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Key Characteristics of an ideal Quality Management System

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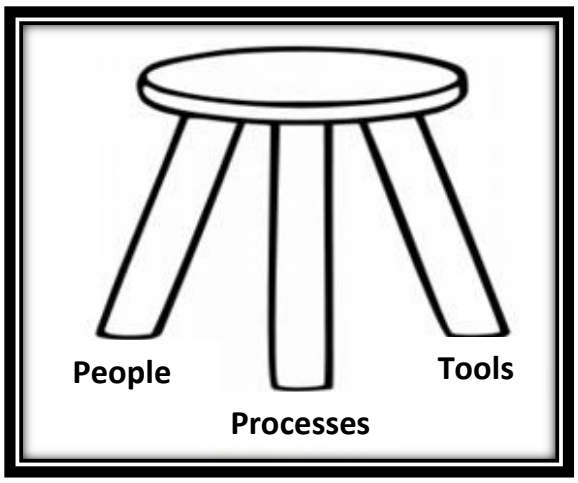


Introduction

When building your Quality Management System (QMS) for your Medical Device Company, use this simple guide to develop the foundational three-legged-stool, comprised of people, process, and tools that make up an ideal system.

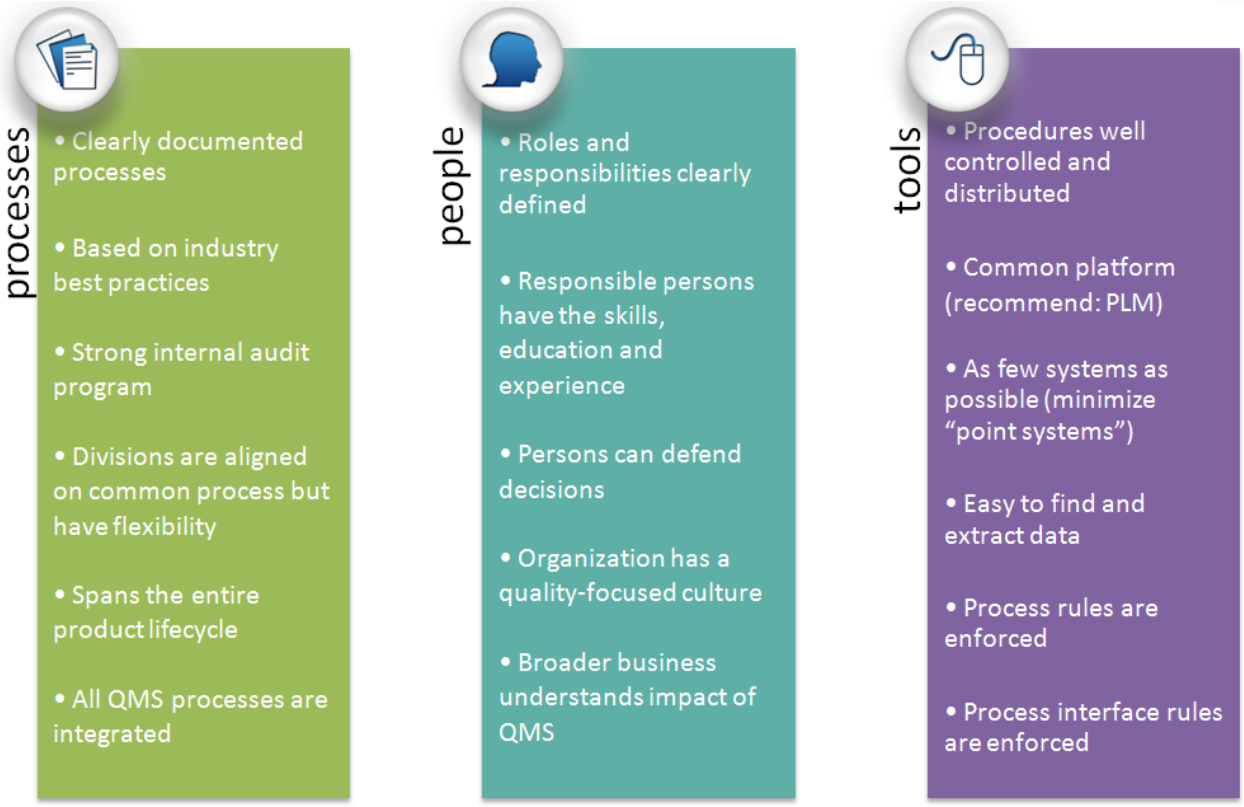
The critical inner workings of best practices for each process is out of the scope of this paper as I plan to cover some key areas such as CAPA, Risk, Complaints, Design Controls in future papers.

