6-3 Providing Safe and Secure Products

Basic Policy

In order to supply our customers with safe and secure products in a consistent manner, our Group has established a quality policy that is shared across all of our bases. By striving to improve quality every single day, we aim for ever better global quality.

Promotional Structure

(1) Structure to Supply Safe and Secure Products

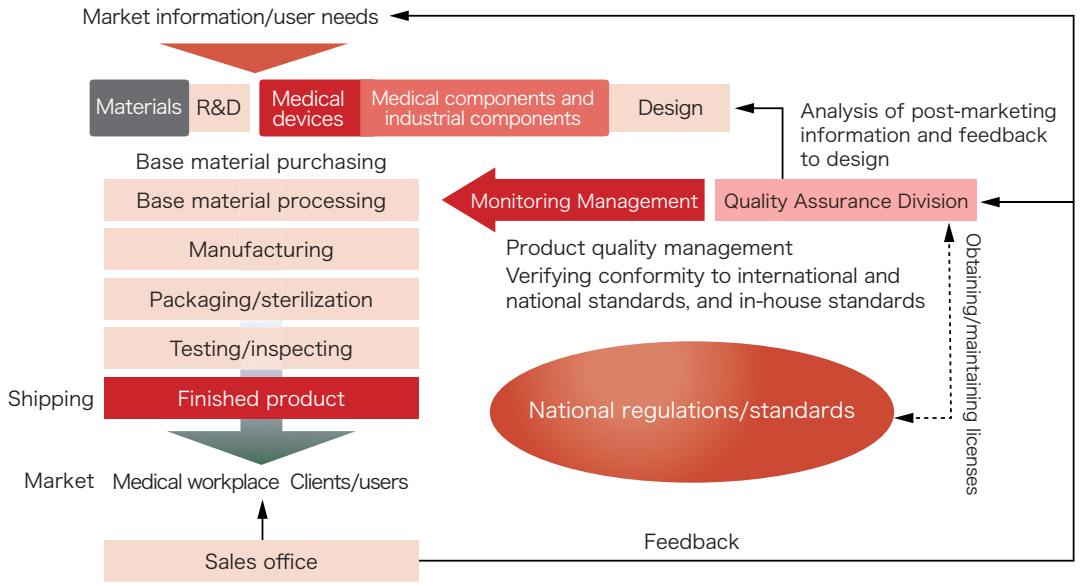
Our Group has established a quality management system that applies the international standards framework of ISO 9001 and ISO 13485 in order to reliably provide our customers with high-quality products and medical devices, and we have developed a structure to assure uniform quality across research, design and development, production, and sales based on the Quality Policy set out by top management. In addition, we regularly undergo rigorous screenings by third-party certification bodies to obtain and maintain certifications such as ISO 9001 and ISO 13485. Furthermore, by complying with the stringent regulations in more than 110 countries and regions to which our Group provides products, we have built a structure that ensures the quality products our customers require.

(2) Thinking on Quality Assurance Structure and Quality Management

Based on our four core technologies, our Group has developed an integrated production system from raw materials to finished products. Medical devices in particular require precise specifications and quality in their materials, and the number of raw material manufacturers capable of steadily supplying materials that meet these standards is limited even on a global scale. Therefore, our Group purchases base materials as far upstream as possible and manufactures them in-house into near-ideal materials, components and, ultimately, the finished products.

Moreover, in order to manage and ensure product quality, our Group has a quality assurance division separate from the research, and design and development departments, production bases, and sales offices. This division inspects and tests our manufactured products to confirm that they conform to the required international, national, and in-house standards, and only the high-quality products that pass these inspections are shipped to market. In addition, an internal quality auditor certified by our rigorous internal certification system conducts internal and intra-Group quality audits to regularly monitor the appropriateness of this manufacturing management and quality assurance structure, striving for continuous improvement.

We have also established a dedicated department to constantly collect and evaluate the latest post-marketing information. We collect and evaluate a wide range of product information after launch and provide feedback on improvements to improve quality and new product designs.



6-3 Providing Safe and Secure Products

Base Certification

Our Group has obtained quality management system certifications by third-party certification bodies as shown in the table below.
(Certification status as of the end of June 2024. For the latest information, see “Information on Certifications” in “ABOUT US” on our website.)

Quality Regulations

Our Group has set documented quality regulations of the quality management system according to the quality policy (shared policy) of Asahi Intecc Group. Operations based on these quality regulations aim to promote high-level quality assurance, and to deliver products beyond the needs and expectations of customers in order to make contributions to society.

Control of Quality Targets

We conduct activities to achieve the quality targets for each fiscal year according to the quality policy. Opportunities of periodic review involving upper management are made for the set targets to achieve improvements.

Quality Reporting Structure

Our Group appropriately monitors product quality by tracking all information on quality in the manufacturing process, from raw material manufacturing to final product shipping, in a timely fashion. The Quality Assurance Division also collects all customer feedback on quality for survey and analysis. By conveying this information to upper management as well as the manufacturing, research, and design and development bases in a timely manner for use in process and product improvement, we have established a structure for supplying safe and secure products.

