Beyond Compliance: Medical Device Product Development

Balancing Product Development Effectiveness with Regulatory Compliance

Kalypso White Paper by Noel Sobelman

KALYPSO

Delivering on the promise of innovation

Executive Summary

Increased regulatory scrutiny is a reality in today's medical device industry. Over the last several years many of the industry's leading companies have been hit with an injunction, undergone a product recall, or found themselves operating under FDA consent decree. At the same time, the pressure for growth on these companies has never been greater. Driven by Wall Street, the pace of new technology, emerging market opportunities, and competition from well funded start-ups, medical device executives find themselves in an environment where they must continually innovate with flawless execution to survive.

Given this challenging environment, medical device companies are working hard to design and implement effective, high functioning innovation engines while simultaneously ensuring full FDA compliance. Finding the right balance between what can seem like competing objectives – and understanding how leading companies are doing so - is the focus of this paper.

Kalypso examined the innovation and new product development processes of more than 20 leading medical device companies between November 2007 and March 2008.

Kalypso research and analysis found:

- Designing and maintaining an effective, high-functioning innovation engine while at the same time ensuring full FDA compliance is of paramount concern to today's medical device executive.
- All companies examined have a defined new product development process structure in place and have implemented some form of Phase Gate or Toll Gate process, embraced the concept of cross-functional teams, and established some form of senior decision making committee to make project go/no-go decisions. Yet, despite having these product development fundamentals in place, over half of the companies examined are not meeting product development effectiveness goals as measured by their own return on R&D investment, new product revenue contribution, time to market, or schedule predictability metrics. Of those, an alarming number report falling far short.
- A well-designed innovation and product development process based on common industry practices is not enough. Leading companies are learning from past failures and are implementing next generation techniques and tools to make step function improvements in development effectiveness while complying with increasingly stringent regulatory requirements.

- Next generation process improvements fall into one of four categories: (1) Process Definition and Work Flow Structure, (2) Innovation Governance and Decision Making, (3) Project Teams and Team Structure, and (4) Software Systems and Tools. The best performing companies have a clear understanding of these elements and have made significant improvements in each.

Process Definition and Work Flow Structure: A Roadmap for Project Execution

A major challenge in achieving improved product development performance is determining ways in which design control processes can be applied without becoming overly bureaucratic. The top performing medical device companies demonstrate a clear understanding of the intent behind design controls and have structured their development process accordingly.

When it comes to product development process structure, medical device firms generally take one of two approaches: (1) a single process structure encompassing both business and design control work flows, or (2) two separate but aligned systems.

Single Process Structure: Business Process and Design Control as One in the Same

With a single process structure, all elements of the product development process are captured within design control procedures using a set of detailed standard operating procedures (SOPs) and work instructions to describe the who, what, and how for each task, whether the task is governed by FDA regulations or not. For example, business-oriented processes such as market assessment, intellectual property assessment, or project financial justification, are spelled out within the same set of work instructions as the Design and Development Plan or Requirements Traceability Matrix.

This approach has the advantage of keeping all development procedures in one place with one system designed to address both business and quality system needs. However, research participants were quick to point out that this approach combines rigidly-controlled design control requirements with more business-oriented processes that the FDA is not concerned about, and therefore can unnecessarily bog down project teams that require more flexibility to adapt business processes to specific project needs. After all, the FDA is concerned about product safety and efficacy, not whether a product makes money or fits the company strategy.

By intermingling business-oriented processes with design control procedures, companies inadvertently increase the opportunities for non-compliance. Once a company starts down this all-in-one path, process bureaucracy can grow as layer upon layer of procedure detail is added to cover each work flow scenario or corner case, regardless of whether or not the tasks are governed by design controls. With more detail, project teams are left with less, not more, flexibility to manage a project's business needs. Nowhere was this phenomenon more evident than in those companies who have experienced a recent FDA warning letter or consent decree. These companies tend to err on the side of more prescriptive procedures, not less. The process pendulum swings to the far end of the bureaucracy spectrum and, as a result, delivery performance suffers.

