VIEW FROM THE TOP

Looking Anew at Technology Management

Founded in 2009, Renovo Solutions differs from other independent service organizations (ISOs) in that it focuses solely on providing healthcare and life sciences technology management services. Tell us about the company's origins and the reasoning for this focus.

My partners and I created Renovo Solutions based on where we felt the future of clinical engineering (CE) and healthcare technology management (HTM) was going. Our primary mission is to provide innovative solutions and services that address the evolving needs of our HTM clients, whether as a fully outsourced solution or as a support role for existing in-house CE programs.

The four founders of the company all come from a background in CE services and collectively have more than 100 years of CE experience. Together, we have successfully implemented and professionally managed more than 500 technology management programs during the past 35-plus years.

We have found that very few, if any, companies in our industry that provide multiple healthcare support services (i.e., CE, food services, environmental services) can be the best at each service line. That is why our sole business focus has been in the area of technology management for both the healthcare market and life sciences market.

What's the biggest challenge you face as CEO? How are you addressing that challenge?

Our market has been, and continues to be, a highly competitive playing field from a price perspective. Our biggest challenge as an organization is to find ways to continue to be the highest-quality provider in the market, while at the same time staying price competitive with our original equipment manufacturer (OEM) and ISO competitors. Some healthcare providers today are simply looking for the lowest price in the market, with little emphasis on quality of service.

As you know, there is a longstanding and at times contentious debate about the service and support of medical devices. What do you make of the position put forth by some manufacturers that only the OEMs should service devices?

In our opinion, there always will be certain very complicated and unique medical devices that are best maintained by the OEM. However, the vast majority of medical devices in use today can adequately be maintained by other service providers, such as qualified ISOs and in-house biomedical engineering departments. Furthermore, I don't understand how some manufacturers can profess that only the OEM should service medical devices, when several of these OEMs are currently providing multivendor maintenance services on other OEMs' devices themselves.

Sandy Morford, CCE, MBA, is chief executive officer at Renovo Solutions in Irvine, CA.

A fall FDA workshop on the question of service and support underscored the passion and competing views on this "third-party service" issue. Do you see some common ground that could be developed among all stakeholders? If so, what is it?

To us, "third party service" providers fall into three distinct categories: 1) OEMs that provide multivendor service, 2) ISOs, and 3) in-house biomedical engineering departments. The issue being raised today centers around quality of service, which often can be interpreted in many different ways. If all parties involved could reach a consensus on how the term "quality" can be measured, then we feel that is a start to a resolution on this matter. With appropriate competencies, along with access to the required AIAT (assemble, install, adjust, test) information currently mandated, third-party service organizations that implement the appropriate quality management systems should have little problem delivering high-quality support.

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How will the service model for healthcare technology be different in 10 or 20 years?

Although asset management principles and processes have not changed substantially in the past 10 to 20 years, technology has. As more medical devices are connected to hospital networks, service providers will need to develop new processes, skills, and tools to effectively manage the safety and security risks introduced by this integration of medical devices into larger systems. Expanding our focus from device support to systems support has helped us create the HTM program of the future. At Renovo, we have implemented a management framework that we call Integrated Systems Management (Figure 1). This framework incorporates the best practices of the Information Technology (IT) industry (Systems Management), along with the Risk Management and Project Management principles, to augment our long-standing Asset Management principles and processes. These processes have been incorporated into our proprietary Maintenance Management Software to automate the data collection, monitoring, and management efforts required for proper implementation.

How do your technicians and other HTM professionals stay on top of changing rules and regulations, both from federal agencies and accreditation organizations? We learned of one situation in which some maintenance changes as desired by the Centers for Medicare & Medicaid Services (CMS) happened so quickly that they were not reflected in The Joint Commission's (TJC's) own accreditation manual.

We have a corporate Clinical Engineering & Quality Assurance department at Renovo Solutions staffed by degreed and certified clinical engineers, whose responsibility it is to stay abreast of current and changing regulatory standards from TJC, DNV GL, and CMS, as well as any applicable regulatory requirements promulgated by various state departments of health services and other regulatory agencies with jurisdiction over our clients. Our company communicates with the individuals within these organizations who oversee the Environment of Care standards on a regular basis, and we also invite them to make web presentations to our team members periodically.

How about training and education overall? Healthcare technology is increasingly complex. How does the Renovo team of HTM professionals maintain its skills?

Rather than spending our training funds on building an internal training center, we devote a substantial amount of resources each year in sending our technical staff to various OEM and independent training schools. For those specialized types of equipment for which we cannot purchase technical training, we have established national master service agreements with certain OEMs and use them to complement our programs.

Does Renovo help its hospital clients develop alternative equipment maintenance (AEM) programs? If so, what are the key considerations that go into the development of such a program?

Renovo is currently an active member of the AAMI-supported Healthcare Technology Management Community Maintenance Practices Task Force. Our participation

includes providing service data that contributes to the task force's effort to create a rational, evidence-based method for efficiently managing planned maintenance (PM) programs for medical equipment. The project has four objectives:

1. Develop, and gain communitywide acceptance for a scientifically sound but simple to understand RCM-based methodology for determining which specific types of medical devices are made safer by periodic PM, along with a clear explanation of why routine PM fails to improve the safety of the majority of medical devices.
2. Develop guidelines and tools to facilitate a rational optimization of PM programs, including a standardized format for the maintenance documentation required to support the RCM-based analytical methods being proposed.
3. Create a communitywide database to provide a substantial body of quantitative evidence to support this rational optimization.
4. Build up a collection of information on each device's demonstrated level of PM-related reliability and safety based on the aggregated maintenance data for each specific manufacturer model version of different types of devices.

