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Product-Centric QMS: A Critical Advantage for Regulated Companies

WHITE PAPER

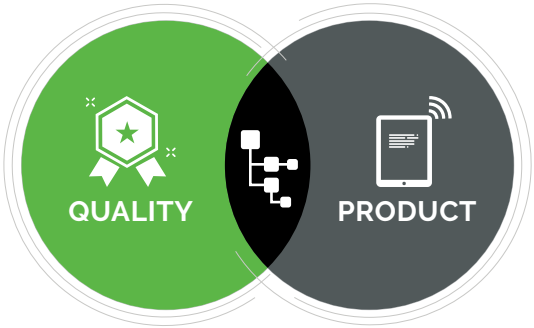
INTRODUCTION

Quality systems for companies regulated by the Food and Drug Administration (FDA) must follow current good manufacturing practices (CGMPs) to comply with 21 CFR part 820 regulations[1]. Furthermore, medical device companies must adhere to ISO 13485 and demonstrate their ability to meet customer and regulatory requirements. Together, the FDA and ISO requirements inform best practices for compliant quality management[2].

In the past, medical device, biotechnology, and other regulated companies could choose only one type of quality management system (QMS) to simplify compliance—document-centric ones. Today, you can choose between two types of QMS—the traditional document-centric or the product-centric QMS. What's the difference and how do you make the best choice for your company?

In heavily regulated environments, the key to introducing safe and effective products is maintaining a tight connection between all of your product information, quality records, training plans, and audit processes. This can be difficult with dispersed teams and partners. To address quality compliance, you must manage the full product recording—including the complete bill of materials (BOM) with dynamic connections or links to the approved manufacturers' list (AML), approved vendors' list (AVL), regulatory and environmental compliance information, and engineering changes (ECOs)—along with all related quality issues and corrective actions. For life sciences companies, regulations also require establishing strong design controls and managing the design history file (DHF) and the device master record (DMR).

Product-Centric QMS



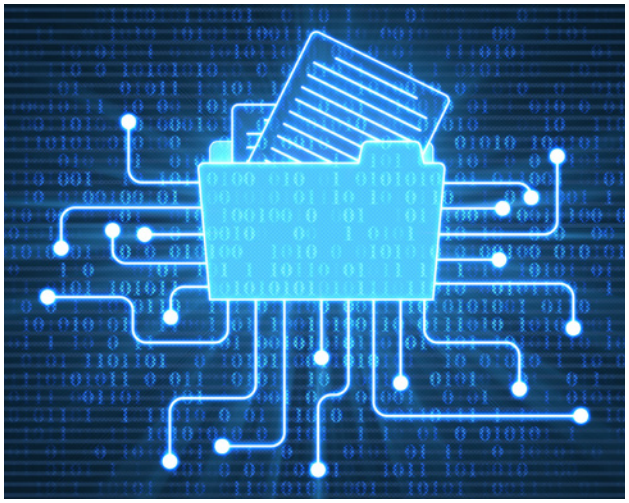
A product-centric QMS solution includes the foundational product record of all mechanical, electrical, and software designs. It enables complete control and traceability throughout the new product development and introduction (NPDI) process to help you ensure regulatory compliance.

WHERE DOCUMENT-CENTRIC QMS FALLS SHORT

Historically, traditional stand-alone QMS systems have addressed only a subset of information necessary to comply with quality regulations imposed by the FDA and other regulatory bodies like ISO and EMA. These solutions have been constrained because they provide a document-centric approach to manage quality, training, and, in some cases, even product design information.

These document-centric QMS systems have focused on only two key areas of FDA quality compliance:

1. Documentation control for standard operating procedures (SOPs), specifications, and other files
2. Process enablement and tracking for auditable processes, including CAPA and training records



Most of these QMS systems simply provide automation of paper-based processes and consequently fail to manage the complete product record comprised of mechanical, electrical, and software components; assembly and test procedures; and other documents specified in the multilevel BOM. Some QMS software providers claim to provide BOM management capabilities, but typically provide flat, nonhierarchical BOMs as references in documents. A key limitation of this approach is it requires manual data entry in planning and production systems as the design moves into production and full commercialization (e.g., ERP systems). This results in delays throughout the new product introduction (NPI) process and potential errors whenever new changes are introduced to the design.

