



## Quality and Safety of Products and Services

We prioritize the quality and safety of our products and services, striving to provide precise and reliable healthcare products and services to our customers, thereby contributing to the creation of a healthier society.

- To secure the quality, effectiveness, and safety of our products and services, we fulfill requirements of Laws and Regulations, and Internal Rules, and promote an effective and efficient quality management system.
- To consistently deliver high-quality products and services to research and medical fields, we establish and maintain a supply chain with our suppliers that ensures quality and safety.
- In the event of a significant issue with the quality or safety of any of our products or services, we provide accurate and transparent disclosures to our customers and other stakeholders of relevant information, take appropriate measures to prevent further harm, investigate the root cause and work toward preventing recurrence.

#### Examples of Key Relevant Laws and Regulations, including but not limited to:

##### Laws Securing the Quality and Safety of Pharmaceuticals and Medical Devices:

<b>Japan</b>	: Pharmaceuticals and Medical Devices Act (PMD Act)
<b>United States</b>	: Federal Food, Drug, and Cosmetic Act (FD&C Act)
<b>Europe</b>	: Medicinal Products Directive (MPD) (Directive 2001/83/EC), Medical Device Regulation (MDR) (Regulation (EU) 2017/745), In Vitro Diagnostic Medical Device Regulation (IVDR) (Regulation (EU) 2017/746)
<b>China</b>	: Drug Administration Law, Regulations on the Supervision and Administration of Medical Devices

##### Laws Establishing the Liability of Manufacturers for Damages Caused by Product Defects:

<b>Japan</b>	: Product Liability Act (PL Law)
<b>United States</b>	: State Laws regarding Product Liability
<b>Europe</b>	: Product Liability Directive (PLD) (Directive (EU) 2024/2853)
<b>China</b>	: Product Quality Law, Consumer Rights Protection Law



## Research and Development

We are committed to understanding the diverse challenges faced by researchers and healthcare professionals and aim to address these challenges through the creation of innovative solutions. Our goal is to contribute to better health for patients by engaging in research and development in a lawful and ethical manner.

- When using research facilities and equipment, we comply with Laws and Regulations, and Internal Rules, with attention to safety and environmental considerations.
- In clinical research and similar activities, we respect the dignity and human rights of research subjects, prioritize their safety, and fully respect their privacy and other legal rights. Additionally, when handling laboratory animals, we adhere to ethical standards such as the “3Rs” principle (Replacement: use of alternatives, Reduction: minimizing the number of animals used, Refinement: enhancing animal welfare).
- We commit to integrity in the publication and reporting of research findings, refraining from any fraudulent activities such as fabrication, falsification, or plagiarism, and do not engage in or support such activities.

Examples of Key Relevant Laws and Regulations, including but not limited to:

#### Laws for Conducting Clinical Research in Medicine and Pharmaceuticals to Ensure Reliable Results:

<b>Japan</b>	: Clinical Trials Act
<b>United States</b>	: Code of Federal Regulations Title 21 Parts 50, 54, 56 and 58
<b>Europe</b>	: Clinical Trials Regulation (CTR) (Regulation (EU) No 536/2014)
<b>China</b>	: Drug Administration Law, Good Clinical Practice for Drugs

#### Laws for the Protection and Proper Management of Animals:

<b>Japan</b>	: Act on Welfare and Management of Animals
<b>United States</b>	: Animal Welfare Act (AWA)
<b>Europe</b>	: Animal Welfare Directive (AWD) (Directive 2010/63/EU)
<b>China</b>	: Regulations on the Administration of Laboratory Animals

#### Laws to Ensure related to the Safety of Chemical Substances:

<b>Japan</b>	: Chemical Substances Control Law
<b>United States</b>	: Toxic Substances Control Act (TSCA)
<b>Europe</b>	: Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
<b>China</b>	: Measures for the Environmental Management of New Chemical Substances