We are always innovating in every aspect of our business.

Chugai in Action

Overview of Activities in 2018

Category	Main initiatives	Connection with IBI 21 strategies* 1	2	3	4	5
Research	• Continuously generating first-in-class[1] and best-in-class[2] drugs	●				●
	• Creating molecular targeted drugs that contribute to personalized healthcare (PHC)	●	●	●		●
	• Strengthening innovative proprietary research technologies and creating innovative antibodies	●				●
	• Providing support and education for researchers from Asia				●	
	• Maintaining high animal welfare standards in accordance with international guidelines					●
Development	• Improving clinical development of drugs to address unmet medical need	●		●	●	●
	• Identifying latent medical need[3] and achieving early PoC[4]	●			●	
	• Increasing productivity and speed of global clinical development for early market launches	●		●	●	●
	• Conducting simultaneous development and regulatory filing of drug therapies and diagnostics that contribute to PHC	●		●	●	●
	• Strengthening lifecycle management to maximize product value	●		●	●	●
	• Obtaining early approval for projects in-licensed from Roche	●			●	
Pharmaceutical Technology and Production	• Providing a stable supply of high-quality drugs and investigational drugs	●	●			●
	• Enhancing the system for faster global launches and simultaneous development of multiple products	●	●			
	• Achieving early PoC by raising the level of CMC[5] development	●			●	
	• Raising the level of competitive advantages from late-stage development to initial commercial production (including investigation of next-generation industrial technologies)					●
	• Achieving world-class quality control, quality assurance and regulatory functions	●				●
Marketing	• Contributing to advances in medicine as Japan's leading therapeutic antibody company		●			
	• Promoting standards of care and proper use of medicines in oncology		●	●		
	• Promoting PHC for optimal treatment options		●	●		
	• Supporting the resolution of medical issues in mainstay product areas and regions		●			
	• Patient-centric consideration of therapeutic approach		●			
Medical Affairs	• Building a consistent global medical affairs promotion system with proper independence of roles		●			
	• Strengthening systems for healthcare compliance and governance of contract-based post-marketing studies		●			
	• Conducting area-based evidence creation and promoting scientific communication activities		●			
	• Introducing, expanding and upgrading global medical information functions		●			
Drug Safety	• Strengthening pharmacovigilance system to meet the world's strictest standards and most comprehensive global regulations					●
	• Providing solutions to patients and healthcare providers using drug safety information		●			
	• Preparing and implementing risk management plans (RMPs)		●			●
Quality and Regulatory Compliance	• Enhancing production system for Actemra, Alecensa and Hemlibra, which are innovative products from Chugai research	●			●	
	• Developing cross-organizational quality and regulatory compliance framework in order to strengthen quality control, quality assurance and regulatory intelligence functions					●
	• Strengthening compliance risk management throughout the product lifecycle and carrying out quality management that fosters a culture of quality					●
Intellectual Property	• Protecting and effectively using rights for broadly applicable innovative technologies		●	●	●	●
	• Filing high-quality patent applications and effectively allocating resources	●	●	●	●	●
	• Aggressively filing patent applications outside Japan with a view to global co-development	●	●	●	●	●

1. An original drug that is highly novel and useful, and will significantly change the therapeutic system
2. A drug that offers clear advantages over other existing drugs in the same category, such as those with the same molecular target
3. Medical need that is not adequately met due to a lack of effective treatments
4. PoC is confirmation that the therapeutic effect conceived in the research stage is effective in humans. Early PoC means that in addition to safety, signs of efficacy or pharmacological effect have been confirmed in a limited number of cases.

*1: Value Creation; 2: Value Delivery; 3: Promote Advances in PHC;
4: Strengthen Human Capital and Conduct Fundamental Structural Reform; 5: Strengthen Sustainable Platforms

Main performance indicators in 2018

- In-house products in development pipeline: 15 (as of January 31, 2019)
- Academic papers and presentations at scientific conferences regarding Chugai's innovative proprietary technologies: 53 (2014-2018)
- Published academic papers regarding Chugai's research findings: 90 (2014-2018)
- R&D expenditures to revenues: 16.2%

- Expanded business at Singapore subsidiary Chugai Pharmabody Research Pte. Ltd.
- Created development projects using Chugai's Recycling Antibody®, Sweeping Antibody®, bispecific antibody and other proprietary antibody technologies
- Started operation of a collaborative lab at IFReC based on an agreement with Osaka University and conducted full-scale assessment and introduction of candidate compounds
- Held "Chugai 3R Day" training on animal welfare for all research staff involved in laboratory work

- Pipeline projects: 48 (as of January 31, 2019)
- New products launched and new indications: 15 (2014-2018)
- PHC-based development projects: 27 (as of January 31, 2019)
- Projects in-licensed from Roche: 15 (2014-2018)

- Projects being co-developed with Roche Group: 37 (as of January 31, 2019)
- Projects in response to development requests for unapproved drugs/indications: 4 (2014-2018)

- Invested in facilities for faster launches and simultaneous development of multiple antibodies and small molecule drugs (established new biological API manufacturing facility at Ukima Plant (UK3), enlarged solid formulation manufacturing facility at Fujieda Plant, etc.)
- Received FDA pre-approval inspection and approval for Actemra (new manufacturing method)
- Received pre-approval inspection and approval for Hemlibra in countries around the world

- Strengthened global supply chain management
- Enhanced next-generation core technologies for API manufacture and formulation
- Strengthened development ability by reducing costs from the early stage onward and planning and implementing a dosage form strategy
- Established a system for quality control functions to enhance specialization and raise operational efficiency

- Share of sales in the Japanese therapeutic antibody market: 24.5%[6]
- Share of sales in the Japanese oncology market: 17.9%[6]
- Satisfaction ranking based on healthcare providers' assessments (hospitals with 100 or more beds)[7]: 1st
- Adequacy ranking for provision of safety information based on healthcare providers' assessments (hospitals with 100 or more beds): 1st[8]
- Education for MRs with a high level of expertise

- Enhanced communication of safety information through use of post-marketing surveillance and adverse reaction databases and cooperation with Safety Experts
- Enhanced marketing functions based on local area characteristics
- Patient-centric support activities for regional healthcare and multidisciplinary team care
- Promotion of proper use of medicines through trial service of an app that supports adherence to medication by facilitating smooth communication between patients and their healthcare providers
- Promoted disease awareness in cooperation with the government

- Contract-based post-marketing studies: 28
- Staff with GCP Passport (JSCTR certification): 154 (as of January 31, 2019)
- Number of joint preclinical studies: 11

- Published research papers on Chugai's preclinical studies: 11
  Presentations at scientific conferences: 5 overseas, 6 in Japan
- Inquiries to the Medical Information Department: 56,120 (including telephone, e-mail and fax inquiries)

- Cases for which drug safety information was collected from Japan and overseas according to global standards for clinical trials and post-marketing studies: 18,400
- Increased capacity for generating drug safety information using advanced technologies such as epidemiology and information technology, and enhanced the activities of Safety Experts, a new specialist position for handling drug safety information

- RMPs prepared and implemented for thorough risk management: 12 products
- Papers and conference presentations on drug safety based on the results of post-marketing surveillance: 9

- Developed quality and regulatory compliance framework for genomic mutation analysis program FoundationOne® CDx Cancer Genomic Profile and obtained regulatory approval
- Prepared for inspection and obtained approval from FDA for Actemra (new production method), and Alecensa and Hemlibra (additional production sites)

- Formulated and circulated a global policy on counterfeit drugs, and raised awareness through activities in cooperation with Roche and at scientific conferences in Japan and overseas
- Carried out awareness activities targeting all fundamental organizational units and introduced risk management methodologies at all companies in order to foster a "culture of quality" as recommended by the FDA

- Patents held (including pending applications): 4,647
- New patents granted worldwide: 213
- Market defense in lawsuits with manufacturers of similar products with the equivalent effect or developers and manufacturers of biosimilars

- Operated a system for monitoring other companies' patents
- Strengthened cooperation with the Research Division and Pharmaceutical Technology Division using IP liaisons as a hub

5. Chemistry, Manufacturing and Controls: A concept that integrates API process research and pharmaceutical development research with quality evaluation research
6. Copyright © 2019 IQVIA. Source: JPM 2018. Reprinted with permission. The scope of the market is defined by Chugai.
7. Copyright © 2019 anterio. Source: Rep-i 201808. Reprinted with permission. Based on a survey of overall assessments of companies by physicians, as defined by Chugai.
8. Based on an anterio market survey in 2018 for understanding safety information needs