What may be unique to this paper over similarly titled papers you have read is the inclusion of state-of-the-art tools to bring everything together in a way that has previously not been possible. Specifically I am talking about Product Lifecycle Management (PLM). This is a capability that automotive and aerospace companies have adopted over the past few decades to transform their businesses. Over the past few years leading medical device companies have begun to adopt this capability also. This paper discusses how PLM will tie into the chief characteristics of your company's QMS.

First, realize that building an ideal QMS takes more than a good quality manual. We must consider people, processes, and tools as critical components of a system that comes together in harmony. Sometimes we call this the three legged stool.

Our goal of building the ideal QMS is to ensure products are produced consistently to a level that satisfies the requirements of the product design and product development and usage process. Typically from both a safety and efficacy perspective (will it work) and does it work as we expected (post-market surveillance).

The following guide is very simple and covers the basic concepts of that ideal QMS.
This content is targeted somewhat to Medical Device Companies, however, most of it is good common sense that would work well in any organization taking quality seriously or adhering to current good manufacturing processes cGMPs.



Processes:

Clearly documented processes:

Each process must be documented in easy to read format. It should cover what the purpose of the process is, who is responsible for what, what are the steps, what are the exceptions, what are the inputs and outputs. Processes are typically documented using a variety of document types that form taxonomy and should be hierarchical in nature. The core of this hierarchy is the Standard Operating Procedure (SOP).

Based on industry best practices:

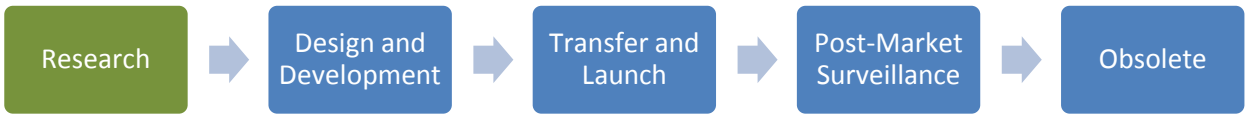
You are not the first person to do this. Without getting too hung up on the definition of "best practices", reach out to industry (or Integware) to get help writing SOPs and related documents. You must do this in coordination with the tools and people aspects of your system (more on that later). What is an example best practice? Take design controls, Integware recommends having a predefined new product introduction process (we can even provide a good starting point) that clearly identifies during new product development what deliverables are required and who is responsible for what. Some of the content produced will form content that you will use in your Design History File (DHF) and be ready to show to an auditor upon short notice.

Strong internal audit program:
It is critical to have a predefined audit schedule that is tracked with both a target and actual date. The audits should cover each portion of the QMS and with enough frequency that is defensible to an FDA auditor (or similar) and fits with your organization. Good audit practices are an entire sub-topic worthy of a separate discussion. This guide provides a nice overview.

Divisions are aligned on common process (but have some flexibility):
While it is okay to have different interpretations at different divisions, ideally we have a common overall process that all divisions follow within your organization. This can be where site specific SOPs differ but the broader SOP will have common characteristics. For example, it would be ideal to characterize risk in the same way across all divisions. I have seen examples where one division has a "severity rating" of 1-10 with definitions around each number that differs greatly from another division that rates it 1-5 with a separate set of definitions. Ideally there is one definition and again, based on best practices.

That said, it's also important to allow flexibility where it is truly needed. For example, in the change process it will very likely be overkill to perform an impact assessment on every change. Although from my observation there is inadequate change assessment controls in most companies I have seen. The need for impact assessments will vary between divisions dependent on the level of risk posed by the nature of the change and the type of products being produced. This is just one place where automated tools can really help lean things out.

