Modern CAD for Medical Device Design

How Onshape Helps Design & Manufacturing Teams Speed Up Production, Boost Collaboration and Increase Innovation

Onshape

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Introduction

It's no surprise why the $400 billion medical device industry is booming. Worldwide, average life expectancy is increasing year after year, mainly due to advancements in biomedical technology improving patient outcomes and reducing hospital stays. The increasing elderly population combined with ongoing healthcare improvements in emerging nations ensures that the medical device market will continue to grow.

Despite these increased opportunities, medical device manufacturers have their own unique challenges. Competition, of course, is fierce from both domestic and international providers. First-mover status may bring you important competitive advantages, such as brand recognition and market share, but the pace at which technology is evolving can erode the benefits of that status very quickly. Newcomers with equivalent, but cheaper and more technologically advanced devices, have the opportunity to displace your products and reduce your market share.

Ongoing R&D in product improvements and new product lines is therefore key to driving your continued success.

Maintaining an accurate design history is absolutely critical to comply with industry regulations. The U.S. Food & Drug Administration (FDA) takes an average of six months to review device submissions, and devices must be resubmitted for approval every time they are modified.

With this pressure to innovate quickly, many forward-thinking medical device companies are re-examining their design and manufacturing process.

In this eBook, you'll read insights from three successful companies who recently switched to a modern, cloud-based CAD system:

- **Thinklabs** (Digital Stethoscope)
- **HydroWorx** (Underwater Treadmills)
- **Vicarious Surgical** (Surgical Robots)

What exactly is a "modern" CAD system and how does it speed up production, boost collaboration and increase innovation?

Glad you asked.

What Makes a CAD System "Modern?"

"Onshape takes away all this infrastructure that we'd otherwise have to manage. It eliminates all these issues blocking collaboration between teams. You don't need to install anything. You don't need to maintain versions. Everything is just managed for you. It's the 21st century version of CAD."

– Adam Sachs, CEO of Vicarious Surgical

It may surprise you, but the truth is that many engineers are still using file-based CAD technology that's three decades old. Parametric modeling was first introduced in 1988 and hasn't fundamentally changed since the 1990s.

These CAD systems were breakthroughs at the time, but they were never meant for teams. Ironically, they are now slowing companies down by blocking collaboration, creating multiple file versions that result in costly errors, and causing engineers headaches from system crashes and lost work.

Onshape is a modern CAD system that frees engineers to focus on doing their best work. Unlike old CAD technology, Onshape unites advanced modeling tools and design data management in a secure cloud workspace that is accessible on any computer, tablet or phone.

You'll never lose your data or deal with design gridlock ever again.

Modern CAD

Advanced Modeling Tools

Built-In Data Management

A Secure Cloud Workspace

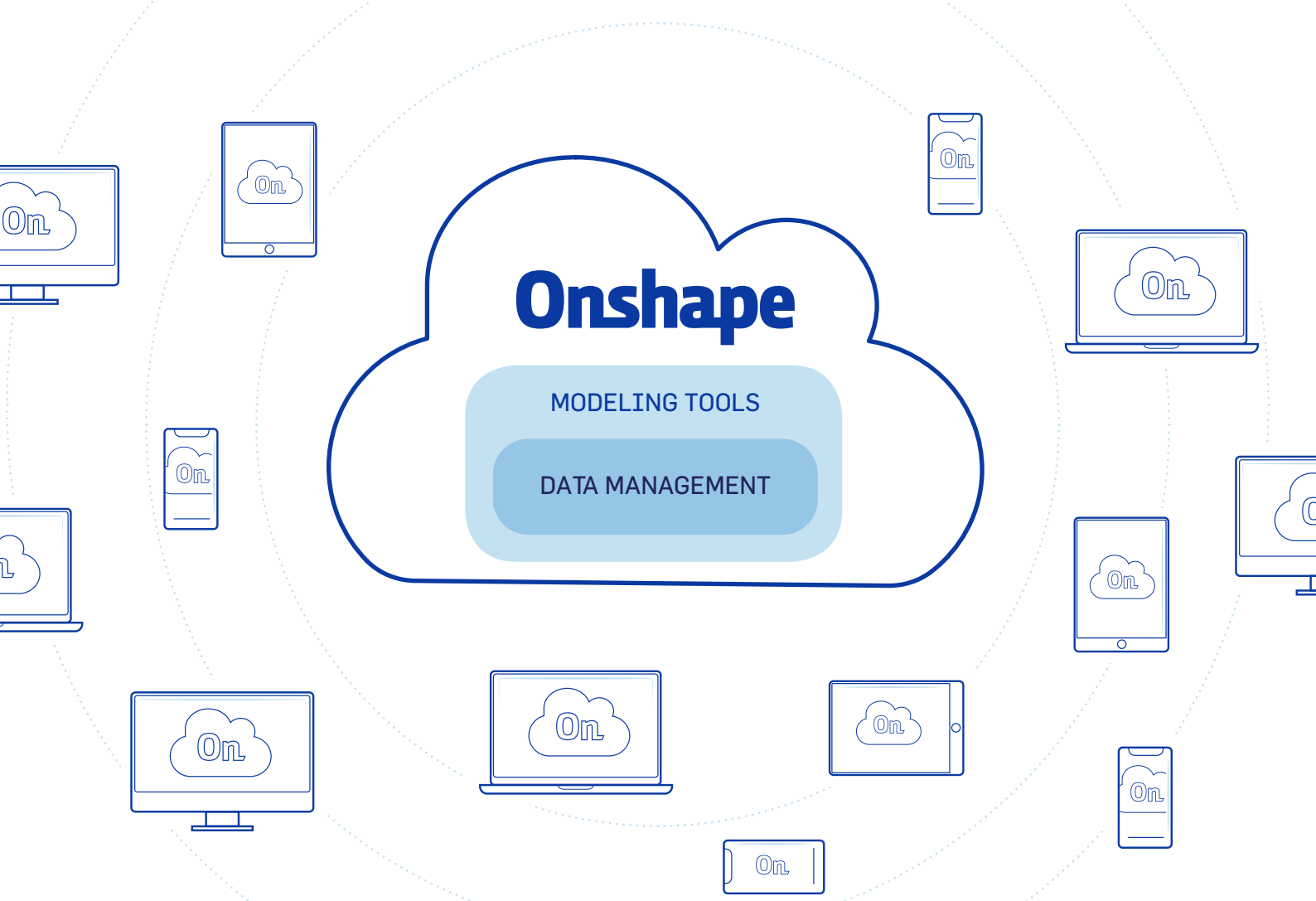
What Makes a CAD System "Modern?"

The founders of Onshape (the same team that founded SOLIDWORKS) were fed up with the hassles of outdated file-based CAD. To prevent engineers from stepping on each other's toes, Onshape first created a real-time data management system – that lets every team member see each other's design changes as they happen – and then built a modern CAD system around it.

This is the polar opposite of old CAD systems that built their modeling tools first and then introduced their data management solutions as a clunky afterthought.

For a deep dive on how Onshape has fundamentally improved the core 3D modeling tools you depend on every day, see page 30. For an in-depth look at how Onshape's built-in data management works (including Release Management & Approval Workflows), see page 32.

But first, let's examine how Onshape's modern CAD system is especially impactful for meeting the challenges of medical device design.



Industry Regulations & Design Controls

1. Keeping Up With Regulatory Compliance

The medical device industry is heavily regulated, for good reason. Expanding your market presence into other geographies comes with its own set of complications as each new device must be approved by each country's or region's own regulatory body. For the purpose of brevity, we'll focus solely on the U.S. market and the Food and Drug Administration (FDA).

Medical device manufacturers must seek marketing authorization for any new device from the FDA. Depending upon the type of classification assigned to your device, premarket approval may also be required. Every year, the FDA clears approximately 3,000 device submissions with an average turnaround time of 180 days. This can be significantly longer if your device is Class III (devices that support life or are implanted, e.g., pacemakers or breast implants).

Once a submission has been cleared, the approval remains in place for the lifetime of the product. However, if the product has been modified or improved, or you want to change its intended use, you must reapply all over again. As competitors introduce new equivalent devices, you may have no option but to enhance your existing product lines or develop new innovative solutions to keep up. However, your time to market and first-mover status may be significantly affected by this lengthy approval process.

In an attempt to expedite submissions, the FDA created a set of quality regulations that enables them to identify device manufacturers that consistently produce high-quality devices. These regulations help to focus the FDA's resources on assisting other manufacturers to raise their level of quality, identify and promote practices that support consistent quality manufacturing and align the FDA's own regulatory, enforcement and compliance approaches with those practices. To implement these quality regulations effectively, medical device manufacturers must therefore rethink their approach to risk and transition from reactive compliance reporting to proactive quality management.