E: Environmental Protection; S: Providing Value to Society; G: Human Resources

Category	Examples of ESG initiatives in each division	E	S	G
Research	• Fostered employee awareness of energy saving through energy visualization	●		
	• Continued joint cleanup activities with a local high school for the Shinkawa River, which flows through the Kamakura Research Laboratories site	●		
	• Conducted activities at Kamakura Research Laboratories to raise awareness of the importance of cancer screening		●	
	• As part of the Company's support for recovery from the Great East Japan Earthquake, held a charity sale at the Kamakura Research Laboratories of specialty products from the affected area		●	
Development	• Fostered a corporate culture where employees can participate actively after returning from childcare or other leave			●
	• Held cross-cultural training to cultivate leaders who can succeed globally			●
	• Held study sessions with instructors from other industries to promote global success			●
	• Held the Quality Forum to foster a corporate climate for becoming a top pharmaceutical company			●
Pharmaceutical Technology and Production	• Reduced greenhouse gas emissions with the scheduled introduction of high-efficiency air conditioning	●		
	• Promoted reduction of energy consumption through an energy visualization task force	●		
	• Conducted firefighting activities in cooperation with local fire departments		●	
	• Promoted "Techno" technology review activities to create new core competencies and strengthen basic technologies			●
	• Held U-MAST (at Utsunomiya Plant), UK-NEXT (at Ukima Plant) and F-OPEX (at Fujieda Plant) as initiatives to train young employees through proposal and improvement activities			●
	• Held interdivisional exchange meetings (Knowledge Cube for Marketing & Sales, Medical Affairs and Pharmaceutical Technology divisions and BRIDGE for Research, Clinical Development, Translational Clinical Research and Pharmaceutical Technology divisions)			●
Marketing	• Promoted proper use of medicines through support for improvements in the rate and accuracy of testing		●	
	• Participated in Lung Cancer Awareness and attended to patient requests regarding drugs		●	
	• Conducted support activities for working while undergoing breast cancer treatment		●	
	• Promoted disease awareness through cooperation with businesses in other industries		●	
	• Held the Bone and Joint Forum 14 times as a measure against locomotive syndrome		●	
	• Disseminated information on a new issue related to cancer treatment (cancer patient dementia) through the Chugai website		●	
Medical Affairs	• Conducted a training program from the standpoint of cultivating global medical human resources			●
	• Measures to evaluate the effect of drugs on improving conditions for working during outpatient treatment		●	
Drug Safety	• Promoted paperless operations for stored materials and meeting materials	●		
	• Provided the latest drug safety information through lectures and awareness-raising activities for the media		●	
	• Contributed to the enhancement of Japan's epidemiological database		●	
	• Contributed to regulatory reforms and strengthening of drug safety monitoring systems in Japan and overseas through industry activities		●	●
Quality and Regulatory Compliance	• Held information-exchange events for contract manufacturing organizations to share examples of Chugai best practices to ensure compliance with new regulations and regulatory trends		●	
	• Promoted reduction in paper consumption through the introduction of an electronic document archive system and digitalization of existing paper documents	●		
	• Provided direct advice on amendments to the Law for Ensuring the Quality, Efficacy and Safety of Drugs and Medical Devices through industry activities		●	
	• Promoted activities to foster a "culture of quality" as recommended by the FDA			●
Intellectual Property	• Created and operated a paperless process for applications for public disclosure approval	●		
	• Established a separate organization specializing in intellectual property disputes (IP Liaison Group)			●

Chugai's 2018 in Review

Products and Development Projects	
January	Tecentriq intravenous infusion 1200mg obtained approval (unresectable, advanced or recurrent non-small cell lung cancer; Japan)
February	Hemlibra obtained approval (hemophilia A with inhibitors; E.U.)
March	Hemlibra obtained approval (hemophilia A with inhibitors; Japan)
April	**Hemlibra received breakthrough therapy designation** (hemophilia A without inhibitors; U.S.)
April	**Tecentriq launched (Japan)**
May	Alecensa obtained approval for additional indication (first line therapy for ALK-positive non-small cell lung cancer; Taiwan)
May	**Hemlibra launched (Japan)**
June	**Hemlibra received priority review designation (hemophilia A without inhibitors; U.S)**
July	Gazyva intravenous infusion 1000 mg obtained approval (CD20-positive follicular lymphoma; Japan)
August	**Gazyva launched (Japan)**
September	**Chugai and Eli Lilly and Company entered into a license agreement for GLP-1 receptor agonist OWL833**
October	Hemlibra obtained approval for additional indication (hemophilia A without inhibitors; U.S.)
October	Perjeta obtained approval for additional indication (neoadjuvant and adjuvant therapy for HER2-positive early breast cancer; Japan)
December	Hemlibra obtained approval (hemophilia A with inhibitors; Taiwan)
December	**Satralizumab received breakthrough therapy designation** (neuromyelitis optica and neuromyelitis optica spectrum disorder; U.S.)
December	Hemlibra obtained approval for additional indication (hemophilia A without inhibitors; Japan)
December	Tecentriq obtained approval for additional indication (unresectable, advanced or recurrent non-small cell lung cancer; Japan)
December	Chugai obtained approval for genomic mutation analysis program FoundationOne® CDx Cancer Genomic Profile (Japan's first program with two functions of cancer genomic profiling and companion diagnostics, it enables oncology gene panel profiling)

Management	
January	Transferred 13 long-listed products from Chugai to Taiyo Pharma
March	Appointed new CEO
March	Entered a license agreement with Roche to begin activities toward commercialization of the products of FMI in Japan
July	FMI business unit established
July	Extended Chugai Pharmabody Research operations for five years and committed to investment totaling 282 million SGD from 2022 through 2026
July	Decided to construct a new building for synthetic research at Ukima Research Laboratories to enhance process development for small and middle molecule APIs
July	Entered into comprehensive partnership agreement with Preferred Networks, Inc.

Stakeholders	
March	Selected as a 2017 Tokyo Sports Promotion Model Company
March	Selected as a Nadeshiko Brand for the fourth consecutive year and recognized in the New Diversity Management Selection 100
August	Obtained Platinum Kurumin certification from the Minister of Health, Labour and Welfare as a company supporting childrearing; the number of male employees taking childcare leave increased sevenfold in two years
September	Selected for the fourth time for Dow Jones Sustainability Asia Pacific Index
September	Donated para-transit vehicles to welfare services
October	Expressed support for the Japan Climate Action Summit Declaration
October	First in the pharmaceutical industry to begin providing a treatment support app for immune checkpoint inhibitors using multidisciplinary SNS
October	Xeloda® adherence support app began contributing to improving communication between cancer patients and healthcare providers
December	Establishment of Gan with, an information website for cancer patients, their families and coworkers

Organizational Facts and Figures

(Non-consolidated; as of December 31, 2018)

Number of employees	5,037
Ratio of female employees	27.3%
Ratio of female managers[1]	13.3%
Number of female officers[2]	1
Average tenure	Male: 18.4 years Female: 13.0 years
Number of employees posted through the Roche Human Resource Exchange Program (2004-2018)	174
Percentage of employees using the telecommuting system[3]	34.5%
Percentage of employees taking childcare leave[4]	Male: 57.7% Female: 100.0%

1. Number of female managers as a percentage of the total number of managers
2. Officers as per the Companies Act
3. Percentage of eligible employees who used the system
4. Percentage of employees who have had children

Research

IBI 18 (2016–2018)

- Continuous new drug creation using proprietary antibody technologies
- Establishment of a technology platform for middle molecule drugs
- Strengthening of the research base for oncology/immunology using external network

IBI 21 (2019–2021)

- Construction of leading drug discovery technologies and continuous addition to pipeline
- Creation and promotion of innovative projects through the deepening of biological research into human diseases
- Expansion of opportunities to acquire new candidate compounds using external network

Continuation → Evolution

S (Strengths)

- Proprietary drug discovery technology, particularly in biotechnology (in-house products: 15[1], no. of academic papers and presentations at scientific conferences regarding Chugai's innovative proprietary technologies: 53[2])
- Efficient collaboration with the Roche Group, including infrastructure sharing (Ratio of research and development expenditures to revenues: 16.2%)

W (Weaknesses)

- Infrastructure for recruiting researchers is incomplete
- Lack of resources for biotechnology research

O (Opportunities)

- Progress in new modalities, including middle molecule drugs
- Mounting social expectations on drug discovery and healthcare as a growth industry

T (Threats)

- Increasing difficulty and escalating cost of new drug development worldwide, and intensifying competition
- Potential paradigm shift due to disruptive technologies, etc.

1. As of January 31, 2019 2. 2014-2018

Functions

Chugai began conducting research and development of biopharmaceuticals more than 30 years ago, and the former Nippon Roche had also established world-class technology for the discovery of chemically synthesized agents. Over the years, we have cultivated knowledge and gained experience through our own pioneering initiatives while also incorporating outside technologies. As a result, we have continuously evolved our capabilities, and have built a technology platform that we can flexibly and appropriately apply to drug discovery.

We are using this platform to generate a steady stream of innovative new drugs with first-in-class or best-in-class potential to address unmet medical need. In addition to developing antibody engineering technologies ahead of other companies, Chugai has industry-leading research and technological capabilities backed by small and middle molecule[1] technologies, the world-class research infrastructure of the Roche Group and a powerful external network with academia and other parties. Through presentations of research findings at scientific conferences and other means, these strengths lead to benefits for the medical community around the world as we leverage them in the creation of in-house projects.

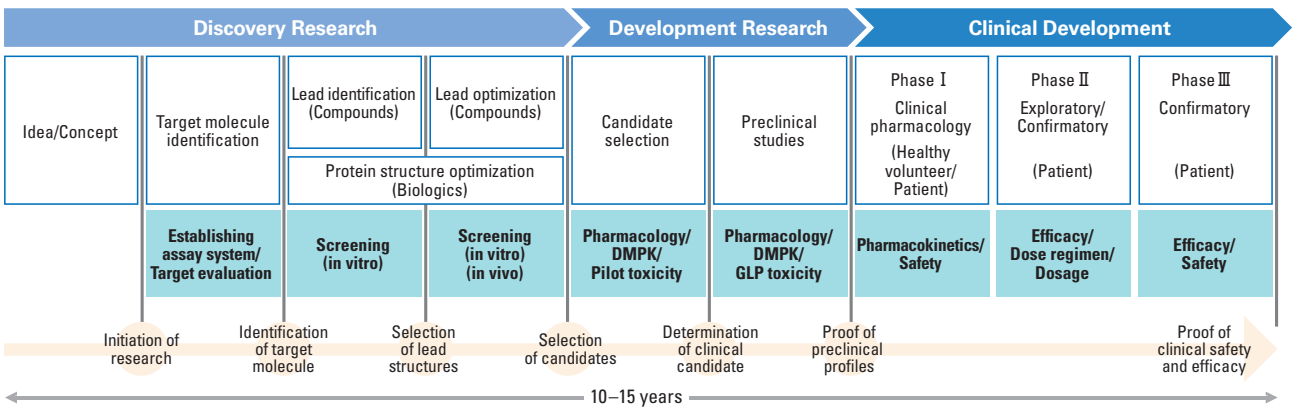
1. Middle molecules have significant potential because they are capable of inhibiting protein-protein interaction (PPI) in intercellular molecules, which is difficult to achieve with antibodies and small molecules.

