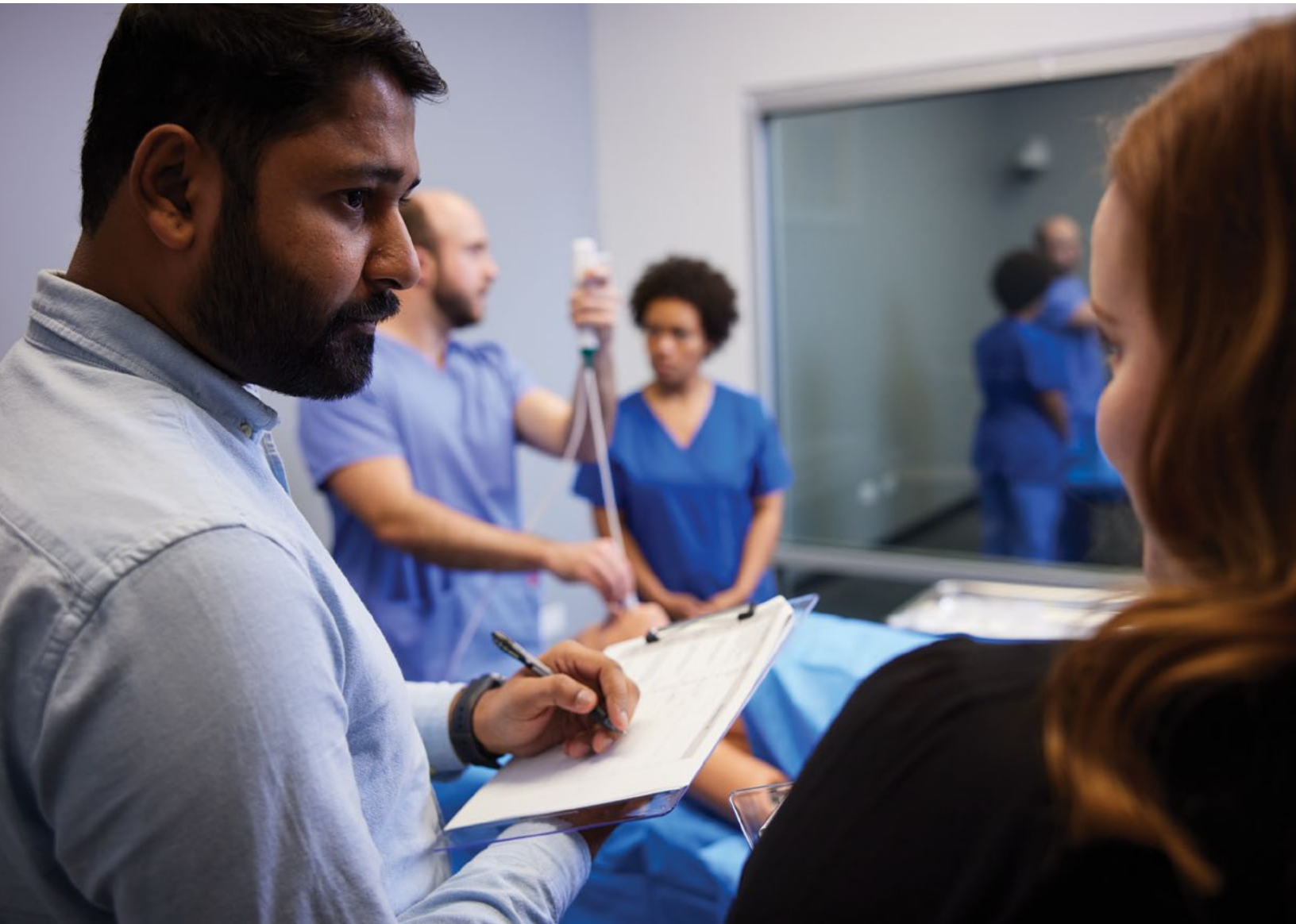
We design growth.

thrive

Human Factors Engineering

We help you design safe, effective, and intuitive medical devices that achieve regulatory compliance and deliver commercial success.

