

# Strengthening Simulation's Business Impact: New Strategies in Medical Devices

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## Executive Summary

Ramping up the volume of new product introductions is a key business driver for investing in digital simulation and analysis for today's medical device industry. Improving clinical efficacy, increasing product differentiation and shortening development schedules follow closely behind. Of course maintaining and enhancing quality – in many cases, effectively zero failure rates – is a baseline requirement. Beyond that, intensifying price competition, often driven by insurers and regulators pressing healthcare providers to rein in costs, challenges more and more manufacturers for whom price had long been no object. And some, facing saturation in volume markets, now seek cost-effective ways to develop lower-volume product for more narrowly targeted disease classes and smaller patient populations. Nevertheless, these companies still experience program-gating constraints on getting the value they need from these technologies and the work processes that employ them. What are they doing about it? To find out, we interviewed experts at industry leaders around the world. We investigated business drivers for investing in simulation, current state of industry practice, constraints on maximizing simulation's value, and new strategies for overcoming these constraints.

This report summarizes our findings:

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This report offers a practical, action-oriented analysis of new directions and emerging best practices for getting more value than ever before from digital simulation and analysis. Program managers, discipline leads and practitioners will find first-hand advice and lessons of experience for planning new and ongoing investments in simulation technology, and for managing these tools to exploit their organizations' simulation competencies to the fullest.

## Digital Simulation and Analysis Investments: Business Drivers

What business goals are best-practice leaders seeking through more effective use of simulation and analysis?

An influential report by the U.S. Food and Drug Administration, *Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products*, analyzes what the FDA calls "the pipeline problem – the recent slowdown, instead of the expected acceleration, in innovative medical therapies reaching patients." According to the report, "During the last several years, the number of new drug and biologic applications submitted to FDA has declined significantly; the number of innovative medical device applications has also decreased. In contrast, the costs of product development have soared over the last decade." The reason? "In FDA's view, the applied sciences needed for medical product development have not kept pace with the tremendous advances in the basic sciences. The new science is not being used to guide the technology development process in the same way that it is accelerating the technology discovery process."

What's the remedy? The FDA believes a "new product development toolkit – containing powerful new scientific and technical methods such as animal or computer-based predictive models, biomarkers for safety and effectiveness, and new clinical evaluation techniques – is urgently needed to improve predictability and efficiency along the critical path from laboratory concept to commercial product."

Clearly, the FDA's call for new "computer-based predictive models" points to the opportunity for more and better application of digital simulation and analysis by the medical device industry. Against this background, what business goals are guiding industry best-practice leaders' use of simulation and analysis?

**Increase new product introductions, improve clinical efficacy, address new markets, increase differentiation, shorten schedules** Paramount is the need to ramp up the volume of new product introductions. Closely related are requirements to improve clinical efficacy, broaden market opportunity, increase product differentiation and shorten development schedules:

*"...we are looking to put out more products that will enhance clinical outcomes – more differentiated products, [and] get them to market before our competitors..." – Surgical instrument manufacturer A*

*"...[key business drivers] – product cycle time is up there..." – Endoscopic diagnostic and therapeutic device manufacturer*

*"...when we start a new project, we always do a thorough assessment of how we're going to differentiate the product in the marketplace – that it will have high value to the customer, and thus will be a high-margin product..." – Infusion therapy device manufacturer*

*"...one [business driver] is to expand the market for our products...[with some products] the number of procedures in which that [product] is used is something we are looking to expand..." – Surgical instrument manufacturer A*

**Safeguard and strengthen quality** Quality, of course, is a must. Many report their products – implantable devices, surgical instruments, diagnostic and therapeutic equipment – must perform with effectively zero failure rates, which is typically validated through a combination of simulation and test. For others, simulation helps ensure that failure modes remain within limits that safeguard patient safety:

*"...[business drivers] – performance reliability is very high. If it's going to fail, it has to fail within the margins prescribed, based on risk indices and [similar metrics]..." – Endoscopic diagnostic and therapeutic device manufacturer*

**First to market** Being first to market is crucial not only to maximize time in market, but even more because this is often the key to capturing brand loyalty, practitioners report. For example, new types of surgical instruments are frequently developed to better support new procedures that have been devised by surgeons. Traditionally, the manufacturer first to market with the new kind of device wins much of the available market – whatever brand doctors use first frequently becomes their brand of choice, until a newer kind of tool supersedes the old one.