Every medical device manufacturer's ultimate goal is to improve patient care with safe, effective and high-quality products. However, not every product can be perfect the first time. Indeed, product recalls and litigation are costing the industry billions each year. These recalls are mostly due to production defects and design flaws which could potentially be reduced by adhering to the quality standards set out by the FDA, which recommends that companies implement:

- **Design Controls**
- **Quality Systems**
- **Production and Process Controls; and**
- **Documentation Control Procedures**

Historically, regulatory workflows and application submissions have been carried out using paper-based systems – a necessary, but significant overhead activity that depletes time, money and resources. These paper-based systems are gradually being replaced by document management and quality management systems, helping to reduce the burden. However, as with all controls and procedures, nothing can be completely automated. These systems are only as effective as the policies, procedures and employee-training programs that you have in place to ensure compliance.

This eBook will focus on Design Controls, specifically how they apply to your use of CAD software (which is used extensively in the design of medical devices) and your overall product development process.

Integrating effective design controls into your product development workflows enables you to transform regulatory overhead into engineering intelligence, providing critical insights to help you continuously improve both your products and your engineering processes.

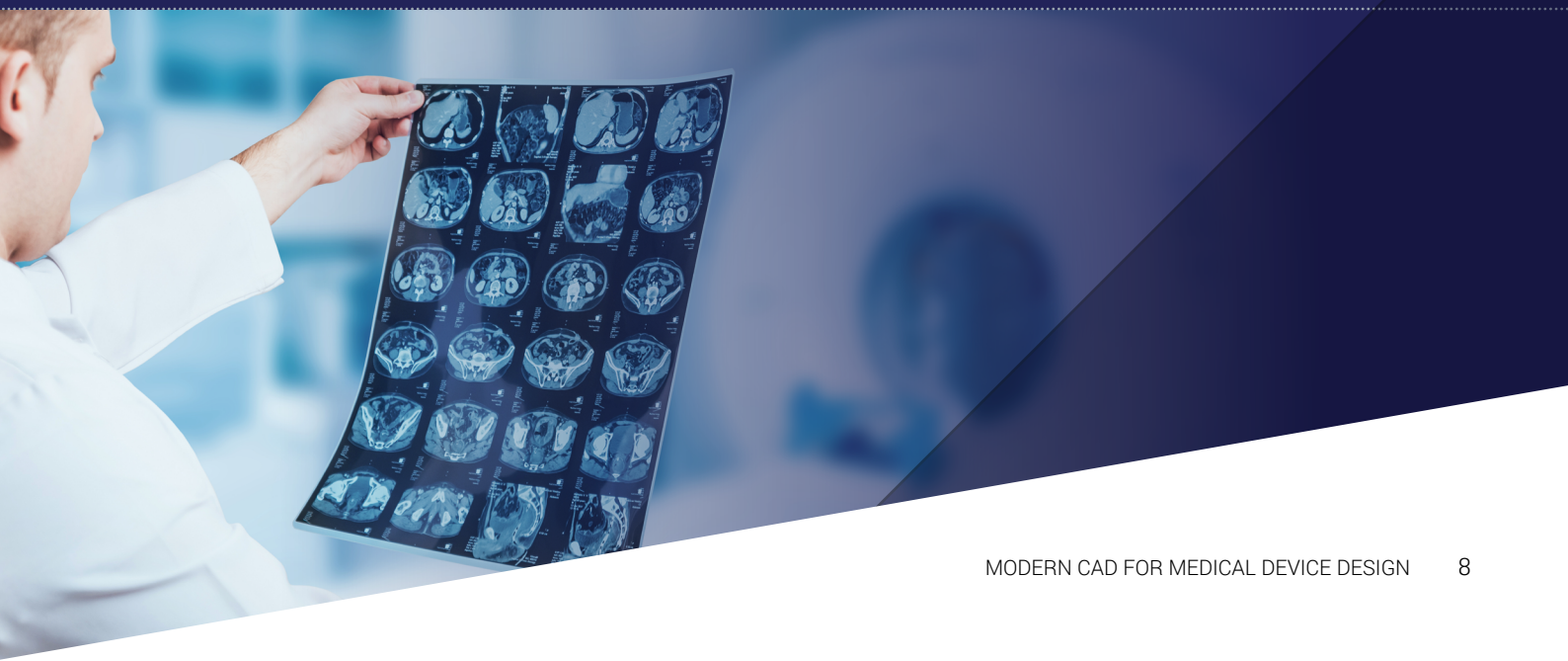
2. How Design Controls Reduce Production Errors

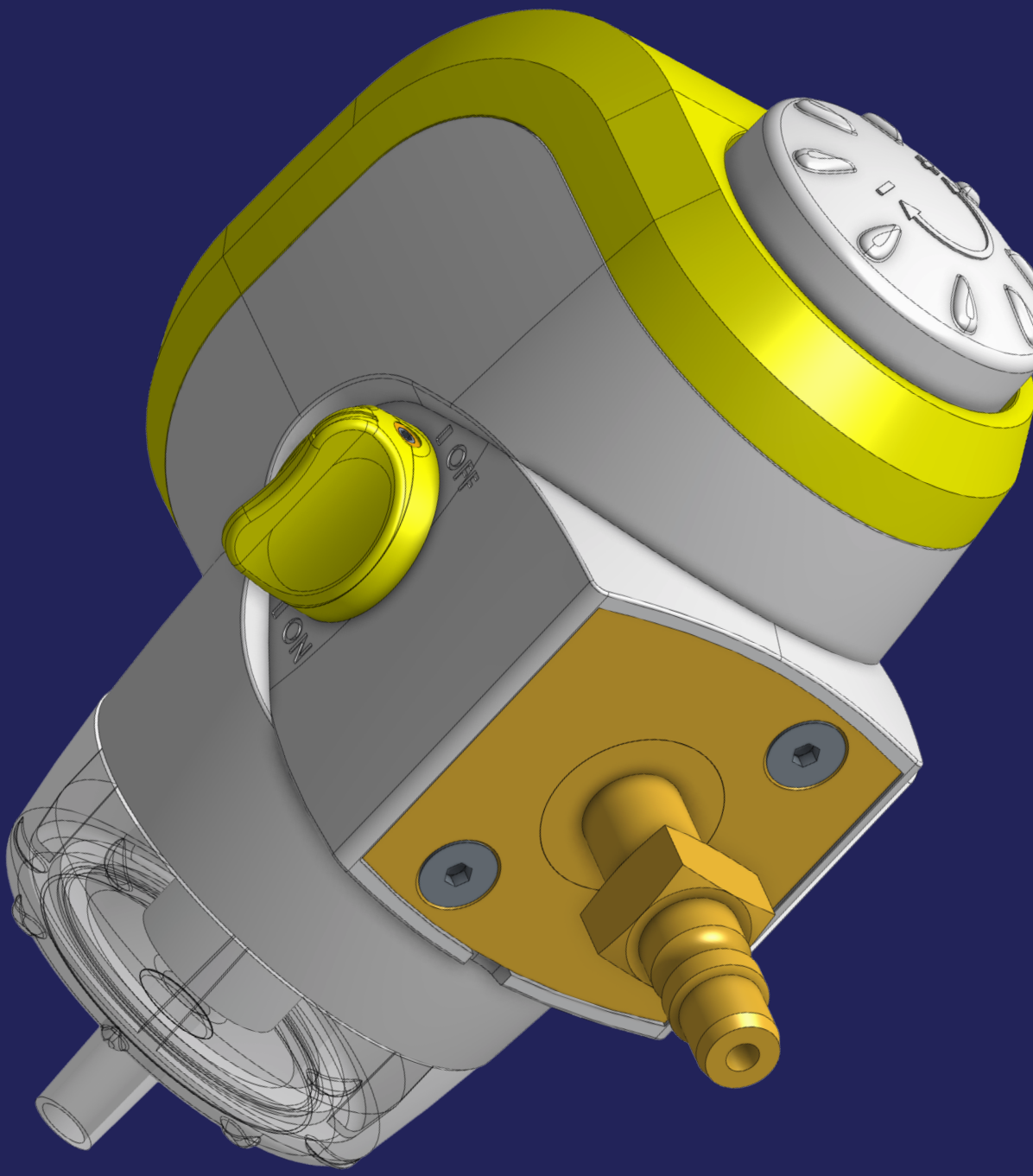
Design controls are used to continually assess and provide improved visibility into your product development process to help identify and correct issues earlier. With improved visibility, managers are able to recognize problems, make corrections, and adjust resource allocations. Designers benefit from improved communication and coordination among all stakeholders and get a better understanding of how their intended product conforms to user and patient needs.

