Get ready for an INTENSE, PRODUCTIVE, and HANDS-ON experience as in2being’s 2-Day Medical Device Development Intensive comes to Kalamazoo! Our veteran product development managers will educate and walk with you through high-value early-stage development tasks — on YOUR project. There’s no better way to learn than by doing.

After training you on the claims- and risk-based world of regulatory clearances, we will together walk through a regulatory classification and pathway analysis. This analysis will be yours to keep and will form the foundation of the rest of your development process.

We will demystify the world of quality systems, showing you how to destroy the procedural bloat that slows many early-stage companies down. Together we will work on how to customize a lean, stage-appropriate Quality Manual and related procedures for your company.

Instead of having to depend on a “one-stop-shop” to do all the things you don’t understand, you’ll know what specific partners you’re looking for and what skills they need to bring to the table.

Your team will leave this workshop with:

| A basic literacy of the medical device development process | An understandable regulatory classification and pathway for your device concept |
| The know-how to navigate FDA databases to support your submission | Preliminary drafts of your design plan, intended use, user needs, technical requirements, and consensus standards analysis |
| A clear understanding of your development hurdles | Familiarity with a stage-appropriate Quality Manual and procedures |

We will lay out a “typical” device development timeline, reviewing common pitfalls, dependencies, and challenges, and then apply this to your project, together creating a design and development plan, and taking the first steps of formally defining user needs, technical requirements, applicable consensus standards, and preliminary hazards.

We’ll coach you on working with vendors. Designers, consultants, manufacturers, component suppliers, sterilization vendors — each partner works at their best when you understand what they are and are not capable of. Learn how to manage them, so that they can do their best work for you.
Thank you in2being! Two days of expert teaching – wow! This was an invaluable experience for me as I navigate this Medical Device Start-Up scene. I highly recommend this seminar. - Rebecca

in2being’s medical device development 2-day intensive is a great primer and foundation for teams to structure a development program. Excellent overview presentations and hands on work introducing us to the keys for device development. - John

Very helpful workshop... the combination of lectures and breakout sessions was great. Going through the templates with our project managers was very helpful. I also really appreciated having time to ask questions both in the lectures and the break out sessions. - Anna