Business Model

One of Chugai's strategic advantages that enables it to continuously create innovative drugs is its ability to concentrate resources on innovative research. Efficient development in Japan of projects in-licensed from Roche provides a stable revenue base while we conduct global development of projects from our own research in collaboration with Roche. This enables us to concentrate personnel and funds on groundbreaking in-house projects, leading to the creation of a steady stream of innovative drugs. Another powerful advantage is our access to Roche's global research infrastructure. The ability to share Roche's global research resources and infrastructure, including a rich compound library for use in high-throughput screening,[2] is a significant plus for Chugai in terms of cost, efficiency and other factors, and has dramatically increased our research productivity.

2. A technology that conducts evaluations at a high speed with robots or other means to select chemical compounds having activities for drug creation targets from a library consisting of a vast number of compound types with various structures

Process and Milestones of Drug Development



In addition, by concentrating on the creation of new therapeutic antibodies, Chugai Pharmabody Research (CPR), which we established in Singapore in 2012, is working to continuously create innovative therapeutic antibody drugs that apply our proprietary antibody engineering technologies and to accelerate the speed of drug discovery.

Allocation of Resources

In allocating research resources, we prioritize each project based on the following criteria:
(1) The project's potential for development as a novel medicine that can be clearly differentiated
(2) Whether it has a scientific basis for addressing unmet medical need
(3) Whether it will enable personalized healthcare (PHC)

At decision points during research, we focus first and foremost on patient need in the belief that creating medicines truly needed by patients and healthcare providers will lead to Chugai's medium-to-long-term growth.

Bioethics and Animal Welfare

To ensure that research using human-derived test material is carried out appropriately, Chugai has established Ethical Guidelines for Research That Uses Human-Derived Test Material and a Research Ethics Committee. More than half of the members of this committee are from outside the Company, enabling fair evaluations from a pluralistic frame of reference.

Moreover, when handling laboratory animals used in research, Chugai acts in accordance with the Guidelines for the Care and Use of Laboratory Animals it has established to respect their lives from the standpoint of animal welfare, and to minimize their pain, keeping in mind the scientific conditions.

In 2018, we also held the Chugai 3Rs Day as part of our promotion of the principles of the 3Rs (Replacement, Reduction and Refinement) and animal welfare. Through such activities, we strive to raise awareness of animal welfare among all employees working in our laboratories.

Main Initiatives and Progress

Creation of Innovative New Drugs

In 2018, PHC-based projects represented 56 percent of our total pipeline, including projects in-licensed from Roche. Hemlibra received approval as a treatment for hemophilia A in the United States in November 2017, and in Europe and Japan in 2018. It is the first project applying our proprietary antibody technologies to be approved.

Collaboration with Our External Network

In April 2017, a collaborative lab began operating under our comprehensive agreement with Osaka University Immunology Frontier Research Center (IFReC) to conduct ongoing assessment and introduction of new candidate compounds from its cutting-edge immunology research.

Immunity is involved not only in diseases of the immune system itself, but also in cancer and various other diseases, and immune-mediated therapies are now becoming mainstream cancer treatments. Combining the global top-class research in immunology at IFReC and Chugai's expertise in drug discovery research, accumulated through its proprietary technologies, is expected to result in the creation of innovative new drugs.

We are also looking to innovate the drug discovery process itself, including for next-generation personalized healthcare, by applying the highly advanced genomic analysis techniques and other capabilities of FMI, which joined the Roche Group in 2015.

Research at Satellite Labs

Research at satellite labs has also yielded solid results, leading to the successful establishment of stable cell lines of colon cancer stem cells in October 2012 and the identification of new drug targets at Forerunner Pharma Research Co., Ltd. CPR is making steady progress in the discovery of new therapeutic antibodies, with GYM329 entering clinical development in 2018 after SKY59. In addition, C&C Research Laboratories in South Korea is conducting small molecule drug discovery research, mainly in the fields of oncology and immunology.

Evolution of Drug Discovery Modalities

In the pharmaceutical industry, modality refers to the material classification of drugs such as therapeutic antibodies or therapeutic nucleic acids. Until around 1990, small

Progress of Development Projects

(January 1, 2018 – January 31, 2019)

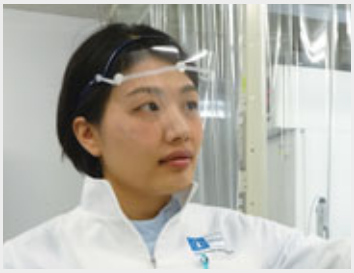
	Number of Projects	Breakdown		
		New Molecular Entities	Additional Indications	Additional Dosage and Administration/ Formulations
Approved	13	6	5	2
Filed	17	3	10	4
Started phase III	10	5	5	0
Started phase II	1	1	0	0
Started phase I	6	6	0	0
Development suspended	4	3	1	—

Comparison of Drug Discovery Modalities

	Small molecules	Middle molecules	Biologics
Molecular weight	Below 500	500 - 2,000	10,000 and above
Target specificity	Fair	High	High
Intracellular targets	Wide range	Numerous	Limited
PPI inhibition	Fair	Good	Good
Administration route	Oral/Injection	Oral/Injection	Injection
Manufacturing method	Organic synthesis	Organic synthesis	Cell culture

*PPI: Protein Protein Interaction

I am establishing a new assay system for selecting middle molecule candidates. By identifying the characteristics of distribution and metabolism within the body, including uptake through the cellular membrane, we will be able to select middle molecule candidates that are readily absorbed following oral administration. This will lead to greater convenience for patients and stable efficacy.



Hengmin Tang
Discovery DMPK Group 3,
Discovery ADMET Dept.

molecule drugs were virtually the only modality available, but modality options are now increasing. Chugai is currently focusing on establishing middle molecules as a third modality in addition to biologics and small molecules, in which it is already strong. Middle molecules are a valuable method for reaching intracellular targets that are difficult to approach using antibodies and small molecules, and we are proactively promoting the establishment of a hit/lead compound generation technology platform as we work toward the creation of development projects.

Enhancing our Intelligence Functions

Rapid scientific and technological advances, especially in life science and information and communications technology (ICT), are bringing dramatic changes to society and the pharmaceutical industry. Chugai's Science and Technology Intelligence (STI) Department was established in April 2017 as an intelligence unit to consider Chugai's response to emerging issues in the healthcare business.

Healthcare in the future is expected to center on PHC, which provides optimal solutions tailored to individual patients, and in addition to diagnosis and treatment, which are the focus of the current model, greater value will need to be provided in areas such as prevention and prognosis. Our goal is to contribute to higher-quality healthcare with solutions that lead to new value, and a critical part of that effort is formulating strategies for disruptive innovation,[3] which will be essential for realizing such solutions.

STI's mission is to find promising seeds for pursuing disruptive innovation, and to create strategies for bringing it about. In the three areas of life science, healthcare ICT, and data utilization, STI will perform radar, hub and intelligence functions in cooperation with internal cross-functional teams of experts. A number of projects have already begun.

In July 2018, Chugai entered into a comprehensive partnership agreement with Preferred Networks, Inc. (PFN), a global leader in AI technology. We aim to create innovative drugs and new value through the application of PFN's cutting-edge deep learning technology and Chugai's expertise, technologies and data.

3. Innovation that disrupts the order of existing business and causes drastic changes in the industry structure

Chugai's Proprietary Technologies

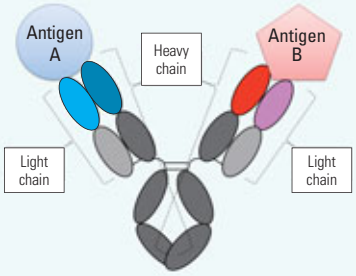
Drug discovery technologies, largely antibody engineering technologies, are Chugai's core competence. We are focused on development of proprietary technologies that are necessary for addressing areas of unmet medical need. Their application leads to the generation of innovative and competitive medicines.

Chugai's research and development operations have focused on the development of new antibody engineering technologies to create a series of technologies that overturned conventional wisdom about antibody engineering. Examples include the development of our Recycling Antibody®, Sweeping Antibody® and bispecific antibody technologies. In addition to antibody engineering and small molecules, we have selected drug discovery technologies for middle molecules as a candidate for our next-generation core technology. We intend to concentrate investments in this area to establish this new technology and quickly generate new projects.

