



Auriga: Healthcare and Medical Devices Expertise

FOUNDED IN 1990 and headquartered in Wilton, NH, Auriga is at the top of the list of the oldest and most adept U.S.-Russian IT outsourcing service providers. Auriga provides comprehensive services that cover the overall software life cycle, for world-known medical product vendors and equipment manufacturers.

Apart from market pressures to improve product quality, accelerate new product introduction, and reduce operational cost, medical devices manufacturers have the additional challenge of operating in a highly regulated and safety-critical environment. The safety and reliability of the end product cannot be compromised; quality is paramount. Auriga understands the special requirements of the medical companies and ensures that a customer not only receives quality software services but that the product is also fully compliant with all current FDA and European Community regulations for medical devices.

The highest level of each service provided for Healthcare vendors is ensured by SPICE assessment focused on life critical software development compliant standards performed in 2008. Auriga provides software development services compliant with FDA 21 CFR Part 820, ISO 13485, IEC 60601-1-8 and IEC 62304, and performs Validation and Verification services for vendors of Class II and III medical devices.

In 2009 Auriga was included in “Best 5 Rising Stars by Industry Focus: Healthcare” of the Global Outsourcing 100 lists by the International Association of Outsourcing Professionals. In 2008, Auriga was named to “Best 10 Companies by Industry Focus: Health Care” sub-list of the same list.

In the complex world of medical technology, proven experience and expertise are critical assets. Auriga is committed to sharing its extensive experience and competence to anticipate and meet your needs. Our portfolio of industry-focused solutions spans a range of services from custom medical device software development to software validation and independent safety testing for industry giants including Dräger Medical.

Auriga provides the whole range of services in the Healthcare and Medical Devices sector including:

- Software development
- Software testing, verification and validation
- Technology conversion (Re-engineering & porting)
- Technology consulting

- Product maintenance and support

The most recent example of Auriga’s experience with a large medical solutions provider is the cooperation between Auriga and Dräger Medical, one of the world leaders in medical equipment manufacturing. Outsourcing various development and testing tasks to Auriga enabled Dräger Medical to get access to a wide pool of highly experienced, competent specialists, establish a stable engineering team, and allow its own engineering team to focus on innovation.

Project Samples

Auriga has completed a wide range of projects in the medical area targeted at creation of platform level solutions for modern medical systems, according to 21 CFR Part 820 and ISO 13485 quality standards.

Central Patient Data Monitor for Large Hospital-Scale Network

Auriga performed the complex porting of a central patient data workstation, integrated with life-supporting medical equipment, for a medical hospital-scale network from AIX/PowerPC to Linux/x86. The core product was designed to provide real-time centralized management of patients by displaying comprehensive patient data (real-time vital signs and hemodynamics, respiratory and ventilator data, and laboratory values, etc.) for both telemetry and bed-ridden patients at one single point.

New version for Critical Care Workstation in Hospital-Scale Network

Auriga’s engineers developed a new version for one of leading products from Dräger Medical’s product line critical care workstation that displays clinical information from a variety of sources at the bedside. The product (critical care workstation) was designed by Dräger Medical to display clinical information from monitors, ventilators, medical imaging archives and hospital information systems at the bedside, and to organize it right at the point of care. The workstation allows for the examination of flow loops, waveforms and long-term trends, including a patient’s past responses to therapy, and reviewing medication records and potential drug interactions—all without leaving the patient’s side. Auriga participated in all stages of the full

life cycle software development (product requirements elaboration, design, prototyping, coding, testing, bug-fixing, optimization) of the product's new version.

Within this project's frameworks, the Auriga team performed the following activities:

- Full cycle software development (product requirements elaboration, design, prototyping, coding, testing, bug-fixing, optimizations)
- Integration of full set of 3rd party applications into the product;
- Participation in the formal verification processes that are used for this product

Communication and Control Package for a Modular Component Monitor Development

While working for the Customer, Auriga's engineers created a number of drivers to support a PCI card, allowing the main processor of Kappa monitors to communicate with other system components. Within the scope of this project Auriga's developers successfully accomplished the following:

- Device drivers development
- 3rd party device drivers integration
- Access library creation
- Solution testing

Boot Loader for a Patient Monitor Development

As a part of development of a new patient monitor, RedBoot boot loader was ported to the Customer's platform and enhanced with the network firmware upgrade support to allow performing firmware and software updates on these monitors in the field. The following tasks were successfully completed:

- Porting the RedBoot boot loader to the Customer's platform
- Creating a module for boot loader that downloads the data via TFTP, puts in Flash, and performs other firmware-specific actions
- Creating a TFTP server that can run on the Customer's critical care workstation

Remote View Subsystem for Modular Monitors Development

The subsystem enables remote connection from one patient monitor to another. This remote connection may be vitally important for life-critical patient monitoring systems. The subsystem allows checking for vital information and patient conditions from other bed-side monitors. While fulfilling this project the following tasks were successfully completed:

- Implementation of a data storage solution for remote

data

- Updating visual elements to display both local and remote data
- Integration into existing system architecture
- Testing and debugging for various types of devices

Testing Framework Development and Implementation

Auriga performed software testing and verification for several healthcare products, including both isolated product components such as services, networking subsystems, reusable software platforms and complete patient monitoring solutions with complex user interfaces equipped with various external devices and communicating with other system via the hospital network. To test and provide diagnostics for various components of the Customer's strategic products, Auriga performed the following activities:

- Definition of the test specifications and manual test implementation
- Design and implementation of complex automated testing frameworks based on Rational Robot and CppUnit unit testing library
- Testing scripts development
- Design and implementation of several debugging and inspecting tools
- Unit tests implementation in accordance with high-level component requirements
- Integration of resulted products into the Customer's components environment

Verification of Microsoft Hot Fixes (QFEs) for the medical environment

To ensure all customer Windows-based medical equipment software against possible vulnerabilities, the Hot Fixes released by Microsoft on the regular basis are applied to the target systems. Auriga selects and analyzes the proper Hot Fixes, and tests them in the appropriate FDA controlled environment to ensure they do not affect the operation of the medical software. Finally, Auriga develops verification reports for the customer.



Technology Expertise

Auriga has extensive experience with various operating systems and processor architectures, as well as with communication protocols and technologies, and industrial platforms.

Operating systems

- Linux, ucLinux (microLinux), embedded Linux
- LynxOS, VxWorks, OSE, pSOS, QNX
- Windows 95/98/NT/2000/XP/2003
- Windows NT/XP Embedded
- Windows CE
- SunOS, Solaris, HP-UX, AIX, Digital UNIX/Tru64 UNIX, SCO UnixWare, SCO OpenServer

Processor architectures

- PowerPC
- ARM and XScale
- MIPS
- Intel x86
- SPARC, Ultrasparc III
- Super-H
- Alpha
- Intel i960