

**Our mission is to be
a meaningful existence in the healthcare
field by playing an indispensable role.**

Business Philosophy

Helping People Lead Healthier, Happier Lives

Management Policy

Customers: Supply Unique and High-quality Products

We will develop and supply pharmaceuticals that are safe and highly effective relative to other drugs, and that in some way contribute to a better quality of life in patients, first and foremost for patients who suffer from illnesses. We will develop and supply high-quality functional food that meets the needs of customers.

Society: Earn the Trust of Society

We will achieve regulatory compliance and adherence to internal rules, and always remember our corporate social responsibility and behave according to high ethical standards.

Employees: Develop Each Employee

We will develop each employee through goal-setting and positive challenges in work.

Guidelines for Action

Challenge: Meet Challenges

We will always take a positive approach in pursuing our goals, with a firm belief and sense of responsibility rooted in an ethical approach.

Speed: Speedy Action

We will always take speedy action to make certain to seize opportunities.

Investigation: Spirit of Investigation

We will carefully investigate and analyze information that we have broadly gathered, and carefully plan to achieve our goals, and make certain to implement plan-do-check-action (PDCA) cycles.

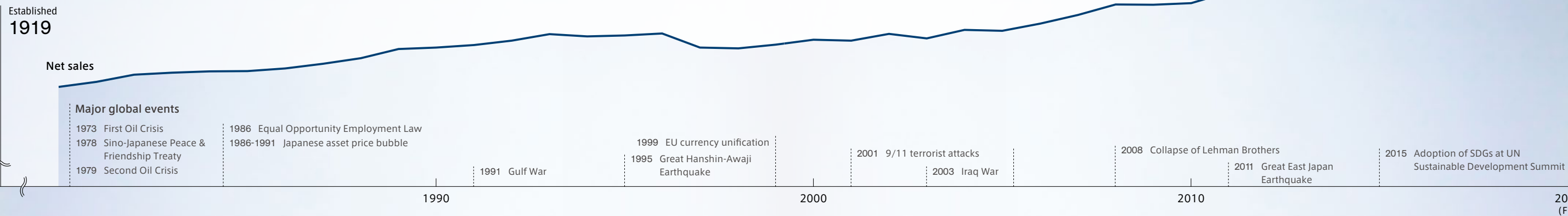
Smile: Keep on Smiling

We will always act with a smile to make certain of smooth communication.

History of Nippon Shinyaku

Using original technology to give hope to those suffering from intractable diseases and to create healthier lives with unique functional foods, we are committed to enhancing life in this new age.

FY2020 Net Sales
¥121,885 million



1970s–1980s Forging an independent path as business conditions evolved

As the period of high economic growth rates ended, Japanese society underwent a major transition with the introduction and development of the social welfare system. The pharmaceutical industry saw demand increase for products that were proved safe and not just efficacious. The system of national health insurance introduced in the 1960s began to prepare for the anticipated aging of Japan through measures to restrict healthcare spending.

1990s Start of global business development and drug discovery

The 1990s were a so-called “lost decade” for Japan after the bursting of the asset price bubble. This led to calls for drastic reform of the drug pricing system as part of fiscal reconstruction. System revisions systematically cut the NHI reimbursement prices of prescription drugs, leading to a new structure in which wholesalers would compete on price at the point of delivery.

With economies and societies starting to globalize, Japan’s pharmaceutical industry began to look to overseas markets.

2000s Reinforcement of business foundation to respond to drastic changes in conditions

At the start of the 21st century, advances in life sciences focused attention on new drug-discovery methods and targets. Amid continued globalization, competitiveness in global markets became the core basis for decision-making in drug development. In Japan, measures to restrict social insurance costs amid rapid falls in birth rates created headwinds for the pharmaceutical sector, prompting consolidation of the industry.

2010s Aiming for global respect as manufacturer in the healthcare field

Measures to restrict healthcare spending accelerated in Japan amid a rapid shift to aging demographics. Drug makers looked for ways to maximize value from soaring R&D costs, including re-evaluating how to manage off-patent products and building new business models to cope with altered conditions. The strategic necessity became to focus R&D on therapeutic areas with high unmet needs and identify targets by focusing on domains of special expertise.

Actions by Nippon Shinyaku

Anticipating the introduction of mandatory Good Manufacturing Practice (GMP: a set of standards for pharmaceutical production and quality control) across the industry, we ensured that our production facilities at Odawara and other sites maintained high quality and were fully GMP-compliant, while also working to keep costs low. We invested in biological research laboratories for mandatory drug safety testing. In 1982, we completed construction of the central research laboratory as a GLP-compliant facility for non-clinical safety testing as part of major investments to upgrade our R&D capabilities. We also led the industry in introducing a 6-month training program for MR education to support professional drug detailing activities.

Our annual net sales passed the ¥10 billion mark in FY1970. By our 60th anniversary in FY1979, net sales had grown rapidly to ¥32.7 billion. Responding to strong social demand for effective pharmaceuticals, we built up our business base while keeping abreast of industry trends.



Odawara plant (now Odawara Central Factory)



Main central research lab (now Discovery Research Laboratories Building No. 1)

Opening offices in Germany and the US, we began to base the development of our international operations on the three poles of Japan, the US and Europe. We upgraded our capabilities for drug discovery and nucleic acid medicine development, constructing a second building at the Discovery Research Laboratories and a new R&D facility in Tsukuba. The first half of the 1990s saw a flood of product launches, and we focused our sales resources to cultivate blockbuster drugs. We also built a new API production facility at Chitose and established the new Functional Food Division as we started to supply health food ingredients.