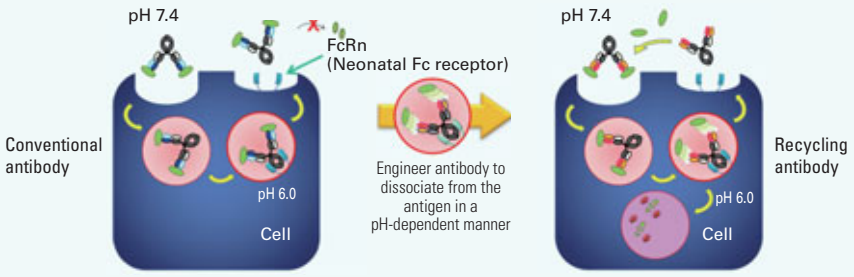
Eight Technologies

Antibody technology	Features
SMART-Ig®	Creates the Recycling Antibody®, which has a longer duration of action than conventional antibodies because it can bind to an antigen multiple times.
SMART-Fc®	Creates the Sweeping Antibody®, which eliminates disease-causing antigens from plasma.
ART-Ig®/FAST-Ig®	Enable large-scale production of bispecific antibodies. Unlike conventional antibodies that bind only to a single antigen, bispecific antibodies bind to two different antigens, and are therefore expected to exhibit efficacy in a variety of ways.
ART-Fc®	Enhances the antibody-dependent cellular cytotoxicity (ADCC) activity using ART-Ig®. Induces enhanced ADCC activity compared with existing technologies. Potential applications in the oncology field.
TwoB-Ig®	Increases binding selectivity of the Fc region to inhibitory Fcγ receptor IIb. Potential applications in autoimmune diseases and other areas.
TRAB®	Activates T cells in an antigen-dependent manner to specifically kill cancer cells.
ACT-Ig®	Reduces clearance from plasma.

Bispecific Antibody



Effect of Recycling Antibody® against Soluble Antigen in Plasma



- Antibody can bind to the antigen only once
- Antigen persists as an antibody bound form, accumulating in plasma

- Antibody can bind to the antigen multiple times
- Prevents antigen accumulation by discarding the antigen within the cell

Development

IBI 18 (2016–2018)

- Maximization of the value of Roche products through simultaneous global development and regulatory filing
- Global development and early acquisition of PoC for Chugai products
- Implementation of an IDCP[1] from the initial stage of development to maximize the value of each Chugai product

IBI 21 (2019–2021)

- Establishment of development methods for Chugai products with new modalities and mechanisms of action
- Further acceleration of development through use of data assets
- Maximization of product value based on VBHC[2]

Continuation Evolution

1. Integrated Development and Commercialization Plan 2. Value-based healthcare

S (Strengths)
- Comprehensive development track record (total no. of clinical trials: 104[1])
- High development success rate of innovative in-house products (FPI[2]: 3 projects; breakthrough therapy designation (BTD)[3]: 1)[1]
- Global collaboration with Roche (global studies: over 60%; joint development projects: 21)[4]

W (Weaknesses)
- Evolution of quality and speed at a top global level in early development
- Constant and cross-functional operation of the process for proof of value
- Infrastructure development and acquisition of human resources for utilization of real world data (RWD), data assets, and cutting-edge technologies

O (Opportunities)
- Increasing expectations for development of innovative drugs using proprietary technology
- Advances in development of personalized healthcare using large-scale data such as genetic information
- Greater flexibility and diversification in the application filing process

T (Threats)
- Intensified global competition in new drug development and escalating development costs
- Potential paradigm shift due to disruptive technologies, etc.
- Decline in competitive advantage of in-house products due to the emergence of new modalities

1. January-December 2018 2. First patient in 3. A system introduced in July 2012 by the U.S. Food and Drug Administration aimed at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms 4. As of December 31, 2018

Functions

Chugai has established a lifecycle management[1] system for project-level integrated management of each of its functions, and cooperates with numerous medical institutions and clinical research centers. In this way, we work to implement clinical trials distinguished by exceptional speed, efficiency and scientific rigor.

Specifically, in clinical development, we draw up clinical development plans based on the latest scientific findings and invite medical institutions to conduct clinical trials. In pharmaceutical technology and production, we examine commercial production that will turn candidate compounds into pharmaceutical products and manufacture investigational drugs for clinical trials. In drug safety, we ensure a high level of safety in clinical trials by gaining an understanding and beginning assessments of each drug's safety profile from the early stages.

Through our alliance with the Roche Group, we are implementing multiple global development projects (multinational studies) and strengthening the process that enables simultaneous development of drugs and companion diagnostics intended for personalized healthcare (PHC). Through these initiatives, we are creating best practices in development and filing for approval in Japan, which we believe contribute to the advancement of the industry.

1. The various measures taken to maximize the potential value of a drug, including shortening development time, expanding sales, extending the product's life, and conducting appropriate cost control. Competitiveness can be strengthened further by using earnings from sales of established drugs to strategically reinvest in new drug development, marketing or other areas.

Enhancement of Functions and Organizational Change

In October 2018, Chugai partially reorganized its Translational Clinical Research (TCR) Division. The aim of the change was to promote the development of in-house products that have passed from research to the early clinical development stage. From this perspective, we changed the name to the Translational Research (TR) Division, which functions as a bridge between preclinical and early clinical development. For overseas development of projects from in-house research, U.S. subsidiary Chugai Pharma USA and U.K. subsidiary Chugai Pharma Europe conduct high-quality clinical trials in close cooperation with medical institutions in the United States and Europe.

We also accelerate global development by sharing knowledge and platforms for clinical development with the Roche Group. Moreover, we utilize Foundation Medicine Inc. (FMI)[2] and others to generate evidence that will lead to PHC from the clinical development stage.

In the Clinical Development Division, we have established the new Clinical Information & Intelligence Department to work as a hub for the collection, management, analysis and transmission of all clinical development data. The aim of the department is to strengthen data utilization and intelligence functions, which enable the planning of optimal clinical development strategies.

2. FMI was established in Massachusetts, U.S.A. in 2010. In 2015, Roche took a majority stake, and then acquired the remaining outstanding shares in 2018 to make FMI a wholly-owned subsidiary. Chugai established the FMI business as a specialized unit in October 2018 to carry out commercialization and product value maximization of FMI's "Comprehensive Genomic Profiling Service" in Japan.

Main Initiatives and Progress

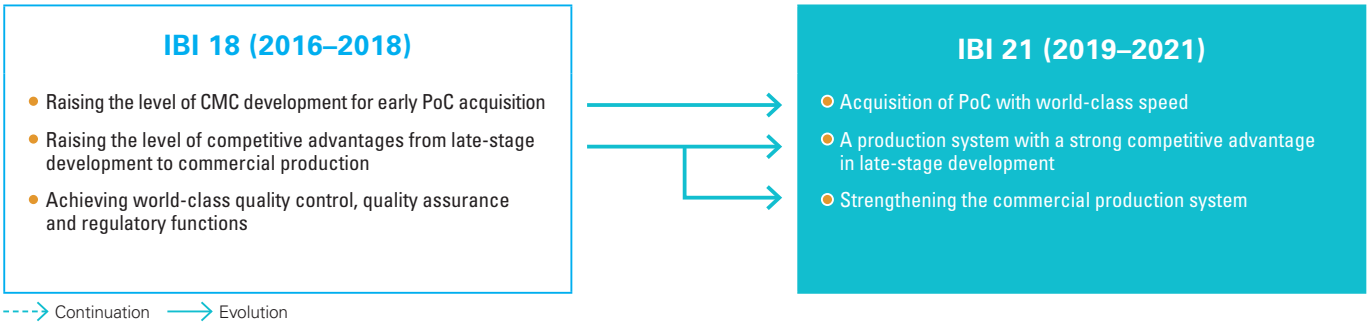
A Well-Stocked Pipeline

In 2018, all projects made steady progress. Chugai filed for regulatory approval for 5 projects, and obtained approval for 6 projects. Chugai's pipeline grew even richer, with 6 new projects in-house or in-licensed (from Roche) advancing to the clinical phase.

Speedy Global Development

Chugai has been working to speed up global development by following a development model with a high probability of success and by making efforts to prove the value of in-house projects from the early stages of development. As a result, Alecensa took just seven years from concept to launch in Japan, and Hemlibra, for which we filed for approval simultaneously in Japan, the United States and Europe, obtained approval in less than five years, far ahead of our initial plan. Hemlibra is dramatically transforming treatment strategies for hemophilia and achieving unprecedented results. Moreover, now that nemolizumab (CIM331) has acquired PoC and satralizumab (SA237) has obtained positive results in global studies under Chugai's management, we are taking on the new challenge of global filings for approval during 2019 in collaboration with Roche.

Pharmaceutical Technology and Production



S (Strengths)
- Advanced therapeutic antibody production technology and state-of-the-art equipment (cultivation capacity: approx. 130,000 L)
- Proven track record of global inspections and applications (New manufacturing processes of Hemlibra, Alecensa, and Actemra)

W (Weaknesses)
- Information collection and system development on the latest global regulations, including data integrity
- Efficient development of production system utilizing external resources

O (Opportunities)
- Fast-track review system to support early approval of innovative new drugs
- Initiation of a system for pharmaceutical quality management

T (Threats)
- Progress in global control over drug costs, the shrinking domestic market amid drastic reform of NHI drug prices
- Loss of premium pricing status for new drug creation on mainstay products and the emergence of generic drugs
- Potential paradigm shift due to disruptive technologies, etc.

Functions

Our pharmaceutical technology and production functions play a wide range of roles in the pharmaceutical value chain – from turning drug candidates into products to stably supplying them. These candidates may be compounds created in our laboratories or projects in-licensed from Roche or elsewhere.

Product creation includes research on production methods for active pharmaceutical ingredients (APIs), formulation and packaging design, production of investigational APIs, and collection and analysis of production data. Among these activities, we have most recently been taking positive steps to build and patent a new technology platform that will give us a distinct advantage in commercial production of innovative medicines such as next-generation antibodies and middle molecules.

