imarc
WE'LL EARN YOUR APPROVAL.

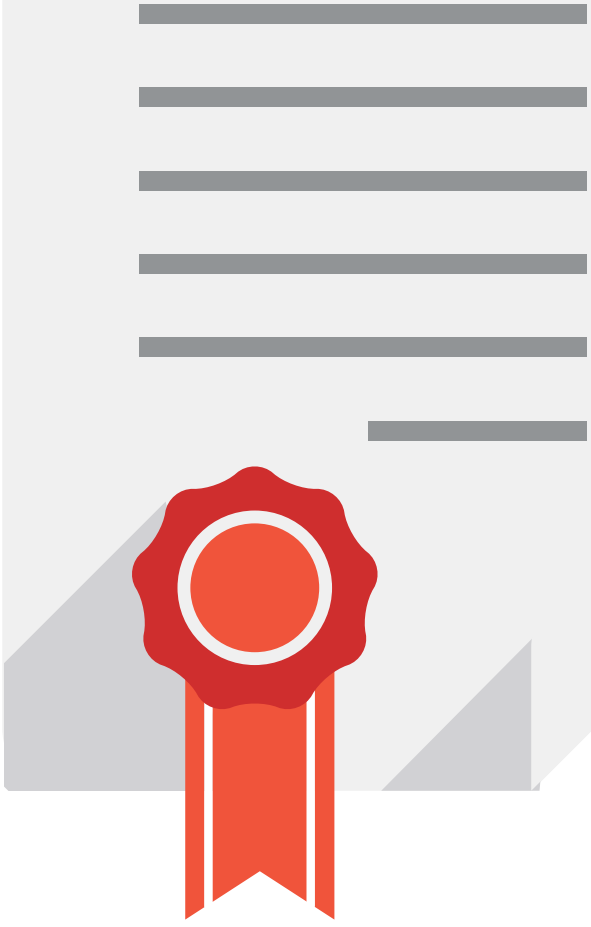
LAUNCHING

A CLINICAL RESEARCH TRAINING PROGRAM

FOR YOUR TEAM

The clinical research industry has always embraced the concept of training. The field is constantly evolving, and having an understanding of new developments and best practices is critical to employees' professional growth and clinical trial success. Yet, many medical device companies face challenges on how best to provide continuing education. These companies typically cannot justify hiring a person to lead their training efforts, but the need for high- quality clinical research training remains.

Given the importance of training, how does a medical device company implement an affordable, easy-to-use training program? Site sponsors, principal investigators and clinical research coordinators must consider employees' hectic schedules, their geographic location, training needs and a variety of other factors that can impact your training needs.