Spans the entire product lifecycle:
When considering product quality it's essential to realize that this begins very early in the process of a product's conception through to production, release, and during post-market surveillance. For some products such as those that are approved based on no predicate device ("De novo" or PMA) post-market surveillance takes on even greater significance as there may be less clinical history to support the usage of the device. We might think of the product lifecycle as depicted below:



The FDA regulation and ISO standards will expect formal management of the quality processes in the latter four stages. However, a good quality system begins to capture knowledge in the research stage and puts it in a format that can be easily found and reused in the later stages or even future product development projects. Equally as important is to allow the research stage to be performed with minimal formalization. For example, change orders typically will not require as many approvals as will be the case with product that has matured further downstream.

During design and development formal processes kick into place including design controls which are covered in documents such as (820.30) and ISO 14971:2003 (4.2.3), through this process the design will be verified, validated and transferred to production. The design will result in an ultimate product recipe referred to in FDA language as the Device Master Record (DMR) (820.181), this describes everything that is necessary to know in terms of how to manufacture service and use the device. Similarly, activities that favor post-market are documented, such as managing complaints, CAPA, and corrections and removals in 21CFR11: 803 and 804, 820.25(b), 820.100, 820.180(b), 820.198, 820.250 and others.

Many other aspects of the FDA regulation and ISO standards span both pre-market activities and post-market activities, such as purchasing controls (how to work with suppliers); this is documented in 820.25(b), 820.50 and ISO 14971:2003 (7.4).

Again specific process discussions are generally out of the scope of this paper. Additional information may be found in materials produced by the Global Harmonization Task Force (GHTF) – that is a coalition of global regulatory authorities and experts driving to a harmonized standard. Also of great relevance is the preamble to FDA regulations, this often captures the intent of the regulations and will be relevant as to how each part is assessed by regulators in practice.

All QMS processes are integrated:

Out of the many short comings I see in a QMS this is one of the most common and is exacerbated by poor technology or point solution technology. What do I mean by integrated processes? Often in the QMS one process will trigger the need for a second process to fire; often this occurs in a daisy chain with loop backs (closed-loop) fashion.

The FDA refers to integrated processes throughout part 820. At a recent medical device conference integrated processes was a constant topic. The real value of the QMS comes to fruition when each process is not only functioning well as its own entity, but with all the other processes that relate to it. For example, it is not possible to think adequately about CAPA without thinking about Risk Management and vice-versa. When we initiate a CAPA we may need to establish if the original risk associated with a product was adequately assessed. A Corrective Action (the event has happened) as opposed to a Preventive Action (the event could happen but has not happened) as stated is the result of some kind of event. Therefore, one needs to ask, "do the circumstances of that event in some way contradict our expected risk profile associated with the product during the design". This is a classic example of integrated processes. The information from the event (e.g. a complaint), will be referenced when developing the Corrective Action and assessing the risk level. Other processes will likely fire as a result of the Corrective Action, such as an Engineering Change Order (ECO).

In other words, the information from one process needs to be adequately carried over to the next so mistakes are avoided and the person executing the process has adequate and correct information. Often the approval process of one process is affected by the nature of an integrated or related process. We use Ed Kimmelman's book frequently to help understand some of the nuances of the integrated processes. There is an entire section devoted to it and it's excellent. Another good example of two integrated processes includes the interaction between an audit and a change order. From an audit we have a finding, this leads to a change order. The change order needs to adequately capture the detail of the audit finding. Ideally we do not want to copy the information from the audit to the change as mistakes can be made. Instead it is better to reference it directly. As the change is processed information included in the audit may feed automated business rules. For example, it may be useful to have the auditor (e.g. an internal auditor) review the change order.

As we will discuss later under tools, a key advantage of using a complete Product Lifecycle Management capability is the enablement of complete integrated processes across the product lifecycle. Essentially, when considering that both of these are chief characteristics of the ideal QMS it becomes apparent that a PLM capability will be heavily beneficial if not essential.

People

Roles and responsibilities clearly defined:

It is critical that each person clearly understands their role as it relates to the QMS. Each business process should define the roles involved and what those roles are responsible for. It is acceptable in many situations to assign a task to a group of people with equivalent roles providing that they have adequate skills, training and experience. As important as understanding the role, it is essential that personnel are trained on the broader relevance of quality as opposed to "you must run this test on each part". People want to do the right thing and will improvise if they get the right thing. Ensuring the right person performs the appropriate task can be supported heavily by tools as activities can be directed to the appropriate parties at the right time.