**Respond to cost constraints** Today, though, price pressures in healthcare delivery are complicating the picture. As a result, more manufacturers are seeking tools and methods that yield product development and manufacturing efficiencies in order to respond to new cost constraints:

*"...In the past, surgeons were the decision makers, but now their influence is dropping off and the purchasing folks are getting much more involved, because of pricing pressures in the health care industry. In that respect, we have to change our approach and not go strictly after the surgeons. In the past our strategy was to provide a premium product with a better clinical outcome, but now pricing pressures – and competitors who turn the product into a commodity – put pressure on hospitals to cut costs by taking product from a competitor who is not 'premium'..." – Surgical instrument manufacturer A*

A related driver for tools and methods that help increase new-product introductions is the healthcare industry's reimbursement mechanisms. Practitioners report that insurers and government agencies involved in setting reimbursement rates are generally willing to recognize companies that bring new products to market – not only new classes of product, but also variants of established products when the new variant is shown to yield improved clinical outcomes. Thus, manufacturers are under pressure to come up with even minor variations of products so they can show insurers and regulatory agencies they have made R&D investments that justify reimbursement. Of course, insurers and regulatory agencies

seek to continually decrease the amounts reimbursable for existing products – manufacturers are expected to amortize R&D and continually drive efficiencies in production. That pressure has the same effect – driving manufacturers to continually increase new product introductions.

On the other hand, this business environment means that direct product development costs are often not a constraint. Whatever it takes to win the race for volume, speed and differentiation in new product introductions is justified:

*“...[simulation tool] cost is not a constraint [within reason]. If we saw software that meets a need not met by current tools, and can provide value early in the design process, a purchase would likely be approved...” – Surgical instrument manufacturer A*

**Regulatory approval** Of course, obtaining required approvals from the FDA and other regulatory bodies is another essential business driver. However, while we found evidence that simulation and analysis results are increasingly included in the information submitted by manufacturers for this purpose, it appears regulatory requirements have yet to drive substantial use of data management tools during product development, especially in conceptual and preliminary design. As products move from design freeze through final prototyping and validation, data archiving comes into use to capture information for submittal to the FDA or similar bodies. Most medical device manufacturers believe their industry has substantial opportunity to improve the effectiveness and efficiency with which it uses simulation by putting greater focus on data and process management within the product development cycle.

**Innovation** Finally, the search for innovation is a perennial driver:

*“Innovation’ – that’s nothing unless you are educated in what you want to accomplish. But a simulation tool, if you are educated, might take you to something entirely new.” – Surgical instrument manufacturer B*

## **Simulation: Current State of Practice in the Medical Device Industry**

Against this background, we interviewed experts at the industry’s leaders to find out how they do it. What best practices have they developed for using simulation and analysis to achieve the business objectives that they and all manufacturers face – shorten program schedules, improve engineering productivity, and reduce development costs?

**Focused on supplementing, then supplanting physical test with earlier and more pervasive use of simulation and analysis...** What we found was that product validation and certification in the medical device industry has traditionally been more strongly oriented toward physical test than toward simulation and analysis. But simulation and analysis can help engineers identify and fix design problems early in a project, before physical test is feasible. Fortunately, practitioners report the industry’s emphasis on test over simulation is changing:

*“...[our industry] doesn’t do simulation and analysis as much as we should...Our primary way of doing things is using [simulation] only when we find a problem in physical testing of the prototype. But I would prefer to do more of that beforehand with analysis...In other [industries] I’ve been in – aerospace, for example – that’s been standard practice, but not here...medical device companies don’t always use analytical tools very deeply. Medical device technology and product development has grown up with a trial-and-error*

*development approach. Now, it's beginning to change..." – Infusion therapy device manufacturer*

