

Assurance of Quality and Safety, and Establishment of an Appropriate Supply System

Stable Supply of High-quality Products to Address Medical Needs Worldwide, with a Global Organization Built around Three Plants in Noto and Shiga in Japan and Suzhou in China

High-Quality Products with a Commitment to Water, Air and People

At Santen, we manufacture high-quality products with a commitment to water, air and people. For example, we use water—the essential medium for any ophthalmic solution—with a level of purity equivalent to that used in injections.

Ophthalmic solutions must be sterile. Containers are filled in a Grade A¹ cleanroom, and we maintain a high level of quality control, with only employees who have passed an in-house qualification test allowed to enter the cleanroom and to handle processes.

Equipment for Maintaining Stable Supply

To achieve stable supply of products to countries around the world according to each country’s medical needs, Santen has established specialized equipment maintenance teams. These teams minimize problems and ensure steady plant operation, thereby supporting a production and supply system capable of round-the-clock manufacturing.

To minimize production line and equipment breakdowns and problems, we operate an equipment management

system and conduct daily planned maintenance. In the event of a breakdown or problem, the personnel in charge promptly carry out repairs. This enables us to maintain product quality and prevent any negative impact on the manufacturing plan.

Maintenance in Cleanrooms

In cleanrooms for manufacturing ophthalmic solutions, maintenance is performed only by employees who have obtained a sterile maintenance qualification for facility upkeep. These employees acquire knowledge that encompasses not only keeping equipment in good condition, but also maintaining and managing a sterile environment, as well as wide-ranging specialized knowledge in areas such as acting in accordance with guidelines for manufacturing sterile medicines using aseptic operating procedures.

High-Level Expertise and Technical Skills

The proper maintenance and management of equipment requires a high level of expertise and technical skill. If a problem occurs at night or on a non-business day, the manufacturer of a device cannot usually be contacted. To respond appropriately, maintenance personnel make full use of their experience and expertise. They make themselves thoroughly familiar with equipment and engage in discussions with manufacturers to collaborate in building better equipment. In addition, they emphasize communication with manufacturing sites on topics such as enhancing operating stability and usability upgrades. With their strong sense of a mission to achieve sustainable and stable supply to patients, our maintenance staff support quality assurance and stable product supply.

Please see Efforts to Enhance Product Safety at

<https://www.santen.com/en/about/activity/safety.jsp>



Members in charge of equipment maintenance at the Noto Plant



Equipment maintenance at a manufacturing site

¹ Fewer than 100 particles of 0.5 μm or larger per cubic meter of air.