Through stable supply of our products, we maintain the trust of patients and healthcare providers – a duty central to Chugai's existence as a pharmaceutical manufacturer. That is why we need to build and maintain a robust supply chain with production bases (including contract manufacturing organizations) in various regions around the world.

Chugai has competencies at Japan's top level, including bioproduction technology and the ability to accommodate inspections. We will leverage our strengths as a member of the Roche Group to become a top innovator in our pharmaceutical technology and production operations.

Main Initiatives and Progress

Improving Flexibility and Speed

In its pharmaceutical technology and production operations, Chugai is aiming for simultaneous development of multiple products for the quickest launches possible.

Specifically, at the Ukima Plant, we have achieved a significant increase in capacity utilization by employing plastic single-use bioreactors, and to prepare for development candidates that apply next-generation antibody technologies we have constructed UK3, a new antibody API facility capable of high-mix, low-volume production from late-stage development to initial commercial products. At the Utsunomiya Plant, we have increased production flexibility by installing tray fillers that can handle filling of liquid medicines without making line changes or modifications, regardless of the syringe type.

Evolving Supply Chain Management

To minimize risks related to the supply and price of raw materials, we promote the globalization of our suppliers of raw materials and intermediate products in tandem with the globalization and establishment of two production bases for each finished product.

Our subsidiary Chugai Distribution Co., Ltd. handles distribution of pharmaceuticals in Japan. The company's computerized inventory management and inspection ensure stable and safe distribution, and the staff conducts ongoing process innovation in packaging.

Thorough Quality Assurance

Quality assurance functions have diversified in recent years in response to the increasing complexity of supplying products and accelerated development with the introduction of the fast-track review system to support the early launch of innovative new drugs.

In view of these trends, Chugai is working to further strengthen GMP* management oversight to promote more rigorous and high-level quality assurance. As part of these efforts, Chugai has created and operates a world-class system for pharmaceutical quality management.

* Good Manufacturing Practice: Standards for pharmaceutical production management and quality control

Biological API Production: Our Facility Portfolio

Plant	Target	Bioreactors	Features	Products
Utsunomiya	Commercial production (Large-scale)	10,000 L x 8 (UT1, UT2: Stainless steel tanks)	• Competitive low-cost production • Dedicated facilities	Actemra
Ukima	Commercial production/ Production of investigational APIs (Medium-scale)	6,000 L x 6 (UK3: Stainless steel tanks)	• Emphasis on flexibility • Can handle high-mix, low-volume production	Future development projects
Ukima	Commercial production/ Production of investigational APIs (Small-scale)	2,000 L x 4 (UK1, UK2: Single-use plastic bags)	• Improved capacity utilization through the application of single-use bioreactor technology	Future development projects

Marketing

IBI 18 (2016–2018)

- Realization of sales growth by concentrating on sales driver products and new products
- Providing advanced solutions through cross-functional collaboration with experts in different divisions
- Establishment of strategic and tactical system adapted to local area characteristics

IBI 21 (2019–2021)

- Maximization of the value of growth drivers (innovative drugs and services)
- Enhancement of consulting activities for innovative products to select the best treatment according to each patient's condition
- Provision of solutions through cooperation with diverse specialized human resources and incorporation of digital technology

Continuation → Evolution

S (Strengths)
- Leading presence in specialty areas, such as biopharmaceuticals and personalized healthcare (PHC)
- A system for providing advanced solutions based on regional and customer characteristics, multidisciplinary team care and drug safety activities utilizing a database of adverse events, etc.

W (Weaknesses)
- Response to an increase in competing products and an increase in new entrants
- Response to the emergence of biosimilars[1] and generic drugs[2]

O (Opportunities)
- Further increase in unmet medical needs as a result of the aging population as well as incurable diseases and orphan drug designations[3]
- Increase in therapeutic opportunities due to early detection and promotion of testing
- Progress in personalized and advanced healthcare, including genetic diagnosis

T (Threats)
- Progress in global control over drug costs, the shrinking domestic market amid drastic reform of NHI drug prices
- Loss of premium pricing status for new drug creation on mainstay products and the emergence of generic drugs
- Tighter regulations on promotional activities due to higher ethical and transparency standards

1. Successor products to biopharmaceuticals whose patent term has expired, made by manufacturers other than the manufacturer that developed the antecedent biopharmaceutical
2. Drugs approved after the expiry of the patents for original drugs with the same active ingredients and efficacy
3. Medical need that is not adequately met due to a lack of effective treatments

Functions

The need for new therapeutic agents to deal with cancers or rare or refractory diseases that lack effective treatments (unmet medical need) is high, and more sophisticated and individualized medical procedures such as cancer immunotherapy and genomic testing are attracting attention. Chugai is pursuing initiatives to meet unmet medical need based on its extensive lineup of first-in-class and best-in-class drugs and new diagnostic technologies.

As medicine becomes more sophisticated and individualized, healthcare providers will be expected to promptly provide high-quality information. Chugai takes three approaches to this process, which it refers to as "consulting."

For patients

We conduct patient-centric consulting that gives the highest priority to patients, including proposing the optimal drug treatment according to each patient's condition, providing relevant information on proper use and safety, and follow-up activities.

For regional healthcare

We aim to provide liaison services for regional healthcare with the aim of solving medical issues according to local area characteristics. We conduct consulting that improves patients' access to treatment by supporting regional healthcare coordination among healthcare providers and medical institutions as well as collaboration among local governments, public entities, and other industries.

For stakeholders

Multidisciplinary team care has advanced in recent years, with various specialist healthcare providers working in collaboration to carry out treatment according to each patient's condition. We conduct consulting to support our diverse stakeholders and multidisciplinary teams who follow up on treatment through proper management of adverse events.

Because consulting activities necessarily require extensive communication with relevant parties, our MRs play a key role. In addition to MRs, we also have a system for providing solutions that meet medical needs through participation in cross-functional teams by members of the Marketing & Sales, Medical Affairs and Drug Safety divisions, who have high-level expertise.

At the same time, we are innovating business processes using the latest digital technologies such as artificial intelligence and the Internet of Things to build a system that can provide more efficient and effective solutions based on higher-quality consulting.

As part of a multidisciplinary team, I am working toward treatments for bone diseases, which can be a factor causing a patient to require nursing care. Through collaboration with medical associations and local government, in 2019 we will create a framework that builds patient awareness and links it to examination and treatment. We then plan to expand this framework prefecture-wide to make Oita Prefecture a place where people have strong, resilient bones.

Yutaro Satake
Kumamoto and Oita Branch, Kyushu Regional Management Office, Marketing & Sales Div.

Main Initiatives and Progress

Oncology

In 2018, sales in the oncology area in Japan decreased 0.1 percent year on year to ¥225.7 billion. The contribution from new products included ¥9.1 billion from rapid market penetration of Tecentriq, an anti-PD-L1 monoclonal antibody launched in April 2018 as a second-line treatment for non-small cell lung cancer (NSCLC) and ¥0.6 billion from Gazyva, a treatment for CD20-positive follicular lymphoma launched in August 2018, including sales due to a switchover from Rituxan. In addition, market uptake substantially exceeded expectations for Perjeta for the additional indication of HER2-positive early breast cancer, and sales increased ¥2.5 billion (18.4 percent) to ¥16.1 billion, contributing significantly to results.

In addition, amid the emergence of various new drugs in each area and their changing position in treatment, we were able to minimize the impact of the decrease in NHI drug prices resulting from the loss of premium pricing status for new drug creation for Herceptin and Rituxan by maintaining sales volume for mainstay drug Avastin and growing sales of new and existing products

In 2019, we aim for further growth in the oncology area led by Tecentriq, which obtained approval for indication as a first-line treatment for NSCLC in December 2018, as well as from market uptake of Gazyva and from maintaining the position of our mainstay drug Avastin as a treatment for multiple types of cancer.

Bone and Joint Diseases

In 2018, sales in the bone and joint diseases area in Japan increased ¥7.2 billion, or 7.7 percent, year on year to ¥100.5 billion. In addition to growth from uptake of Actemra as a first-line biologic for the treatment of rheumatoid arthritis (RA), sales growth continued for Edirol, which has been recognized as a base treatment for osteoporosis, and for Bonviva, which was launched in an oral formulation in April 2016 in addition to the intravenous formulation. Sales of Actemra outside Japan including exports to Roche increased ¥19.7 billion, or 32.3 percent, to ¥80.6 billion as firm global sales by Roche compensated for the negative effect of exchange rates.

In 2019, we expect continued firm sales of treatments in the bone and joint diseases area in Japan. Outside Japan, we expect growth in sales of Actemra, mainly due to further uptake of the subcutaneous formulation for RA and sales for giant cell arteritis, which became an additional indication in 2017.

Renal Diseases

Sales in the renal diseases area in Japan in 2018 decreased ¥3.0 billion, or 7.6 percent, year on year to ¥36.3 billion. Mircera, which only needs to be administered once every four weeks, has established a reputation in the pre-dialysis segment for convenience and long duration of action, and prescriptions are increasing. However, sales decreased slightly due to competition from biosimilars and other therapeutic agents in the dialysis field, in addition to the NHI drug price revision in April 2018. Sales of Oxarol decreased partly due to the impact of generics.

In 2019, we aim to maintain and improve the market presence of Mircera and Oxarol in the pre-dialysis and dialysis stages through ongoing provision of information and patient-centric activities rooted in our high level of expertise in the area of renal diseases.