We have begun implementation of preliminary standardized maintenance documentation and analytical methods that will support our clients AEM implementation efforts. We will be participating in a presentation of the task force's progress at the upcoming AAMI Annual Conference & Expo in Austin, TX.

We are increasingly hearing about the need for a "bridge role" between HTM and IT staff, and HTM professionals have much to learn as the HTM and IT worlds merge (e.g., unique device identification, interoperability). What are you doing to prepare your HTM staff for these new challenges?

In addition to the Integrated Systems Management framework we have introduced earlier, we have created new roles within our organization that we refer to as clinical systems engineers. These hybrid biomedical/IT professionals possess advanced computer and network technology skillsets. We also
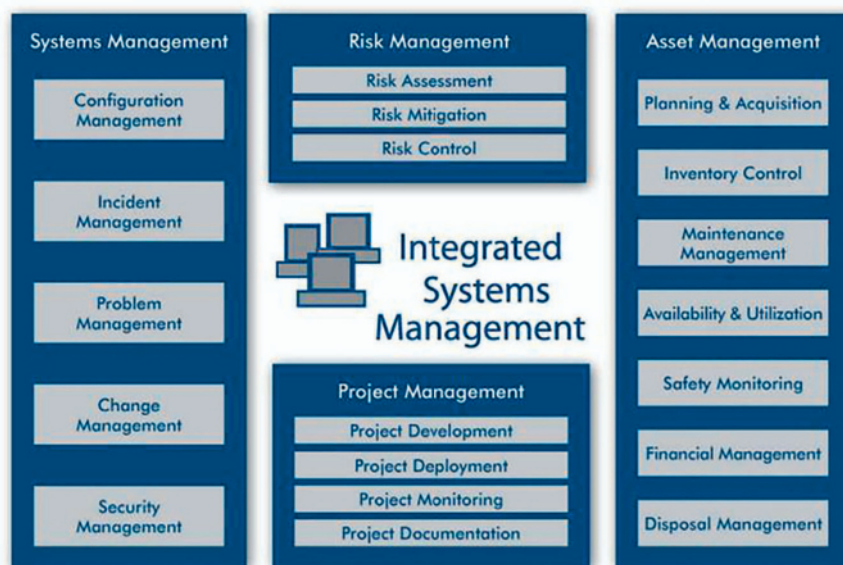

Figure 1. Integrated Systems Management framework used at Renovo Solutions

have recently partnered with a national training organization to provide online IT skills training and certification opportunities for our technical staff. We believe the "technician of tomorrow" needs to be well versed in both medical electronics and IT.

What role do Renovo HTM professionals have in combating the ever-escalating cyberthreats facing healthcare today?

Renovo has pioneered the development of the first comprehensive networked medical device management software (CE-ITLive), as both a configuration manager and an active service management tool. In addition, we are the only CE service provider that incorporates the Information Technology Infrastructure Library (ITIL) framework into the medical equipment support environment. Renovo provides comprehensive support and training to assist with managing a hospital's networked medical devices. We assist with Health Insurance Portability and Accountability Act (HIPAA) security standard compliance, in addition to ensuring that the facility's enterprise IT policies and procedures are followed. Our programs and engineers specialize in:
- Identifying and documenting unsecured medical device networks.

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- Applying configuration management processes along with remote support tools available in our ISM support module.
- Assisting with the implementation and administration of security management programs.
- Assisting facilities considering the consolidation of their CE and IT functions.
- Design and implementation of risk management programs for networked medical devices that provide regulatory compliance (TJC, HIPAA, ANSI/AAMI/IEC 80001).
- Implementing the ITIL process framework into the CE environment.
- Providing education programs that improve computer and network competence of CE staff.
- Providing selection assistance, implementation, and ongoing support of integrated medical device data systems.

The disciplines of risk management and systems engineering are starting to take root in the healthcare world. What is Renovo doing to embrace these trends?

With the incorporation of security management tools within our CE-ITLive management software, we can provide our clients with a complete risk assessment (at both the organization level and device/system level) to complement their business systems risk analysis. This report enables thoughtful risk rating and eventual mitigation planning efforts. We work collaboratively with our client IT counterparts to implement mitigation efforts along with ongoing system administration.

How is Renovo responding to the trend of more healthcare (and healthcare technology) moving outside hospital walls and into homes? Do you or will you service healthcare technology in private homes?

We have yet to encounter any requests from our clients regarding the service of healthcare technology in private homes, but we do provide service to numerous non–acute healthcare sites that are affiliated with our acute care hospital clients.

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Does Renovo use benchmarking to measure HTM? If so, how?

Our proprietary computerized maintenance management system, RENOVOLive, collects data, both operational and financial, on every service event our technicians are involved with. We use these data to look at trends and anomalies with respect to equipment maintenance, which then allows us to establish benchmarks for future comparisons.

What advice would you give to HTM professionals working in the field today on how to better position themselves for the future?

Start understanding the world of healthcare IT and how it integrates with HTM. We feel that HTM professionals are uniquely positioned to play an important role in managing the safety and cybersecurity risks our clients are facing. If you haven't met the chief information officer of your hospital, plan to introduce yourself as soon as possible.

Finally, as someone who sees healthcare technology evolving, what technical advancement has impressed you the most and why?

Wearable technologies have the potential to affect our health and healthcare tremendously. Thoughtful design, implementation, and integration with analytics tools could have tremendous impact in the very near future.

In addition, networked remote diagnostics and monitoring capabilities are constantly evolving. This advancement in technology provides the HTM remote support team the ability to proactively monitor, diagnose, and apply solutions through software or identification of suspect part(s) for timely and seamless service remediation, enabling maximized up-times and the efficient return of medical equipment back into the clinical environment. ■