*"...to demonstrate that [your product] meets [regulatory requirements] historically has been done by physical testing. But often you can substantiate physical testing with simulation. And I think acceptance of substituting simulation for testing has been increasing, both by us product manufacturers and by the regulatory agencies..." – Endoscopic diagnostic and therapeutic device manufacturer*

One decision factor is simply which approach is more time-efficient, all else being more or less equal:

*"...for reliability testing, the time it takes to construct a simulation model versus the time it would take to conduct physical testing sometimes determines which way you go. Sometimes it takes too long to create a finite element model, so then the tendency is not to go that way..." – Endoscopic diagnostic and therapeutic device manufacturer*

However, in growing numbers of cases – very small implant devices such as stents and valves, for instance – manufacturers have recognized that simulation can yield higher-confidence results than physical test:

*"...we have used analysis software to support cases where physical testing was not clear. For example, materials – based on certain very complex geometry of very small parts, when you get into very small parts with very high tolerances, micro-machined, it's difficult to quantify some of that performance through physical testing. It has to do with complexity of the part geometries...A lot of what we want to simulate is geometry behavior. Because a lot of these geometries are not linear but complex, predicting some of their behaviors is complex..." – Endoscopic diagnostic and therapeutic device manufacturer*

Even in many of these cases, though, simulation remains an adjunct to test:

*"...we [in the medical device industry] tend to be more conservative – we do a fair amount of analysis, but we still have to cut the steel and try it out...Currently, analysis helps in the decision process – it's a supportive tool to help build confidence in certain aspects of the decision-making for the engineer – but I don't know that it has replaced fully, or even to any great degree, physical testing..." – Endoscopic diagnostic and therapeutic device manufacturer*

Correlating simulation results with physical test data is important to building confidence in analysis tools and processes:

*"...[we] take physical test data and do validation of the software tools by correlating [simulation results] with physical test. Our engineers do a lot of that – taking simulation results and lab tests, and correlating them to validate CAE results..." – Surgical instrument manufacturer A*

As higher confidence leads to more extensive use of simulation, many foresee gains not possible through test alone:

*"...had we used more [simulation in a recent project], we would have identified some stress points that we didn't catch until our design validation process – in physical test, where devices have to be test-dropped three feet..." – Infusion therapy device manufacturer*

In sum, today many in the medical device industry recognize the limitations of the industry's historical reliance on physical prototype-based product development processes, and are working to establish simulation as a primary tool for design discovery and refinement:

*"Generally speaking, we are trying to bring in CAE earlier in the product development cycle. It is not always available to all who need it, because of their skill levels. But generally the organization is working to bring CAE in earlier and use it throughout the process, and they are doing a pretty good job of that. It is a goal of the organization to use these tools early to find good designs..." – Surgical instrument manufacturer A*

**...but working to achieve still more: higher-fidelity simulation of device interactions with living tissue** Looking ahead, a primary focus is on how to achieve better software characterizations of interactions between medical devices and the human patient – what the industry terms the "anatomical interface":

*"...evaluating [design] concepts for their pluses and minuses, without having to build prototypes – often we do it, but it's not an automated [simulation-based] process. A lot of it is [based on] intuition, experience, gut feel. I think that could be embedded in software – in our specific field, one thing that's missing is the 'anatomical interface.' If there were ways to construct that anatomical interface, then you could [more readily] use simulation software to test a product concept and its interaction with the anatomy..." – Endoscopic diagnostic and therapeutic device manufacturer*

For any class of medical device whose function is heavily dependent on physical interaction with living tissue, simulation/test data correlation is especially critical:

*"...[much of the value of simulation] depends how well we can correlate simulation results with what we see in the physical realm. That's the risk [of over-reliance on simulation]. If we can get into the 93%-94% correlation realm, it would not be risky. But to date that's been very difficult. Often we have to go into actual tissue models – through animal models, in vivo studies, or using cadaver parts..." – Endoscopic diagnostic and therapeutic device manufacturer*

## Constraints on Maximizing Simulation's Value

What constrains medical device manufacturers from achieving the goals laid out above? We found that constraints fall into two primary categories: (1) technology constraints and (2) organizational and work-process constraints.