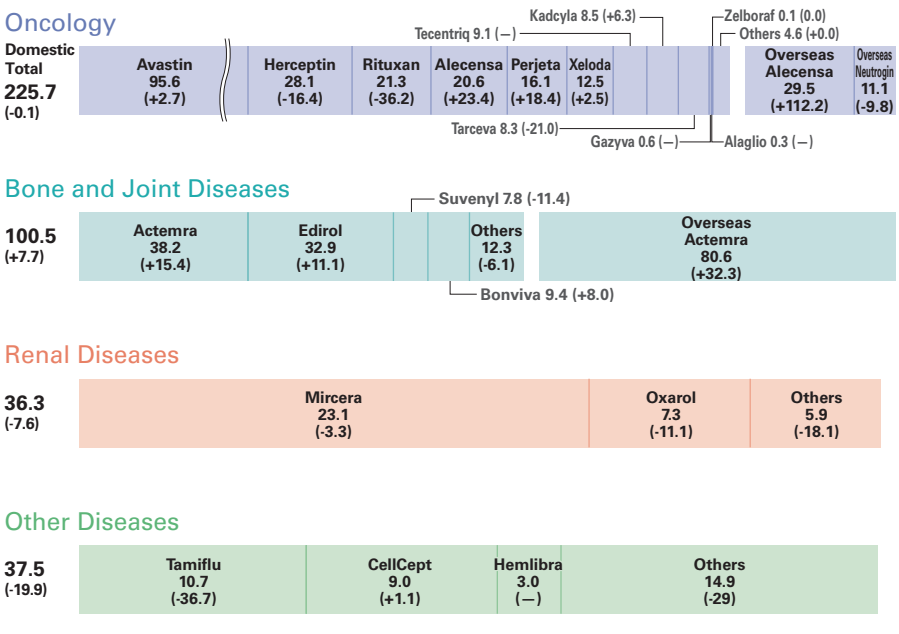
Other Diseases

Hemlibra is a bispecific antibody created using Chugai's innovative antibody engineering technologies. It obtained approval for routine prophylaxis in people with congenital hemophilia A with blood coagulation factor VIII inhibitors in March 2018, and received a drug price listing and was launched in May. Hemlibra's product characteristics are different from those of conventional coagulation factor agents. We focused on providing information on clinical results demonstrating its high level of efficacy in reducing the frequency of bleeding episodes, and sales in Japan were ¥3.0 billion in 2018. In December 2018, Hemlibra also obtained approval for an additional indication for people with hemophilia A without factor VIII inhibitors, enabling administration regardless of the presence of such inhibitors. The approval also allowed dosing intervals of two weeks or four weeks in addition to once-weekly administration, enabling treatment options according to the needs of people with hemophilia A and their healthcare providers. In 2019, by focusing on collecting and providing safety information on people with hemophilia A with factor VIII inhibitors who are already using Hemlibra as well as activities to promote its proper use among people with hemophilia A without factor VIII inhibitors, we anticipate further uptake of Hemlibra as a treatment for congenital hemophilia A.

In the influenza segment, where Chugai plays an important role as a provider of Tamiflu, we focus on providing information on the product's safety and effectiveness, including prevention of the disease, based on extensive clinical data accumulated over a long period. Sales of Tamiflu, including sales for government stockpiles, were ¥10.7 billion.

Sales of CellCept, an immunosuppressant, increased ¥0.1 billion, or 1.1 percent, to ¥9.0 billion in 2018 due to the effect of an increase in kidney transplants and an increase in use in treating lupus nephritis, a refractory disease for which it received approval in May 2016. We will continue to maintain a presence in the transplant segment in 2019 and expect further uptake for lupus nephritis.

2018 Product Sales by Therapeutic Area (Billions of yen)



Note: Figures in parentheses are year-on-year percentage changes.

Medical Affairs

IBI 18 (2016–2018)

- Acceleration of evidence creation
- Promotion of medical affairs in Japan and overseas

→ Continuation → Evolution

IBI 21 (2019–2021)

- Contribution to healthcare through acceleration and advancement of evidence creation
- Promotion of innovative medical affairs through strengthening collaboration with all stakeholders and actively introducing new technologies

S (Strengths)
- Extensive track record in evidence creation
- Global collaboration with Roche and overseas subsidiaries

W (Weaknesses)
- Systematic development of clinical research infrastructure

O (Opportunities)
- Increase in opportunities to use internal and external databases following the promulgation of the Next Generation Medical Infrastructure Act
- Unmet medical need appearing with the advancement of medical care

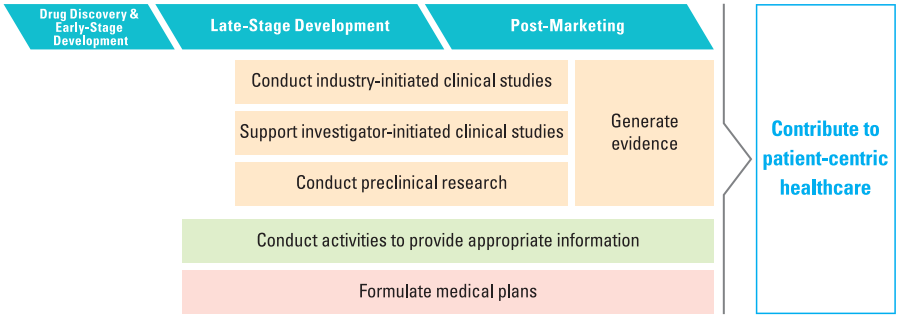
T (Threats)
- Changes in the clinical research system in association with the promulgation of the Clinical Trials Act
- Potential paradigm shift due to disruptive technologies or other factors

Functions

In addition to creating a steady flow of innovative drugs, Chugai recognizes the importance of ensuring that the value of its products is delivered accurately to patients, which will lead to better treatment. We have been focusing on creating evidence in support of this objective and supplying appropriate information to healthcare providers. We have also been working to establish a global support system for post-marketing studies. Our efforts have included being one of the first companies to operate a scheme for contract-based post-marketing studies to guarantee the independence and transparency of research, and establishing a research support structure that conforms to the GCP[1] guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) to raise the quality and reliability of research. In addition, we have been preparing an implementation and support system for post-marketing studies under the Clinical Trials Act that was promulgated in Japan in April 2018. We also started a new initiative in anticipation of the Next Generation Medical Infrastructure Act, which was promulgated in May 2018. In 2017, Chugai acquired third-party accreditation[2] for its medical science liaison (MSL) certification program from the Japanese Association of Pharmaceutical Medicine, and we maintain global-level compliance standards, including transparency in funding and appropriate separation of marketing and medical affairs.[3] At the same time, we are working to further enhance our internal systems to help raise the quality and scientific level of clinical and preclinical (basic) research and to deal with changes in our operating environment.

1. Good Clinical Practice: Standards for conducting pharmaceutical clinical trials
2. Composed of evaluation criteria (a total of 222 items in 42 categories) from the three perspectives of independence from promotional activities (compliance system), medical and scientific expertise, and the training system. In the accreditation examination, mail-in and on-site surveys of the evaluation criteria are conducted to evaluate whether the MSL certification program at the applicant company is being properly implemented.
3. Activities that contribute to healthcare from a scientific standpoint

Main Medical Affairs Activities



Main Initiatives and Progress

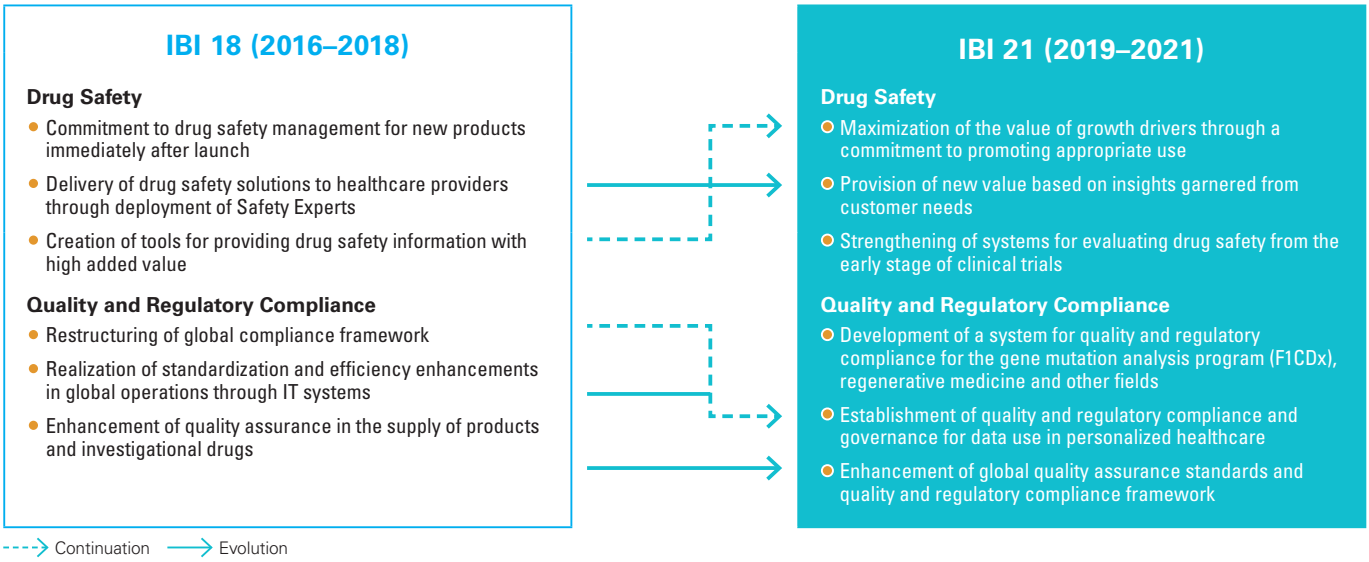
Activities to Generate Evidence

We conduct and support contract-based post-marketing studies to create, communicate and disseminate evidence on efficacy and safety in the clinical setting and non-clinical studies (basic research) to shed light on the modes of action of drugs. Conducted in cooperation with medical institutions and healthcare providers, these studies are based on complete transparency.

