Qt Group

WHITE PAPER

Safe and Effective Medical Device Development with Qt Group Products

Time, resources, cost. These key factors, among others, can 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 upon.

You will learn about Qt's core functionalities and its widely used key product add-ons for medical device manufacturers, among which Qt design and Quality Assurance tools. You'll receive a comprehensive product security overview and see how Qt Groups end-to-end software development offering 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 seventy 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. The history of Qt 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, dependable, and responsive user interface (UI). Expectations are high as millions of people worldwide 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 several different operating systems (OS). Bringing a medical device to market takes a significant monetary, resource, and time investment. A 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[1]. 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 know of the various libraries and toolsets enabling your software team to develop faster. Developers can focus on creating the best user experiences instead of coding what has already been coded for you. The workflow of Design – Develop – Test– Deploy is faster and more efficient with Qt. Qt also supports your regulatory and compliance efforts through its internal resources or industry-leading partner network.

- **Scalable Solution:** Qt is a cross-platform UI framework, compatible with a multitude of operating systems and hardware types. All you need is to write your code once, and Qt enables to deploy your app on any platform. You do not need teams of developers coding specifically for different hardware architectures and/or operating systems. Deploying apps on multiple devices extends usability, by enabling remote interaction and access to complex functionality, for instance, from our mobile phones.

- **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.

- **Future proof your medical device design and development:** Qt interactive design and development tools enable the automatic conversion of UI designs into functional code that can easily be deployed and tested on different systems and form factors. Platform-agnostic code and such rapid, iterative workflow bring independence from hardware suppliers, with reduced risks of being impacted by supply-chain disruptions or chip shortage.

In the following pages, we will explore how Qt is revolutionizing the medical industry by providing leading-edge solutions for medical device manufacturers. Our discussion will cover the core functionalities of Qt and its popular solutions targeted specifically to the medical device industry. We will also examine how Qt supports the regulatory requirements of the medical industry. Finally, you will discover how Qt has established itself as a thought leader in the medical industry by participating actively in various professional organizations and medical device working groups.

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.

Product Overview

Qt is a complete design, development, and testing framework for UI software creation. The Qt framework contains a comprehensive set of highly intuitive design and development tools, libraries, and APIs to simplify your medical device development. Qt produces highly readable, easily maintainable, and reusable code with high runtime performance and small footprint.

Qt is 100% cross-platform which means that regardless of the target operating system or hardware, Qt toolchain is all you need to build safe, effective, modern, aesthetic, intuitive, and interactive user experiences. On the one side, cross-platform setup allows for consistently branded and fully functional multiplatform experiences, ensuring full correspondence between mobile app experience and the on-device experience. On the other, it is a guarantee of futureproofing your medical device development against possible shifts in hardware of OS specifications. For example, if the initial releases of your medical device were on a Linux system and you need to change to a Real Time Operating System (RTOS), Qt ensures easy portability to the new OS. No code re-writing is needed. This also applies if you want to change the target hardware, just port the Qt code to the new hardware. No need to re-write any code.

Design

Qt Design Studio – For the creation of functional UI applications from visual designs

Qt Design Studio has features that transform your design into a fully functional user interface. When imported in Qt Design Studio, your design becomes a real UI application. You can test, preview, and fine-tune your UI components to pixel perfection, in real-time preview, emulator, or target device.

Qt Design Studio is a UI composition tool that turns design visions into functional applications. It's also the best tool for adding visual magic to your UI design through animations, transitions, 2D and 3D graphics, and visual effects. The tool enables a new level of collaboration between designers and developers, where the visual component of the UI and the backend functionalities can be advanced cooperatively in parallel.

Designers can create UI assets with both 2D design tools (Figma, Sketch, Adobe XD, Adobe Photoshop, and Adobe Illustrator) and 3D design tools (Blender, Maya, and Qt 3D Studio). When imported into Qt Design Studio, such graphics assets are automatically converted into QML code and ready to be converted into fully functional applications. Developers can simulate interactions, validate dynamic behaviors, preview their designs in real-time, fine-tune the UI to pixel perfection, and test them on any target device.

