Core Competencies and Areas of Expertise

We provide software development and contracting / outsourcing support predominantly in the following areas:

1. **Medical device development**

- **Regulations, Standards, Regulatory Audits, Compliance (FDA and ISO 13485)**
  Compliance with these standards involves rigorous testing, documentation, and traceability throughout the development and production processes to ensure devices are safe and effective.

- **Specific Development Methodologies for Medical Devices**
  Specialized methodologies like Design Controls and Risk Management, which align with regulatory frameworks. These methods emphasize thorough documentation, risk assessment, and iterative testing to meet high standards of safety and effectiveness. Common methodologies include Waterfall, V-Model, and Agile approaches adapted for medical devices, each of which supports stringent validation, verification, and documentation practices.

- **Product Development Know-How – From Initial Prototype to Validated Market-Ready Product**
  Transforming an initial concept or prototype into a fully validated, market-ready medical device. It includes stages like feasibility assessment, design, prototyping, testing, regulatory approval, and final validation. Each stage ensures the product meets design and quality specifications, is scalable for manufacturing, and complies with regulatory requirements, resulting in a reliable and compliant product ready for market launch.

2. **Patient Management Optimization & Automation**

- **Efficient Appointment Scheduling & Resource Utilization:**
  Solutions to optimize patient scheduling, ensuring minimal idle time and maximum resource utilization. These systems help reduce the number of missed appointments and improve patient flow, leading to better resource management and increased revenue.

- **Seamless Follow-up and Tracking:**
  Our systems provide robust capabilities for tracking patient progress and automating follow-up procedures, ensuring no patient is left behind, and enhancing overall care.

3. **Hospital System Integration & Support**

- **End-to-End Hospital Systems Integration:**
  Streamlining communication between hospital systems, enabling seamless data sharing and improving the quality of care. Our services also include managing complex complaint investigations and swift troubleshooting, ensuring smooth daily operations.

- **DICOM and HL7 Compliance:**
  Our team has extensive experience with industry standards such as DICOM and HL7, ensuring your systems are fully interoperable and compliant with global healthcare communication protocols.

4. **Regulatory & Compliance Expertise**

- **FDA and ISO 13485 Regulatory Compliance:**
  We are proficient in **FDA** and **ISO 13485** regulations, providing comprehensive support in developing documentation that meets these stringent standards. We assist in preparing for audits, participating in audit processes, and conducting **root cause analysis** to identify and resolve any issues, ensuring your systems adhere to the highest regulatory standards.

- **FDA Regulation & Formal Verification Processes:**
  In addition to ISO 13485, we navigate complex FDA regulations, ensuring your medical devices and systems meet all necessary requirements. Our formal verification services include comprehensive auditing and documentation, reducing risks and ensuring compliance.

- **DICOM Conformance Statement & EU Regulatory Process:**
  We understand the intricacies of EU regulations, and we are capable of guiding your organization through the DICOM Conformance Statement process to meet all regional and international standards.

5. **PACS & Third-Party Tool Integration**

- **Picture Archiving and Communication System (PACS) Support:**
  Our expertise includes seamless data transfer and integration of third-party tools with your PACS, ensuring smooth data archiving and retrieval for medical imaging systems.

6. **Medical Imaging Expertise Across Modalities**

o We bring specialized knowledge in all key **medical imaging modalities**, including:

  o **X-ray Radiography**

  o **Computed Tomography (CT)**

  o **Magnetic Resonance Imaging (MRI)**

  o **Ultrasound (Sonography)**

  o **Single Photon Emission Computed Tomography (SPECT)**

  o **Positron Emission Tomography (PET)**

  o **Mammography**
     Whether upgrading your existing imaging systems or integrating new technologies, our solutions ensure accurate, high-quality imaging that enhances diagnostic accuracy and patient outcomes.

7. **Advanced Image Contouring & R&D Support**

o **Smart Contouring Solutions:**
   We reduce manual workload through advanced image contouring technology, cutting down the time and effort required for radiologists and technicians, allowing your team to focus on more critical tasks.

o **R&D Project Collaboration:**
   Our team is ready to partner with you on research and development projects aimed at creating new, innovative imaging technologies.