# The Engineering Training Solution to 5 of the Biggest Challenges in Medical Device Design

SOLID *Professor*

**Identifying Key Skills for Medical Device Product Development Teams**

# Introduction

## In This Guide

## New product development has become a top challenge for medical device companies.

The changing regulatory environment will always be the most complex obstacle for the medical device industry. But in recent years, another challenge is standing out from the rest: new product development.

Emergo's Global Medical Device Industry Outlook survey[1] has found that new product development is the next biggest roadblock after regulations for companies of all sizes, significantly surpassing other traditional hurdles such as funding/financing, profitability, and competition.

There are several reasons why medical device design and development has become such a challenge for the industry, but the right skill sets and efficient training programs can ensure engineering teams in the industry are equipped to combat them.

[1] Emergo by UL. Global Medical Device Industry Outlook for 2019. 2019.

# Medical Device Design Challenges

## The Engineering Design Training Solution to 5 of the Biggest Challenges in Medical Device Product Development

In addition to the common challenges faced by product design teams across industries (e.g., reducing design cycle time, cost reduction, fewer errors and ECOs), the medical device industry is up against a unique set of challenges that make developing new products even more difficult.

Most organizations attend compliance training to help make sense of the regulatory environment. Compliance training helps medical device professionals understand any regulatory changes and use best practices to avoid any violations. Engineering design training can similarly help by providing product development teams with techniques to not only comply with regulations, but help mitigate the pressure of other medical device design challenges as well. Adding engineering design to the train-ing mix can equip teams with the technical tools they need to succeed.

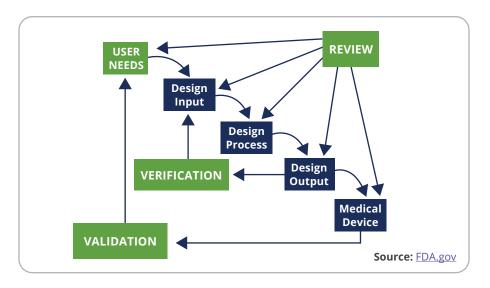## Regulation Compliance & FDA Design Controls

### Challenge

Keeping up with regulations is top-of-mind in the industry for good reason: FDA medical device regulations are incredibly complex and change constantly to adapt to new product capabilities. While it's a concern for everyone from quality assurance employees to medical

device salespeople, regulations can be particularly tricky for engineering design teams.

In the medical device industry, design teams must follow FDA Design Controls. These controls are set to help medical product developers with quality control, meeting all product requirements, and preventing future issues or recalls. There are FDA Design Controls[2] for every stage of the design and development process:

- Design & development planning
- Design inputs
- Design outputs
- Design review
- Design verification
- Design validation
- Design transfer
- Design changes
- Design history file

Clearly, the product design cycle becomes much more convoluted for medical devices because of the controls at each stage. This is best illustrated by the FDA's widely-used waterfall diagram[3]:



**Source:** FDA.gov

---

[2] Nico Kruger, Perforce. FDA Design Controls: Plain & Simple Guide for Medical Device Developers. June 2019.

[3] FDA. Design Control Guidance For Medical Device Manufacturers. March 1997.

## Solution

As we mentioned previously, many medical device companies send their employees to compliance training (including training specific to FDA Design Controls) to learn how to work with regulation requirements, and engineering design training serves as a natural complement to this. Honing design skills can improve performance at each stage of the process, making it easier for engineers to create and change designs so they comply with regulations. Understanding how to manipulate designs earlier in the process saves significant time and money later on by avoiding rework after review. (Not to mention, the cost of online engineering training is insignificant compared to the cost of many compliance training sessions.)

In addition to making the design cycle more complicated, FDA Design Controls also require organizations to maintain a complete record of design changes and design history files. Improving documentation skills such as Geometric Dimensioning and Tolerancing (GD&T) and learning advanced file management tools (e.g., SOLIDWORKS Enterprise PDM) can make these stages much easier to handle.

**Key Courses for Regulation Compliance & FDA Design Controls:**

- SOLIDWORKS Essentials for Parts and Assemblies
- SOLIDWORKS Drawings
- SOLIDWORKS Efficient Modeling and Design Intent
- SOLIDWORKS File Management
- GD&T Techniques
- SOLIDWORKS PDM*

    *Available with a SolidProfessor Team Membership*

## Design Risk & Patient Safety

### Challenge

In any industry, there are certain quality design requirements in place to make sure products will perform as intended and minimize the chance of malfunction or failure. Once again, this challenge is more difficult in the medical device industry, for several important reasons: product design failures can cause patient injuries or even fatalities. Designs for medical devices, especially invasive implants suchs as cardiovascular stents and hip replacements, must essentially perform flawlessly.

This reality makes it pertinent for design engineers in the medical device field to be extremely cautious and skilled with their product testing as there is no room for error. Most medical device development teams conduct rigorous simulation analysis through their CAD software to ensure this level of reliability.