For sophisticated medical device companies, having relational, hierarchical BOMs is essential to define and control the entire product structure from the top-level finished good all the way down to the lowest level of the assembly. Relational BOMs provide the complete "recipe" necessary to plan, source, and build high-quality devices that work as designed. Arena QMS comes with a comprehensive BOM management solution that "speaks the same BOM language" from early CAD design through prototyping and into final production by enabling the seamless passing of BOM information from one system to another.

While control of quality processes is essential in the medical device industry, a document-centric approach may suffice for some life sciences companies (e.g., pharmaceutical, hospitals, services) that do not create and manufacture a discrete medical device product comprised of electrical, mechanical, and/or software components. Medical device manufacturing companies are required to carefully track, control, and release product design changes to market quickly and effectively.

ARENA'S PRODUCT-CENTRIC QMS APPROACH

> A big advantage managing quality in Arena is the ability to link quality records to the part record and bill of materials. Since our initial implementation, we've improved complaint investigation duration and timeliness of CAPA management through process improvements supported by Arena's product-centric quality management system approach.
>
> —Chris Hill, Director of Quality, Organ Recovery Systems

Arena QMS is a compliant product-centric solution to control and manage your NPD processes from product concept through sustaining, improvement, and end-of-life. To do this, Arena QMS aggregates your product information into a hierarchical BOM that specifies all of the components, subassemblies, and associated documents required to design, test, build, and ship your product. Managing the complete product record along with the quality system requirements in a single solution helps you ship quality products on time. Product-centric QMS accelerates your NPD process and facilitates tighter control of your product design as you strive to reduce cost, improve compliance, and drive continual improvement.

Arena QMS connects quality records and closed-loop processes to a comprehensive product development platform. The QMS software solution helps manage design controls, device master records (DMRs), and design history files (DHFs), while providing increased visibility and traceability. Arena QMS also provides software validation services and automated review and approval processes with electronic signatures that simplify compliance to FDA 21 CFR Part 11.

For superior document management, Arena's cloud-based QMS controls versions and revisions of drawings, specifications, standard operating procedures (SOPs), assembly and test instructions, software code, and any type of files in context of the entire product record. The difference with Arena's connected QMS approach is that every document, part, manufacturer, and vendor is linked directly to its related specific component or item on the BOM. This ensures everyone can see every document and how it relates to the product design.

Design History File Management

With Arena QMS, you can effectively capture design decisions, meeting notes, design quality documentation, and quality records while providing a process to guarantee that all information is tracked, controlled, and documented as you move through the design and development process. Our comprehensive approach to DHF management provides not only the control you require but also the invaluable transparent links to any part of the DMR you need to increase product success.

A Different Way: Managing Records With Live Links

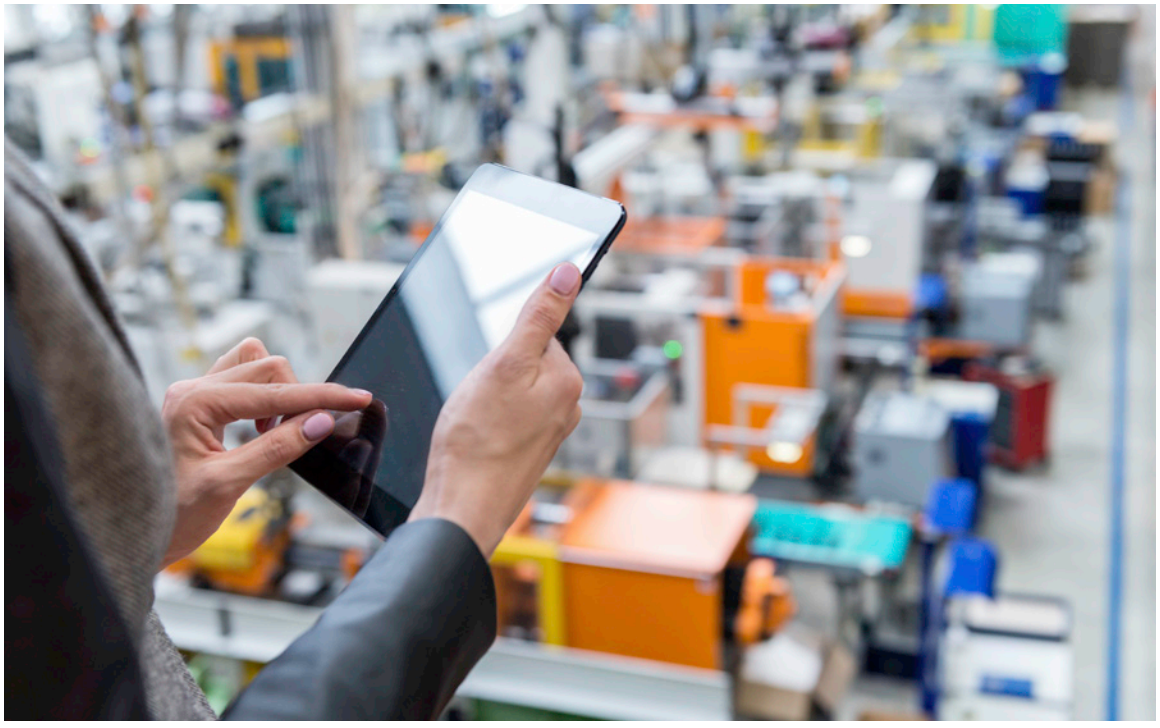
Arena takes into account that documents, change orders, BOMs, suppliers, CAPAs, DHFs, DMRs, and other product information are interrelated.