Design controls are just one part of a comprehensive quality system that should be used to manage a device from initial requirements through design, production, distribution, use, maintenance, and eventual obsolescence. Although the name suggests that design controls apply only to the initial design of a device, they also apply to any and all changes to the device or manufacturing process, including those occurring long after a device has been introduced to the market. This includes evolutionary changes such as performance enhancements as well as revolutionary changes such as corrective actions resulting from failure analysis. Design changes are necessary to ensure that your medical devices continue to meet the needs of the user or patient.

Therefore, your design control processes must be revisited many times during the life of a product.

Let's take a look at some specific design controls that can be implemented easily and that will have maximum impact on your design process.





Meeting the Challenges of Medical Device Design

Design Challenge:

Organizational Responsibilities

During the initial development of design requirements, it is important to ensure that the design process is controlled and appropriate organizational responsibilities are assigned. Identifying each major task, what each deliverable should be, and defining individual responsibilities enables managers to exercise greater control over the design process and communicate policies and procedures.

If a product development team is composed of employees, suppliers, contract manufacturers, users and outside consultants, their responsibilities and authority should be clearly defined, documented, coordinated, and controlled. Regardless of who developed the initial product concept, all personnel involved in the design of a product play a key role in developing design input requirements. Their input should be included as part of any development plan as some team members may have more domain knowledge in a particular field of expertise.

As the design progresses, the development plan may need to be refined to take account of any unforeseen incidents beyond your control, such as staff turnover, material shortages or unexpected design issues. Adding more staff or hiring extra contractors can help to compress lead times on projects that are behind schedule, but as with all design activities, it is difficult to estimate their individual impact. Therefore, the plan should be continually monitored and updated so that management can make informed decisions and be confident in meeting overall schedule and performance objectives.

Scheduling pressures often give rise to rushed work, cut corners and design defects. Good planning can reduce this, but not all risks can be eliminated. With design teams under pressure to meet product performance criteria, while also meeting business objectives such as costs and time, it is important that management is kept fully informed so that correct decisions can be made based on all relevant factors.

Meeting the Challenges of Medical Device Design

With traditional CAD and PDM setups, designers are assigned projects and tasks to work on. Until their copies of the master CAD data are checked back into the PDM vault nobody, other than the designers themselves, knows what has been worked on and what has changed since the last check-in. This makes it near impossible for a project lead or management team to ascertain if a project is on schedule and whether they need to assign any more resources to it.

Assigning external resources to a design project comes with its own challenges. A contractor must have a copy of the same CAD software as you and be on the exact same version for file compatibility issues. The easiest way to ensure this is to provide your contractor with one of your own CAD licenses. If you need to purchase a new license for this to happen, factor in a week or so of lost time while waiting for your CAD reseller to process your order and for your IT department to source a powerful enough workstation, install it and ship it to its intended recipient.

Data integrity and security is also a concern when working with people outside of your organization. Copies of CAD data must be sent over the internet using an extra license of your PDM system (or worse, through email) and stored locally on each contractor's or supplier's machine. When they have finished working on the project or task, they must then send those copies back. The data, however, still exists on their computer and is therefore liable to loss or accidental distribution to third parties.

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Meeting the Challenges of Medical Device Design

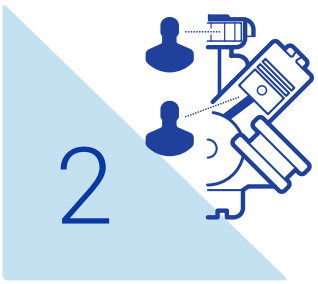
Design Challenge: Organizational Responsibilities

How Onshape Helps Organize Your Design Projects

Onshape keeps your design data secure at all times. No data is ever transferred outside of your company and no copies of any design data ever resides on anyone's computer hard drive. All data is stored in a secure cloud workspace and accessed through a web browser, so no special hardware is required. Every user works on the same CAD data and the same version of the same CAD software at all times, so there is zero IT overhead and zero concerns over data compatibility.

For an external contractor to work with your design data, they must first be invited into your company and given specific permissions to access projects or individual design documents. This is managed by role for each project, so a contractor could be a designer on one project, but a reviewer on another, giving you complete control over their level of access. Once a contract expires, simply removing them from your company will immediately revoke their access to all of your company data. No more worries about data security.

Keeping track of the status of each project is easy with Onshape's reports and analytics, giving you unprecedented visibility into each project, your design processes and your overall effectiveness. You can review which Documents are being worked on, who accessed them and when, determine if a project is on schedule and allocate additional resources to ensure success. Detailed reports on user activity help you to determine if a design is being problematic as well as track the progress of external suppliers.



Design Challenge:

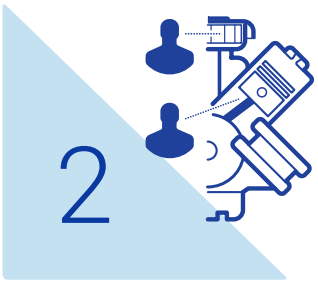
Concurrent Engineering

Once all initial requirements and design inputs are known, the detailed design of a new device can begin. When the design is complete, it is handed over to production so that other departments can begin developing their own processes to manufacture and service the product. If only it were that simple!

Historically, this may have been the way things were done, but this method of "throwing the design over the wall to manufacturing" often caused issues on the shop floor, resulting in rework or scrap. Thus, the notion of concurrent engineering was born, where designers and manufacturing engineers work together to solve design and production issues upfront, leading to reduced lead times, production costs and higher product quality. The very nature of concurrent engineering, however, makes applying effective design controls much more difficult.

As with all engineering companies, in all industries, design is an iterative process with regular design reviews and verification stages to ensure that the product will perform as intended and satisfy the initial requirements and design inputs. To accelerate this process, most companies have adopted concurrent engineering methodologies with varying degrees of success. As the development of production processes becomes more of a design activity rather than a manufacturing activity, and long lead time items enter production before the design is complete, a comprehensive matrix of reviews and approvals must be put in place to ensure that each component or process is validated before production.

Managing all these reviews and approvals and applying effective design controls is difficult. File-based CAD and PDM systems enforce a serial flow of data from one designer to another and then on to the manufacturing team, which totally contradicts the concept of concurrent engineering.



Meeting the Challenges of Medical Device Design

Designers can work on different parts of the design at the same time, as long as they don't need to use the same files. This makes designing complex assemblies a chore as each designer is unable to work on the design as a whole while other engineers have files checked out of their PDM system. Formal design reviews also become problematic as every project engineer must stop work, check-in their data and attempt to resolve any conflicts, so that all participants have access to the latest data.

While CAD is a necessity for design engineers, it is often seen as a luxury item for managers and manufacturing engineers, who rarely get access to a full seat of CAD mainly due to costs. Viewing software, paper prints or frequent design reviews must therefore be used to validate a design for manufacturing. Design reviews take time and are difficult to coordinate. Viewing software and paper prints can become out of date very quickly, so how do you know if you're looking at the correct version of the design? All these issues and more represent considerable roadblocks to effectively implementing and managing design controls.

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Meeting the Challenges of Medical Device Design

Design Challenge: Concurrent Engineering

How Onshape Improves Concurrent Engineering

In a modern CAD system like Onshape, design data is not stored in files or complex, disconnected PDM systems. Onshape stores all your design data in a secure cloud workspace, where every stakeholder has instant access to the latest project information and no special viewing software is required. Each authorized user – designer, manufacturing engineer, manager, contractor or supplier – can interrogate the design, add comments or even edit the design if permissions allow. This enables a true collaborative workflow where every stakeholder's input is captured and recorded.

Your extended team can work on the same project data, simultaneously editing the same assembly, same part or even the same sketch. This eliminates all the bottlenecks associated with file-based CAD and PDM, dramatically compressing design cycles and reducing errors and rework.

Since every stakeholder can view or edit the design (depending upon permissions), the frequency of formal design reviews can be reduced. When it does come time for a design review, each person is able to review the data before the official meeting to gather their questions and concerns ahead of time. This results in shorter meetings, better actionable data and higher quality products.

Meeting the Challenges of Medical Device Design

Design Challenge:

Change Control

Product designs are seldom right the first time. Design reviews and verification activities will usually uncover errors or omissions that require design changes. Problem reports may originate from anywhere, from the design team right through to the end user, which can result in expensive product recalls. Catching problems early saves you time, money and your reputation.

The change control process must be carefully managed to ensure that all changes are tracked to completion and all design documentation is updated. Corrective and preventive actions can fix one set of issues while inadvertently causing others, so it's important to document and communicate changes to all stakeholders so that the total impact of any change can be assessed. If the number and frequency of changes is high, this might suggest that the initial design specification was flawed or insufficient resources were devoted to the early stages of development. Managers can use these insights to improve the design control process.

For change control to be effective, all design documents related to a project should be indexed and easily accessible to all stakeholders. Approval, sign-off and obsoletion procedures should also be formalized and a history of all revisions maintained. If a change request is accepted and corrective action deemed necessary, all affected documents should be identified, a team of engineers should be assigned to the problem and all change requests should be communicated to anyone whose work might be impacted by the change.

