet of Medical Things) keeps growing and with it the need to develop very modern, accurate, and reliable UX on smaller and smaller embedded medical devices (i.e. handheld devices and wearables). Qt Lite allows you to configure and optimize Qt and your specific device environment.

## User Interface Libraries and Tools

### Qt Quick

Qt Quick provides everything needed to create a rich application with a fluid and dynamic user interface. It lets you build UIs around the behavior of UI components and connect them with one another and provides a visual canvas with its own coordinate system and rendering engine.

The Qt Quick module is the standard library for writing QML<sup>2</sup> applications. While the Qt QML module provides the QML engine and language infrastructure, the Qt Quick module provides all the basic types necessary for creating user interfaces with QML. It includes types for creating and animating visual components, receiving user input, creating data models and views and delayed object instantiation.

Qt Quick is another tool option for a medical device manufacturer to quickly and easily build precisely the type of modern and responsive user interface they require. Development time is shortened without sacrificing the ability to create a very safe and reliable user experience.

### Qt Quick Controls 2

Qt Quick Controls 2 and QML make designing UIs with buttons, switches, dials, sliders and other UI controls easy. Use the ready-made UI controls in Qt Quick Controls 2 instead of creating your own from scratch and speed up the creation of great looking UIs. Qt Quick Controls has a selection of built-in styles based on various design guidelines allowing you to create UIs that are familiar to a medical device manufacturer's end-user.

Qt Quick Controls 2 was launched in Qt version 5.7 to further improve the performance on embedded and mobile platforms with a focus on devices with less-powerful hardware. Qt Quick Controls 2 made huge improvements to the responsiveness of complex interfaces on these types of devices. Of course, Qt Quick Controls 2 continues to work flawlessly on desktop applications. Each control was redesigned from the ground up to be as performant and simple-to-use as possible.

Developers can easily design very modern, responsive, safe, and effective user interfaces regardless the operating system or how powerful the hardware. To the end user, the UX will be similar to that of their smartphone, which frees the end user from feeling the need to "babysit" their medical devices and instead focus on their patients.

### Qt Widgets

Qt Widgets are the primary elements for creating user interfaces in Qt. Widgets can display data and status information, receive user input, and provide a container for other widgets that should be grouped together. Qt Widgets are traditional user interface elements that are typically found in desktop environments. The widgets integrate well with the underlying platform and provide a native look and feel on Windows, Linux and Mac OSX. The widgets are mature and feature-rich UI elements suitable for mostly static user interfaces.

The widgets are a good choice for developing medical devices with traditional, desktop-centric UIs. Additionally, widgets are commonly used to develop user experiences such as a nurse's workstation and numerous types of healthcare IT solutions.

### Qt 3D Studio

With Qt 3D Studio, a developer can rapidly build and prototype high-quality 2D and 3D UIs. It is very intuitive to use by both software developers and graphic designers, because you can either use assets from Qt's built-in material and effects library or import custom design assets created in Maya, Photoshop, MODO, and Blender. Qt 3D Studio allows a developer to edit the UI in real-time while deploying between the desktop development environment and the target hardware. This lets the developer quickly choose which hardware would be best suited for the UI being created. It also sets up an environment where you can achieve very quick and efficient human factors testing.

Qt 3D Studio is great for modeling human organs on the UI display.