Measures to Improve Quality

In our Group, the quality assurance division and each manufacturing base screen the material and product R&D and design processes from the very first stage, taking a third-party perspective. Doing R&D and design with a perpetual awareness of the manufacturing process and use as a marketed finished product helps solve problems with existing products, resulting in development and manufacturing of higher-quality materials and products.

Reception and Conduct of Quality Audit

Production business sites handling medical devices and the Quality Assurance Division in our Group undergo regular audits by ISO, the administrative authority, and our customers. In addition, internal auditors conduct periodic and irregular audits; in FYE June 2024 we underwent 97 external audits and conducted 28 internal audits.

■Status of Quality Management System Certification (as of the end of June 2024)

Base	Quality management system certification
ASAHI INTECC CO.,LTD.	Medical Division ・ISO 13485 / EN ISO 13485・MDSAP Device Division ・EN ISO 13485 / ISO 13485
ASAHI INTECC THAILAND CO.,LTD.	・ISO 13485 / EN ISO 13485 ・ISO9001 ・MDSAP
ASAHI INTECC HANOI CO.,LTD.	・ISO 13485 / EN ISO 13485 ・MDSAP
TOYOFLEX CEBU CORPORATION	・EN ISO 13485 / ISO 13485 ・MDSAP ・ISO9001
Filmecc Co., Ltd.	・EN ISO 13485
ASAHI INTECC USA, INC.	・ISO 13485

6-3 Providing Safe and Secure Products

Respect for Bioethics in Research and Development

In the research and development of medical devices, animal experiments may be necessary to confirm the efficacy and safety. From the viewpoint of animal welfare and environmental conservation, our Group strives to apply alternative methods unless animal experiments are absolutely necessary.

Our Group does not conduct animal experiments in-house, and outsources them to an external organization. However, when outsourcing animal experiments, we do so after confirming that relevant laws, regulations and guidelines have been established by the outsourcee from the viewpoints of animal welfare and environmental conservation, as well as from the viewpoint of ensuring the safety of testers who conduct animal experiments.

Cleanliness Level of Medical Division

Our Group is manufacturing the medical devices for our medical division in controlled areas in accordance with Class 7/8 of ISO 14644 series as international standards, etc. (Cleanrooms and associated controlled environments).

Education/Training of Employees and Suppliers

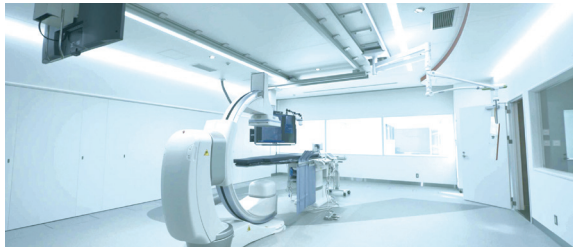
Our Group is building a proprietary system to manage employee skills and qualifications based on applicable regulations, standards, and in-house standards. We thoroughly ensure that only trained employees whose skills and qualifications have been confirmed are involved in developing, manufacturing, inspecting, and all other work on products for customers. Our Group recommends that our base material providers also use such a skill/qualification management system, and regularly review and verify them. The number of in-house certified auditors who are allowed to conduct internal audits and supplier audits in our Group is 208 as of the end of June 2024.

Instruction on Product Use

In interventional radiology (IVR) such as PCI, sophisticated skills of medical workers to maneuver guide wires, catheters, and other equipment as well as catheters and guide wires which deliver operation at the proximal end to the distal end accurately are needed to reduce the burden on patients while maintaining the treatment's efficacy. Choosing the right products from among many options for the patient and body part to be treated is also important.

Our Group provides detailed explanations on product use, selection, and care to distribution agents and medical workers in each country to help them use the products safely and effectively. We educate on IVR and use of our products through case studies and demonstrations by KOL doctors at academic conferences and seminars around the world on a day-to-day basis.

At our Global Headquarters and R&D Center, our Group provides medical workers with training in an environment almost identical to a clinical setting using our simulation system and human models recreating an actual operating room.



Quality Assurance through the Value Chain (Measures During Development, Design [Testing], Sale, Use, and Manufacture)

From the research and development of material to the manufacture of final products, our Group's focus is being relevant and realistic about the setting, product, and situation (Three Actuals). Furthermore, having developed an optimal sales structure for over 110 countries and regions, we can rapidly collect feedback from the market, actively collect and analyze post-marketing safety information, and apply it to improve our processes and products, which enables us to surpass market needs with our product development and reliable supply throughout the entire value chain.

As a result of implementing these measures throughout the entire value chain, our Group has been recognized for high-spec products and a large global market share based on unique technology. In 2020, we were chosen as one of the Global Niche Top 100 Companies (selected by the Ministry of Economy, Trade and Industry) for our indispensable role in the global supply chain.