Figure 1 uses a two-by-two matrix to contrast varying levels of compliance burden (i.e., compliance process bureaucracy) against a spectrum of new product development process maturity. Kalypso found that medical device companies typically fall into one of the four resulting quadrants, with the highest performing companies falling in the upper right hand quadrant. The High Performers have achieved:

- Well defined development processes ingrained in company culture
- Project selection governed by a well functioning portfolio management process that is linked to innovation strategy
- High functioning core teams accountable for project execution
- Platform strategies that encourage design re-use
- A well defined technology development and open innovation process linked to product roadmaps
- Accountability for process performance metrics that track annual improvement
- A well functioning quality management system that has not become unwieldy with unnecessary layers of process bureaucracy

Companies who found themselves in one of the other three quadrants were not getting the business results they desire. The goal is to move your company to the upper right quadrant without jeopardizing regulatory compliance, ultimately achieving a mature product development process coupled with low compliance burden.

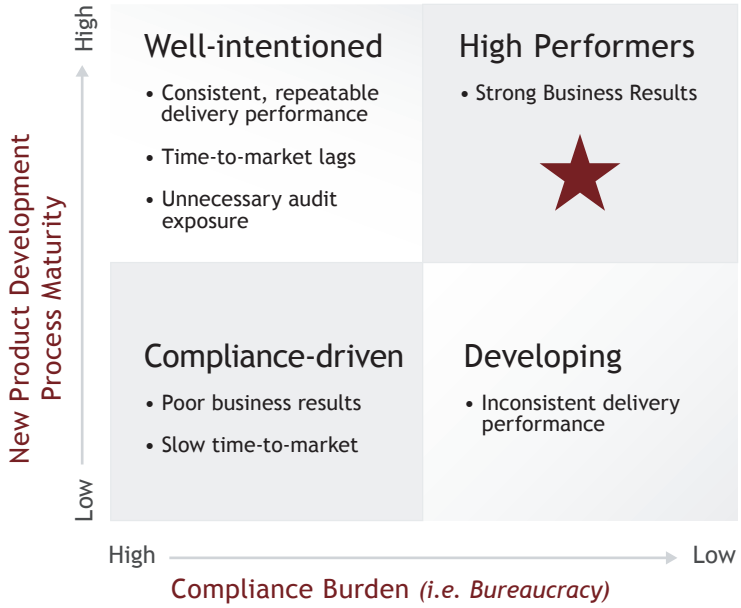

Figure 1: NPD Maturity / Compliance Framework

The goal is to move your company to the upper right quadrant without jeopardizing regulatory compliance

Separate But Aligned Systems Allow Flexibility Where Appropriate

Top performing companies have established two separate, but aligned systems as an alternative to the single process structure. Business-oriented processes that require room for judgment and flexibility are set up as a supplement to rigorously-controlled design control procedures. While an important part of the overall delivery process, deliverables such as business plans, go-to-market strategies, sales plans, and support plans do not go through the same level of process adherence scrutiny as design control deliverables such as the Design and Development Plan, Requirements Traceability Matrix, Risk Management Plan, Design Validation Report, or Manufacturing Transfer Plan. However, linkages between the two distinct processes are highlighted to draw attention to interdependencies or key connection points (see Figure 2).

Sue Pierce, Senior Director, Product Development Process for Ventana Medical Systems, a cancer screening equipment company, explained the benefits of this approach. "By separating business-oriented processes from rigidly-controlled design control procedures, we have, in effect, given our project teams more flexibility to adapt work flow to specific project needs. Project teams no longer feel like they have to follow process for process sake. Instead, they are able to adapt business process guidelines using experience and judgment without jeopardizing design control compliance."

