Special Report

ISO Certification: Paving the Way for a Future of Innovation and Collaboration

Written by Onna Koeneman,
QUALITY RISK MANAGER

At ASG, ISO certification has been much more than a compliance effort. When ASG achieved ISO certification in the United States in November 2025, it marked a shift for the organization — and an effort that touched every part of the company. We achieved the goal by working together. ISO 13485 is a companywide certification, and it requires a companywide effort.

Across the organization, teams and individuals took a close look at how work was being done. They asked each other questions: What worked well? What could be improved? Could systems grow as the company grew? Sometimes the work was incredibly demanding. It took clarity, patience and a willingness to adjust. We're proud of the results. With outstanding leadership and teamwork, we reached our goal. The milestone is important, but the way we grew while reaching it matters just as much.

Quality leadership

Onna Koeneman is ASG's quality risk manager, a team lead and the management representative for ASG's quality management system. She spearheaded ASG's ISO certification process and continues to help ensure ASG follows established standards.





Clear traceability and objective evidence of how decisions are made gives our clients confidence in our work and ensures we consistently meet our commitments.

The How

Ready to grow

Documentation was a big part of the ISO certification process, and, along with our leadership team, I helped guide employees as they mapped and cross-referenced policies and tied them to standards. The medical device industry is heavily integrated and heavily regulated. It's important to make sure employees are safe and that whatever you're creating provides value. ISO reinforces our adaptability and know-how.

We held a high bar for traceability that became central to the process. Credibility in a regulated space is built on demonstrable evidence. It's important to produce written proof of what you did. Blind faith is not enough when you're dealing with patients and their health, whether it's directly, indirectly or further down the line.

Learning together

Throughout the project, we focused on training, growth and ASG's value of continuous learning. Team members needed to feel like they were an integral part of the effort and to see their contribution as part of a larger whole. When people grow in their competencies, they get brighter, they gain understanding, and the whole team grows. Our goal was to help the team better articulate and demonstrate what we do, and we achieved that goal. Now we have a set of documents that shows what we do and how we do it. With that standard in place, our team members have guardrails. The ISO framework gives everyone the freedom to really own what they do.

Our work went far beyond preparing for an audit. We translated regulatory language into everyday practice, making sure the systems in place made sense. As project leader, I assigned ownership, examined how decisions were documented and clarified accountability. I shared these responsibilities with ASG team members across the organization who managed much of the detail work.

HIGHLIGHTS

ASG's ISO 13485 certification:

- **Standardized processes.** Achieved in the U.S. in November 2025, the certification process formalized ASG's documentation process, responsibilities, version control and tracking of decisionmaking and performance.
- **Enhanced quality.** Teams consistently examine whether processes are practical, repeatable and continuously improving.
- **Strengthened collaboration.** Certification involved every ASG business line and required alignment across systems, teams and workflows.
- **Supports growth.** ASG Europe is applying lessons from ASG's U.S. certification as its Dublin-based team prepares for ISO certification in 2026.

Certification makes us stronger

Three ways ISO certification makes ASG better:

1. **Improved quality.** Improved documentation and alignment create evidence of compliance, which improves trust both internally and externally.
2. **Streamlined processes.** Processes are reviewed, revised and documented to make sure they're practical, easy to track and predictable.
3. **Team alignment.** Clear documentation and workflows help teams across the organization collaborate efficiently.



Team members updated procedures, mapped workflows and assembled evidence for review. It was my job to provide structure around the team's efforts so our work could move forward while remaining consistent. We kept the big picture in view: to build systems that would support the company as it grows. Leading this effort meant reinforcing standards while discussing and examining what people do on a day-to-day basis and seeing where their work overlaps with the new standards.

Synergy shapes us

Since certification touches every part of ASG, the ISO process involved every person on the ASG staff. ISO certification was a system-level evaluation of how ASG operates. The process required alignment of all of our systems and was applied across our three main business lines: clinical sample supply, design and development and the ASG studio. Each business line and the team members involved in it had to have general quality and process alignment to reach our goal.