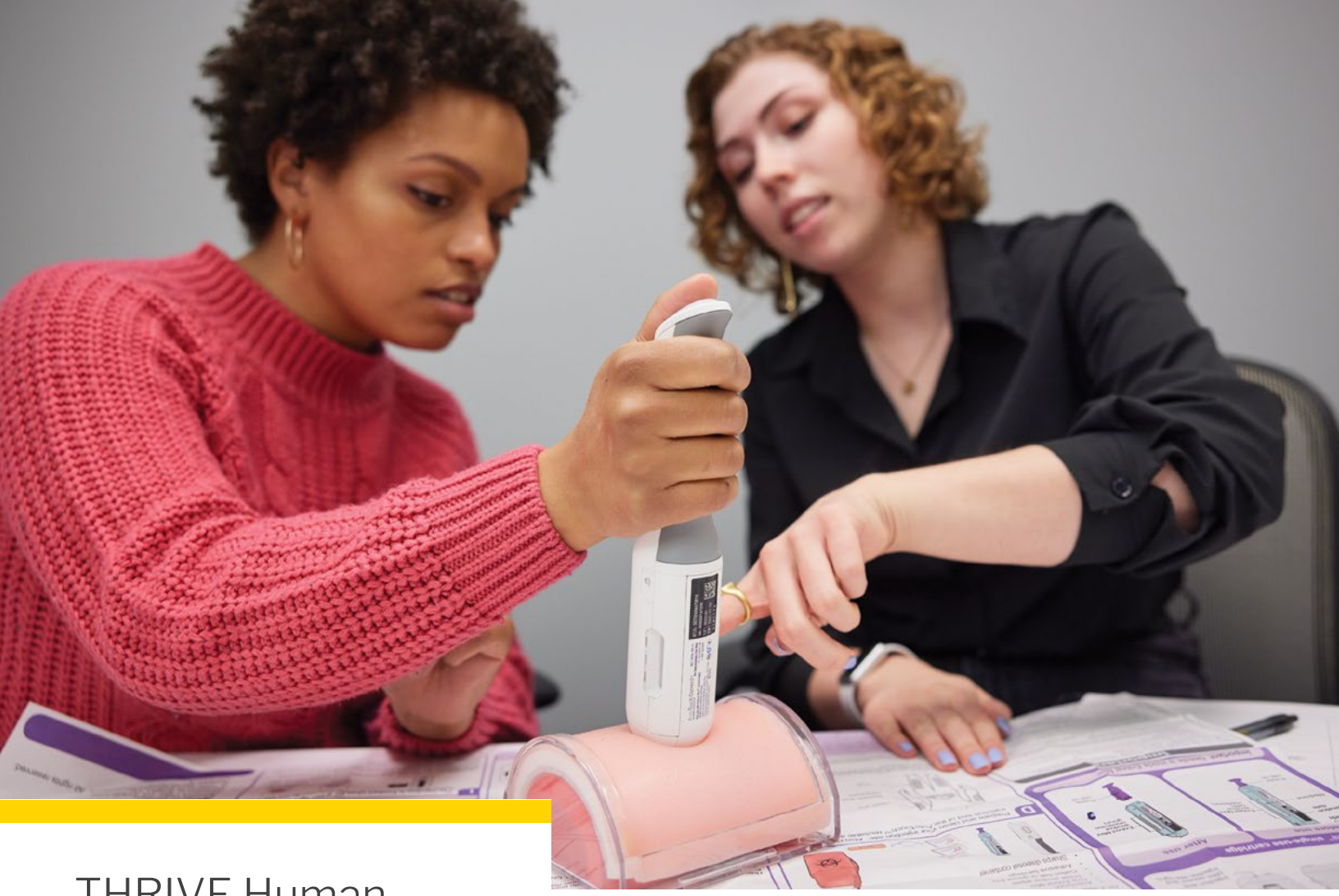


Our Experience

We have extensive Human Factors Engineering experience ranging from combination products used by laypeople in their homes to surgical devices used by healthcare professionals. Our Human Factors experts work alongside our Design Researchers, Product Developers, and User Experience Designers to integrate stakeholder and user needs throughout the design and development process. Whether you need guidance interpreting industry standards, applying the Human Factors/Usability Engineering process, or conducting a Human Factors study—we're here to help.