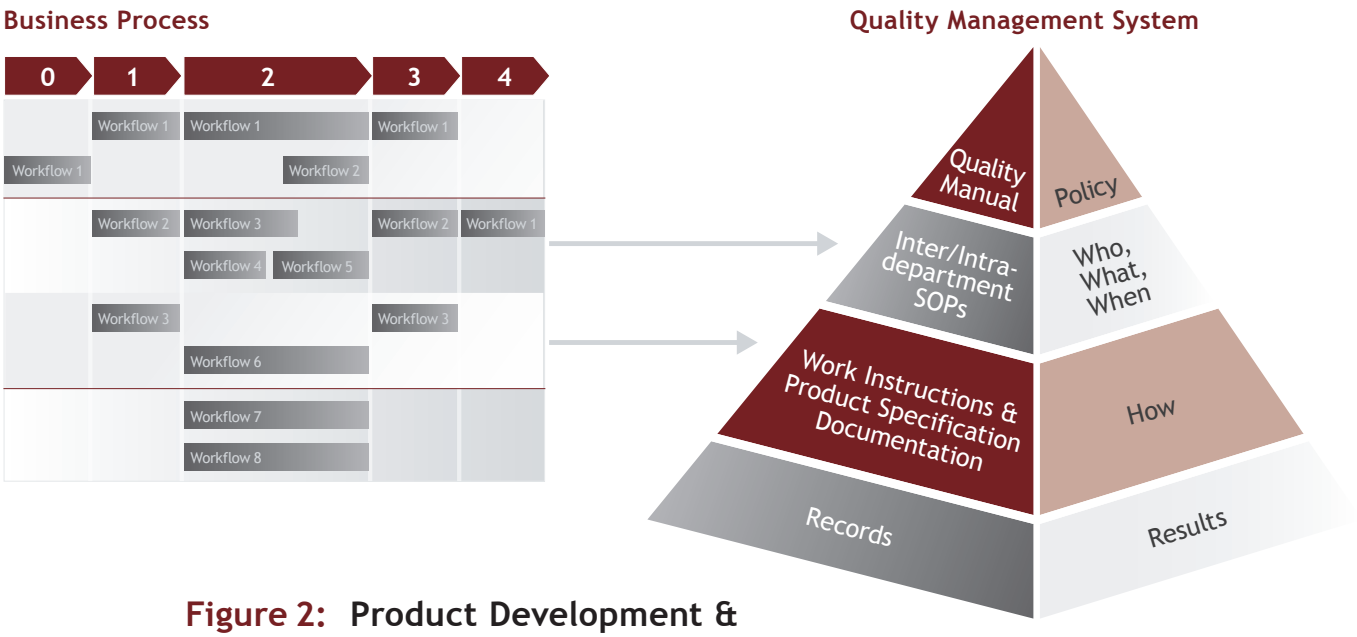

Figure 2: Product Development & Quality Management System Linkage

The new product development process provides work flow guidance to project teams for effective development execution. It references the Quality Management System where necessary for more prescriptive design control procedures and work instruction.

Companies that have adopted this approach have discovered additional opportunities to streamline by decreasing the total number of development deliverables and reducing the number of deliverables that need to be circulated for sign off. One leading medical device company went so far as to not require any signatures on their business deliverables, as going back to each executive to collect a signature provided no added value and only delayed the process. Instead, Governance Committee approval at each phase gate ensures that the deliverables are complete and provide the information necessary to make the phase gate go/no-go business decision.

Another leading company, with a mature, high performing phase gate process, decided to document their business and design control procedures under one quality system, but established two distinct deliverable categories. Prescriptive templates without room for interpretation are in place for deliverables that fall under design controls. All other process documentation, including business-oriented deliverables, uses simplified outlines that leave room for the judgment of experienced project team leaders. Project team leaders can also recommend eliminating certain process steps or deliverables without having to go through multiple layers of approval. They simply include their recommended exceptions in their initial project plans. The only caveat is for those deliverables ordinarily required in the Design History File (DHF) which require formal written justification.