### Qt Design Studio

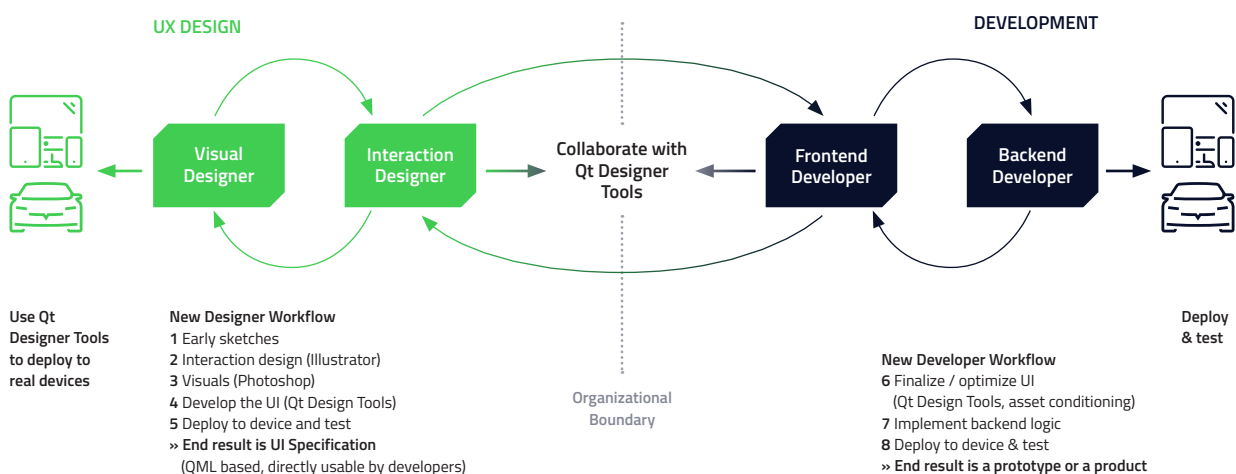
Qt Design Studio is one of the tools inside Qt Creator that has improved significantly over the previous versions. Qt Design Studio is a visual editor for Qt Quick, that lets you drag and drop your UI layout, built in Photoshop as an example, using Qt Quick Controls 2. You can manage their hierarchy, properties and directly connect them to each other. It also separates the UI presentation, the UI form files, from the UI logic, so you do not need to work directly with generated code.

Qt design tools like Qt Design Studio and Qt 3D Studio provide an enhanced workflow that lets designers focus on creating fluent, modern UIs, while developers can focus on the imperative logic which powers Qt's cross-platform capabilities. This means both designers and developers can work in environments in which they are comfortable. For example, designers can work in Photoshop and import their work into the Qt Design Studio instead of learning how to work directly in the Qt environment or relying on the developer to manually create in Qt what they have graphically designed in Photoshop.

Additionally, human factors testing is simpler because the graphical design only has to be changed once, e.g. in Photoshop, and then imported into Qt Design Studio for every UI iteration. This is instead of matching what is graphically needed in Photoshop and then having to change the code in Qt to implement it on the medical device. Qt Design Studio will be available with the Qt 5.11 release!

With Qt Creator and Qt Design Studio, you can easily do rapid UI prototyping. Modify and tweak your UI visually, and with a single click in Qt Creator, you can immediately deploy the new outcome to a desktop application or directly onto your embedded device.

## Enhanced workflow with Qt Design tools



### Key Benefits

- Deploy to real devices very early in the design process – prototype in production in minutes
- A lot less waste due to reusable assets (QML, asset import / export)
- Gives more time for developers to focus on business logic and optimizations
- A lot smaller design / develop feedback loop enable quicker time to market with better overall UX

## Connectivity and Interoperability Functionality

### Bluetooth and Bluetooth Low Energy (BT / BLE)

Qt Bluetooth provides a cross-platform API for Bluetooth functionality. Bluetooth Low Energy (BTLE) is an important way for IoMT smart sensors and devices to communicate.

Digital Health is experiencing rapid growth in the medical industry. The need for very accurate patient data in order to prevent, diagnose or treat diseases and ailments requires clinical-grade wearable technology classified as medical devices. Technologies such as Bluetooth are what makes it possible for the “things” in the IoMT ecosystem to exchange data via the cloud.

### WebGL Streaming and VNC Server (Access to Headless Devices)

Qt is compatible with both WebGL (Web Graphics Library) and VNC (Virtual Network Computing) Server. Both of these programs allow someone to control a device remotely either through a web browser or a client/server. In medical, a common use for this is in remote patient monitoring. Consider a Holter monitor. The device is worn by the patient but is controlled externally by a nurse or physician. The monitor can be programmed remotely via web portal through WebGL Streaming or a VNC client/server.