### Solution

Thermal, vibration, contact, fatigue, motion, and more: design professionals in the medical device industry need to maintain skills across the spectrum of simulation analysis. Regular training on basic methods (e.g., FEA) and more advanced training (e.g., Flow Simulation) can help designers feel more confident in their design reliability and minimize the potential for failure.

**Key Courses for Design Risk & Patient Safety:**

- Finite Element Analysis (FEA)
- SOLIDWORKS SimulationXpress
- SOLIDWORKS Simulation
- SOLIDWORKS Simulation Professional
- SOLIDWORKS Flow Simulation
- Computational Fluid Dynamics (CFD)

## Higher Design Proficiency

### Challenge

Aside from the skills engineers need to meet challenges that are more unique to the industry like regulations and safety, medical device development teams need to maintain a higher level of design proficiency than engineers in other industries. Designers will often be faced with a set of design requirements that must all be considered but are conflicting to implement. For example, a prosthetic limb must not only meet special functional requirements such as range of motion and durability, but it must also be lightweight and user-friendly, aesthetically pleasing for the wearer, *and* use affordable materials.[4]

### Solution

Improving simulation skills will greatly help with meeting functional requirements, but upskilling in other advanced CAD software modeling techniques will enable design teams to reduce design cycle time, solve problems more easily, and work within complex design parameters. Using an online learning platform will make this even easier: working alongside video tutorials means minimal disruption.

> **Tip:** Earning software and technical certifications is a great way to measure a range of skills from beginner to advanced levels.

**Key Courses for Higher Design Proficiency:**
- Advanced SOLIDWORKS Assemblies
- Advanced SOLIDWORKS Parts
- Certified SOLIDWORKS Associate CSWA) Prep
- Certified SOLIDWORKS Professional (CSWP) Prep
- Certified SOLIDWORKS Expert (CSWE) Prep



---

[4] SOLIDWORKS. Improving Medical Device Design with Simulation Technology. 2017

## Increasing Device Complexity

### Challenge

Medical device designs increase in complexity every year, incorporating new materials, new methods and technologies, and new functionalities entirely. For instance, in its short history, pacemakers have undergone a major evolution. The original pacemaker only paced the bottom chamber of the heart and had to be replaced frequently. Today, pacemakers pace both chambers of the heart, can increase heart rate with activity, last for over a decade, and can even be wireless.[5] While this may provide incredible new benefits to the end user, this adds yet another layer to the challenge of new product development. Medical device development teams need to be equipped with the skills to manage the increasing complexity of existing and new technologies.

### Solution

It might not be possible to train on design skills for complex device technologies that don't exist yet, but keeping software skills current and honing specialized CAD techniques will prepare medical device engineers to adapt to and incorporate new innovations as they arise.

**Key Courses for Increased Device Complexity:**
- SOLIDWORKS Annual Update Training
- SOLIDWORKS Surfacing
- SOLIDWORKS Sheet Metal
- SOLIDWORKS Mold Tools and Plastic Design

## Industry 4.0 Innovation

### Challenge

And finally, there are new product development opportunities for medical devices thanks to Industry 4.0. Industry 4.0 encompasses many things: artificial intelligence, the Internet of Things, rapid prototyping, 3D printing, additive manufacturing, robotics, automation, and more. The impact of Industry 4.0 on medical device development will be (and already is) immense, as all of these innovations are likely to have innumerable applications.

### Solution

So, what can medical device design teams do today to prepare for the vast changes that Industry 4.0 will bring? First, it's important to make time for training on the skills that will address the existing product development challenges. From there, medical device engineers can start training on the latest methods that will make it easier to adopt new innovations as part of the design process.

**Key Courses for Industry 4.0 Innovation:**
- 3D Printing
- Design for Manufacturing
- Design for Additive Manufacturing
- Design for Machining

---

[5] Dr. Marc Wish, Inova. History and Development of Pacemakers.

# About SolidProfessor

SolidProfessor is an online learning platform for engineering design and product development teams. We're helping leading teams across the medical device and life sciences industries to innovate with increased speed, complexity, and accuracy. The platform features 5,000+ on-demand video lessons in a wide range of methods and software including SOLIDWORKS Simulation and certification prep, SOLIDWORKS PDM, FEA, GD&T, Design for Additive Manufacturing, and many more.

**In addition to full access to the course library, SolidProfessor Team memberships include:**

- Guided Learning Paths and 100+ Technical Certificates
- Dedicated onboarding support
- Customizable training programs and assignments
- An admin dashboard with reporting and progress tracking
- The opportunity to preserve your team's tribal wisdom with knowledge capture

## Contact us to get started

Find out how SolidProfessor's online learning platform can help your team improve design efficiency and reduce costs. Get in touch to learn more and schedule a free demo.

**Schedule a Demo**

+1 (619) 269-8684

com-sales@solidprofessor.com

www.solidprofessor.com/teams

> " SolidProfessor is one of my main tools for staying up to date with the latest [CAD] features and functionalities. It's a great resource, not only for onboarding novice users but also for someone experienced like me. There's always update training. There's always new content and resources."
>
> *- Adrian Velazquez, Senior CAD Engineer at Dexcom Continuous Glucose Monitoring*