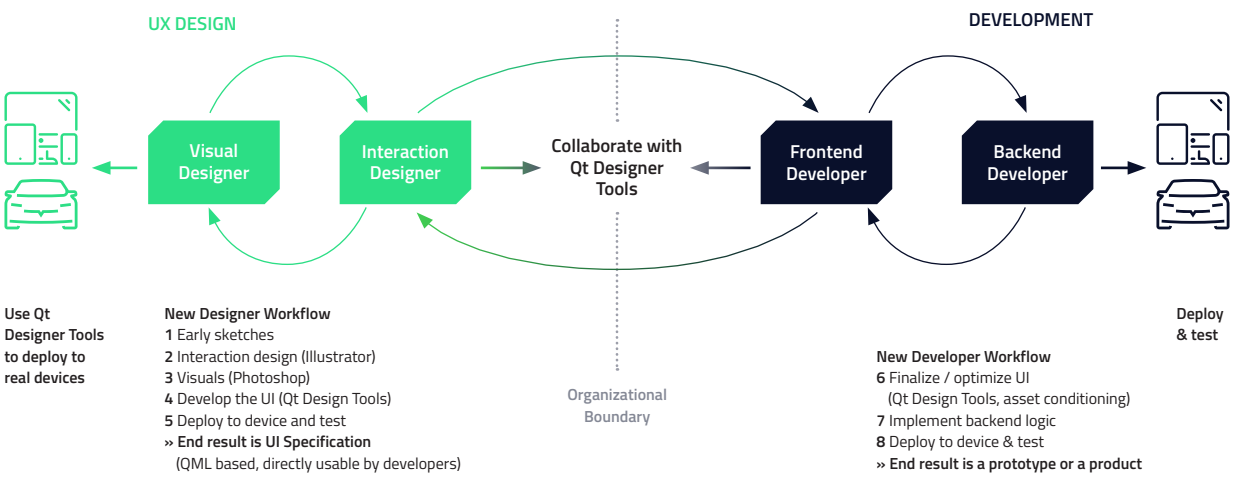
Everything built in Qt Design Studio is cross-platform by nature and can be compiled into any hardware or operating system. With one unified framework, one common language, fewer feedback loops, and faster iterations, Qt Design Studio closes the gap between designers and developers.

Qt Design Studio - Connecting Stakeholders Across the Entire Medical Device Development Workflow

Qt Design Studio seamlessly connects the UI creation workflow between graphic designers and software developers. But this is just the beginning. Other stakeholders do not have to wait for a finalized product to begin other types of clinical and human factors testing. By using Qt Design Studio, your clinical and human factors teams can review prototypes and test very early on functional UI/UX prototypes enabling early corrections and faster iterations. Changes can be designed-in during development, with clinical and human factors testing input, instead of retrofitting them when such type of testing commences.

Using our web-based Qt Design Viewer, stakeholders can access and interact with the actual UI application over the web, not only to see its appearance, but to actually vet and test the intended functionality. The benefit is that formal clinical trials and human factors testing may require only minor fixes, if any, that are easy to implement and do not require any medical device design rework.

Enhanced workflow with Qt Design tools



Develop

Qt Creator – A Cross-platform IDE for software development

Qt Creator is a cross-platform integrated development environment (IDE) built for the maximum developer experience. Qt Creator runs on Windows, Linux, and macOS desktop operating systems and allows developers to create software across desktop, mobile, and embedded platforms.

Qt Creator's advanced code editor lets you write software in C++, QML, JavaScript, Python, and other languages. It features code completion, syntax highlighting, refactoring and has built-in documentation at your fingertips. Qt Creator integrates with most popular version control systems, including Git, Subversion, Perforce, and Mercurial. UI developers use Qt Creator to build and run software on desktop, mobile and embedded operating systems. The build settings allow you to easily switch between targets.

The Qt device emulator allows you to test and debug applications under the same conditions of your actual target device. The Qt Quick Compiler allows you to compile source code into native machine code, accelerate start-up time and UI performance, and protect your source code and intellectual property.