Let Us Help You:

- Strategize and scale Human Factors activities for your device
- Plan and conduct formative and summative Human Factors validation testing
- Leverage our state-of-the-art usability testing suites to deliver seamless and integrated research experiences
- Conduct relevant analyses to inform safe and intuitive device design
- Document Human Factors work using our validated processes and templates
- Prepare for regulatory submission and advise on regulatory questions
- Conduct post-market device evaluations



THRIVE Human Factors Engineering

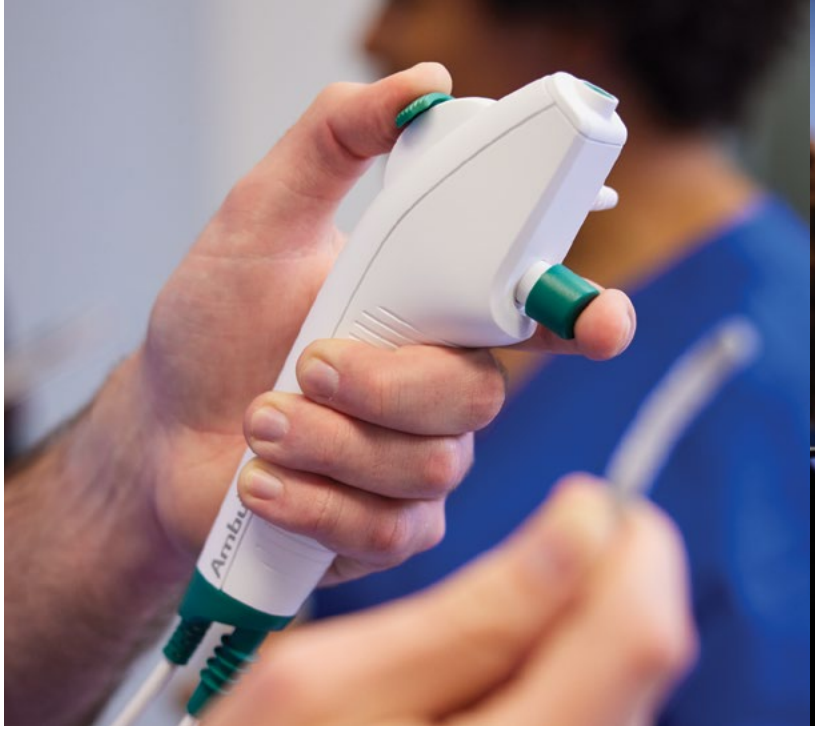
Enriching Lives Through Better Device Design

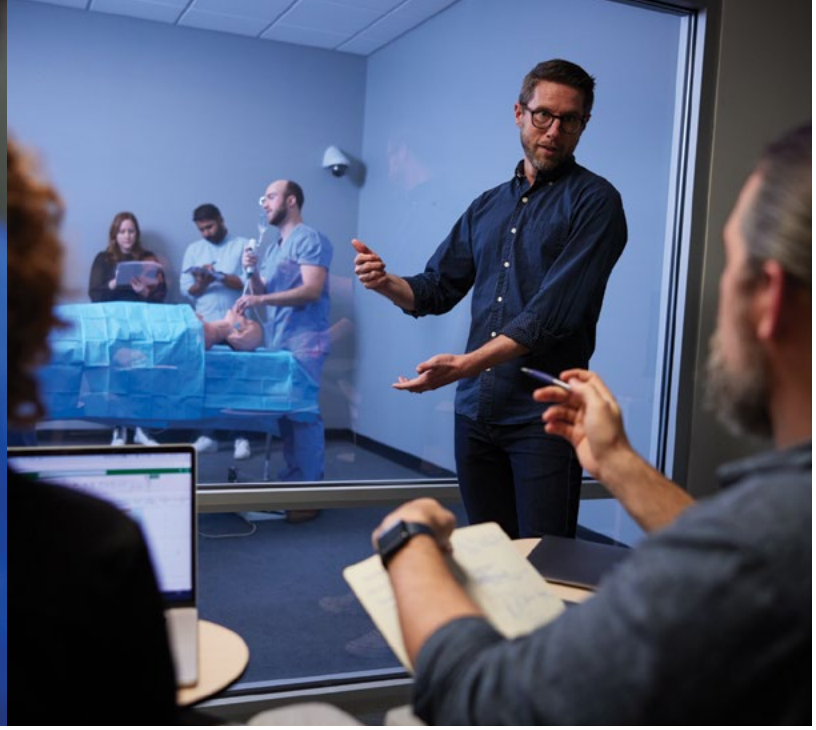
Our human-centered approach puts people and their needs at the heart of the design and development process to create devices that are not only safe to operate and effective under real-world conditions but also desirable, intuitive, and easy to use.