### Web/Hybrid

The Qt WebEngine module provides the WebView API which renders web content within a UI otherwise built with QML. WebView lets an application load pages either by URL or an HTML string and navigate within the session history. With Qt WebEngine APIs, you could mix different technologies by exposing C++ functionality into the web. This is a very powerful mechanism to create hybrid apps where native and web code co-exist.

There might be a need to display web content on your medical device UI. An example of this content might be as complex as a hospital administration dashboard or as simple as a search engine. A developer has all the tools they need to create hybrid applications by mixing JavaScript, style sheets, web content, and Qt components freely.

## Safety Critical Functionality

### Qt Safe Renderer

The Qt Safe Renderer makes it easy to create safety-critical systems that also have a rich graphical user interface. Safety-critical requirements for a medical device UI can be satisfied when the UI is built with Qt and the Qt Safe Renderer is used.

To create a certified system, the safety-critical features must be separated from the other parts of the system. The safety-critical functionality can be separated, for example, by running in own memory-protected processes with a certified Real-Time Operating System (RTOS). This leaves two parts that need to be addressed in a safety critical system:

- Certified tooling to produce the UI design workflow
- Designing, writing and certifying the safety-critical code

The Qt Safe Renderer solves both of these by providing tooling to design safety-critical UI items and dedicated software to reliably render the elements in a Qt-based, safety-critical system. With Qt Safe Renderer you are able to separate the safety-critical parts of your software to prevent unacceptable harm to people by lowering the impact of failures.

The Qt Safe Renderer is certified to both IEC 62304- Medical Device Software, Software Lifecycle Processes, and IEC 61508- Functional Safety of Electrical/Electronic/Programmable Electronic Safety-related Systems.






## Approach to the Medical Device Regulatory Environment

Qt software is used across numerous industries, the medical industry being one of them. Qt software on its own is not a medical device. Qt is the software framework of choice for medical device manufacturers and medical application developers to create very safe and effective user interfaces and user experiences. Medical devices built with Qt have passed Class I, Class II and Class III FDA certification and Class I, Class IIa, IIb, and III and European Union (EU) certification and are currently on the market in the US and Europe. Although Qt is not required to certify or comply with any FDA, EU or other Ministry of Health standards, The Qt Company recognizes the importance of aligning their regulatory and compliance strategy with that of their customers. Also, as a commercial off the Shelf software, Qt is considered Software of Unknown Provenance (SOUP), according to the IEC 62304 standard. In order to strategically align with medical device customers, to harmonize processes, and to satisfy requirements of SOUP under IEC 62304, Qt has established a three-lane approach to the medical device regulatory environment:

✔ **Certification:** Qt is ISO 9001:2015 certified with an established Quality Management System. As mentioned earlier, the Qt Safe Renderer makes it easy to create safety-critical systems that also have a rich graphical UI. The Qt Safe Renderer is certified to both IEC 62304- Medical Device Software, Software Life-cycle Processes, and IEC 61508- Functional Safety of Electrical/Electronic/Programmable Electronic Safety-related Systems. IEC 62304 is a standard which applies directly to the medical industry while IEC 61508 is a general functional safety standard which applies directly to other industry verticals in which Qt is used. Under the advisement of Qt's notified body, TÜV Nord, The Qt Company chooses to only certify safety critical tools and libraries within the Qt software stack.

 **COTS/SOUP Transparency:** Understanding that the Qt Safe Renderer is the certified tool in the software stack and that the Qt software in its entirety is SOUP, the question is often asked: Can Qt be used for the GUI of a safety critical medical device? The choice of technologies is up to the system designer. None of the standards will tell you to choose one software toolkit over the other. The manufacturer of the medical device is responsible for making sure that the medical device itself is safe and effective. Additionally, IEC 62304 requires that the manufacturer makes a conscious decision about their third-party software choice.