### Technology constraints

A central problem is the need for better data integration between CAD and CAE, and also among CAE tools for different disciplines.

**CAD-CAE gaps** A perennial constraint has been the technological gaps that exist between product definition geometry on one hand, and simulation models on the other – and the resulting penalties in time and, sometimes, accuracy exacted by the need to prepare geometric and functional models for input to analysis.

*"Inadequate data sharing is the biggest hit to design/simulation productivity because, with current processes, you get design data that's out of date, out of synch – it's not an efficient process." – Diagnostic equipment manufacturer*

Narrowing or even eliminating the gaps between CAD and CAE geometry environments is the goal software developers should pursue, some believe:

*“Say that a designer and an engineer need to design a medical clip of some kind. The majority of their simulation activity will be focused on simulating the mechanical functioning of that clip. Going forward, we want this kind of simulation to be increasingly embedded in the design software, so that the designer and engineer can easily validate such things as whether the material of which the clip is made will break in use.” – Surgical instrument manufacturer B*

Even very early exchange of preliminary CAD models is seen as offering high value in enabling early directional simulation:

*“I firmly believe you can get 80% of your learning from a model that has 20% of the final detail in it. You still capture the essential physics. Unlike in engine development, where you have a commodity and are truly trying to optimize the design, here in our industry – a highly regulated industry – the safety factors are so high that people could arrive a good solution early.” – Diagnostic equipment manufacturer*

**Cross-discipline analysis gaps** Similar barriers impede sharing of results between analysis tools in different disciplines.

*“[After simulating the mechanical behavior of a medical electrotherapy clip], the design team heads down to the other end of the process – determining what’s going to happen between the clip and the tissue with which it will interact. That’s a place where there exist many more than just a single physics event: when I send electricity through tissue, I want to know: Will I change the temperature of the tissue? Will I change the flow of blood? And so forth. There, multiphysics simulation tools will help us predict what will happen in the tissue where the clip inputs electricity. That multidiscipline, multiphysics interface with the human is the place where I think modeling and analysis will advance most rapidly in the near future.” – Surgical instrument manufacturer B*

**Need for better simulation data/process management** Another chief constraint is the need for robust, capable simulation-specific data management and process management tools. Indeed, many name simulation data and process management as the biggest technological challenge constraining the value available from simulation and analysis today.

Staffing and schedule limitations are more significant obstacles to getting more value from simulation than availability of software tools or software budget, our research found. A collateral constraint is the need for more focus on simulation data management and global sharing:

*“...[what constrains] the product development cycle? We do an extremely good job of expediting schedules and getting things done quickly. But what gets lost in the process is global data sharing...” – Diagnostic equipment manufacturer*

Regulatory requirements in the medical device industry impact data sharing and collaboration, with mixed results. Product quality and patient safety are safeguarded, but product development efficiency sometimes takes a hit. Comparison with other industries such as vehicle powertrain development makes the point:

*“...being a regulated industry, we have a sharp line between design activity and release of the 2D drawing (electronic, but still a 2D drawing). When we release that drawing, [the product development process] moves into the regulated part of our industry. In a perfect world, I would like to see a system where we could get 3D models right to the supplier or available for quality checks, but that’s a huge limitation. It’s a vastly different level of information interchange from the engine industry, where we could be exchanging 3D data with the shop and right down to inspection...” – Diagnostic equipment manufacturer*

**Need for simulation knowledge capture and reuse** Better ability to capture and then reuse simulation knowledge is emerging as a key to helping manufacturers overcome the twin constraints examined earlier in this report – not enough trained, knowledgeable analysis professionals, and not enough time in the schedule to do all the analysis you want. One practitioner explains the challenges in medical device development:

*“...business processes in place today limit the propagation of CAE data that could be useful to other teams and other designers. Today when an analysis is done, it is a one-off thing. Somebody checks a box and says, ‘I did it,’ instead of collecting and leveraging that information across the business. We want to do more of that, but we’re not there yet. It’s probably a combination of technology and existing business processes that need to be adjusted...” – Surgical instrument manufacturer A*