Engineering change orders (e.g., ECRs, ECOs, deviations, stop ships) are more than static documents or simple forms in Arena. They drive complex workflow approval processes and post-release actions. For example, when all of your stakeholders have approved any given change order, its release automatically incorporates all BOM redlines into the latest revision. This release can then trigger the transfer of the new items, BOMs, suppliers, and manufacturers' information into your ERP system for planning and production purposes.

The release can also include an SOP change that may require a training plan review.

Arena maintains the necessary relationships between the change order and its affected parts, assemblies, quality records, and documents. To drive procurement and manufacturing accurately, the ECO's disposition codes—coupled with effectivity dates—allow for optimized planning and production. And the relational BOM includes component quantities and units of measure to drive your enterprise resource planning (ERP) later in the new product introduction process.

AML, AVL, and associated part information also require unique functionality. Arena's AML/AVL capabilities provide management of manufacturers' part numbers, internal part numbers, and the supplier's (or distributor's) part numbers so that your procurement teams can effectively plan and procure parts. With Arena, our AML functionality helps you identify and eliminate the use of duplicate manufacturers' parts, reducing costs through higher volume purchasing.



WHAT ARENA DOES—DIGGING DEEPER

What truly makes Arena unique is the ability to manage linked relationships between DMRs, DHFs, BOMs, individual components, AML/AVL, documentation, product history, and any changes or quality issues. Anyone with appropriate access privileges can view the related quality, change, and product records to understand better the actions required to resolve problems. Leveraging information quickly and easily facilitates robust change control, supply chain collaboration, quality management, and key product-related business processes. Consider how Arena QMS addresses the following business needs and external requirements.

CHALLENGE: Corporate-Wide Visibility of Full Product Record and Associated Processes

Engineering creates and documents product designs comprising the complete product record, and then everyone else uses this information to verify, validate, source, manufacture, and support the products. But who is everyone else? They can be teams from manufacturing, quality, regulatory, clinical, purchasing, supply chain partners, and field service groups.

When evaluating solutions, consider every aspect of the product. The complete product record includes BOMs that define electro-mechanical assemblies with reference designators to identify a component in an electrical schematic or on a printed circuit board (PCB). The product record is further enhanced with the supporting manufacturers' information (i.e., relational AML/AVL), drawings, specifications, and procedures.

SOLUTION:

With Arena, every team has instant access to the complete product record, which means they can perform their jobs more quickly and more accurately. When an issue arises, Arena empowers impacted teams to resolve the issue. For example, if there is a sourced component quality issue, purchasing can easily view the AML to find and select approved alternate parts.

CHALLENGE: Disparate Systems

As companies grow, they use different systems to manage different elements of the product record. The BOMs may be in spreadsheets on a controlled, shared drive. The AML may be in ERP with changes managed by email correspondence. And the engineering changes may be logged in yet another system. Quality processes, like CAPA, often require a complete view of the product.