Of course, your change control procedures should ensure that all corrective and preventive actions are thoroughly reviewed, the impact of the change is evaluated against the device's intended use and all change requests are tracked and documented.

Meeting the Challenges of Medical Device Design

Setting up an effective change control system with CAD relies heavily upon the capabilities of your vendor's PDM system. Some systems have clearly defined and rigid change workflows, while others require a lot of custom coding to achieve the desired results.

Changes to CAD data can be documented in PDM and changes to other non-CAD files can be included in an approval process. However, since files are stored as separate objects in a PDM system, this process is reliant upon one or more people to ensure that all required documents are updated and included in a release. Typically, this would have to be the same person performing all activities – otherwise, too many errors or omissions may occur. If several people are working on the same design problem, it is not uncommon for multiple unmanaged copies of your design files to be scattered across multiple computer systems. This situation becomes a logistical nightmare trying to manage who has the latest version and trying to prevent designers from overwriting each other's work.

All file-based CAD systems suffer from the inability to readily share data. This makes it difficult to assign more than one person to a task. Communicating required changes, current progress and other important information across multiple team members is disjointed and at risk of introducing errors. Managing resources on a project with many change requests, therefore, becomes a challenge in itself.

Design Challenge: Change Control

How Onshape Handles Change Control

After a change request has been reviewed and approved for corrective action, a team can be assigned to address it. This team may consist of employees, contractors and suppliers spread across multiple locations. Since Onshape gives every team member easy access to your design data from anywhere on any device, there are no barriers to prevent a design change from being implemented in a timely manner, with all design changes documented for future reference.

While a certain corrective action may be identified in a design review, it is not possible to predict the outcome of that action until a design change has been thoroughly reviewed and verified. Onshape enables multiple people to work on the same design problem at the same time, with each person creating their own individual branch or workspace within the same Document. These branches are completely isolated from the rest of the Document and the rest of the team (unless more than one person is working in a branch). This means that each designer can explore new design scenarios without affecting other people's work. If a design idea is no good, it can be deleted or saved for future reference. If it's a great idea, it can be merged back into the main design. If multiple areas of the same product are being redesigned at the same time, multiple branches can also be merged together.

With Onshape's built-in data management capabilities, you can use branching, merging, versions and history to iterate your designs faster with a minimum of fuss.

Design Challenge:

The Design History File

Collecting and recording data for the purposes of design control is critical. The compilation of this data, from your CAD system or any other system used in the design of your devices, is often referred to as the design history file. This file should record enough design information to be able to validate a design and maintain it throughout the lifetime of a device. Failure to record sufficient information reduces your ability to recall when and why a particular design decision was made: an employee may leave or move onto another project, a contractor's term may expire, or a decision may have been made so long ago that the engineer has no memory of it. Since design decisions often directly affect the well-being of device users and patients, it is in the manufacturer's best interests to maintain an easily accessible knowledge base about the design of a device.

Design decisions are made all the time, many of which occur between design reviews as the designer goes about his or her logical approach to solving the current design problem. These decisions may affect other areas of the product without the knowledge of the designer. Hopefully, these will get picked up at the design review, but even if they do, there is still no way to know when and why a detail was changed or even who changed it. The design process is like a black box – specifications go in and drawings come out – there is little to no visibility into the design process.

Much more than just CAD data must be recorded. Often, design ideas are scribbled in notebooks or in word processing documents and calculations are contained within spreadsheets. Without maintaining these records as well, the design history file is incomplete. While PDM systems can store and revision control non-CAD documents, managing their revision status and building release packages with all relevant documentation can be a very time-consuming and demanding task. If the composition of a project team changes, you'll want to make sure that the company owns any and all documentation pertaining to the design of a product and ensure that no errant copies are in general circulation. This data must also be easily inspected by a project supervisor to ensure that records are complete, accurate, and legible, so additional PDM (and possibly CAD licenses) must be available for use.

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Meeting the Challenges of Medical Device Design

Design Challenge: Design History File

How Onshape Manages Your Design History

Onshape's unique database architecture stores every design change automatically without ever having to press a "Save" button.

This ensures two things:

1. **Every design decision is recorded for the lifetime of the project;**
2. **No data is ever lost, accidentally or otherwise.**

Onshape's comprehensive edit history gives you complete insight into who made each design change and when. The "why" should be documented in the version or revision comments when a design is submitted for approval.

Since an Onshape Document may contain any type of computer file (image, video, spreadsheet, etc.), these are version controlled at the same time as the CAD data. This ensures that any new design notes and their corresponding CAD implementations are revision controlled at the same time, making it easier to match one with the other. Previous versions can be recalled in an instant, so a complete record of the evolution of a design is always available for inspection.

Onshape's unique reports and analytics give you even more insight into the design process. You can track which employees, contractors or suppliers worked on a project and for how long, which Documents they opened or edited and what changes they made. Release packages chronicle which Documents, both CAD and non-CAD, were approved and by whom, with a detailed list of all data included with each release. Company settings within Onshape can be set to force users to enter comments when submitting designs for approval.

Your own company policies and auditing should, of course, enforce how detailed that information should be.

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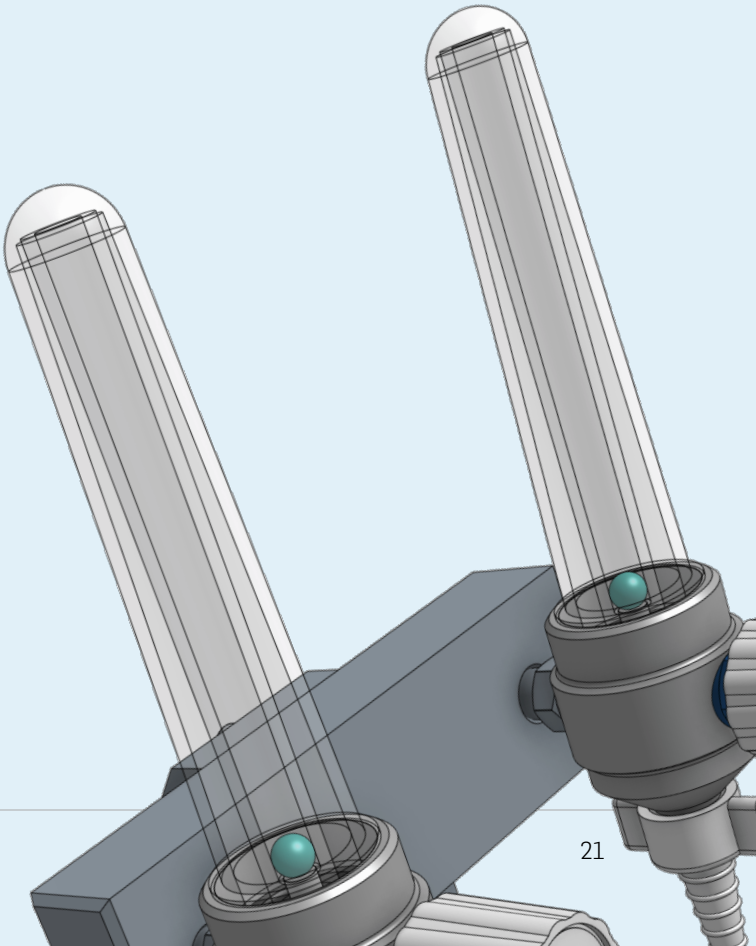
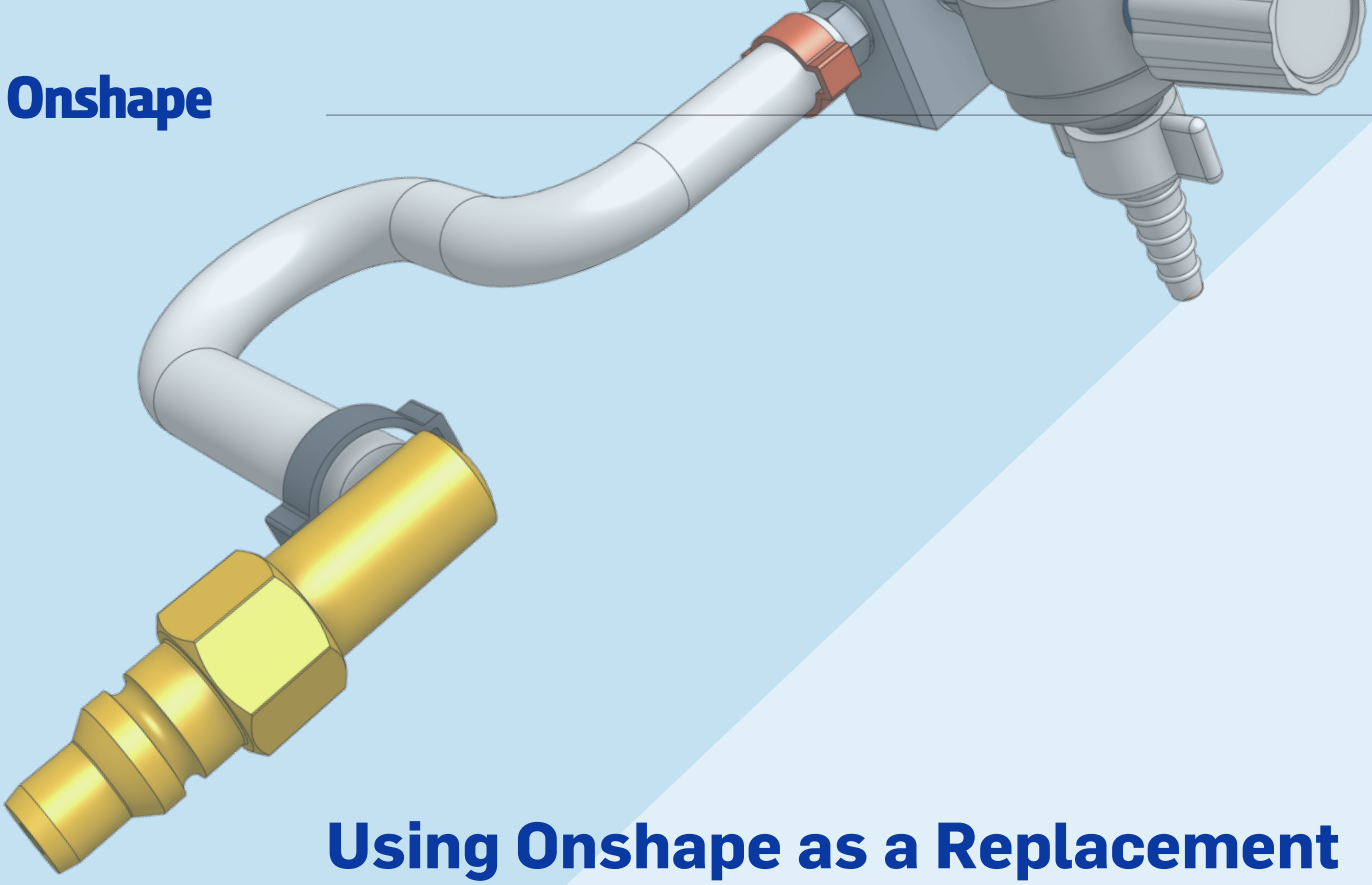
Meeting the Challenges of Medical Device Design