Responsible persons have the skills, education, and experience:

I attended an excellent seminar from Ed Kimmleman on QMS a while back. Ed discussed that much of what an auditor will be looking for is those that make the decisions have the adequate experience, knowledge and training to make those decisions. Having a good training management system is an important part of this to be able to demonstrate that people have the experience.

Persons can defend decisions:

The FDA part 820 and ISO 13845 will only guide you so far. Therefore, it is critical to embrace the spirit of the standard (or in the case of part 820) when developing and managing the QMS. If something is side stepped, that can be okay providing that a person of this description made it and they documented the justification. An example might be that on a CAPA no action is desired, we identified the root cause and determined that no action is necessary (we document this with justification) – for example there was a failure with a supplier quality (a characteristic of the root cause), but we no longer use this supplier and since completely revamped our incoming inspections and purchasing controls clearly demonstrating that the original poor quality this supplier provided would no longer be tolerated.

The organization has a quality focused culture:

While it is not necessary for everyone in the company to be an expert in QMS, as stated previously roles and responsibilities must be clearly defined and people are adequately trained to those responsibilities. It is most important that people internally embrace and tenaciously seek the goal of quality. Each employee should understand therefore being compliant is not the true goal, compliance is a proxy for quality, and in other words quality is the goal.

It is said that certain agencies keep two lists: those that get it and those that don't. In other words, those that get it, embrace the spirit of quality and take the regulation seriously (obviously that would be you since you are reading this) vs. those that simply see it as annoying red tape or just think of it as a job.

The team must be of the kind that makes quality the goal vs. the task (or compliance). Has the quality engineer truly thoroughly understood and articulated all the potential hazards and harms associated with your device? Their job is to be creative and research all the ways things could go wrong, analyze them, and mitigate the risks. Do things get recorded in adequate detail or do things get skipped routinely? Do quality issues get followed through or do they get ignored and reprioritized downward? Are the CAPAs being prioritized based on risk to public health vs. risk to the business? Are we being proactive in developing preventive actions vs. simply fixing things when they go wrong?

The biggest objection I see to true quality (let alone compliance) is that it gets in the way of innovation. This does not have to be the case, as we will discuss under the tools section things can not only be done in efficient ways, but in fact will aid overall productivity. **I challenge the notion that there need be a polarity between compliance/quality and innovation/time to market**. I assert that a threshold can be passed with the right people, processes, and tools in place that one supports the other. Take a very simple example, if documents aren't readily organized think how long an engineer might spend looking for the right one and know it's in fact the correct revision.

Broader business impact of quality is understood:
Building on the theme of those that get it and those that don't, it is essential for the management team to understand the broader impact of quality. There are two reasons for this. The first is obvious, which is that great products means happy customers, everyone knows that. The second reason is legal exposure. Recently we attended a great seminar from the FDA. They said that everyone talks about how the FDA is the thing that keeps them up at night. They challenged this, in fact they said we are here to help, instead you should be concerned about what it means to hurt someone not to mention the potential for recall and litigation. Compliance risk is small compared to litigation risk in this industry. The management team needs to Google cost of recalls in the industry to get a sense for this.

Tools

Procedures well controlled and distributed:
All procedures must be exceptionally well controlled; this goes back to a tenacious quality team. They should be managed and guarded like the crown jewels. Developing a product to a wrong revision could lead to expensive scrap, rework or worse an adverse event in the field, 483 (that's the form used when FDA has findings) or a warning letter from the FDA (a publically available scolding), litigation or worse. For this reason I do not recommend the use of hard copy of procedures in manufacturing or elsewhere. It is important to have proper revision control so that there is no illusion as to what is the latest correct revision. Old revisions should be marked as obsolete, ideally stamped with a watermarking tool. When a procedure is released it must be approved by the appropriate personnel. All of this can be easily automated with a slew of tools available on the market today.

Common platform we recommend "Product Lifecycle Management" (PLM)
There are generally three types of automation tools available to support QMS automation:

1. **Document management systems**. Very common especially in pharmaceutical companies. They solely focus on managing documents and are very good at that. The problem with these types of tools is that they don't manage the many other business processes associated with quality and therefore fall completely short of the needs of the tenacious quality organization. Other processes might be tracked by point systems such as an Microsoft Access database or possibly a Quality Management Automation System (discussed below).