Additional Process Definition and Work Flow Structure Best Practices

The study revealed a number of other proven practices to consider:

Meeting with the FDA early and often to receive feedback on regulatory plans well before starting full-scale development. FDA representatives are often glad to provide candid feedback and can save a company countless hours pursuing the wrong path, but avoid presenting the FDA with open-ended questions and approach them with a pre-conceived solution instead. If there are flaws with a planned approach, the FDA will point them out, leaving time to adjust. The alternative is to find out further downstream when corrections will cost you significant amounts of time and money.

Where possible, moving validation activity upstream in the design cycle. Leading companies recommend investing in rapid prototyping capabilities and to start testing as soon as production equivalent test units can be produced. Despite the risk that any subsequent design change would trigger repeat testing and drive up development cost, negatively impacting resource utilization, and in the end, delaying product introduction, these companies concluded that this approach was worth pursuing, especially for their Class I devices.

> "If the design is 20 percent new and 80 percent design re-use, we now test 20 percent, not 100 percent."

Avoiding time spent testing complete product systems by testing only those subsystem design elements that are new. One company that had recently made time-to-market gains through a design re-use initiative was also able to improve their test efficiency when they realized how much time and money they were wasting by testing complete product systems when only certain subsystem design elements had changed. By testing only those subsystems that were new, this approach not only saved time and resources, but also eased a significant test reporting burden. As one executive described, "if the design is 20 percent new and 80 percent design re-use, we now test 20 percent, not 100 percent." This approach is facilitated by utilizing a new modular platform architecture and with software automation tools that simplify archival and retrieval of past test reports

Boosting efficiency and regulatory filing success rate by simply keeping regulatory submission in mind at each stage of the design cycle. Early stage reports are written with regulatory submission in mind and build toward final submission. This concept is reinforced in all deliverable templates and training materials.

Innovation Governance and Decision Making: Knowing the Who, What, When, and How – And Sticking to It

Kalypso research revealed that while all of the participating companies utilize a formal phase gate process with an executive governance team in place to make project go/no-go decisions, some have proven more effective than others. Those companies more effective in meeting business objectives utilize the following practices:

- Staff a complete multi-function governance team, including representation from Quality and Regulatory Affairs
- Clarify the governance team's role as business decision makers
- Establish a governance team leader who holds team members accountable and actively drives the team to make the tough calls
- Take responsibility for ensuring proper resource allocation across all projects
- Utilize pre-established gate objectives and decision making criteria
- Ensure that gate decisions are in alignment with portfolio objectives
- Make clear, unambiguous decisions that stick
- Leave the implementation-level decisions to empowered project teams
- Keep product review meetings focused on the business decision at hand without getting off into the weeds

The top performing companies are making improvements and achieving clarity around the "who, what, when, and how" of the decision making process. Key to meeting business objectives is ensuring this approach is consistently applied.

Project Teams and Team Structure: Establishing Roles to Achieve Both Compliance and Project Success

While all participating companies have implemented some form of an empowered cross-functional project team structure, few felt that their project teams were consistently high performing. The most common problems cited were missed schedules caused by changing product requirements, unanticipated regulatory requirements, and ineffective resource allocation.

Leading companies with high-performing project teams recognize that implementation-level decisions are best left to accountable project teams

who are closest to the day-to-day work. They establish an appropriate team structure, provide the right level of guidance, staff the teams for success, and get out of the way.

All companies felt it was critical to staff core project teams with a knowledgeable Regulatory Affairs representative. While most companies include both Quality and Regulatory representatives on core project teams from the get-go, Kalypso research found that the effectiveness of the role varies greatly from company to company. On more successful project teams, the Quality and Regulatory representatives not only advise team members on how to stay design control compliant, but also play an active role in helping the project team when making the delicate and all too common tradeoffs needed to meet higher level business objectives.