While it's not possible to totally replace any design history file system you are using now, every version or revision created in Onshape is immutable, or in other words, it cannot be edited. This makes it a permanent and unique representation of your design and accompanying documents at a point in time and is a good way to document changes throughout the design lifecycle.

Each version has a unique URL, so making references to information stored in Onshape is easy using a simple hyperlink. This link can be indexed in a more comprehensive design history file that contains information about your device from all your other systems.



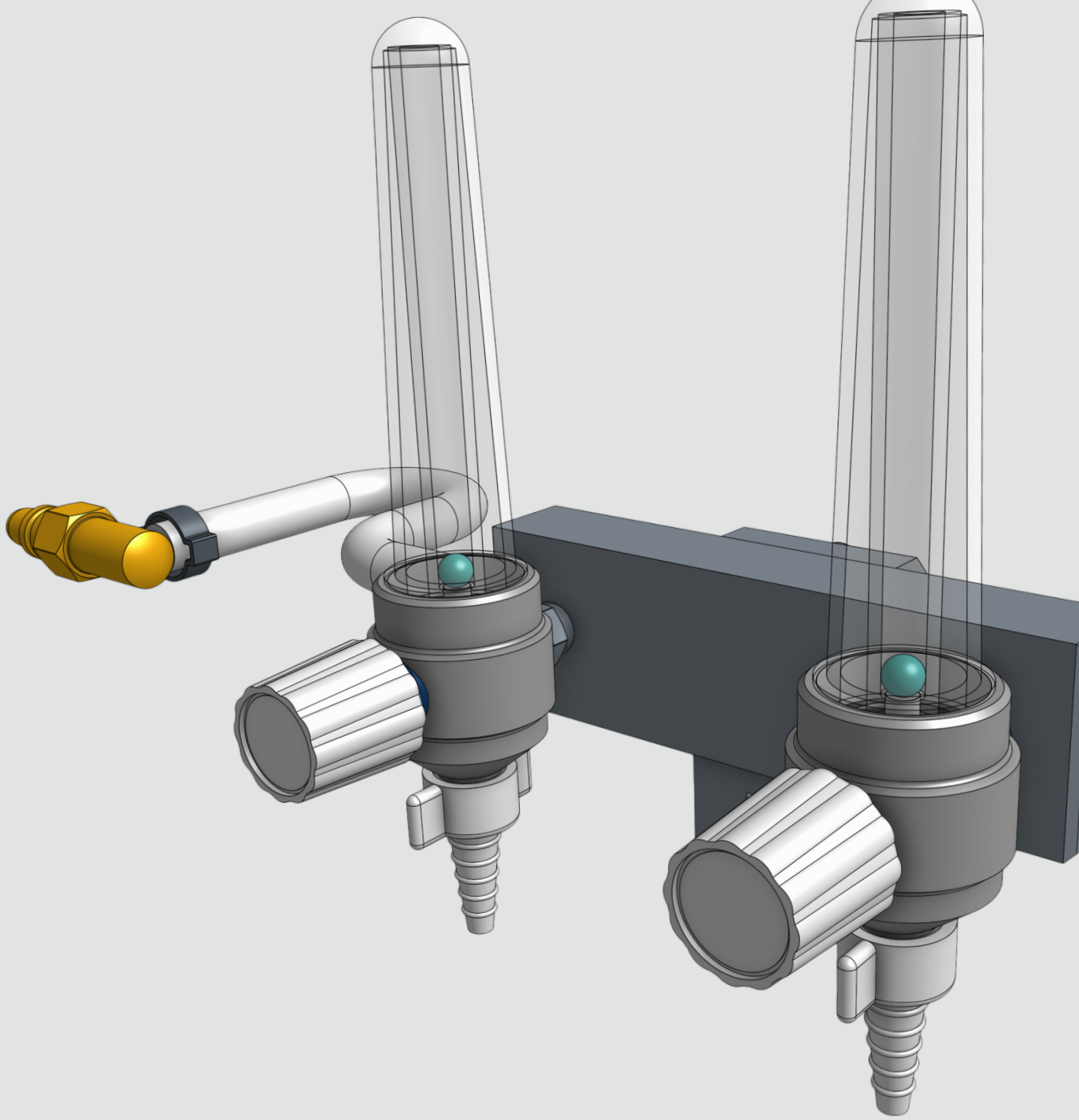


Using Onshape as a Replacement for Your Old CAD and PDM Systems

Onshape is first and foremost a data management system with CAD tools built-in. While it can address many of the issues medical device companies face in their day-to-day design challenges, it cannot address all of your compliance requirements. Detailed company policies and procedures must be followed to ensure all requirements are met to the satisfaction of your regulatory body.

CAD is an integral part of the design process and old file-based CAD and PDM systems impose a number of unnecessary design bottlenecks that Onshape completely eliminates. If you do not currently include CAD design processes as part of your design controls or CAD data as part of your compliance submissions, Onshape can still help you become more efficient. Simply put, replacing your old CAD and PDM setup with Onshape completely removes all issues related to software and CAD files. The headaches and inconveniences related to downloading and installing software and managing and distributing design data are gone for good.

Further benefits can be realized when you expand your design team to include external contractors and suppliers. Easy sharing of design data with granular permissions ensures each stakeholder has easy access to the data they need and no files are ever left scattered around on hard drives. Onshape's unique reports and analytics give you unprecedented insight into your design processes to help you address issues quickly and reallocate resources as required.

