

A background image showing a medical monitor displaying vital signs like heart rate (105), blood pressure (82/65), and SpO2 (100). To the right is a control panel with buttons labeled in Russian: 'Откл. тревоги', 'Отчет', 'Основной экран', 'Выход из меню', 'Выход из экрана', 'Отслеживание', 'Меню'.

DRIVE YOUR INNOVATION FASTER

With Base2 medical device development expertise

Medical devices manufacturers are under increasing pressure to bring innovative, fully compliant products to market faster, with higher quality and lower cost margins. Delivering high-quality products on time in strictly regulated industries like yours can challenge even the most well-organized company. To get a competitive edge you need to embrace Digital Innovation – new technologies, methodologies, and culture.

Base2 specializes in helping your software development organization embrace Digital Innovation for immediate impact, as well as ongoing agility and efficiency. We partner with you to help solve your most pressing problems by delivering proven processes and best practices to speed and improve your development processes. Faster, higher quality product delivery means reduced operating costs, increased scale of delivery, and quicker time to market – all of which leads to better customer experiences

OUR MEDICAL DEVICE EXPERTISE

Our team has comprehensive experience in the full spectrum of medical device development processes, from underlying regulatory and consensus requirements through product and service realization.

We've helped leading life sciences and medical device companies overcome project delivery, budget, schedule, and regulatory compliance challenges, including:

- > A user-friendly SaaS cold chain application that integrates with smart shipping containers, generates excursion alerts and delivery notifications to provide real-time tracking. The system also includes a patent-pending shelf-life timer solution for supply chains handling time-sensitive shipments.
- > Rapid remediation of two long-outstanding Corrective and Preventative Actions (CAPAs) for a Class III life-saving device. Analysis uncovered root cause of noncompliance, and quick resolution allowed products to continue shipping without costly design changes.
- > Business intelligence roadmap and an agile, innovative technical architecture resulting in a dashboard providing real-time detail into 17 KPIs, including number of patient visits, visit durations, diagnoses made, and drugs prescribed in order to quickly detect trends and improve customer experiences.
- > Migrated an innovative imaging device accessory from lab to production on a battery-operated tablet, running an embedded operating system and scripting language. New software architecture enabled tracking of device state, such as battery life, and optimized performance to swiftly display images.



Where We Can Help

Your existing products need sustainment while you develop new products.

Our team can deliver on critical elements necessary for sustaining existing products for revised technical standards, RoHS compliance, labeling updates, usability, etc. This frees your core staff to develop new and innovative products.

Your CAPA backlog is diverting resources from NPI and product sustainment efforts.

Our consultants can rapidly integrate into your remediation teams to reduce your CAPA load. We specialize in root cause analyses to drive long-term solutions to prevent recurrence.

NPI needs a kickstart.

Our systems and software engineering experience can help you early in the NPI process to identify and document all new product requirements while you concentrate on your core focus of developing innovative products.

You need a technology change agent.

Marrying legacy systems or programming languages with today's technologies can be difficult if your team lacks expertise in new technologies. Our experts can guide these technology changes to help your team stay current with changing product and market demands and to add new functionality to older systems.

Your product lifecycle process needs improvement.

The highest quality products result from a complete product lifecycle that is well managed. We can guide you through the entire process – end-to-end. This starts with an accurate product definition that incorporates the voice of the customer; a product roadmap that sets out product features, minimum viable product (MVP), and market window; all the way through to regulatory compliance, production and support.

You're looking for specific expertise.

We can lend a hand by filling gaps in your team's skillset either temporarily or on a long-term basis. Our DevOps and systems engineering staff can work with your team to help improve processes that will streamline and accelerate your development. And, we can develop peripheral parts of software to integrate or tie in with your core system – all fully verified and validated to meet all system requirements.

How We Help: Our Services

Improving product development has real business value, from reducing operating costs to enriching customer experiences. Base2 can help accelerate and improve your product development processes, while also helping you embrace Digital Innovation for more agility and efficiency going forward.



CUSTOM SOFTWARE

Our experienced software engineers develop innovative cloud, web, and mobile software applications that give you a competitive edge. Our engineering services range from embedded systems to enterprise application development and cloud services, including AWS and Azure.



SYSTEMS ENGINEERING

We build on the strength of your internal development and product teams to solve large, complex problems. We apply systems engineering tools, techniques, and processes to bring products to market more efficiently so that you can hit your delivery targets on time and within budget.



DEVOPS

We excel at refining DevOps practices. With our industry experience and tool sets we can increase the quality and speed of critical software projects throughout the entire development lifecycle. Your digital systems need to operate at peak efficiency 100% of the time; we ensure that your cloud infrastructure is always available, secure, and scalable.



SYSTEM INTEGRATION

Our consultants help connect diverse, proprietary, and legacy systems to the new, technologies necessary to be innovative and competitive. We build the technology bridges your product development lifecycle requires for quality, speed, and Digital Innovation.



INFORMATION SECURITY

Security is inherent in all our customer engagements. We provide the guidance, processes, and services to safeguard data, protect your assets, and ensure compliance whether through security architecture and design, software code-coverage solutions, auditing and remediation, penetration testing, or white box testing.



ARTIFICIAL INTELLIGENCE & MACHINE LEARNING

Smart, interconnected devices generate troves of data. From increasing business knowledge, reducing data storage and transmission costs, to eliminating unnecessary code we help you leverage AI and ML in the most beneficial manner for your products and development processes.

Our Unique Approach

We aren't your average consultancy.

We have expertise and hands-on experience across a number of industries, especially highly regulated ones. That gives us a head start and speeds the learning curve when it comes to understanding your company and your products.

We are an extension of your team.

Your business objectives and project goals become our top priorities. We become an extension of your team—complementing your skilled engineers, technologists, and product managers. And we partner together to determine where we can add the most value, the quickest. We bring top talent who are experts in their field and are passionate about solving tough problems. We also utilize and share best practices and processes—to overcome obstacles and accelerate growth.

We earn your trust – every step of the way.

We've earned—and we cherish—our clients' trust. We deliver quality work—every time, and we take great pride in our results and in developing enduring relationships with our clients.



Base2 assists companies in giving form to Digital Innovation and delivers the processes and practices needed to develop complex interconnected systems. We help companies solve challenging problems by taking a whole systems approach to designing and developing the technology, processes, security and Systems Engineering required for

success. Companies across heavily regulated industries, such as aerospace, defense, transportation and medical devices, have utilized our expertise and best practices to speed up product development and accelerate time to market. To learn more about how Base2 helps drive Digital Innovation, please visit www.base2s.com.