### **Organizational and work-process constraints**

Human resource and schedule are chief constraints on simulation's use:

*“...human resource is the constraint [on making more use of simulation]. I would love to see more use of the simulation tools, because I firmly believe you can get 80% of your learning from a model that has 20% of the detail in it – you still capture the essential [imaging] physics. Unlike engine development, where you have a commodity and are truly trying to optimize design, here in our highly regulated industry, the safety factors are so high that people could arrive at a good solution early. But it’s not that way today...” – Diagnostic equipment manufacturer*

*“...we’re not using [simulation] more because of limitations on people’s time. Engineers have enough to do go get a product out; they don’t have all day to mess around with FEA tools – they just need to get the information they need, and move on...” – Surgical instrument manufacturer A*

Still, some see opportunity to do more:

*“...simulation is clearly used early. Is it used as much as I would like to see it? Absolutely not. And it is not as ubiquitous as we would like to see. Too often, our project engineers are too busy, too challenged, their job is too fast-paced for them to develop a deeper competency in these tools – you do need to have a certain consistency of using the tool to maintain proficiency with it. So the tools are not as broadly used as they could be. And another symptom is that engineers, whether it be a simulation tool or doing fundamental checks with spreadsheets, don’t [analyze designs] as much as they ought to...[Nevertheless] we do a very good job of identifying the risks to be retired, and applying it there...” – Diagnostic equipment manufacturer*

## **Overcoming Constraints: New Directions, Emerging Best Practices**

Fortunately, our research identified significant progress now being made on all these fronts.

### **Overcoming technology constraints**

**Toolset integration: CAD-CAE** We found substantial progress in efforts to narrow the gaps between design and simulation models. Best practice in overcoming toolset gaps is about finding tools and processes to better manage and automate the flow of data between CAE and CAD, as well as between different simulation and analysis tools.

A number of companies we studied use an integrated design/analysis software suite that provides smooth data flow between geometry modeling and simulation, especially structural analysis:

*"...the flow of data from design into simulation is pretty good, mostly because we use [an integrated software suite] for both design and mechanical simulation. There could be better flow into some of the other tools such as thermal, but that's not a big loss..." – Diagnostic equipment manufacturer*

Part of the solution is software ease of use. Many we interviewed report significant use of midrange solids modelers and collateral first-pass analysis tools – even in some companies where a different design system is the corporate standard. Especially at Surgical instrument manufacturer As and makers of small electromechanical devices such as personal infusion pumps, initiatives to incent designers to use simulation early are being advanced by the ease of use offered by this class of tool. Abetting these efforts is the wide latitude enjoyed by individual R&D managers and product managers to introduce whatever tools they judge will help the project succeed; such software purchases are frequently funded from the project budget. Of course, the need to bring this data into the corporate standard remains:

*"...in our organization, we are trying to promote the big picture – high-level workflow, and the importance of consolidating on tools to streamline processes. Our [project managers] have not fully embraced that line of thinking. As a result we do have a lot of free-for-all work going on out there, but at the enterprise level it is a single system, single process. We do have guys who will do their work in [a midrange modeler], but as an organization we don't support release of product data in [that format], so they have to translate their work into [the corporate CAD system format]..." – Surgical instrument manufacturer A*

Complementing the use of first-pass analysis for design exploration, of course, is downstream use of advanced simulation tools – linear and nonlinear structural, thermal, CFD – by dedicated analysis groups for design validation.

**Toolset integration: cross-discipline analysis** Similarly, we found substantial progress in integrating the tools used in the various analysis disciplines.