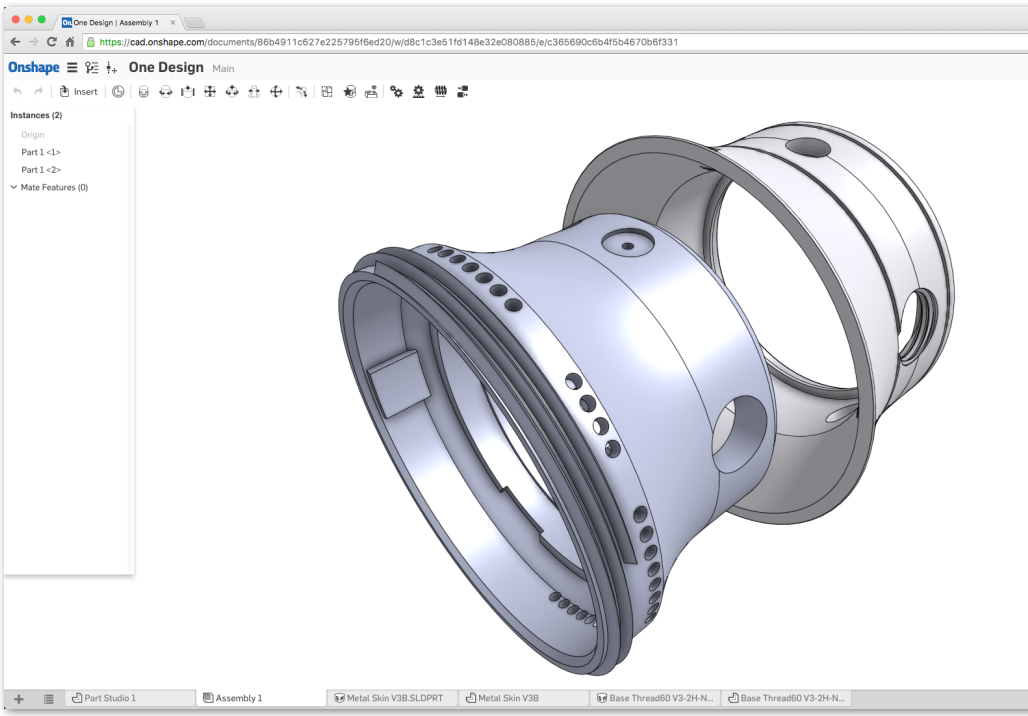


How 3 Medical Device Design Companies Use Modern CAD to Solve Design Challenges

How 3 Medical Device Design Companies Use Modern CAD to Solve Design Challenges

Thinklabs® One Digital Stethoscopes

Based in Colorado, Thinklabs Medical LLC introduced a paradigm shift in stethoscope design in 2004, replacing the hollow-tube style that predates the U.S. Civil War with an electromagnetic diaphragm to measure chest vibrations. The Thinklabs One Digital Stethoscope amplifies heartbeat sounds more than 100 times the audio levels from traditional stethoscopes.



"We decided to completely break the mold and do something very different and very radical," says Thinklabs CEO and founder Clive Smith. "We've developed proprietary technology for producing very high-quality sound. The digital stethoscope has patented transducers and audio sensors that capture sounds from the body better than any other device."

"You can barely hear anything when you use a regular stethoscope," he adds. "The sound is very distant and faint. When you use our stethoscope, it's significantly amplified. Instead of saying 'Can I hear that sound?,' you're more focused on what IS the sound. What's the diagnosis? There's no reason in this age of electronics and amplification why doctors should struggle to hear what's going on."

As Thinklabs continues to challenge conventional thinking in the medical space, it is also adopting new approaches to design and manufacturing, which is done 100% in house. Although the company's first digital scope was created with an old file-based CAD system, all new design improvements as well as the development of new products are being done in Onshape.

Thinklabs® One
Digital Stethoscopes

"We switched CAD systems because our company is all cloud based," Smith says. "We're running Chromebooks and Netbooks and now any one of our production people can use Onshape while they are building our product."

"Let's say they are building something and they think, 'You know, it would be really convenient if we had a jig that holds the frame that holds the product in a certain way.' They can just hop on Onshape and design something and 3D print it. They can print a tool that they need for production," he adds.

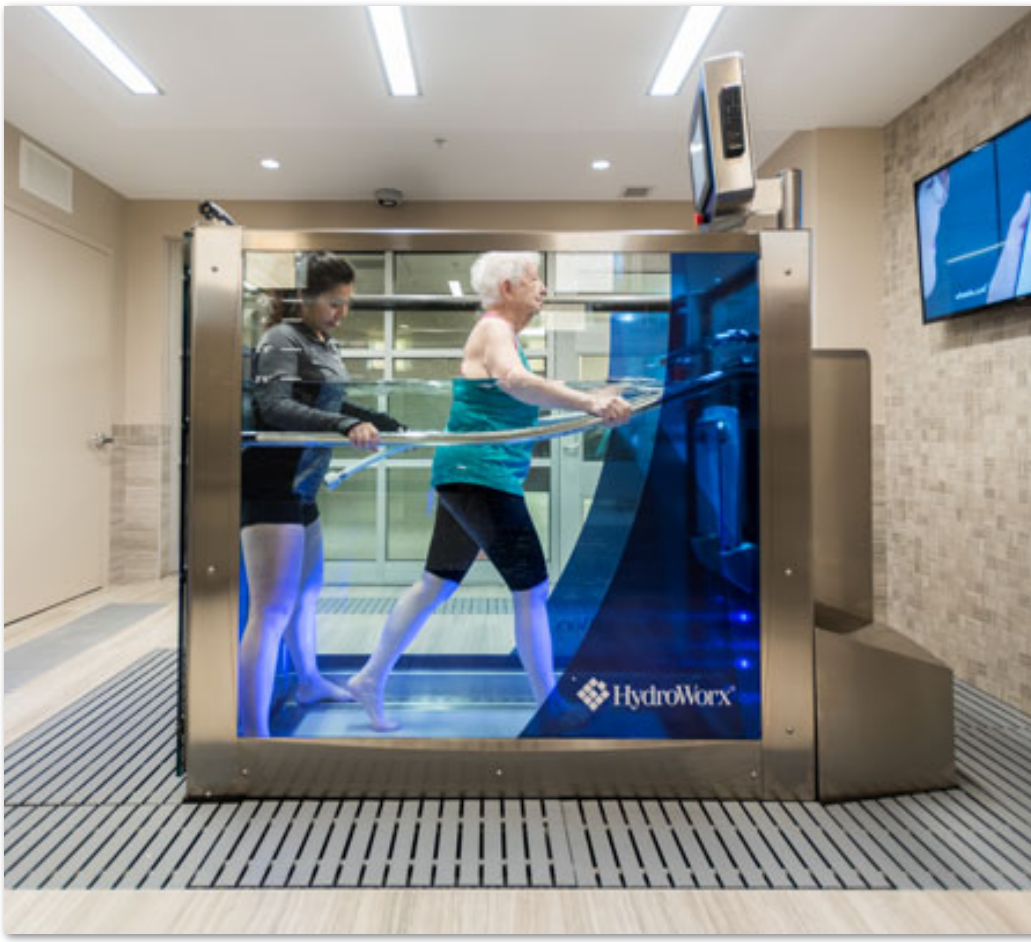
Smith says he manufactures digital stethoscope parts with 3D printing rather than injection molding, allowing Thinklabs to rapidly deploy design changes as they happen.

"3D printing liberates the design of our products, and Onshape in many ways liberates our production people to be very creative," he says. "We're no longer tied to one computer. The old way was being forced to share what one of my engineering friends calls 'the shrine.' You had to go to the powerful computer with the one copy of installed CAD software and figure out who's going to get a turn."

"What happens now is that everyone can just pick any computer and work when they need to. Onshape makes our production process much more efficient."

How 3 Medical Device Design Companies Use Modern CAD to Solve Design Challenges

Based in Pennsylvania, HydroWorx International develops aquatic therapy solutions to fit healthcare, senior living and sports/ fitness applications. HydroWorx's patented underwater treadmill technology helps provide relief for joint and muscle pain, osteoarthritis and other chronic pain conditions. Patients can bear as little as 20% of their body weight while exercising chest-deep in the water.



Jeremy LaCombe, Director of Engineering for HydroWorx, typically manages 3 to 4 outside engineering firms when developing a new underwater treadmill. When his company was previously using SOLIDWORKS®, he used a Product Data Management (PDM) system to help his team keep track of the latest version of each design and prevent colleagues from overwriting each other's work.

Ultimately, however, he found that the PDM system significantly slowed down the design process.

"We had the typical issues where an engineer works on something and no one else can see it until he checks it in – and then others find out they were working on a design that was four versions old and it won't work anymore," LaCombe recalls. "Or we'd have a guy leave for vacation for a week with half the server checked out and there's no way to continue the work until he gets back."

"In the middle of one project, we had an engineer's hard drive crash while he had a bunch of files checked out. We got him a new laptop up and running, but we couldn't get those files opened up because the hard drive ID was different and PDM is linked to your hard drive," he adds. "We spent two weeks with the tech department at SOLIDWORKS just so we could start over again."

Using Onshape's real-time data management, HydroWorx can now have multiple engineers simultaneously work on the same assembly. Whenever someone makes a design change, everyone else on the team instantly sees it. And every engineer is automatically always working on the latest version of a design. No PDM is required.

LaCombe says he especially values Onshape's comprehensive Edit History that allows CAD users to revert to any prior stage of the design, the equivalent of having "unlimited undo."