SOLUTION:

With Arena, product companies can eliminate the use of multiple disparate systems. Arena provides a single, scalable enterprise platform to manage the items, BOMs, DMRs, DHFs, and all associated product documentation. This simplifies control, supports quality processes, and increases traceability throughout the product lifecycle.

CHALLENGE: Training Record Compliance

Ensuring your internal teams and partners are trained and can prove competency is required for FDA 21 CFR Part 820. Recent FDA audits reveal that more findings relate to training processes than to personnel training. In 2019, the FDA reported 64 training-related findings[3]. Inadequate "procedures for training and identifying training needs" resulted in 37 findings and a lack of "personnel training documentation" was cited 24 times.

> "Arena Training is a one-stop shop that records and provides a historical record for each employee. I like that this tool allows quizzes to be added, which holds the employee accountable for actually reading and understanding the material content.
>
> —Cindy Lalowski, Senior Quality Systems Manager, AEye

SOLUTION:

Arena Training manages training records so managers know which employees have been trained on applicable standard operating procedures (SOPs), policies, and manufacturing process instructions. Arena provides a single, comprehensive solution to manage training processes and records to ensure you are always in compliance, can respond to audits easily, and guarantee that your employees are continually trained.

CHALLENGE: Enterprise and Supply Chain Collaboration

Regulated med-tech companies rely on distributed teams of experts to design, manufacture, and support their products. These experts can be direct employees, contractors, or other design and manufacturing partners. Without access to the single product record, the various experts could use different revisions or the wrong documents. Without automated quality and change processes, they could not know about important product updates. The results include extra design cycles, missed release dates, or manufacturing errors.

> "Arena is used throughout our organization for BOM management and for quality management. We are able to collaborate on solving nonconformance reports and complaints and share BOMs and specifications with our suppliers. Arena also helps us demonstrate RoHS compliance. Every audit by our certification body is supported by Arena's system, whether using search results for the particular area under question or printouts from reports generated.
>
> —Avraham Harris, Director Quality Affairs & Regulatory Affairs, Accellix

SOLUTION:

Arena facilitates teamwork with notifications, dashboards, access control, and a range of collaboration options to share information between all impacted stakeholders. Automated notification can be driven by key actions, such as when ECOs need to be reviewed and approved. Arena also controls access so that internal employees and external partners see only the product information needed to do their specific job.

This access improves innovation and quality while reducing cost and process cycle times. For example, design for manufacturability (DFM) processes are compressed when the manufacturer can review designs earlier and give feedback to source different parts or change the design for ease of manufacturing.

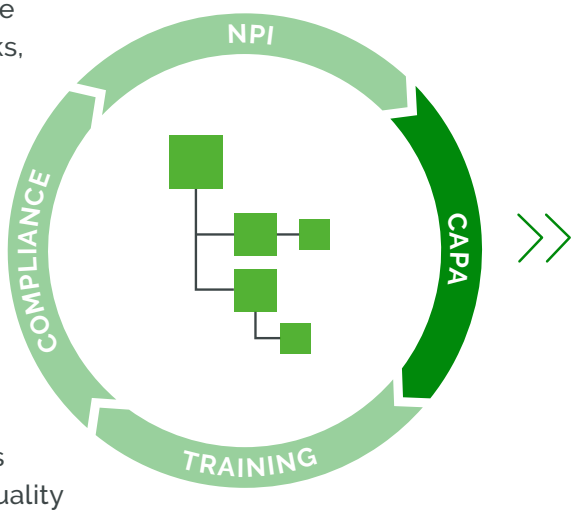
CHALLENGE: Closed-Loop CAPA Processes

For many medical device companies, the lack of a well-implemented CAPA process is the primary concern for audit issues, observations, or nonconformance reports (NCRs). CAPA processes are complicated by multiple approval disciplines, difficult root cause closure, and multiple quality processes that require a sophisticated ability to traverse product history for time sensitivities. CAPA processes often trigger an engineering change process to resolve product defects and other issues. A single quality issue may affect one or many products. And one product may have one or many quality issues. Mastering CAPA processes provides significant payback directly tied to company success, but it requires a system that supports the process demands.