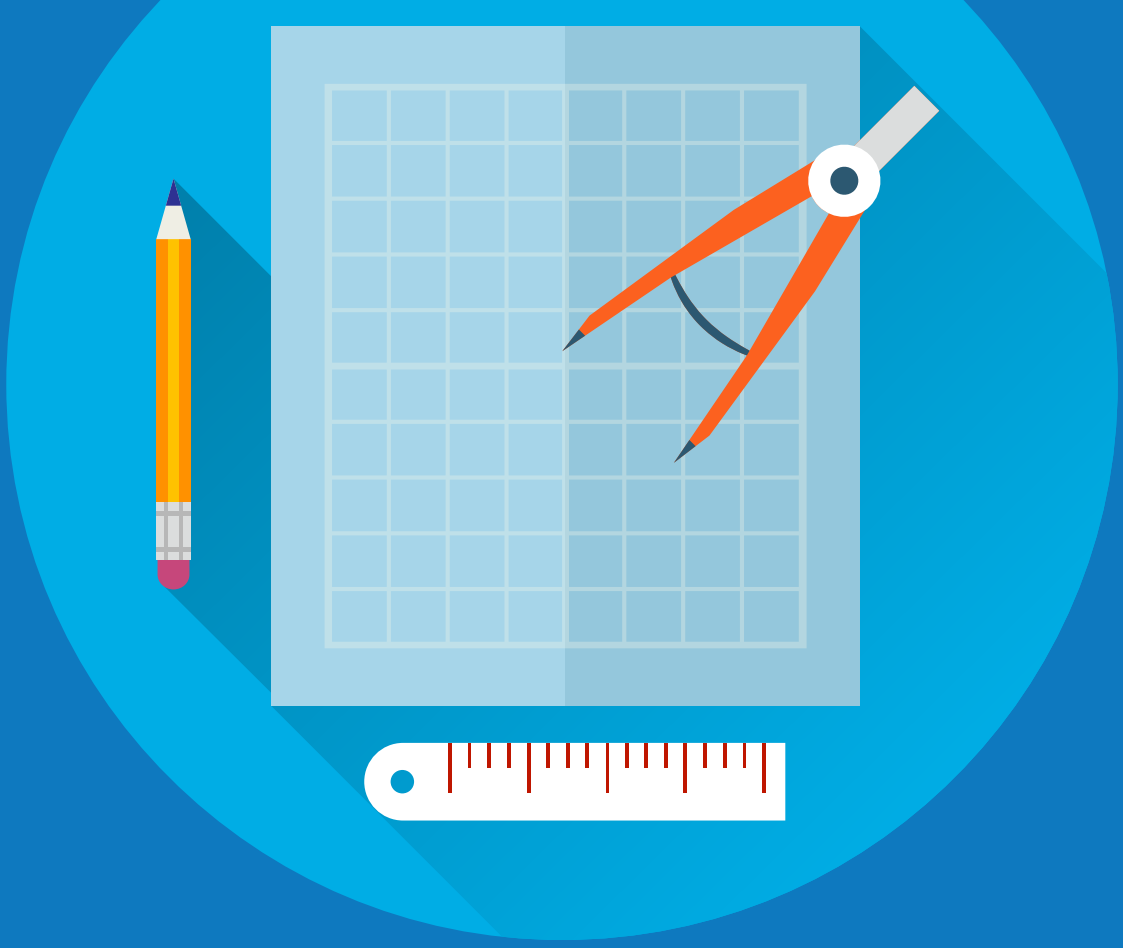


Medical device companies have discovered online clinical research training is a flexible and cost-effective alternative to in-person training sessions.

There are many considerations to make when implementing an online clinical research training program, including:

- Which team members need instruction
- What topics should be covered
- What type of infrastructure is needed to support and host training
- Who will conduct training
- How team members will be held accountable for completing training
- Which team members need instruction
- How success will be measured

Given the complexities of developing and hosting online clinical research training programs in-house, sponsors are increasingly turning to partners with expertise in this area.



CREATING A BLUEPRINT FOR TRAINING WITH IMARC UNIVERSITY

IMARC has more than a decade of experience ensuring patient protection and regulatory compliance for clinical research trials through clinical monitoring, auditing and more. Our team also has extensive expertise training other teams, relying on knowledge gained through our own continued work in the field. To meet the growing demand for cost-effective, flexible training, we have brought that knowledge online tthrough IMARC University, a series of continuing education courses designed to prepare teams and individuals for clinical research compliance. These courses cover many aspects of the clinical research process, from FDA regulations and GCP standards to adverse event reporting and advanced monitoring topics. Teams can access or upload existing training or create new training programs through IMARC University's training portal.

HOW IT WORKS:

- A training leader will assess your team's specific needs and develop a training blueprint
- IMARC will work with you to identify your training needs for all members of your team
- IMARC will customize the training platform that will work for you
- IMARC will set up and manage your users' access to high-quality clinical research educational content
- IMARC can provide regular reports on learners' progress
- IMARC can upload your corporate content into a centralized, online platform
- IMARC can develop new content upon request

Customizable Options: What Does Your Team Need?

For sponsor or CRO employees who will be taking on new job responsibilities, role-based training for Monitors or Project Managers offers a solid regulatory and good clinical practice foundation as well as competency-based training on activities specific to those functions.

For those who may simply need a refresher or expansion on a particular topic, courses are available on specific topics, including:

- FDA Inspections 101
- Human Subjects Protection
- Maintaining the Sponsor Trial Master File

Principal Investigators and Research Coordinators at participating research sites may require documented training to conduct medical device studies in order to meet regulatory requirements for selecting only those who are “qualified by training and experience.” Role-based packages are also available to instruct site team members on their responsibilities when conducting clinical research.

Training options should meet the needs of all members of the study team and be relevant to their backgrounds and roles in the study. Additional courses are available for sales and regulatory professionals, clinical scientists and data managers, as well as data safety monitoring board, clinical events committee and IRB members.

