Business Strategies by Process

Supply Chain

Promote rebuilding of supply chain system to adapt to changes in the business environment

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Basic policy

The Production Technology & Supply Chain Management Division was established in April 2018 with the integration of the CMC[1] Division and the Production Division. It plays a role in facilitating and flexibly promoting *monozukuri* (manufacturing with production technology and supply chain management), from the manufacture of investigational drug products used in clinical trials to product design for launch, commercial product procurement, production and supply.

In fiscal 2019, we will steadily promote development projects and maximize product value through product design from the customer's point of view. At the same time, we will restructure our Japan-centered *monozukuri* system into a system capable of adapting to our U.S.-centered business development.

1. CMC: The acronym for Chemistry, Manufacturing and Control ("the chemistry, manufacturing and quality control of drug ingredients and pharmaceuticals"). Comprehensive research that supports pharmaceutical manufacturing and quality.

Fiscal 2018 summary and fiscal 2019 initiatives

In fiscal 2018, when our division was established, we formulated a plan for restructuring our production and technology bases under our "Strategic Future Vision for Production, SCM[2], and CMC." In fiscal 2019, the steady implementation of this restructuring plan will be a priority issue.

For example, this restructuring plan will include factors such as further strengthening of our capabilities in the field of global supply chain management. Leveraging the experience and know-how gained from Radicava, we will create a system that enables rapid supply of globally developed products such as MT-1186, ND0612, MT-8554, and MT-7117, from investigational drug products to commercial product supply.

In addition, we will leverage the characteristics of our domestic production bases to achieve an efficient production system. Based on the product life cycle, the Onoda Office will be responsible for everything from the manufacture of investigational drugs to the timing of their introduction and growth, while the Yoshitomi Office will promote the reallocation of production items following the restructuring of production bases, and will changeover to a system that supports *monozukuri* from growth period onward, and provides efficient and stable supply.

Furthermore, we will rebuild our production technology to create unique value and deliver it globally. To achieve a seamless connection between CMC and production functions, a new research building, CMC Innovative Laboratories (CIL), will be constructed at the site of the Onoda Office and develop it as a *monozukuri*

base. In addition, technology and know-how not located in-house will be acquired through partnering including collaboration with industry, academia, and government.

2. SCM: Acronym for Supply Chain Management. A business management method for optimizing the entire process from raw material procurement to manufacturing and supply to consumers.

Medium- to long-term strategy

The mission of our division is to grasp the needs of the market, rapidly create the products that are needed, and stably deliver products of both reliable quality and reasonable cost to customers around the world based on our high technological capabilities.

As typified by the three growth drivers, we need to shift not only investigational drugs, but also our product supply system to the U.S. to accompany the shift of development and sales areas to the U.S. Along with these changes, the functions of our division must be changed, and therefore we will build the systems that we need in the future.

To contribute to the company's global growth, we will also focus on the early development of human resources who can properly build and manage supply chains, who can manage positive relationships with various stakeholders, and who can properly respond to new modalities and markets.

A message to shareholders and investors

While raw materials suppliers, manufacturing sites, and sales regions of pharmaceuticals have globalized, global products have to be supplied according to different regulations and local requirements for each country, so it is increasingly difficult to demonstrate economies of scale by manufacturing one product together from a supply chain perspective.

In addition, manufacturing sites with special raw materials and technologies required for new modalities are limited, and there may be risks that could affect stable supply due to unexpected natural disasters and accidents. As countermeasures to these risks, we have developed rules and manuals for responding to crises with a view to business continuity, and have identified specific risks for each key business in the supply chain.

Because the market, patient needs, and required technologies are constantly changing, we will strengthen *monozukuri* from the customer's point of view and create a supply chain system that adapts to changes in the business environment so as to achieve "reliable products and sustainable supply," one of our material issues.

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Viewing the reorganization as an opportunity, we will introduce new technologies while ensuring quality

The Group is currently reorganizing its bases with the aim of establishing a global new drug supply system and switching to a flexible and efficient production system that is resistant to environmental changes. Accordingly, I'm in charge of transferring manufacturing technology between factories and outside the Company, and every day I feel how difficult it is to transfer manufacturing technology and continue to manufacture products of the same quality as if it were nothing. Complex factors such as raw materials, machinery, and manufacturing environment may affect quality, even in the same process and procedure. Moreover, the transfer of manufacturing technology substantially changes manufacturing conditions, so high technology is required to ensure the same quality.

For example, when the technology used to manufacture a tablet at our plant was transferred to a new plant, the brand name printed on the tablet was changed to appear on both sides instead of just one, and as a result, many technical issues needed to be solved. Therefore, working closely with the manufacturing division, we reviewed the process from the beginning and conducted repeated trial and error, such as changing the method used to polish the tablet surface. As a result, we not only ensured quality, but were able to achieve significant reductions in work time and defect rate. In a situation that requires close collaboration with other departments and related companies, we reaffirmed the importance of leading the project by having our technical staff carefully examine a wide range of information. Furthermore, viewing each change as an opportunity to achieve a higher quality, lower cost, and more stable supply than before, we review data analysis at the time of the manufacturing technology transfer. At the same time, we are actively introducing new technologies such as non-destructive and non-contact analysis technologies and continuous monitoring methods.

Also, to improve my expertise and acquire further problem-solving skills, I'm registered as a visiting researcher at a university under a work-study program. I will further enhance cooperation between the production and research divisions while combining the experience gained at the Company and the knowledge learned at the university so that we can manufacture and provide even safer and more secure pharmaceutical drugs than before.