*"Providing suites of integrated multiphysics tools is the answer to bringing together the different stakeholders in complex device development. Integrated multiphysics and multidiscipline tool suites provide a workspace in which a physician can talk out a problem with an engineer, and both can investigate what will happen. Simulation has to go everywhere: simulating what individual devices do, and also what the whole system including the patient tissue does. With multiphysics simulation, everyone can see why anyone is asking to make a change in the design – because all can see what happens as a result." – Surgical instrument manufacturer B*

Although multiphysics and multidiscipline analysis software is in the early stages of wide adoption, medical device practitioners foresee this accelerating, aided in part by academia's rapid acceptance of the technology:

*"As a simulation software tool becomes more standard, the company will ask that everyone use it. But multiphysics tools – for example, to simulate interaction between a device and the human body – are forward-edge, not standard. Someone will always be asking for these kinds of new applications. The company will be more than happy to spend \$20,000 on one copy or a few seats of such new tools, to demonstrate that is a useful investment. I come from industry, but I also see that the new multiphysics tools are being taken up more quickly by academia than by industry, or at least by more people in*

*academia – and that is a very good thing that will accelerate their adoption by manufacturers.” – Surgical instrument manufacturer B*

**Implementing simulation data/process management** Some practitioners we interviewed described new initiatives to address the need for better global data sharing:

*“...global data sharing, including across different sites ...is something we are working on with [a commercial PDM provider]...Making that process more efficient and robust and less error-prone [by eliminating] manual intervention is a big opportunity for us...[inadequate] data sharing and global collaboration is the biggest hit to productivity because, with today's [work process], you get data that's out of date, out of synch – it's not an efficient process. That's why we are moving to a true global data vaulting tool...[a related] component is knowledge retention...” – Diagnostic equipment manufacturer*

Best practice here focuses on capturing a company's methods and work processes in the form of design rules, and embed these rules in its simulation, analysis and CAD tools. Also key is better managing the flow of data between different simulation and analysis tools, and between simulation/analysis tools and CAD tools. It's also about being able to capture, archive and retrieve simulation models, input conditions and results, together with related assumptions and conclusions.

Indeed, integration appears to be more important in some respects than the functionality of any given point solution. All the experts we interviewed stressed the need for integration – the value in eliminating work and errors associated with different data formats is clear.

Another problem that better CAE data/process management can address is limited availability of people and time. Our research found that a key constraint on getting more value from simulation is the availability of trained professionals and time, not a shortage of software tools or budget. Best practice for overcoming these constraints is to use knowledge capture, data/process management and open tools to make more efficient use of existing investments in staff and technologies.

Overall, we found that practitioner priorities are focused on capabilities to:

- Automate data exchange between analysis disciplines, and between geometry modelers and mesh generators
- Ensure that CAD-CAE data exchange capabilities are multi-CAD – partner/supplier collaboration requires this
- Readily re-run or update analyses months or years later
- Ensure that design changes trigger re-analysis; ensure analysts receive correct inputs from modified design; ensure re-analysis results feed back to design

**Implementing simulation knowledge capture and reuse** We also found cases where manufacturers are working to implement technologies that automate the capture, classification, storage, retrieval and re-use of knowledge. The goal is a greatly enhanced capability to capture, archive and retrieve simulation models, input conditions and results, together with related assumptions and conclusions. Beyond simply securing information, it involves the collateral activities of classifying data and putting it in meaningful context, so that subsequent consumers will find the information both meaningful and trustworthy – transforming an organization's “implicit knowledge” into “explicit knowledge.”

*“Knowledge retention is quite a challenge, especially in organizations that are both global and very fast-moving. Our company is a dynamic organization, with people changing jobs and roles quite often, so to grow and retain the corporate knowledge is tricky.” – Diagnostic equipment manufacturer*

Most often, best practice is to seek technologies that enable a company's knowledge, methods and work processes to be captured in reusable process wizards and other tools that encapsulate knowledge and automate its application.