Analyze & Test

Quality Assurance Tools

Qt's Quality Assurance tools allow you to perform in-depth analysis and testing to ensure your software meets the high standards that apply to medical devices: from verifying your software architecture and static code analysis to minimize technical debt and check compliance with coding guidelines and standards to analyzing the code coverage during testing and performing automated GUI testing – simply select the tools your need for your project.

Squish

The Squish GUI Tester is a tool for functional UI test automation. From within the rich Squish IDE, users can record, author, debug, and execute scripted or behavior-driven test cases for their desktop, mobile, web, or embedded UI. Squish is a cross-platform technology enabling test automation on any toolkit in the market, with unparalleled support for the
Qt framework.

Coco

Coco is a multi-language, multi-platform code coverage analysis and profiling tool. It reveals untested code and limit use cases by reporting the portions of code that haven't been executed during a run. A perfect fit for safety-critical systems, Coco can be used in compliance with regulatory safety mandates in automotive, medical, avionics, railway, or other industries.

Test Center

Test Center is a centralized test result management platform which organizes, aggregates, and monitors your software test results as your application evolves. Web-based, lightweight, and easily accessed from any browser, Test Center quickly provides application health insights at a glance for the whole team in a collaborative way. Test Center also includes ready-made integrations to test-and-requirement management, bug tracking, and widely used CI tools to establish traceability and connect test automation to the entire development process.

Axivion

Axivion Architecture Verification and
Axivion Static Code Analysis are industry leading analysis tools, which are ideal for developing safety-critical software. Continuous analysis of your software architecture allows you to use it as a guide and standard for discussing the impact of new features. Ensuring any modifications made to the code are in-line with the specified architecture, makes long-term targeted and planned development of your product possible.

By automatically reviewing your code on a daily basis, you can uncover and stop software erosion (also known as technical debt). Checks for clones, cycles or unreachable code are performed during the static code analysis, while at the same time ensuring compliance with metrics, coding guidelines and standards such as MISRA or ISO IEC 62304.

Data Management and Analytics

The Solution to Support Your Post Market Surveillance

Under EU MDR Article 2(60) and US FDA Section 522 regulations, post-market surveillance is an essential requirement for medical device manufacturers. These frameworks mandate that manufacturers collect, record, and analyze relevant data throughout a device's lifecycle to identify necessary corrective or preventive actions and demonstrate a favorable benefit-risk profile. Other global governmental ministries of health have similar or identical post-market requirements to the EU and the US.

One of the foremost challenges of implementing a reliable Post-Market Surveillance System is obtaining accurate, complete, and trustworthy data.

Traditional methods heavily rely on the following:

- Subjective surveys from healthcare organizations
- Time-consuming and expensive third-party studies
- Limited clinical registries
- Retrospective user and patient feedback

These approaches create significant blind spots, producing delayed, filtered, and often incomplete insights about real-world device performance. Manufacturers frequently make critical decisions based on limited data samples that may not accurately represent actual device usage in clinical settings.

Qt Insight Tracker eliminates these blind spots by providing analytics directly from your medical and IVD devices. It differs from traditional methods:

- Captures authentic user interactions as they happen
- Delivers objective performance metrics instead of subjective reports
- Identifies specific features causing user friction or technical issues
- Provides continuous data streams rather than periodic snapshots
- Reveals unexpected usage patterns that surveys might never uncover

The direct device-to-insight pipeline transforms your regulatory compliance by:

- Detecting potential safety or performance issues before they escalate
- Supporting CAPA plans with quantifiable evidence
- Revealing precise usage patterns across different environments
- Documenting real-world benefit-risk profiles with actual performance data

With Qt Insight Tracker, manufacturers can stop relying solely on the traditional fragmented and delayed feedback methods and access a continuous stream of actionable insights from their devices in real clinical use. This fundamental shift in data quality strengthens regulatory compliance and provides the evidence needed to truly understand how your devices perform throughout their lifecycle.