Enhancing Intelligence Functions and Measures for PHC

In the future of healthcare, along with elucidation of the causes of diseases and pathological conditions, progress is expected in establishing preventive and treatment methods based on individual genetic, environmental and lifestyle differences. We will respond promptly to this changing environment by enhancing our intelligence functions, such as using ICT and other means to obtain medical information and gain insights from its analysis. At the same time, we intend to provide more suitable treatment methods through the generation of new evidence with higher scientific value and other activities that provide solutions. Through these measures, we will contribute to the development of patient-centric medical research and advanced healthcare.

Drug Safety/Quality and Regulatory Compliance



S (Strengths)

Drug Safety
- Industry-leading achievements (introduction of the database tool and establishment of Safety Experts, etc.)
- Solid partnership with the Drug Safety Division of Roche Group
- A track record of industry activities in areas utilizing epidemiological and medical data

Quality and Regulatory Compliance
- Excellence in global inspections and quality assurance
- Corporate culture and organizational climate in pursuit of compliance and quality

W (Weaknesses)

Drug Safety
- Response to the constant shortage of high-quality human resources

Quality and Regulatory Compliance
- Response to expected cost performance demands and need for high-speed development
- Countermeasures against counterfeit pharmaceuticals

O (Opportunities)

Drug Safety
- Rising need for safety information from healthcare providers to effectively launch innovative new drugs
- Possible automation of some business operations and solutions due to disruptive technologies
- Deepening personalized healthcare through advancements in science

Quality and Regulatory Compliance
- Rising expectations on quality management through technology revolution
- Advancement of pharmaceutical regulations and compliance for global standardization

T (Threats)

Drug Safety
- Strengthening of global pharmacovigilance (PV) regulations in Europe, Asia and other regions
- Dramatically increasing safety information
- Fewer opportunities to convey drug safety information as a result of tighter regulations on visits to medical institutions

Quality and Regulatory Compliance
- Need for enhanced quality compliance in complex business partnerships
- Strict demands for quality data integrity and digital healthcare

Drug Safety Functions

In Japan and overseas, Chugai handles numerous biopharmaceuticals, molecular targeted therapies and other pharmaceuticals with innovative modes of action. To promote the appropriate use of these pharmaceuticals around the world and gain acceptance from patients and healthcare providers, Chugai establishes pharmacovigilance protocols with Roche and other partners and collects safety information on a global level. We consider expert safety evaluation and speedy decision-making to be essential for timely provision of safety information and implementation of measures to ensure safety. Consequently, Chugai has established an independent Drug Safety Division and a system directly linked to management. Through measures such as these, Chugai is building greater credibility, with the aim of providing truly valuable safety data and contributing to patients and healthcare worldwide.

Quality and Regulatory Compliance Functions

Protecting the rights of patients and clinical trial subjects and ensuring the reliability of data are serious responsibilities for the pharmaceutical industry. The Quality & Regulatory Compliance Unit is responsible for ascertaining trends in pharmaceutical regulations and ensuring the soundness of the quality management system spanning our business processes. It also ensures the reliability of data by confirming, improving and verifying the validity of these business processes through quality audits throughout the product lifecycle. In proactively leading cross-divisional activities for the purposes of introducing a global IT system and maintaining and improving quality, the unit aims to foster a self-sustaining quality mindset Company-wide and build a sturdier quality management system. Moreover, by engaging in dialogue with regulatory authorities through industry activities, it is also working to align regulations with society's demands, in ways including revisions to the Law for Ensuring the Quality, Efficacy and Safety of Drugs and Medical Devices.

Main Initiatives and Progress

Collecting and Managing Safety Information

Post-marketing surveillance, which includes all-case registration surveillance, is conducted in (real world) clinical settings to collect safety information unobtainable in clinical trials. In post-marketing surveillance, data on safety are collected from medical institutions through electronic systems. Information on the results obtained from analysis of this data is provided to medical institutions and announced via scientific conferences, papers and other means.

Numerous anticancer agents, innovative new biopharmaceuticals and other drugs require wider-ranging and more rigorous management, such as thorough management of distribution and confirmation of conditions of use, in addition to all-case registration, in which all patients administered a product are registered. With its extensive experience in all-case registration surveillance and other areas, Chugai leads the industry in drug safety evaluation and safety measures. In accordance with the revised Ministerial Ordinance on Good Post-marketing Study Practice (Revised GPSP Ordinance) that came into effect in April 2018, we are contributing to the implementation of epidemiological research, including a survey of post-marketing databases utilizing a network of domestic medical information databases.

Leading the Industry in Risk Management Plans

Chugai has been ahead of its competitors in drawing up and applying risk management plans (RMPs) to several of its products, and discloses them on its website. We consider RMPs to be part of our commitment to patients and healthcare providers. In applying RMPs, we believe we need to strengthen our ability to analyze data from an epidemiological standpoint. To achieve this, a specialized internal group in charge of epidemiology functions is cooperating with specialized companies and others to help upgrade Japan's epidemiological database. We are also driving the industry in ways such as proactively working to formulate industry-wide recommendations and guidance for database research.

Enhancing Drug Safety Evaluations

Chugai is committed to highly transparent and speedy reporting and release of drug safety information. We collect a large volume of safety information from countries around the world and evaluate it from a medical standpoint. Using advanced information technology, we have established a system for recording the information in a database and conducting signal detection of adverse events using that database. Under this system, we are able to promptly consult with regulatory authorities in each country regarding safety measures. In addition to managing this large volume of safety information, we have in-house doctors with abundant clinical experience who also conduct expert safety evaluations.

Communications on Safety

Communications with customers include providing information on noteworthy adverse events to medical institutions and academic societies. We also distribute information leaflets for patients, post information on our website and present a variety of lectures. In particular, our ability to rapidly provide information according to patient characteristics using the post-marketing surveillance database tool (PMS DB tool) and safety information database tool (SAFETY DB tool) that we developed in 2016 has won praise from healthcare providers.[1] With these tools, which include post-marketing surveillance and domestic post-marketing safety data, we can respond in a timely manner to urgent needs for safety information. In 2018, we broadened our contribution through the rollout of a clinical trial database tool for safety information on phase III multinational clinical trials so that healthcare providers can use new products with confidence immediately after their launch. Also, we have started using an app[2] that supports adherence to medication in conjunction with a multidisciplinary social networking service (SNS). The app helps to alleviate the anxiety of patients undergoing treatment by facilitating smooth communication between patients and their healthcare providers. In addition, we have assigned Safety Experts as professional staff in each region to support risk communication geared to local area characteristics, and are strengthening safety-related consultation according to needs and building networks with local doctors and pharmacists.

1. Source: Online article by Nikkei Medical Publishing, Inc. on AGING Web "Chugai's Ideal Information Prescription: 'PMS and SAFETY Database Tools' Providing Necessary Information to Those Who Need It, When They Need It" (Japanese only)
   Part 1 (November 10, 2017) http://www.nikkeibp.co.jp/aging/article/ innovator/2017111001/
   Part 2 (November 17, 2017) http://www.nikkeibp.co.jp/aging/article/ innovator/2017111701/
2. A service developed by Chugai to support multidisciplinary team care in cancer treatment. The app is linked with MedicalCareSTATION, a completely private SNS developed exclusively for healthcare providers and operated by Embrace Co., Ltd., and promotes drug adherence and adverse event management.

I am working with in-house epidemiological specialists and colleagues from other departments to plan post-marketing database surveillance and drug use-results surveys, so that we can provide patients with the information they truly need in a proper and timely manner, while responding to changes in the social environment.

Yuki Miyano
Real World Data Planning Group,
Real World Data Science Dept.

New Efforts for Quality and Regulatory Compliance

- Ensuring quality and regulatory compliance in innovation and digital healthcare
- Comprehensively improving quality to achieve patient-centric medical care
- Fostering a culture of quality

In addition to the creation of new drugs, Chugai's innovation will expand into medical devices, regenerative medicine and gene therapy. This innovation will include generating evidence in support of these areas, as well as to digital healthcare. Furthermore, as a leading innovator, we feel a heavy responsibility to create and champion related new quality assurance methods.

It is particularly important to realize patient-centric healthcare, and by refining our process for responding to patient requests we will improve our products and the quality and timeliness of the information we provide. It is our mission to comprehensively improve quality by proactively sharing experiences and knowledge regarding quality and regulatory compliance with stakeholders and affiliated companies involved in production, development and other processes, and thereby raise the competence of all parties.

To accomplish the above, fostering a culture of quality is essential. There are numerous procedures and rules in place at Chugai. However, given the successive appearance of new drug regulations, continuing to upgrade our systems for quality and regulatory compliance is vital. Particularly when we find faults in our rules, we must harness a Company-wide autonomous quality mindset that pushes forward with improvements and reforms. By infusing this attitude toward quality among employees, we will cultivate a culture of quality that further increases the trust we earn from all stakeholders.