2. **Quality Management Automation systems**. These types of systems are designed to handle core aspects of the quality process in an automated way. There are two chief challenges to QMS automation systems. First, they are focused only on aspects of the QMS regulation such as CAPA, documents, and complaints. While some have capabilities that span more areas they are

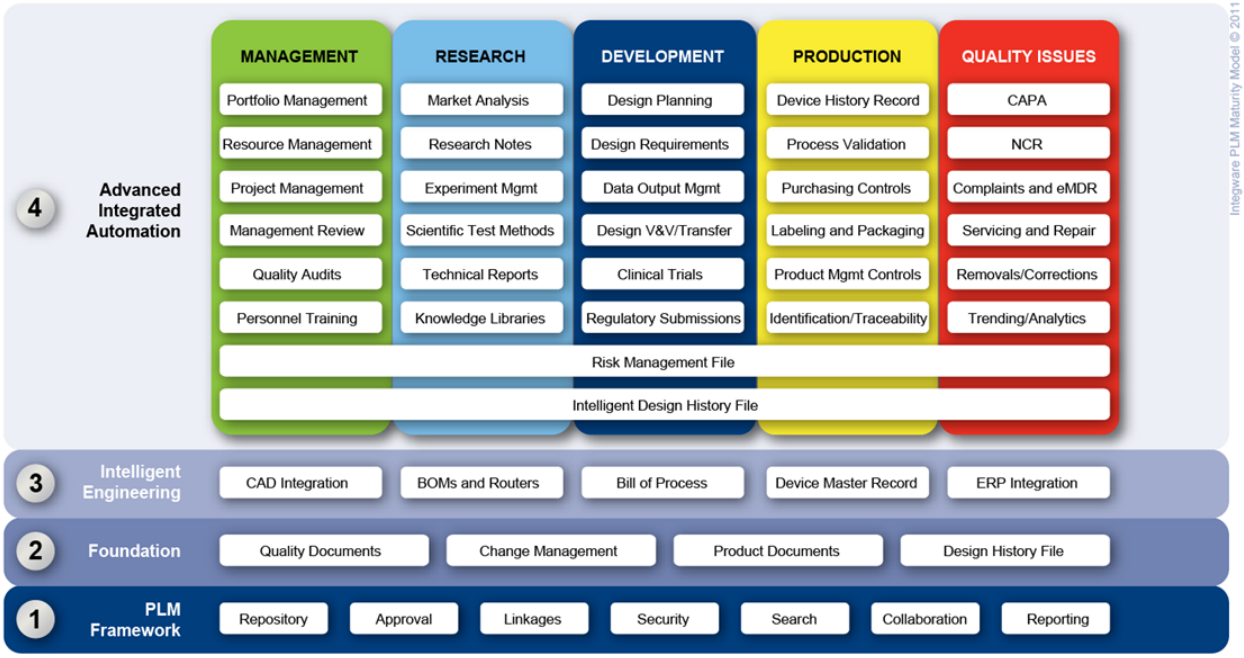
usually limited in scope. For this reason we refer to these as point systems. Second, many of these tools focus on documenting the results of a process but don't manage the process. While these statements are a broad characterization and some are better than others, generally I have found them to be relatively accurate. They lack depth and breadth needed to adequately manage quality.

3. **Complete Product Lifecycle Management systems**. These types of systems traditionally grew out of CAD and engineering information management in the 80s and 90s. In the late 90s and through the past decade their scope has exploded to cover the entire product lifecycle. Since then, new breeds of PLM systems have grown up that have few roots with CAD.

   The FDA while not specifically recommending PLM they advocate management of a Total Product Lifecycle Approach (TPLC) as the way they prefer to see quality managed in an organization. This is entirely logical because by reading the regulation and understanding quality it is essential that all processes that go into the product lifecycle can be managed together seamlessly and integrated. Better breed PLM systems are also designed to model new processes where an out-of-the-box module is not readily available or can adapt those modules to unique needs. Even better modules are rich with real best-practices related to the medical device industry and make the process of validation much less painful.