Approach to the Medical Device Regulation 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 effective safety-critical 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 Group 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. 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 Lifecycle 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 Group chooses to only certify safety critical tools and libraries within the Qt software stack.
Qt Quality Assurance tools Squish and Coco are fit to be used for safety-critical software applications in compliance with IEC 62304 and ISO 13485. Axivion Static Code Analysis has been certified suitable in development of safety related software according to IEC 62304 up to Class C and IEC 61508 up to SIL 4. SGS-TÜV Saar GmbH confirms this up to the highest level of the safety requirement contained in the respective standard.

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 UI 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 ensuring 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 Group provides documentation and transparency into its development process, product performance, and internal validation and testing. The types of documentation provided to customers with commercial 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.

Third 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.

For Qt Software Quality Solutions, Qt Group provides Tool Qualification Kits. The results of the Tool Qualification Kits are used as an evidence that tool is working according to safety standards. These kits do not provide any certification for the Qt software quality solution (Axivion, Qt Squish, or Qt Coco) or for customer products. Rather, these kits help the certification process to validate the Qt software quality solution with less customer effort and shorter lead time. For Qt Squish and Qt Coco, a small professional service is necessary to set up and run the qualification tests. For Axivion, the test kit is provided to the customer to run themselves; however, Qt Group can also run the tests for the customer for a nominal professional services fee.

Global Market Clearance (FDA, EU, ROW): Several of the Qt Group's customers need specific help with navigating global regulatory registrations (FDA, EU, Health Canada, etc.) to sell their medical devices in certain markets. The Qt Group 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.

Qt Product Security Overview

Qt Security Overview

The Qt Group has implemented regular processes to reduce the risk of introducing security vulnerabilities into the Qt code-base and releasing them to other Qt users. A Core Security Team of Qt developers was established with the responsibility of ensuring that this policy is followed.

The established code review process and commit policy prevent bad or compromised actors from committing malicious code or backdoors to the Qt codebase. Furthermore,

- The Qt source code is regularly scanned using static code analysis tools.
- Qt functionality that is designed to consume untrusted data is regularly tested using fuzzing.
- High priority issues discovered through static code scans and fuzz testing are reported as security issues and addressed before the next release.
- For each Qt release, third-party components are updated to the latest version that is compatible with the respective Qt release.
- For each release, the Qt installer and other binary content in the released packages are scanned with antivirus tools.
- The Core Security Team monitors the Common Vulnerabilities and Exposures (CVE) database for vulnerabilities in third- party components and coordinates the application of necessary patches with the module maintainers

Trusted and reliable cybersecurity

With almost 30 years of successful use across more than 70 industries worldwide, the Qt Group delivers battle-proven technology particularly suited for building high quality, secure applications. Providing access to the source code, Qt is a reliable partner with a dedicated QA tools offering and a large customer and partner ecosystem whose collaboration, use cases, and feedback help mitigate cybersecurity risk.

Code review

Qt's development is both auditable and transparent with a mandatory code review process with clearly defined requirements, a merit-based review system, a continuous integration system, and frequent releases with security updates. Software development is organized in The Qt Project under open governance. The Qt code review process includes mandatory review for all changes (patches), merit-based approver/maintainer roles, and code review and code commit policies. Qt security-critical code is reviewed and tested to cybersecurity industry best practices. Software development processes are consistently reviewed and updated so that critical code is captured and identified for this process.

Continuous Integration

All changes must pass the Continuous Integration System. This includes compilation tests in various platforms and configurations, unit tests to ensure no functional regressions, and documentation and license scans.

Security Test Magnitude

Over **10M**	Tested on **~50**	**~20,000**	**Multiple**
lines of code	operating system / platform configurations	automated test sets run per config	processor architectures (Intel, ARM)

Third-party code

Qt source code contains code from third-party origins. The third-party code is regularly updated before Qt releases. Security-critical third-party code is blocked from Qt releases unless the third-party code is up to date to its most recent release. Upstream releases and Common Vulnerabilities and Exposures (CVE) of third-party code included in Qt are regularly monitored.