A device manufacturer will have to provide evidence of the following to satisfy the IEC 62304 requirements:

- The software provides the functionality and performance required
- The device provides the support necessary to operate the software within its specification
- The software performs as required for the system

In order to help medical device manufacturers satisfy their IEC 62304 requirements, as well as their FDA, EU, or other global certification efforts, The Qt Company provides documentation and transparency into its development process, product performance, and internal validation and testing. The types of documentation provided to customers with commer-

cial Qt licenses include, but are not limited to, Qt's Quality System, Qt's development process and proof of internal testing, source code, QA practices, test reports, and standards certificates.

3rd party software component validation is focused on risk analysis. The medical device manufacturer identifies all risks associated with the medical device they are developing and is the one responsible for performing the validation. IEC 62304, FDA, and EU regulations do not define a certification process for third-party software; therefore, the best way a vendor can support a medical device manufacturer is by providing good documentation of its development process and proof of internal testing.

 **Global Market Clearance (FDA, EU, ROW):** A number of The Qt Company's customers need specific help with navigating global regulatory registrations (FDA, EU, Health Canada, etc.) in order to sell their medical devices in these markets. The Qt Company has a very experienced and diverse partner ecosystem. Leveraging our close relationship with The Emergo Group allows our customers to better understand and anticipate the effects of pending regulations. Through this partnership our customers can best align their product development cycle with the regulatory certification cycle, making their overall go-to-market process (development + regulatory) faster and more efficient.





## Medical Industry Thought Leadership and Involvement

The Qt Company recognizes the importance of immersing itself in the medical industry in order to be a frontrunner in this dynamically changing industry. To accomplish this, The Qt Company is a member of two leading medical technology professional organizations, the Advanced Medical Technology Association (AdvaMed) and the Massachusetts Medical Device Industry Council (MassMEDIC), stepping into the integral role of industry advisor and enabler of technological innovation. In this role, The Qt Company helps influence the direction of the standards and regulations that govern the medical device industry on a global scale and has the opportunity to introduce new medical device technology advancements.

AdvaMed is a trade association that leads the effort to advance medical technology to achieve healthier lives and healthier economies around the world. MassMEDIC is an organization of medical device manufacturers, suppliers and associated non-profit groups in Massachusetts and the surrounding region. AdvaMed and MassMEDIC work closely with national and international organizations such as the FDA and EU to advocate and promote policies directly from the medical community.

The medical industry is evolving rapidly, and The Qt Company's goal is to help influence the direction of technology innovation and the standards and requirements that govern the sector worldwide. With membership in AdvaMed and MassMEDIC, The Qt Company actively contributes to Digital Health, Software, and Standards Working Groups. As a part of these working groups, Qt is collaborating with peers to help medical device manufacturers deliver the best possible health outcomes to consumers all over the world.

## Conclusion

A product offering is much more than just the features and functionalities of the product itself. It is the holistic approach for a solution to answer the problems, needs, and issues facing an industry, the focus of this paper being the medical industry. This solution does include the various features and functionalities that make users more productive and make the product itself safe, effective, reliable, and user-friendly. In addition, the solution takes into consideration the regulatory environment and further evolution of the solution and the product roadmap as a result of the deep immersion into the medical industry. The Qt Company embraces this approach in order to develop the Qt software solution with medical device manufacturers and their end-users in mind, which enables safe, effective and innovative user interface and user experience design on a wide variety of device types.

1) "FDA Impact on US Medical Technology Innovation", Josh Makower MD- Consulting Professor of Medicine, Stanford University, Aabed Meer MD-MBA Candidate, Stanford University, November 2010.

2) QML (Qt Modeling Language) is a declarative language with which designers and developers can easily build fluid, animated user interfaces and optionally connect them to any back-end C++ libraries.



The Qt Company develops and delivers the Qt development framework under commercial and open source licenses. We enable the reuse of software code across all operating systems, platforms and screen types, from desktops and embedded systems to wearables and mobile devices. Qt is used by approximately one million developers worldwide and is the platform of choice for in-vehicle digital cockpits, automation systems, medical devices, Digital TV/STB and other business critical applications in 70+ industries. With more than 250 employees worldwide, the company is headquartered in Espoo, Finland and is listed on Nasdaq Helsinki Stock Exchange. To learn more visit <http://qt.io>