   Not only do these tools document the results of the process but they manage it through the various states and guide the user for success. They also allow process integration in a way described in the ***The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices – Amiram Daniel and Ed Kimmelman.*** For example, now I can process a complaint and tie it to my FMEA (used for product design and process risk analysis). I can see if the level of occurrence matches that assumed by the quality engineer and if not adjust accordingly. I might need to execute a CAPA from the complaint and link the two together, then understand how the BOM and broader Device Master Record (DMR) is tied in, possibly executing a change order along the way. We now have a closed-loop between quality, regulatory, and engineering. This is the ultimate experience for the persistent quality organization. Any tool that can do all that is considered by Integware as Complete PLM.

As few systems as possible (minimize point systems):
Referring to Integware's PLM Maturity Model® (illustrated below), there are at least 40 distinct process areas that can be automated. In your organization you may have specialty processes (such as custom device requests with hospitals) that go beyond the maturity model.



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Most companies I visit are either running their organization primarily on paper or have created or purchased a multitude of point systems to run individual business processes. Neither of these approaches is realistic in the increasingly complex manufacturing world. Indeed it is not uncommon to see companies literally have hundreds, and I have even seen cases where there are thousands of individual systems, that are used to manage the business. Not all of these relate to QMS or the product lifecycle, but many are and are completely unnecessary.

As discussed, with PLM many of these can be collapsed into a single integrated system. However, a challenge to automation is the speed by which it can be implemented. Often when I show off the potential for PLM people say "wow it can do all that, we want it all and we want it now". While we have made massive strides to speed up implementation by offering best-practice configurations directed at the medical device industry, the time it takes to get the people and process executed still becomes a physical limitation as to how fast the technology can be implemented. For this reason we recommend a phased approach and for that you will need to develop a strategy as to what is most important first.

While it is technically possible to start anywhere then by all means include that in your first phase. I highly recommend focusing on the Device Master Record and the associated Change Order process that accompanies it (unless you have a more pressing process area). Why? Because this is the backbone of your product and all quality surrounds that inner definition of your product. A single phase can include more than 1 or 2 business processes, in fact we have successfully implemented as many as 7 at time, but any more than 7 seems to push the limits of the organization.

Easy to find and extract data:
I can't tell you how many times I have seen a great system ruined by this lack of a simple feature. Users must be able to find things quickly and when necessary (such as during an Audit) get information out very quickly. Finding information can be done in a variety of ways (search, content search, navigation between integrated processes and predefined views and reports of information). Of all of these I find that having a good search tool is the most important. People want Google style UIs if at all possible and they don't want to have to think too hard. Going hand in hand with this is performance. The search should be fast, so test the system for scalability and network latency if you have remote locations accessing the system.

Process rules are enforced:
Each QMS business processes will include many rules and conditions by which the process must operate. Tools should be able to support these rules with automated checks. When selecting a tool it will be important to establish that it doesn't only capture the information but it also processes the information and when doing so can enforce business rules. Just because someone has a CAPA module does not mean they enforce a CAPA process.

A simple example might include checking to ensure dates have been adequately entered when logging a complaint. The FDA requires certain types of complaints be reported within a specified time frame. If the tool does not enforce the capture of the adequate date fields there is no way to establish whether this happened. Even though it may have happened, without the record to prove it, as industry insiders jest "it's just rumors".

Process interface rules are enforced:
Enforcing process specific rules is important and generally quite straight forward even with point systems or limited scope QMS solutions. However, also important is enforcement of the rules that occur as a result of two or more processes intersecting. This is another reason why a complete PLM solution becomes essential. Now we can see which DMRs (product recipes) are affected by a change triggered by an audit finding. The change order impact assessment is heavily influenced by both the audit findings and the DMR, as well as the Risk Management File, Regulatory Submission history and on and on.

The various interaction rules between such processes must carefully be considered and enforced. Once again many of these types of rules are characterized in the **The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices – Amiram Daniel and Ed Kimmelman.**

About Integware

Integware is the recognized leader in providing revolutionary PLM solutions in a rapid, cost effective, and efficient manner. We help our clients overcome and transform their most pressing business challenges by accelerating innovation, reducing product development costs, maintaining compliance, and driving strategic business development. Our deep understanding of software, process, and industry standards has helped us develop a rich set of best practices that can be leveraged across all industry segments. Realize the value of your PLM investment rapidly, just as many other successful clients are.

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