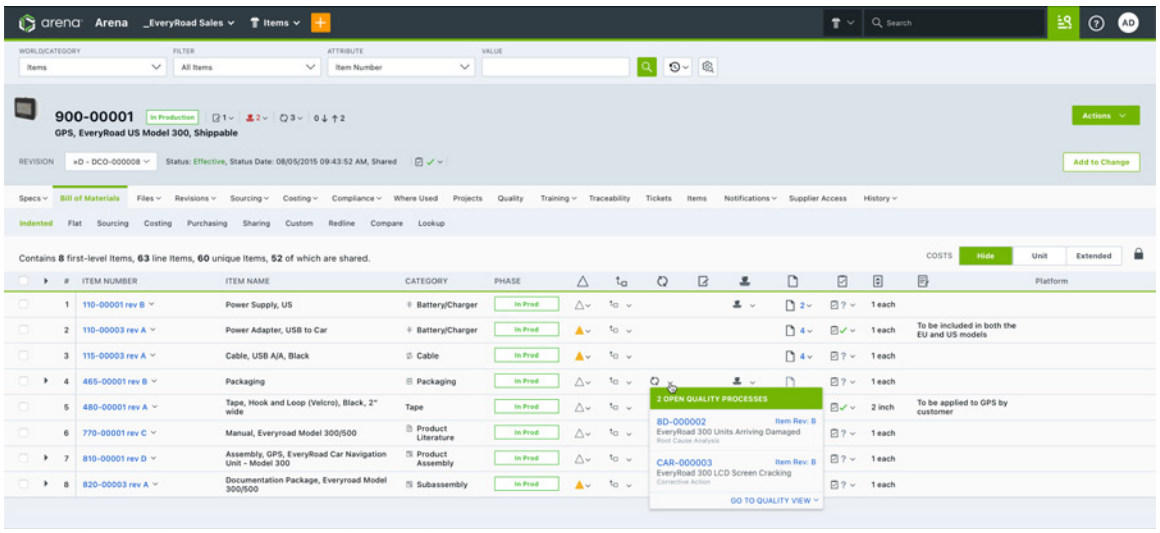
SOLUTION:

Arena maintains all these relationships via live links, so users can instantly move from documents, parts, and multilevel assemblies to quality issues or vice versa. Arena provides visibility between the CAPA records and related change orders, which may include BOM and AML redlines. In this way, internal auditors, quality and regulatory affairs, and other affected groups can instantly access and view all the issues, actions, and steps through final resolution in one central system.

CAPA Process



Connected CAPA Processes in Arena



View of BOM showing pending quality issues for selected components.

CHALLENGE: Enterprise Software System Validation

Medical device companies are required to validate enterprise software systems that are part of the quality system for their intended use, according to established protocols (per 21 CFR 820.70(i) and 21 CFR 11.10(a)). Regulated companies understand this requirement means each enterprise system upgrade can have a major impact on business operations. However, enterprise systems must be upgraded or enhanced periodically to meet expanding business requirements, provide technological advantages, and better meet industry demands.

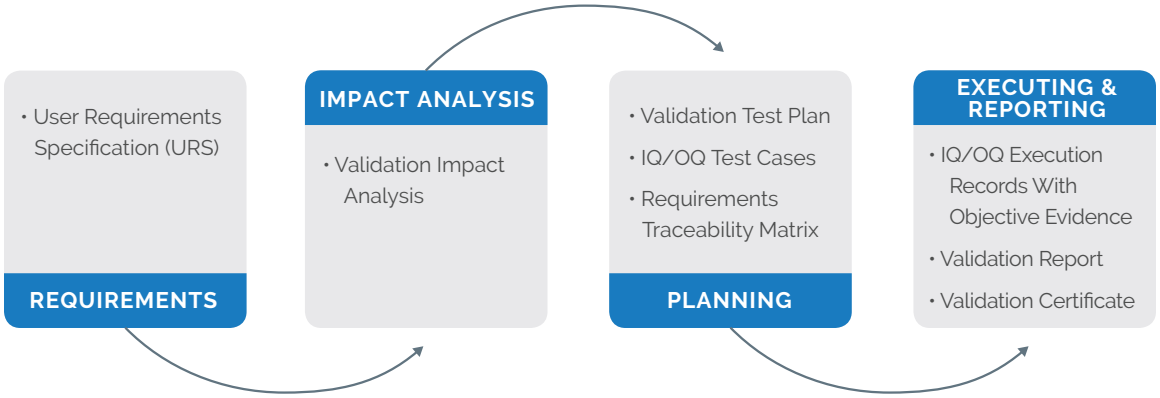
SOLUTION:

Arena Validate, an industry-leading software validation service, is designed to speed FDA 21 CFR Part 820 and Part 11 compliance, which allows your teams to focus on their core competencies and spend significantly less time validating Arena's software application. We provide the critical elements of change and document management, design controls, electronic records, electronic signatures, and quality management.

> "We've … added in an impact, a root-cause analysis, and risk management observation process. Each one of these different processes can call the other ones, or demand that another process be used. They can also be linked together so that when you get an audit, you have a tightly integrated cross-linked evidence chain for whatever problem you're dealing with.
>
> —Chief Operating Officer, Swan Valley Medical

Arena validates each Arena release against a predefined set of intended uses common to all medical device manufacturers. Arena then distributes the results of validation testing to all subscribers. As a result, Arena's regulated customers

can leverage 100% of the enhancements to yield additional benefits. With Arena's cloud-based QMS and validation service, you are able to adopt every new software release without the fear of being revision-locked on your QMS software system and without having to complete a difficult upgrade process.



CHALLENGE: Collapsing Internal and External Audit Time

Audits, both internal and external, are a constant reality for medical device product companies. And how well you perform during audits determines not only the success of your team and product but sometimes your company's very existence. One approach to an audit is to engage valuable people resources in the task. These people may be asked to obsessively and manually collect all of the product and process details and become the historians of the DHF/DMR. Yet, this method exposes you to many failure points (e.g., reliance on tribal knowledge, introduction of human errors, lack of visibility, communication delays). It is also a costly process to maintain as your product lines grow and mature.

SOLUTION:

Arena provides the functionality to achieve and maintain regulatory compliance easily while performing product and quality processes. Peace of mind is a priceless benefit when you have all of your quality actions and change processes linked to the product record. Having the full product design history and product record controlled and tracked in one system provides you confidence during stressful audit processes.

> "Implementation was made very easy by Arena giving us complete IQ and OQ documents. The wide range of standard out-of-the-box functionality narrowed the scope of our work even more. This resulted in a very productive and complete PQ while requiring much less management than other IT system implementations I have been a part of.
>
> —Ed Reith, Supply Chain Engineering Manager, Ebb Therapeutics

WHAT ARENA DOES BETTER THAN DOCUMENT-CENTRIC QMS

Product-Centric QMS Benefits	Functionality
Provides Enterprise-Wide Visibility	• Captures everything required to design, produce, and ship product for all teams—a single source of product truth • Provides controlled access for the entire enterprise, including supply chain, for collaboration
Unifies Quality and CAPA Process With the Product Record	• Links CAPA records with the product record and engineering changes (e.g., ECRs, ECOs, deviations)
Facilitates Quality Considerations During the Product Development Cycle	• Reuses approved manufacturers' parts and other purchased subassemblies • Manages dynamic links between all components, quality issues, and documents to help engineering prevent recurring quality problems
Simplifies Enterprise Software System Validation	• Documents validation test results for every product upgrade to subscribers • Eliminates the fear of upgrading whenever new functionality is available (known as "revision lock")
Reduces Internal and External Audit Time	• Links and indexes entire product record, including the DMR and DHF, for easy searching

CONCLUSION

Arena enables rapid collaboration by providing secure access anytime and anywhere to guarantee all impacted internal teams and partners are using the latest and greatest release of Arena's cloud-based solution. Arena QMS links quality records, requirements, issues, projects, and change processes to the active product record—most importantly, the complete multilevel assembly or BOM. This helps you speed new product development and commercialization to get high-quality, compliant products to market fast.

With Arena's Cloud QMS solution, you can "check the FDA regulation box." And regardless of your industry, we help many regulated companies that deal with non-FDA compliance as well.