To facilitate the process, project leaders Suna Sibi, Jason Schnaus and Tom Stegall shared their expertise and knowledge, consulting on each business line. Although their "business line lead" title was unofficial, these leaders provided vital information and coordination within and across the business lines. ISO impacted leadership, operations, documentation, environment, training and audits, and it moved through each business line in different ways.

Ensuring alignment within and across business lines was central to achieving ISO certification. At a small company like ASG, it required all hands on deck. "For us it's been very hands-on," said Meagan Koeneman, ASG's business marketing manager. "Much more so than other companies where I've helped guide the ISO process."

A team effort made it possible for ASG to become ISO certified. The cultural changes that inspired attitudes of compliance and quality assurance among everyone at ASG were a necessary and natural part of the process.

About ISO 13485

According to the official International Organization for Standardization (ISO), ISO 13485 is the internationally recognized standard for quality management systems used by organizations involved in the design and manufacture of medical devices. It outlines specific requirements that help organizations ensure their medical devices meet both customer and regulatory demands for safety and efficacy.

> ISO certification gives our clients the knowledge that we have standardized, traceable processes. We're constantly trying to get better.



ISO Is Everyone's Business

Here's how ISO 13485 certification made an impact on ASG's business lines.

Development and Clinical Sample Supply



SUNA SIBI, BUSINESS LINE LEAD AND TECHNICAL PROJECT MANAGER

Suna Sibi and her team serve as a bridge between design and commercialization.

This business line is responsible for delivering samples, supporting traceability, product realization and clinical readiness. The team serves as a bridge between developing a product design and its eventual release into the field. This role allows them to help ensure configuration and documentation.

The team focused on how samples are planned, built and tracked to support research, characterization, verification, marketing studies and clinical trials. They also worked to ensure availability while strengthening visibility into how changes were recorded and communicated across teams and other business lines.

Design and Development



JASON SCHNAUS, SHARED SERVICE LEADER AND TECHNICAL PROJECT MANAGER

Jason Schnaus and his team help create real solutions for real problems.

This business line is responsible for translating client and patient needs into practical, scalable and compliant medical device solutions. The team helps design prototypes and write technical documentation. This means they help take real problems and design real solutions that can be produced smoothly in any amount while clearly documenting the process.

In this area, team members reviewed how prototype devices transition into fully realized products. They examined how design input, risk management decisions and product validation steps were documented. This was to make sure the documentation from concept to regulatory readiness was clear and defensible.

The ASG Studio



TOM STEGALL, BUSINESS LINE LEAD AND TECHNICAL PROJECT MANAGER

Tom Stegall and his team provide regulatory testing to help ensure compliance.

This business line provides metrology services, material and device characterization and regulatory testing services. These services ensure compliance with relevant standards, support testing development, digital data management and internal investigation. This can improve traceability, efficiency and accuracy.

During the ISO certification process, Tom Stegall and his team evaluated workflows to support procedural and physical product testing. They also looked closely at the testing environment, equipment and document control practices to ensure they aligned to produce consistent, traceable results.

The What

What ISO Required

ISO 13485 sets the standard for quality management systems in the medical device industry. It's an industry standard based on evidence that engineers have developed over time. In a nutshell, it's what you need to provide good quality and mitigate risk. But ASG wasn't starting from scratch. Strong practices were already in place, established in the ASG Handbook and company values. For certification, the work was about aligning and formalizing these extant practices so they were consistent across the organization.



As consultants, our job is to make sure a client has all the options and provide a recommendation. ISO certification gives our clients the knowledge that we have a traceable process: We don't do things differently every time we do something for them. Our processes are standardized, and we're constantly trying to get better.

That's how we mitigate risk. ISO requires clear document procedures, defined responsibilities, version control and evidence that processes are followed consistently. It also requires training records, management review, internal audits and a structured approach to continuous improvement. You have to have a standard. When something deviates or breaks down, you need to know that and put it back where it needs to be.