"If an engineer goes down the wrong road, we can quickly go back to where we were earlier and not waste time getting back on track," he says. "Doing this with our old CAD and PDM systems would have involved a lot of redesign work. Onshape saves us a lot of time."

How 3 Medical Device Design Companies Use Modern CAD to Solve Design Challenges

VICARIOUS SURGICAL

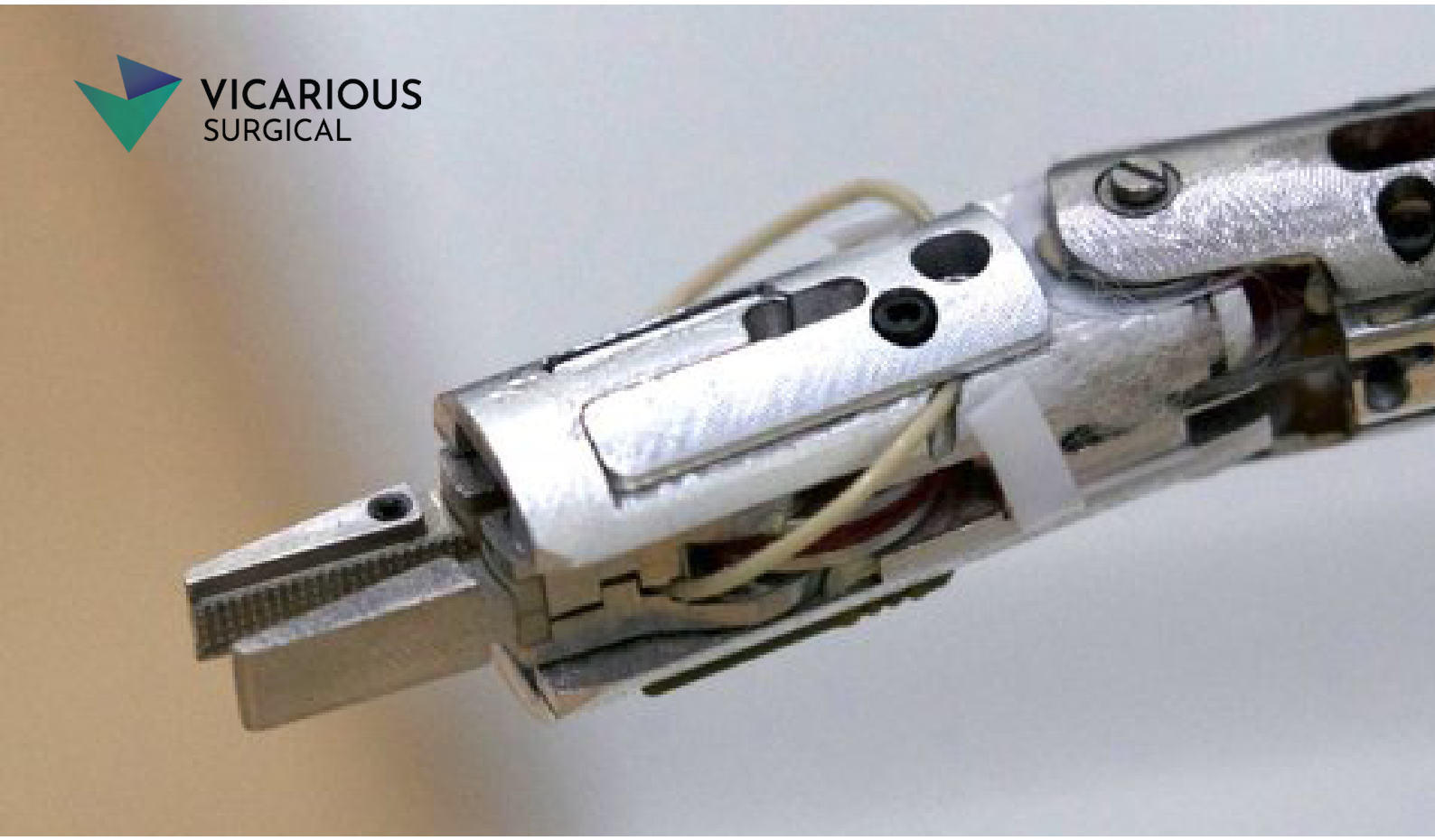
Based in Massachusetts, Vicarious Surgical is revolutionizing the field of surgical robotics. The company's mission is to improve the lives of patients, enhance the ability of surgeons, and expand worldwide access to high-quality care through the use of surgical robotics. Vicarious engineers have reimagined what is possible by building a human-like surgical robot and combining it with the world's first virtual-reality surgical camera to allow surgeons to perform micro-invasive surgery with the ease of an open procedure.

Through its innovative technology, the Vicarious Surgical engineering team has achieved what has been the goal of surgical robotics since the field's inception – to shrink the surgeon and put them inside the patient.

One of the main reasons that Vicarious chose Onshape as its primary CAD system is its built-in collaboration tools that allow multiple engineers to simultaneously work on the same part or assembly. When one team member makes a design change, everyone else on the team instantly sees it.

"With other CAD systems, only one person can work at a time," says Vicarious Surgical CEO Adam Sachs. "If somebody else wants to work on another part within that assembly, then they need to check things back in and check them out – and that causes delays."

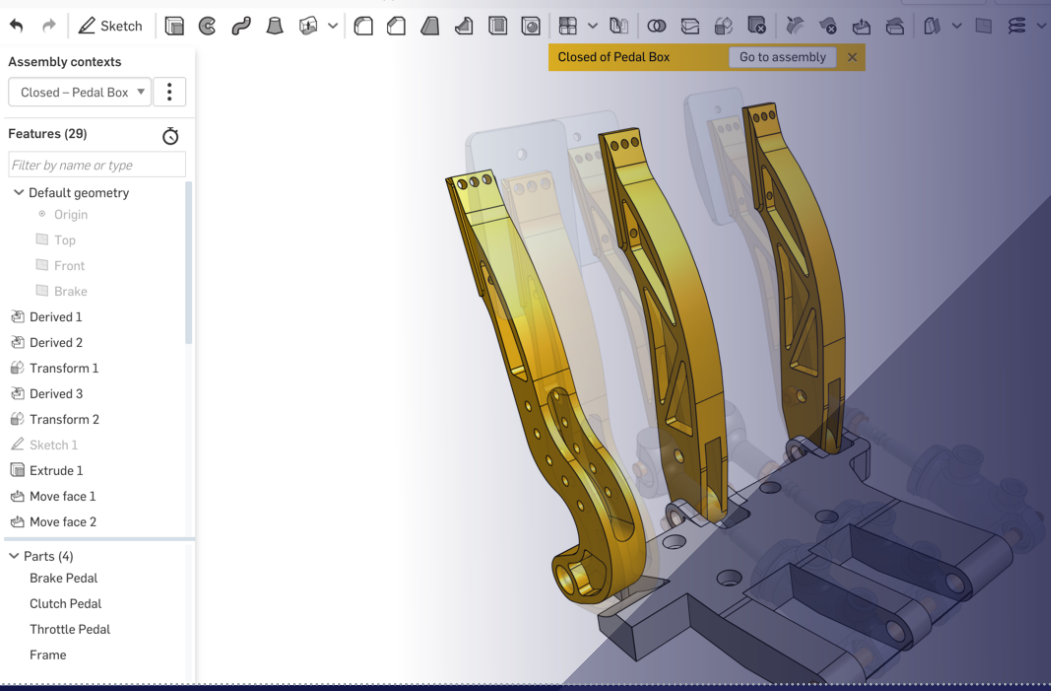
"The biggest difference with Onshape is there's no need to use a PDM system. My past experience with PDM involved a lot of texting or calling colleagues, saying 'Hey, can you check this in? I want to work on that part.' With Onshape, all that is unnecessary," he adds.



Sachs says his design team also values the Branching and Merging feature, which allows engineers to explore alternative design ideas in separate branches and later merge the best elements into the same model.

"We branch off designs all the time to test new ideas," he says. "When you try that in PDM, you usually end up screwing things up. You wind up making a different version of the design that can't easily be merged back in. But with Onshape, branching and merging is seamless."

"We really believed in Onshape's vision early on, and they have delivered on it," Sachs adds. "Onshape takes away all this infrastructure that we'd otherwise have to manage. It eliminates all these issues blocking collaboration between teams. You don't need to install anything. You don't need to maintain versions. Everything is just managed for you. It's the 21st century version of CAD."



Onshape

Peace-of-Mind
Using Onshape's Managed In-Context Design ensures that your CAD models will always update the way you expect them to – even if there is motion (a big troublespot for other systems).

A closer look at...

Onshape's Advanced 3D Modeling Tools

Parametric feature-based CAD was first introduced back in 1988 – and the fundamental ways that engineers model really haven't changed much since. Using an ordered list of parametric features to make a part worked very well back then and many things still work well today. But many things don't.