A team of passionate collaborators, THRIVE works alongside you to progress your project, fill in resource gaps, and guide you and your Human Factors Engineering work. Our Human Factors Usability Engineering approach is based on ANSI/AAMI/IEC 62366 and FDA Guidance, ensuring safe and effective device design with efficient regulatory approval.

Our Full-Service Approach is to Your Advantage

THRIVE is a full-service consultancy with a diverse team working to solve your problems at any stage of the medical device design process. Working as an integrated extension of your team, we expand your ability to develop innovative medical devices through a seamless process that spans capturing user needs and defining requirements to detailed product design and evaluation. Our consultants are particularly adept at integrating Human Factors into large organizations' design processes, bringing the objectivity and expertise needed to navigate regulatory hurdles and achieve full compliance successfully.





Identify the Critical Insights Needed for Better Device Design

We provide tailored formative evaluations to identify potential usability issues and unanticipated use errors with your device. A fundamental tenet of our approach is the importance of early, regular assessment throughout the device design process employing heuristic analysis, expert analysis, task analysis & use-related risk analysis, known use problems analysis, comparative/threshold analysis, and formative Human Factors studies for optimum results.

Achieve First-Time FDA Approval

We make it easy for the FDA to approve your submission the first time. Our Human Factors validation testing approach generates the correct data to give you peace of mind that your regulatory submission is comprehensive and successful. We eliminate the need for multiple summative validation studies, using data strategically throughout the design and development process, pinpointing critical tasks, and expertly creating a Human Factors Engineering Report—explicitly tailored to meet FDA requirements.

Understand How Your Device is Used in the Real World

It's essential to fully understand how usable your device is in its actual operating environment after launch. We work with you to plan and conduct post-market evaluations, actively and systematically collecting data to detect trends, design issues, and usage problems. These evaluations include real-use device observations, surveys administered to the device users, and complaint analysis to assess and improve the usability of your device.

Advising and Education to Help You Succeed

THRIVE provides custom training and educational programs to ensure your team has the knowledge to incorporate Human Factors into the device design process successfully. Our consultants offer expertise in interpreting, setting up, and executing on regulatory requirements and integrating Human Factors into a quality management system. We also help organizations understand and apply these concepts practically while highlighting leadership's role in promoting this approach—building capacity amongst staff members and ensuring the right tools and processes are in place so they can put theory to practice.

We Work with Ambitious Leaders

In THRIVE, the healthcare industry has a trusted partner. We work with the world's leading medical device and pharmaceutical companies to develop products from early concept through to commercial launch.