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A holistic approach

ISO certification influences every aspect of our work at ASG:

1. **Documentation and control.** Documents are current, aligned and accessible. This reduces confusion, strengthens client trust and supports consistent execution.
2. **Environment.** Ensuring employees have a self and welcoming place to work keeps team members happy, healthy and productive.
3. **Leadership and training.** Good leadership and proper training empower team members to do and be their best.
4. **Our way of working.** Processes are standardized and continuously improved, ensuring consistency and quality.
5. **Accountability.** Clear traceability and objective evidence of how decisions are made strengthens client confidence and ensures commitments are consistently met.

Internally, ASG's work has often been described through five focus areas, or spheres of influence: documentation and control, leadership and training, practice, environment and accountability. These themes helped condense ISO into something practical and understandable. They provided a framework for examining how decisions are made, how work flows across teams and how responsibility is shared among everyone in the organization.

Defining our identity

ISO has helped ASG more clearly define its identity. The company has always used these processes, but ISO required the team to talk through them, make sure they could be executed consistently and give them names.

The ASG team is small and its members are relatively young. Many have never been directly exposed to something like the certification process. It was a learning experience and an interesting journey. Defining ASG's process and identity required both inexperienced and senior team members to examine how they did their work.

It has been a rewarding process. Now people realize they're not just working in the lab or on a piece of equipment or a medical device. All the components need to come together. Everything is interconnected.

ISO has helped ASG more clearly define its identity.



The Why

What does it mean?

ISO certification isn't just about procedural change. It's a cultural shift. Now, teams talk to each other more proactively. Instead of asking whether something will pass review, people ask whether the process makes sense and can be repeated the next time. This question is the backbone of quality.

Quality is not a checkpoint to be reached at the end of the process, it's part of an ongoing conversation. At ASG, we want to be the best we can be, and ISO reinforces that commitment.

In addition to managing processes, each member of our team will keep growing both personally and professionally. That's part of quality management: an ongoing commitment to maintaining and improving how we work. We don't just focus on quality to pass an audit or to get ISO certified. We focus on quality because it's our mission to make a meaningful impact on patients.

> Our clients may not see every procedural or cultural change, but they'll feel the difference in steadier execution and clearer communication.

A culture of compliance

As we went through the certification process, our organization changed. Ownership is clear. Every document has someone responsible for it, and version control is tighter. Every change is documented and reviewed. Decisions that previously might have only existed in an email exchange now live in systems others can easily access.

Our clients may not see every procedural or cultural change, but they'll feel the difference in steadier execution and clearer communication. Certification builds confidence and trust that our work is done thoughtfully and consistently. Pete Howard, an ASG founder who now works as a consultant, summed up the impact this way: "ISO certification opens doors. It's like having a degree from a college or university."



Ultimately, ISO has created a culture of compliance within ASG and prepared us for the future. Our new guidelines were designed to stand the test of time, whether they're being used to produce five devices or five million devices.

The Future

What Comes Next?

Certification in the United States isn't the finish line. ASG Europe, based in Dublin, Ireland, is preparing for ISO certification in late 2026. Experience gained in the United States is already shaping the work the Ireland team is doing. Employees are working from a stronger baseline with fewer unknowns, and building on the work done in the United States. Processes designed and refined in one region will be adapted in another. This will create consistency across ASG's locations while leaving room for local execution.

"With ISO certification, we'll be even better equipped to act on our clients' behalf to provide investigation support through our metrology services," said Jason McGlynn, Director and General Manager, ASG Europe. "The ultimate goal is to help clients release products in the marketplace."



JASON MCGLYNN, DIRECTOR AND GENERAL MANAGER, ASG EUROPE

Jason McGlynn leads the ISO certification effort for ASG Europe.

With ISO certification, we're even better equipped to act on our clients' behalf to provide investigation support through our metrology services.

Consistency, clarity and community

ISO certification supports growth, but it doesn't replace the daily work it takes to maintain a commitment to quality. Consistency is key. Systems will continue evolving, training will be reinforced and reviews will keep happening to ensure accountability.

The biggest message is about community. Everyone worked hard and came together to make ISO certification happen. The 2025 milestone helped define how ASG works. The future is about sustaining that clarity and carrying it forward.

ASG is growing and looking forward to a future of innovation and collaboration. **Contact us** to learn what ASG can do for you.