A primary role for the Quality and Regulatory representative is to keep implementation-level decisions consistent with corporate-wide quality and regulatory strategies. Research showed that projects tend to get into trouble when their Quality and Regulatory representatives take on a process enforcer role and are viewed as "process policemen" who only speak up when there is a process "violation," pointing out problems instead of taking an active role in guiding the team toward solutions. Companies would like to see the role shift from compliance adherence to both compliance ***and*** project success. This change is behavioral and requires a mindset transformation that is best achieved when reinforced from the highest levels in the organization. When this is successful, project teams willingly consult their regulatory representative, who is viewed as someone who knows how to interpret regulations and has the experience to figure out what the FDA really wants.

The more effective Quality and Regulatory team members are able to anticipate issues and help their project teams create a strategy early in the project's planning stages. Several companies indicated they assign a dedicated Regulatory Representative while the project is still in the concept phase and, in some cases, as early as idea approval. At that point in the program, the Regulatory representative is tasked with formulating a robust regulatory strategy. Even at this early stage enough information is known about the product concept to allow the Regulatory team member to initiate regulatory plans in parallel with market confirmation and project planning tasks. Leading companies who have realized the benefits of early Regulatory involvement in project planning are reaping the benefits through fewer project re-directs, more accurate budgets, and improved schedule predictability.

In formulating a regulatory strategy, the Regulatory team member looks at the proposed product's intended use, desired and "must-have" claims, and known label requirements. Plans for clinical studies are formulated, including study objectives, the number of studies, duration, timing,

"Leading companies who have realized the benefits of early Regulatory involvement in project planning are reaping the benefits through fewer project re-directs, more accurate budgets, and improved schedule predictability."

and cost. FDA classification, international regulatory requirements, predicate devices, approval requirements, alternate submission approaches, submission risks, contingency plans, and timing are all determined. The Regulatory team member also looks at the regulatory plan's impact to production, product cost, competitive positioning, and the overall project schedule and budget. Many of the companies interviewed have also added reimbursement strategy as a Regulatory Affairs responsibility.

Software Systems and Tools: Improving Development Effectiveness and Easing Compliance Challenges Through Automation

Kalypso research revealed that the top performing companies are benefiting from the use of software solutions in design processes, quality functions, and project management. When applied at the right time with a well thought-out, strategic implementation plan, software tools can help accelerate the path to development process maturity, improve team collaboration, and remove much of the administrative burden associated with regulatory compliance.

Design Process and Information Management

The majority of top performers have implemented a requirements management software package. Requirements management packages can make it easier to manage the complex landscape of product requirements, which can often number in the hundreds. More and more, companies are using tools like these to trace product requirements back to user needs or even to the original voice-of-customer input, and forward to resulting hardware or software specifications. This complex web of traceability can quickly become an administrative nightmare when using desktop applications such as Word or Excel. A robust requirements management software package can greatly simplify document generation and more importantly, make it easier to flag all requirements that must be revisited when downstream requirements change. This functionality makes the entire change history much more transparent, simplifying the audit process and making FDA or internal audit requested change justifications and approvals easy to find.

One company, whose requirements traceability administrator had been using a requirements management software package for eight years, couldn't imagine life without it: "In terms of change history, we went from trying to find a needle in a haystack to giving everyone on the program clear visibility literally with the touch of a button." Other added benefits include simplified revision control and more efficient collaboration with co-development partners.

"In terms of change history, we went from trying to find a needle in a haystack to giving everyone on the program clear visibility literally with the touch of a button."

All participating companies use some form of electronic document control, mostly focusing around Design History File management, ongoing Device Master Record management, and FDA submission document management. Leading companies utilize a system to provide a single "product data record" or "source of truth" that is then integrated with other systems for manufacturing and quality management. Leading companies are also utilizing those document control systems that provide full text search for advanced information access (AIA), document linking, and electronic signature capabilities compliant with 21 CFR Part 11. Companies have reported a cost savings of close to 70 percent based on reducing the amount of time necessary for product development teams to search and utilize existing documents, and in reducing the time necessary for gaining sign-off on necessary design steps.