*"It's easy to characterize nonorganic materials; it's far more difficult to do that for the human body. If you break the human body up into sets of mechanical, electrical and optical properties, the mechanical aspect seems to be hardest. One group in our company spends all its time working to simulate products such as a gastric band. But they find it difficult to validate their models because compression of body tissue is nonlinear. It seems that we can simulate electrical functioning of body tissue more easily than the mechanical aspects. For the longest time, therapeutic surgical devices were based on mechanical actions – cutting tissue, clamping tissue, sewing tissue – where the tissue behaviors are not well characterized. Whereas with the electrotherapy products that I focus on, it's pretty well understood what happens electrically in tissue. I told one colleague about my need to model two parallel electrical needles, inserted into tissue five millimeters apart: I asked if he could simulate the tissue pushing on them, and tell me whether they are going to become non-parallel or deflect; he spent 15 minutes telling me why that's a hard thing to do. So our mechanical product engineers are working to develop in-house databases of our knowledge of the mechanics of tissue behavior." – Surgical instrument manufacturer B*

Technologies that support these initiatives to capture knowledge in standardized, easily accessible ways will make it easier for anyone in the organization to understand, trust and reuse others' data and processes. A related benefit of these activities is securing corporate knowledge assets against generational turnover in the workforce. However, to be practical, knowledge-capture technology must not impose too great a burden on those tasked with building the knowledge bases. Success lies not just in the ability to build tools, but the ways users can capture knowledge – for example, selecting technology that lets users build one single application to capture knowledge and automate an activity that currently takes four separate applications to execute. Best practice involves capturing what users do, then building that into a repeatable automation tool.

The resulting capabilities will empower experts to capture, manage and reuse best practices throughout a given product development cycle as well as across different projects and programs. Making these best practices and key project learnings readily available for re-use through data mining will powerfully support organizations' continuous-improvement initiatives. Product quality is improved because performance data can then be delivered in time to positively impact design decisions.

### **Overcoming organizational and work-process constraints**

Of course, with even the most optimal technology implementations, much of the progress in optimizing simulation usage and maximizing its impact has to do with organizational considerations and people factors.

*"...that's something we struggle with: how do you get people to use [simulation]? You can't tell engineers how to do development – they'll resist [a new tool or method] until they believe it's useful. So we're trying an approach where we get each project leader to try out a new tool – he agrees to put it into a development project. That's a way to get [simulation technology] into an organization: show it has value once, then it usually gets used again..." – Infusion therapy device manufacturer*

**People factors** In the medical device manufacturers we studied, we found engineering cultures frequently less oriented toward simulation than toward physical test, and low C-level

awareness of the potential of simulation technology to advance corporate goals. Nevertheless, we found that best practices for managing people factors focus on two areas:

- Create incentives for discipline leads, analysts and engineers to take ownership
- Reinforce executive awareness

**Create incentives for discipline leads, analysts and engineers to take ownership** In many medical device manufacturers, primary constraints on broader use of simulation and analysis are staffing and schedule:

*"...[simulation] tools are readily available, and we've done a good job of making them available. Lack of use is more a function of [constrained] staffing levels, which many businesses are facing these days...and engineers' time and schedule. And what goes hand in hand with schedule constraint is limited opportunity to mentor junior users of the tools...part of the role of my team is to try to increase the awareness [of simulation], mentor people, and be a mechanism for knowledge transfer and growth in these areas. [That's needed] but it's difficult to do with the current pace of product development..." – Diagnostic equipment manufacturer*

Together with this informal mentoring and knowledge transfer, a related best practice is to use central engineering "tiger teams" as channels to disseminate simulation knowledge throughout the organization and build designers' and project managers' confidence in analysis tools and methods:

*"...[one] function my team serves is to be the 'glue' uniting our company's global mechanical engineering community – we work to deliver tools and best practices to the business...we [deliver and support] the mechanical CAD and simulation tools to the various project teams...we also deliver top-tier [engineering] expertise to the different projects..." – Diagnostic equipment manufacturer*

Another best practice to help overcome the constraint of not enough trained professionals is to implement tools and environments for knowledge capture and data sharing.

**Reinforce executive awareness** Our research found that C-level awareness of simulation and analysis tends not to be high in the medical device industry. Senior management tends to conceive of their companies' missions in terms of healthcare-delivery and clinical-outcome goals, and not to be closely involved in details of the tools and methods needed to achieve those goals.