Transparency

Qt has a strict release process with defined milestones and additional processes for security issues with prioritized handling of these security related issues. These strict milestones guarantee no "rushing in" of features for any given release. There is a feature freeze approximately 13 weeks before targeted release date for both major and minor Qt releases. The Qt Group provides public snapshots for broad testing and before each release with extensive Release Test Automation (RTA). The Qt Installer and other binary content in the released packages are scanned with antivirus tools. Security fixes are released immediately as patches and are not required to be held until the next scheduled release.

Long term support

Qt long-term-support (LTS) releases are especially important for regulated industries, which must adhere to additional quality and safety requirements. With its LTS policy, the Qt Group ensure that medical software built with older versions of Qt will be maintained over long periods of time. Medical device manufacturers can trust that Qt code is always supported, without the need to move to new versions and request new certifications.

Security

A Security Issue is defined as an Error that may cause a vulnerability in a system that uses the Licensed Software. Should a security incident arise, Qt has a defined process for handling these security related incidents. The Qt Group will make commercially reasonable efforts to solve any errors reported by Designated User(s) with a response time not to exceed 1 day for any security issues reported.

Static analysis and fuzzing

The Qt code goes through extensive static analysis and fuzzing. Static code analysis tools used include Qt's own static analysis tool, Axivion, along with other tools independent of the Qt product line. Qt API are fuzz tested using OSS-fuzz, and the results are publicly available. Additional measures taken include clone management, cycle detection, and detecting unreachable code.

Auto-Generated Software Bill of Materials (SBOM)

Medical device manufacturers globally are managing new SBOM requirements designed to strengthen cybersecurity across the industry.

These requirements come from regulatory bodies like the FDA and European Medicines Agency, as well as industry standards. A Software Bill of Materials (SBOM) is simply a complete list of all software components used in a medical device.

European compliance centers on the Cyber Resiliency Act (CRA), which requires machine-readable SBOMs covering top-level dependencies as part of CE Mark certification for medical devices and IVDs.

US requirements focus on internet-connected devices and those with cybersecurity exposure. Under Section 524B(b)(3) of the FD&C Act, manufacturers must document all commercial, open-source, and off-the-shelf software components, including names, versions, suppliers, and dependencies. The FDA extends this requirement to include support timelines, end-of-support dates, and known vulnerabilities, particularly for third-party components.

The scale challenge makes manual SBOM creation impractical. Qt 6.8.0 addresses this through automated generation during builds, enabling vulnerability scanning, license compliance checks, and file integrity verification.

Qt's "Build SBOM" approach compiles data from source files, dependencies, existing components, and build processes. Each Qt Framework repository produces an SPDX v2.3 formatted document in both tag:value and JSON formats. Online installer users receive SBOMs automatically in a dedicated directory.

This automation transforms a complex compliance requirement into a streamlined process, delivering the comprehensive software documentation regulators require while supporting ongoing cybersecurity management throughout your device lifecycle.

Medical Industry Thought Leadership and Involvement

The Qt Group 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 Group 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 Group helps influence the direction of the standards and regulations that govern the medical device industry on a global scale and can introduce new medical 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 Group'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 Group 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 an holistic approach to solve the problems, needs, and issues an industry is facing. Qt includes the required features and functionalities that make users more productive and products safer, more effective, reliable, and user-friendly. In addition, the Qt framework takes into consideration the regulatory environment and further evolution of the solution and the product roadmap as a result of its deep immersion into the medical industry. The Qt Group embraces this approach in order to develop the Qt software solution with medical device manufacturers and their end-users in mind, enabling thus safe, effective, and innovative UI/UX experience on a wide variety of devices.

Qt Group

About Qt Group

Qt Group (Nasdaq Helsinki: QTCOM) is a global software company, trusted by industry leaders and over 1.5 million developers worldwide to create applications and smart devices that users love. We help our customers to increase productivity through the entire product development lifecycle: from UI design and software development to quality management and deployment. Our customers are in more than 70 different industries in over 180 countries. Qt Group employs some 700 people, and its net sales in 2022 were 155.3 MEUR. To learn more, visit www.qt.io.

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06 - 2025