Additionally, the top companies do not utilize a paper back-up process for document control, but adhere to strict and robust data archiving and disaster recovery policies and procedures. The most effective companies even utilize the document control system during audits by the FDA, as opposed to printing documents for the regulators to review.

Quality Functions

Based on the FDA Quality System Regulation (QSR), all medical device companies must have a corrective action / preventive action process (CAPA) in place. The majority of medical device companies utilize some form of software for managing the manufacturing issues, customer complaints, and Medical Device Reports. Those utilizing enterprise class software tools have seen great benefit including an 88% time improvement in Non-conforming Material Reports (NCMR) closures, and a 60% time improvement in CAPA closures.

Surprisingly, with the high value of product quality information in guiding product improvement and opportunities for new product sets, most medical device companies do not have any form of electronic integration between their quality management systems (home-grown or commercially available off-the-shelf (COTS)) and their product development software systems. Leading companies however have implemented enterprise-class CAPA management systems and have successfully integrated them into their product development systems.

Project Management

All research participants use some form of software for project management, with the overwhelming majority utilizing stand-alone Microsoft Project® as the schedule management tool. Many leading medical device manufacturers have gone beyond MS Project® and are utilizing enterprise-class project management tools, which not only allow individual project managers and team members to update their specific projects, but also provide visibility to management across multiple projects in various locations. However, these companies have not simply implemented technology; they have also systematically increased direct accountability for all new product development resources, provided communication training to support accountability (e.g., what does "done" mean), and allowed an appropriate level of flexibility for empowered project teams to determine what aspects, information, and even process steps are involved in launching individual products or platforms.

Common Software Tool Challenges

A key point to consider in the use of any software solution for the purposes described above is the concept of security and access control. Those companies who used fewer systems but cordoned off access to specific areas, fields of data, or applications based on the function of the individuals were more likely to rate their new product development process as mature and effective.

Additionally, an important but costly aspect to the implementation and use of software solutions for new product development in the medical device industry is the requirement for validation of these systems per the Quality Systems Regulation. The QSR states that if "computers or automated data processing systems are used as part of production or the quality system, the [device] manufacturer shall validate computer software for its intended use according to an established protocol" (see 21 CFR §820.70(i)). Research indicates that medical device companies who implement enterprise software technologies from vendors who provide a validation protocol for the base-line implementation state of their software save approximately 50% of the time and cost to validate those systems (e.g., Some systems come "out of the box" with validated workflows for CAPA).

Finally, software systems users sometimes found the tools to be too complex for their own good. In trying to capture the functionality needs of all potential customers, the systems end up with many features that rarely get used. Companies feel compelled to use the advanced features, change their processes to integrate them, and end up frustrated when they find they are not used often enough to be worthwhile. The old adage rings true that automating poor processes just amplifies problems and that broken processes should be fixed first. The companies interviewed also underestimated the importance of executive-level and cross-functional "buy-in". Companies can avoid these issues by taking a more strategic approach to system selection and implementation, starting first by gaining agreement on the business imperatives.

Medical Device Companies Can Balance Product Development Effectiveness with Regulatory Compliance

Medical device companies are experiencing growing pains as they navigate the challenging waters of regulatory compliance while simultaneously keeping up with the pace of innovation. When it comes to implementing product development processes that comply with regulations, many have overcompensated, resulting in overly-bureaucratic systems that are impacting delivery performance and causing them to come up short on time to market, R&D ROI, new product revenue, and schedule predictability goals.