*"...culturally, we are a sales- and marketing-driven company, not an engineering-driven company..." – Surgical instrument manufacturer A*

How to strengthen and reinforce executive awareness and backing? Align simulation/analysis with key business drivers and corporate goals – number of new product introductions, clinical outcomes, product differentiation, time to market. Enlist the support of engineering-savvy executives responsible for business-unit success:

*"Our management is aware of simulation, because they like to use it when you have to do a brief but concise presentation – to everyone, both internally and to customers. For a presentation involving our CEO, the company needed a poster showing a simulation laid over how the device actually performed in vivo – this showed how powerful simulation is, and how well it predicts what happens in tissue." – Surgical instrument manufacturer B*

## Next Steps

To drive change in an organization, a powerful call to action can be to benchmark the organization's maturity level against industry best practices. Using this report as a starting point, compare practices in your organization with those of your most successful rivals. Identify areas where more effective use of simulation and analysis would put you in the lead.

One way to begin is to assemble a multidisciplinary team – include representatives from the analysis groups, design, test, and program management – to audit current practices, identify gaps and bottlenecks, and develop recommendations for improvement. First review the constraints identified by practitioners in this paper. Determine which of these is most severely gating progress in your organization today:

### *Technology constraints*

- *CAD-CAE gaps*
- *Cross-discipline analysis gaps*
- *Need for better simulation data/process management*
- *Need for simulation knowledge capture and reuse*

### *Organizational and work-process constraints*

- *Human resource constraints*
- *Methods development, work-process integration requirements*

Then investigate sources of solutions for both classes of constraints.

## **Technology solutions**

Unlike CAD and PDM purchase decisions made by corporate committees with heavy IT involvement, analysts call the shots in simulation/analysis tool purchases. Nonetheless, it's important that simulation/analysis purchase decisions be grounded in not only technical but also business criteria.

Criteria for qualifying and selecting a solution provider, conditioned on what constraints you need to address first, include:

- *Functionality of solvers*
- *Functionality of meshers, gridders, other tools for problem setup and results execution*
- *Competence as integrator of diverse functionality – multi-CAD, multi-CAE, other product lifecycle functionality from requirements capture through manufacturing into service, support and sustainment*
- *Commitment to providing help with process change, people/cultural issues*
- *Commitment to providing:*
  - *Simulation data management framework*
  - *Process automation tools*
  - *Knowledge capture tools*
- *Reliability as long-term partner*

Another key business criterion is staying power. Manufacturers in some respects bet the company on those relationships: these are the companies that help with the essentials of tool integration, process definition, data management, knowledge capture.

In your organization's next procurement cycle, revisit your qualification and selection policies for simulation solutions to ensure they address your requirements not just for superior point functionality but also for simulation data management, tool integration and process optimization.

*“One way to validate simulation's impact would be to measure the number of animals I would have had to use in testing without simulation. If I am doing R&D to validate a product for human trials, and if I would otherwise have had to use 100 animals, I could predict that number, and then see how many animals I save by using simulation to get closer to the answer the first time. Maybe I could go from 100 animals to ten, or from ten animals to just one or two, to get the design right. That would definitely save money and time.” – Surgical instrument manufacturer B*

### **Organizational and work-process solutions**

#### **Optimize simulation/test tradeoffs**

Audit three past projects – one highly successful, one typical and one that could have gone better – to gauge whether superior management of the tradeoffs between simulation and test contributed to the success. Examine whether over-reliance on test or under-utilization of simulation played a role. Use the audit to map existing processes for design discovery, refinement and validation, and identify opportunities for improvement.

#### **Manage people factors**

##### ***Create incentives for discipline leads, analysts, and engineers to take ownership***

Foster informal mentoring and knowledge transfer to designers by analysts and senior engineers. Use central engineering “tiger teams” as channels to disseminate simulation knowledge throughout the organization and build confidence in analysis tools and methods. Assuage human-resource and schedule constraints by automating knowledge capture and data sharing, so existing staff can accomplish more.

***Reinforce executive awareness*** Arrange regular presentations of simulation/analysis achievements and business contributions to both top management and business-unit heads. Align simulation/analysis with business drivers and corporate goals – number of new product introductions, clinical outcomes, product differentiation, time to market. Enlist the support of engineering-savvy executives responsible for business-unit success.

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