Medtronic · BD · Bristol Myers Squibb

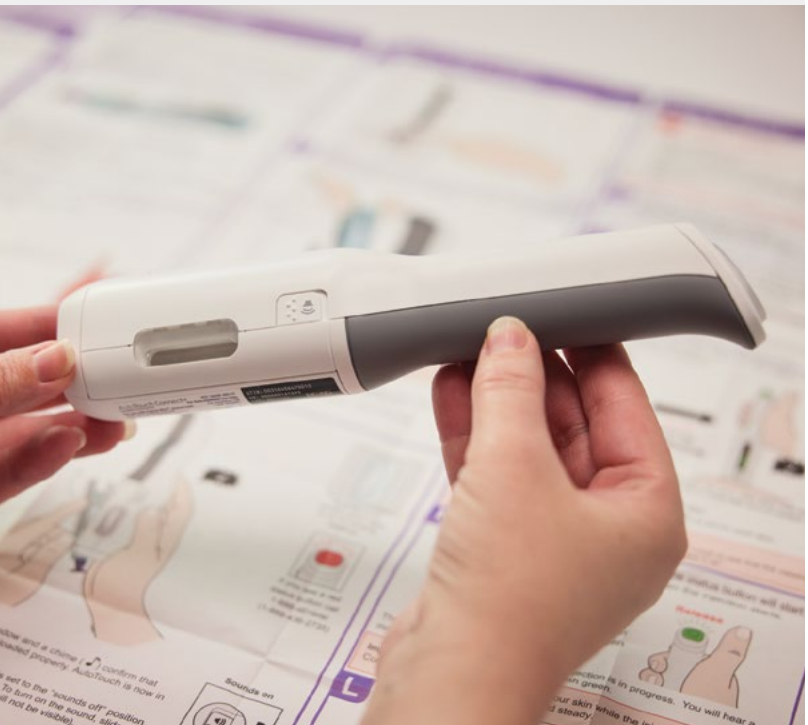
Insulet · Intuitive · Biogen

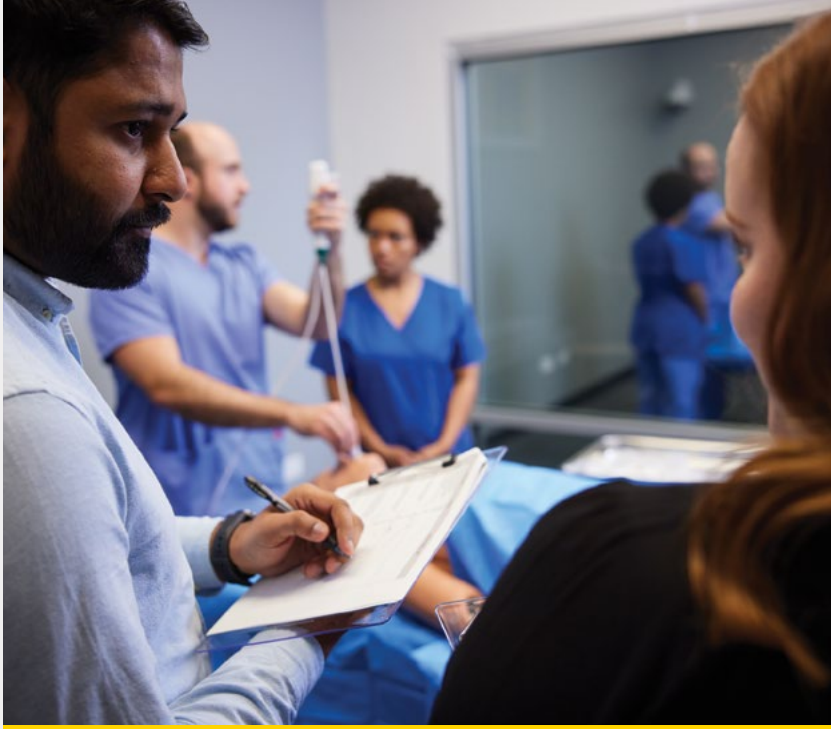
Hillrom · Halyard · embecta

Amgen · UCB · Johnson & Johnson

AtriCure · Fresenius Medical Care · CardinalHealth

Bard · sanofi · Wright





What Our Clients Are Saying

"THRIVE is a joy to work with. Always standing in our shoes, aligning with our vision, and creating innovative designs that improve the treatment experience in our quest to develop more patient-centric products."
Yusuf Oni, Associate Director of Drug Product Development, Bristol-Myers Squibb

"THRIVE is a trusted extension of our team. Whatever challenge we present to them, they always go above and beyond. Getting up to speed quickly and becoming true subject matter experts."
Nick Wright, R&D Program Manager, Oncology, BD

"I'm a big fan of THRIVE and love working with them! They own the problem and perform more like a key employee, not a hired hand. I always thank them for their help and appreciate how much time and money we save since we're not trying to do this alone."
Jeff Beale, Senior Principal R&D Engineer, Medtronic

"The THRIVE team is outgoing, fun, and great communicators. Throughout the project, they were accessible and worked seamlessly with my team. I couldn't have asked for a better group of consultants."
Rafael V. Andino, Vice President – Engineering & Manufacturing, Clearside Biomedical, Inc.

thrive

How Can We Help?

THRIVE's Human Factors professionals have decades of experience applying Human Factors to products ranging from medical devices used by specialized healthcare professionals in clinical environments to therapeutic products used by laypeople in the home.

If it's your first time applying Human Factors and you need a comprehensive end-to-end Human Factors program, we'll scope out the program and conduct the activities on your behalf, leaving you time and resources to focus elsewhere. If you're a resource constrained HFE professional, we'll step in, providing the teamwork, collaboration, and support to help you meet your goals. Or, if you just want a final sanity check to ensure you've met the latest and greatest expectations, we'll do that too.

Contact us today at **404.228.7342** or email **business@thrivethinking.com** to get the conversation started.

Atlanta | Chicago

thrive

2018 Powers Ferry Road SE,
Suite 700
Atlanta, GA 30339
thrivethinking.com

THRIVE is a strategic design firm innovating at the frontiers of health and well-being.

ISO 9001