Companies are under pressure to re-evaluate current processes and determine how best to implement a development approach that meets design control requirements while ensuring a fast, effective flow of successful new products. Though a single process design has the advantage of one system for both business and quality system needs, this approach increases opportunities for non-compliance and hinders project teams that need flexibility to adapt business processes to specific project needs. Separating business-oriented processes from rigidly-enforced design control procedures enables project teams to use judgment and experience in adapting process guidance to specific project needs without jeopardizing design control compliance.

Other process definition and work flow practices that save time and avoid development delays include meeting with the FDA early and often to receive feedback before starting full-scale development, validating as soon as production equivalent product test units can be produced and testing only subsystem design elements that are new instead of complete product systems.

To meet product-driven business objectives, structuring governance and decision making processes to achieve clarity around the "who, what, when and how" is necessary. A formal phase gate process with an appropriately

staffed executive governance team can be leveraged by aligning gate decisions with portfolio objectives, establishing clear leadership and leaving implementation-level decisions to empowered project teams. Additionally, project teams must be structured to dually achieve both compliance and project success with a Regulatory Affairs representative who advises the team on how to stay design control compliant and plays an active role in helping to meet higher level business objectives. An effective Regulatory Affairs representative keeps implementation-level decisions consistent with corporate-wide quality and regulatory strategies, anticipates issues, and plans appropriate contingencies during the early planning stages.

Lastly, the advantage of software tools can be significant when applied at the right time with a well thought-out, strategic implementation plan. Software tools can help accelerate the path to development process maturity, improve team collaboration, and remove much of the administrative burden associated with regulatory compliance. Business processes that can be aided with software tools include requirements management, project management, portfolio management, document management, and quality management.

Implementing a program that couples product development effectiveness with compliance is no easy task, but deploying a methodology that includes improvements in process definition and work flow structure, innovation governance and decision making, project teams and team structure, and software systems and tools can help companies realize benefits including:

- Meeting and exceeding development effectiveness goals
- Achieving time to market goals
- Hitting planned product launch dates
- Eliminating unnecessary process bureaucracy
- Accelerating product development process maturity

These are benefits being realized today by companies that have achieved an effective balance of product development processes maturity and regulatory compliance. A mature, high performing product development process with low compliance burden is the goal.

Top performing medical device companies are demonstrating how to achieve this goal and have overcome industry challenges to deliver safe, effective, and commercially successful medical devices.

About the Author

Noel Sobelman is a Partner with Kalypso, a leading innovation consulting firm serving the medical device industry. Noel has over 18 years of consulting and industry experience working with both small, fast-growth startups, and multi-division, well-established corporations. He has held product line and business unit general management positions with several leading technology-based companies, including Motorola, Honeywell, and Kyocera, where he championed successful new product and market growth initiatives.

Noel has a broad range of medical device company experience in the areas of innovation management, portfolio planning and rationalization, product development, and new product introduction. He has designed and implemented portfolio planning systems, established technology and product strategy processes, facilitated voice-of-customer and ideation workshops, implemented phase gate governance and decision-making procedures, and led collaborative development and open innovation initiatives. Noel has also led several high profile product development programs that have received national recognition, including the USA Today/Rochester Institute of Technology's Quality Cup, PC Magazine's Editors Choice, PR Magazine's "Best High Tech Consumer Launch", and CNET's "Best of CES" awards.
noel.sobelman@kalypso.com

Contributors: Marcus Yoder, Senior Manager marcus.yoder@kalypso.com
Jay Schierloh, Manager jay.schierloh@kalypso.com
Emily Adams, Consultant emily.adams@kalypso.com

About Kalypso

Kalypso is a consulting firm serving the world's most innovative companies. The firm helps clients to deliver on the promise of innovation. Service offerings encompass all aspects of innovation including product strategy, development, introduction, commercialization, lifecycle management, and PLM systems selection and implementation. In addition to the firm's deep industry, technology, operational, and training expertise, Kalypso provides a flexible, collaborative approach to deliver unparalleled client satisfaction.

www.kalypso.com