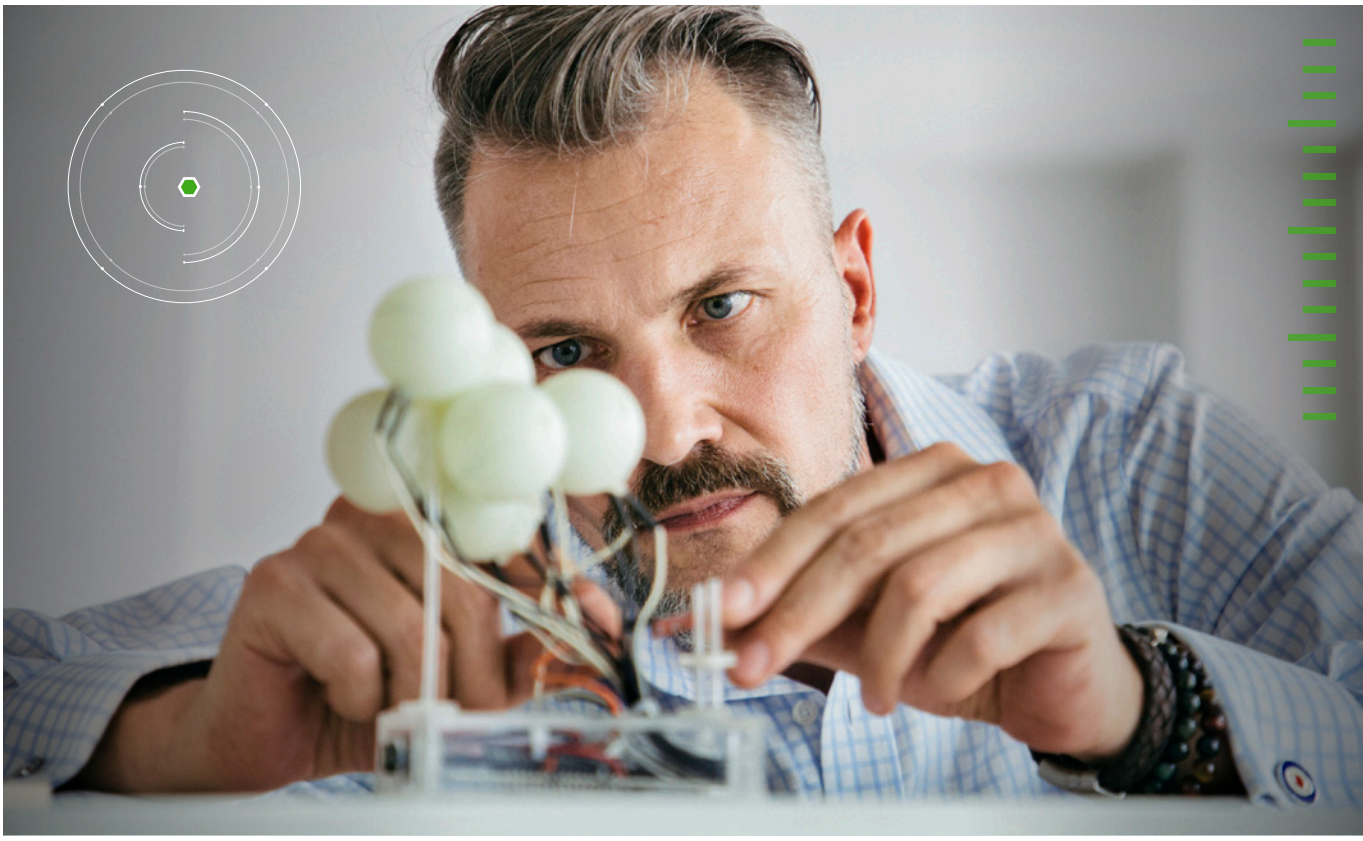
To learn more, check out our product-centric QMS solution or download our 7 Principles of Product-Centric Quality Management ebook.

REFERENCES

1 Retrieved 14 March 2016 from http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/qualitysystemsregulations/

2 Retrieved 14 March 2016 from http://www.iso.org/iso/catalogue_detail?csnumber=36786

3 Source: FY 2019 Inspectional Observation Summaries. See 21 CFR 820.25(a) and 820.25(b).



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