Onshape's new "Parametric Modeling 2.0" approach improves the best parts of old parametrics and eliminates the weaknesses. Parametrics 2.0 ushers in systematically better ways of modeling in such areas as:

1. **Multi-Part Design** – In Onshape's Multi-part Part Studios, all parts related to one another are designed together in one place – where it most makes sense – instead of modeling them in separate files. Multi-part design is now a much smoother experience.

2. **Configurations** – When creating part configurations, old CAD systems require you to build monstrous tables – sometimes with hundreds or thousands of rows – for each conceivable permutation. Onshape has dramatically reduced the number of required table rows and cells, making sophisticated and complex configurations more manageable. For example a 375-cell configuration table in old CAD can be expressed in Onshape with just 3 tables of only 5 cells each.

A closer look at...

Onshape's Advanced 3D Modeling Tools

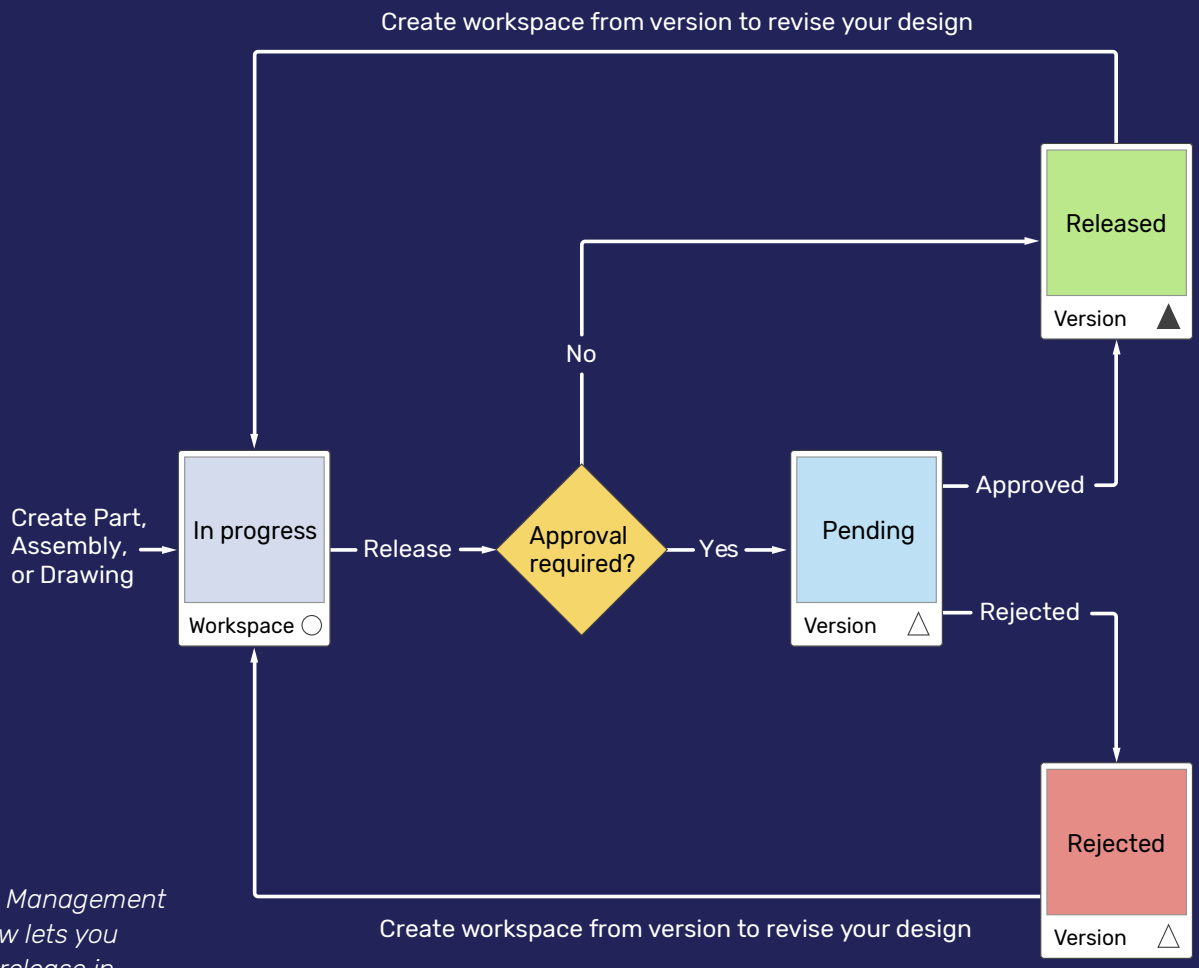
3. Standard Content – In Onshape, fasteners (screws, bolts, washers, nuts, etc.) have built-in mate connectors, making standard content smarter and making positioning in assemblies much easier. Onshape has added the "fit" to "form, fit and function."

4. Managed In-Context Design – Old file-based CAD systems offer users the ability to add in-context relationships between parts in the context of an assembly so modifying one part will affect another. Unfortunately, changing these in-context parts often erroneously changes other parts in unpredictable ways. Onshape's Managed In-Context Design tools have ended this madness. Your CAD models now always update the way you expect them to – even if there is motion (a big troublespot for other systems).

5. Simultaneous Sheet Metal Tools – Seeing flat, folded and tabular sheet metal views side-by-side allows you to visualize errors and interferences immediately. When you edit one view, the other two are synchronized automatically. These simultaneous tools ultimately reduce scrap and wasted time.

6. Custom Features – Ever wish you could change the way your CAD system's features work? Onshape's open programming language, FeatureScript, lets you create custom industry-specific CAD features that eliminate repetitive tasks.

Onshape didn't invent parametric modeling, but it has fundamentally improved it at the core.



Onshape's Release Management & Approval Workflow lets you create a proposed release in minutes instead of hours.

A closer look at...

Onshape's Built-In Data Management

As explored earlier in this book, Old CAD's approach to data management relied on the error-prone process of locating, validating, organizing, and archiving hundreds (if not thousands) of individual design files. This archaic process often led to version control problems – confusion over which version of a design file was really the latest version.

And for those companies using expensive and outdated Product Data Management (PDM) systems, there has been a different set of gridlock problems: Frustrated colleagues waiting for each other to check in and check out files before they can continue their own work.

So what's different about Onshape's "Design Data Management 2.0" approach?

Onshape

A closer look at... Onshape's Built-In Data Management

Here are the key reasons why modern CAD users can stop worrying about organizing their data and focus more on creating innovative designs:

Database Architecture, Not Files – Onshape stores designs in a cloud-hosted database that presents data to users as virtual documents showing all design history. We log all actions by all users at the feature level and allow you to go back to any previous state of your model – forever. It is always clear what is the latest version, who has access to it, and who did what. Onshape users also never lose work due to CAD crashes.

Secure Cloud Workspace, Not Scattered Copies – Onshape stores design data in a secure cloud workspace accessible from anywhere by authorized users. Administrators can prevent users from making local copies or exporting sensitive data. When a user no longer needs access, administrators can revoke it and ensure there are no extra copies floating around.

Parallel, Not Serial – Onshape's unique database architecture allows engineers to explore multiple design directions in separate branches and then later merge desirable changes back into the main branch. This allows engineers the freedom to explore alternative designs in parallel, resulting in faster, better innovation.

Instant Collaboration, Not Meetings – Onshape provides robust tools for sharing designs with other engineers or stakeholders, offering and receiving comments on designs, and comparing and accepting changes – all in a single cloud workspace without having to make copies. This allows teams and extended groups of stakeholders to stay in sync, instantly see what each other is doing, and keep work flowing without the friction, confusion, and time-sucking meetings that plague the old CAD collaboration process.

Design and Data In One Place, Not Many – Onshape puts the data management experience right in the design experience instead of forcing the user to switch between their modeling tool and their PDM system. This theme of deep integration and putting the right interface in front of the right user at the right time is something our UX team has championed since day one, and our production customers absolutely love it.

Zero IT – Onshape set out to deliver a system that would never require dedicated IT, installation of servers, or installation and upgrading of desktop software. For engineers who have been forced to master these tasks, there is a collective deep sigh of relief!

Extending the foundational principles outlined above, Onshape's Release Management & Approval Workflow now lets you create a proposed release in minutes instead of hours, including any combination of parts, assemblies, configurations and other assets. This eliminates the need to buy an expensive PDM system. And once a release is defined, Onshape's built-in approval workflow allows designated supervisors to approve or reject designs without interfering with their team's other current activities.

TRY MODERN CAD: REQUEST AN ONSHAPE DEMO

If you'd like to press the reset button and stop feeling blocked by old CAD technology, contact us today and we'll show you what Onshape can do. Request an Onshape Demo!

REQUEST A DEMO

Onshape

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