When other company or study-specific training content is needed, such as on company procedures or the study protocol, customized content can be developed and hosted on the centralized training platform.

Flexible and Efficient With a Central Training Portal

With a training portal, team members can log on and complete training when it fits into their schedules, anywhere they have an internet connection. And they can pick up where they left off to continue completing a course or package.

Read on to learn more about how to map out a high-quality training program.

Qualities of a successful training platform:

A. Cover the basics with a strong foundation that includes the following elements:

U.S. Code of Federal Regulations (21 CFR)

- **Part 312** Understand investigational drug regulations, safety reporting requirements and researcher responsibilities
- **Part 812** Understand federal regulations for investigational medical devices, safety reporting requirements and researcher responsibilities
- **Parts 50, 56, 54, and 11** Understand and follow guidelines for the protection of human subjects and consent, IRB requirements, financial disclosure and electronic records and electronic signatures

Good Clinical Practice Guidelines

- Ensure clinical studies follow all guidelines for ethical conduct, record keeping, and quality assurance

Human Subjects Protection

- Review ethical principles for human subject research, including informed consent required elements and documentation

Subject Confidentiality – HIPAA and HITECH

- **HIPAA** - Understand how patient privacy laws apply to research and what constitutes a violation
- **HITECH** - Understand how the federal expansion of electronic protected health information widens the scope of privacy and security protections and impacts clinical research

The History of Clinical Research

- Understand how clinical research regulations have evolved and how important events resulted in the protections in place now

How to Answer Compliance Questions and Concerns

- Be able to think critically to understand whether an issue is a violation of research requirements and respond with confidence

B. Include role-based requirements for the members of your team:

INVESTIGATORS

All regions are in agreement that the people serving as investigators on a clinical research study should have adequate documentation of training and qualification.

REQUIREMENT	21 CFR 312	21 CFR 812	ISO 14155	ICH GCP
Investigators shall be qualified by training and experience	*21 CFR 312.53 (a)*	*21 CFR 812.43 (a)*	*Ch. 9.2*	*Ch. 4.1.1*

SITE PERSONNEL

In some cases, the regulations/standards point to the investigator as the one responsible for ensuring the appropriate qualifications of his or her site team to perform their delegated duties. In other cases, clear instruction is given that the sponsors are responsible for conducting the training. In all cases, the monitors are charged with ensuring the adequacy of the site's qualifications throughout the study.

REQUIREMENT	21 CFR 312 & 21 CFR 812	ISO 14155	ICH GCP
Investigators delegate to qualified individuals	*Guidance for Industry-Investigators Responsibilities (section III.A)*	*9.3*	*4.1.5*
Sponsors conduct training	*Guidance for Industry-Investigators Responsibilities (section III.A.2)*	*8.2.1*	*5.6.2*
Monitors confirm adequate qualifications	*Guidance for Industry-Oversight of Clinical Investigations (section VI.B)*	*8.2.4.3*	*5.18.4*

C. Incorporate best practices in training and development:

1. Expect flexibility in choosing courses that meet your training needs
2. Demand quality with practical examples
3. Consider training when it's convenient for you

Ensure Your Team Is Fully Prepared to Achieve Compliance

Having a well-trained staff ensures you use a consistent process that meets the most stringent standards of patient safety and compliance and reduces turnover.

Whether you are working with new staff or experienced veterans, IMARC offers training to advance their skills and teach them to think critically. IMARC University's online courses allow your team to learn at their own pace, whenever it's convenient for them, and earn continuing education credits as they go. Whether they need to gain additional expertise in specific areas, such as adverse events reporting, or just review the regulations, our courses offer flexibility.

You can't afford to wait to make an investment in your team. Teams that lack proper training are more likely to compromise the safety of human subjects and receive FDA warning letters. They are more likely to experience delays in the approval process, which can delay the time it takes to bring a device to market and become profitable.

If your team is serious about your research, you also need to give serious consideration to training.

IMARC University can be a tool to help facilitate your training program. We provide you with an immediate solution that can be expanded as your training needs evolve.

To learn more about clinical research courses available through IMARC University, request a copy of our course catalog

DOWNLOAD

Contact John Lehmann, Director of Business Development, at 440.801.1540. to start creating your custom training program blueprint.

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