As business conditions became steadily more challenging, annual net sales passed the ¥50 billion mark in FY1992 before staying around that level for several years. We upgraded our environmental protection initiatives in the 1990s, instituting a set of global environment guidelines in 1992, followed by the Nippon Shinyaku Basic Environmental Policy in 1998.



Discovery Research Laboratories Building No. 2



Discovery Research Laboratories in Tsukuba

To create a business foundation to respond to the altered business environment, we formulated medium-term management plans based on a vision aligned with our business philosophy. We reorganized internal structures, creating the Corporate Strategy Office; flattening the research organization for efficient development of drug candidates; and creating a dedicated training center to upgrade our education systems for MRs. In 2002, as part of the global development program, we relocated NS Pharma to New Jersey to support local clinical development.

We also focused our R&D on cutting-edge nucleic acid medicines in a bid to build Nippon Shinyaku’s global reputation as an R&D-led specialty pharmaceutical maker. These marked the first steps on the road to creating a new generation of high-quality medicines needed by society.



MR training session



NS Pharma

To create a new therapeutic area to drive the growth of the business, we initiated Japan’s first antisense oligonucleotide research program. We also invested in related manufacturing infrastructure to support business expansion, constructing new production facilities for clinical trial APIs in Kyoto and for highly active solid formulations in Odawara to enable the development of nucleic acid medicines and other highly active pharmaceuticals.

With the “pursuit of originality” as our management theme, we focused in-house drug discovery and in-licensing efforts on niche areas where major pharmaceutical firms are less involved, actively targeting diseases with unmet medical needs based on a philosophy of delivering new hope to patients. We created a stream of new products while applying product life cycle management (PLCM) methods to manage the portfolio of existing drugs.



Clinical trial API manufacturing facility



Highly active solid formulation production facility (Odawara Central Factory)

Challenges We Face

Challenge #1 Patients affected by rare diseases

400 million

Compared with cancer, diabetes or other conditions that affect many people, rare diseases affect relatively small numbers of people. Different definitions exist, but more than 7,000 rare diseases have been reported that affect roughly 400 million* people worldwide. Many rare diseases are intractable, with no cure or effective treatment. This leaves patients with an uncertain future, and, in many cases, requiring lifelong medical care. There is a clear need to develop treatments to help these patients as quickly as possible.

* Source: RARE Disease Facts, Global Genes (NPO)

Challenge #2 Food waste

1.3 billion tons/year

Each year approximately 1.3 billion tons of food, equivalent to roughly one-third of global food production, goes to waste. In Japan, annual food waste is estimated at 6.12 million tons* (FY2017). Some of this waste is unsold goods and returns by retail stores (commercial waste), and some is classified as domestic food waste by households. The Japanese government has set a target of halving food waste by FY2030 compared with FY2000 levels.

Neglecting the issue of food waste risks environmental degradation or future food crises if human populations continue to increase. Reducing food waste is a vital issue that must be addressed globally.

* Source: Consumer Affairs Agency (reference materials on food waste reduction, November 30, 2020)

Challenge #3 Worst-case temperature rise by 2100

Approx. 4°C*

The world faces growing environmental impacts each year from extreme weather events and natural disasters. The COP21 conference in Paris saw global leaders agree to the goal of restricting the rise in global temperatures by 2100 compared with a pre-industrial baseline to no more than 2°C, and if possible to a rise of just 1.5°C. Ensuring future generations inherit the bounty of nature means recognizing that business activities must co-exist in harmony with the Earth's environment.

* IPCC Fifth Assessment Report (published 2014)

Nippon Shinyaku's Approach

Approach #1

Find small molecule or oligonucleotide drugs through innovative R&D

Based on innovative in-house R&D, Nippon Shinyaku has developed small molecule and oligonucleotide drugs as treatments for two rare diseases: Uptravi for pulmonary arterial hypertension, and Viltepso for Duchenne muscular dystrophy. These products offer new and effective therapeutic options for patients affected by these rare and previously intractable diseases.

Yet many rare diseases still lack effective treatments. Our goal is to develop more treatments for rare diseases with high unmet medical needs, focusing not only on small molecules and oligonucleotide drugs, but also on new drug discovery modalities such as gene therapy. Through R&D, we aim to offer hope to patients and their families by delivering new and effective medicines for rare conditions.



Approach #2

Help to reduce food waste

Developing long-life foods is an effective way of reducing food waste. Utilizing in-house R&D, Nippon Shinyaku is working to develop original technology to create long-life formulations for different foods. Incorporating AI-based technologies, we are developing preservatives to enable longer shelf lives for foods without loss of taste or quality. Such products can play a role in reducing global food waste.



Approach #3

Take positive action on climate change

Having previously identified measures to address climate change as a materiality issue, Nippon Shinyaku has instituted the Basic Environmental Policy to define our corporate social responsibilities towards the environment while guiding the efforts to mitigate environmental impacts across our entire business operations as a critical management issue. We have set related environmental performance targets that are reviewed and managed using a 3-year PDCA cycle. Under the 6th Nippon Shinyaku Environmental Targets Plan (FY2020–2022), we aim to reduce CO₂ emissions by 25% relative to the baseline year of FY2013 by FY2030. Programs to reduce emissions are focused on cutting energy consumption and generating more energy from renewable sources, among other measures.