Intellectual Property

IBI 18 (2016–2018)

- Realization of IP activities that help to acquire and demonstrate global top-class competitiveness
- Strengthening of rights formation functions globally
- Strengthening of strategic utilization of IP including in patent disputes

IBI 21 (2019–2021)

- Creation of a database of Chugai's competitors and use it to search out opportunities for utilizing the Company's rights
- Utilization of antibody engineering technology patents through licensing and other means
- Formulation and execution of a scenario for combating biosimilars and generics

Continuation → Evolution

S (Strengths)
- Expanded and upgraded portfolio of technological patent applications
- Progress in securing rights for products

W (Weaknesses)
- Negative impact on the development of technological patent rights due to early applications for "Freedom to Operate" (FTO)*
- Limited to capturing one-time opportunities for utilizing technological patents

O (Opportunities)
- Increasing importance of protecting intellectual property based on the establishment of drug discovery technology infrastructure
- Increase in opportunities to generate intellectual property due to progress in digital technology

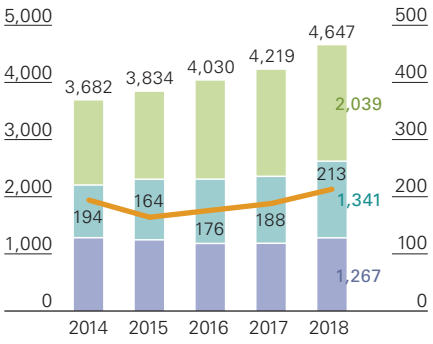
T (Threats)
- Ensuring FTO in the intense, competitive R&D environment.
- Market erosion due to increase in biosimilar products

* The ability to conduct business without the possibility of infringing the rights of others

Implementation of Our IP Strategy

Chugai views its global intellectual property (IP) strategy as the foundation for creating innovative new drugs. By integrating it with our business and R&D strategies, we protect the competitive advantage of our products and ensure operational flexibility. We focus resources on and secure IP rights for high-priority R&D projects. At the same time, we actively work to secure rights outside Japan with a view to global co-development with the Roche Group. When we apply for patents for products, we include filings for our inventions related to formulation, production method, diagnostic method and personalized healthcare in addition to those for the substance and use. We also work to establish rights globally for significant drug discovery technologies such as innovative antibody technologies, and use those rights in planning and executing our IP strategy. Moreover, we are building our own database for patents related to antibody engineering technologies, which are becoming increasingly complex and sophisticated, and are using this database to plan IP strategies, including monitoring trends at other companies.

Number of Patents Held (Including Pending Applications) and New Patents Granted



Patents held (including pending applications) (left scale)
- Oncology
- Bone and joint diseases
- Others

New patents granted (right scale)

Main Initiatives and Progress

Integration of IP and Research Strategies (Strategic Mix)

At Chugai, we view our antibody engineering technologies as a core drug discovery technology platform, and we are deploying research and development strategies both to cultivate basic technologies and to apply them to product development. Since 2018, we have been dispatching IP liaisons to the Fuji Gotemba Research Laboratories and Kamakura Research Laboratories to strengthen cooperation at the initial stage of research, and they are enhancing and promoting a strategic mix that builds a portfolio of our own technologies and development compounds in the white spaces (gaps) of technologies and rights. IP liaisons hold monthly meetings to review intellectual property with the Pharmaceutical Technology Division, which is also promoting the same strategic mix in manufacturing.

Current Patent Portfolio

Bone and joint diseases account for approximately 29% of patents by therapeutic area, oncology for approximately 27%, and other areas including chronic disorders, hematologic diseases, and drug discovery technology for approximately 44%. Supported by technological development, we have structured a well-balanced patent portfolio that reflects the diversity of products and development projects generated through Chugai's own R&D. In addition, in 2018 Chugai acquired 213 patents in Japan, the United States, and major European countries, as well as other countries worldwide.

Creating Opportunities to Use the Company's Rights and Establishing an IP Liaison Group

With the globalization of our product portfolio, the chance of conflicts arising over product-related IP is increasing. In addition, more sophisticated execution of strategies for utilizing lifecycle patents are required given the growing importance of generics, including biosimilars, in our IP strategy. Chugai will raise the sophistication of its strategies for using drug discovery technology patents by quickly identifying competitors that might use its proprietary drug discovery technologies and delineating drug discovery technology patent rights and their use. Moreover, we have established the IP Liaison Group as an implementation unit to resolve conflicts over IP rights, which are expected to increase in the future. Through these actions, we will continue to maximize the value of our business.

Human Resources

IBI 18 (2016–2018)

- Promotion of talent management to become a top pharmaceutical company.
- Structuring of a world-class platform shared across the Group.
- Productivity improvements through the promotion of diversity and inclusion and work-life synergy.

IBI 21 (2019–2021)

- Assignment of the right people to the right positions using position management and talent management and provision of growth opportunities.
- Promotion of talent management to quickly identify and develop leaders and highly competent specialists to accelerate strategy execution and innovation.
- Maintenance and deepening of employee engagement and fostering of an organizational culture for the pursuit of innovation.

Continuation Evolution

Talent That Spearheads Innovation

Our people are our greatest asset in realizing management strategies and generating innovation, and we therefore position human resource management as a key management theme. Our Envisioned Future is to become a top innovator in the healthcare industry. Chugai will pursue this objective by building understanding and connection with the Mission Statement (corporate philosophy) among all employees. Furthermore, we will encourage employees to embody the Mission Statement while fulfilling their potential in accordance with their role.

Establishing an Organizational Culture That Generates Innovation

Chugai provides career development support over many years so that employees can excel in roles that reflect their expertise, ability and aptitude. Since 2012, we have instituted various measures and systems, including introducing a talent management system, promoting diversity and revising our personnel systems. As a result of these initiatives, we have secured leaders capable of driving sustainable growth, assigned roles and growth opportunities according to each individual's ability and aptitude, and created an environment that supports the success of women.

At the same time, the speed of change in the business environment is escalating. Clarifying each employee's approach and responsibilities to improve quality, speed and success rates in strategy execution will be essential to realizing our management strategies and establishing a competitive advantage. In addition to these issues, an important theme is to support our employees in proactively taking on challenges to generate innovation and new added value.

We have determined the following human resource management priorities as measures for these objectives and themes. With these measures, we aim to establish an organizational culture in which employees support each other to continuously generate innovation.

Through the introduction of a new mid-career recruitment system focused on a thorough understanding of people, we will acquire excellent talent who can adopt the perspective of patients and contribute to fulfilling Chugai's Mission. By designing and implementing a leadership development program with an eye to 10 or 20 years down the line, we will develop the next generation of CEOs capable of achieving sustainable corporate growth.

Tom Mayes
Talent Management Group,
Human Resources Management Dept.

Changes to the All-Employee Survey

Chugai has regularly conducted its all-employee survey for instilling and promoting its identity as a top pharmaceutical company, initiatives to change organizational culture, and mid-term business plans. However, the high level of survey results in recent years made it difficult to set higher goals and to satisfactorily identify issues, and we were unable to use the results to compare Chugai with global companies and others. Therefore, in 2018 we transitioned to an employee survey that enables comparison against benchmarks.

Our objective for the new employee survey is to identify organizational change issues linked to the strategies of IBI 21. We will address the issues we identify with Group-wide and divisional PDCA cycles, while working to achieve our ideals.

Overview of Employee Survey (2018)

Participants and response rate	Participants: 6,994 (6,498 in Japan, 496 overseas) Respondents: 6,806 (6,321 in Japan, 485 overseas) Response rate: 97.3%
Question categories	Employee engagement, environment for utilizing employees, strategy and direction, leadership, quality and customer orientation, respect for individuals, opportunities for growth, compensation and benefits, performance indicators, authority and discretion, resources, education and training, framework for collaboration, business processes and organizational structure, and innovation
Benchmark data	Average results from global companies, leading companies, pharmaceutical companies and Japanese companies

Survey Results (Overall Trends)

- In all question categories, Chugai scored above the average for Japanese companies. In Japan, Chugai is a leader in terms of employee awareness.
- Chugai is on par with global companies. Employee engagement is on par with top global companies.
- Issues for further improvement are the environment for utilizing employees, as well as the resources, framework for collaboration, and business processes and organizational structure that underlie that environment.
- The percentage of employees who gave employee engagement and working environment high marks is at the level of global companies.

1. Assignment of the right people to the right positions using position management and talent management and provision of growth opportunities
2. Promotion of talent management to quickly identify and develop leaders and highly competent specialists to accelerate strategy execution and innovation.
3. Promotion of diversity and inclusion (D&I) to accelerate the success of women.

In addition, we switched to a new employee survey in 2018 to set more ambitious targets and identify issues more accurately. Based on the results of this survey, we will conduct organizational reforms linked to IBI 21.

Main Initiatives and Progress

Competency-Based Development

Upgrading Standards and Platforms to a Global Level

In competency-based human resource development, a prerequisite for implementing talent management, we clarified the mindset and behavior that Chugai requires and are standardizing Group-wide competencies on which employees are evaluated. Under IBI 18, we identified the type of global-level employees we are looking for and articulated these competencies in our decision-making standards and behavioral standards. As a basis for developing human resources, we conduct workshops and training for the managers of individual organizations to encourage dialogue between supervisors and their staff based on these competencies.

In addition, in 2017, we revamped our backbone system for human resource management. The new system, called "CAPTAIN" (Chugai All Persons Talent Information system), is a multilingual, cloud-based global personnel system. The use of a common personnel database throughout the Chugai Group will enable managers to conduct unified talent management and real-time monitoring and analysis of organizational conditions, leading to faster, more effective enhancement of our human resource capabilities.

In new mid-term business plan IBI 21, in addition to talent management, we will conduct position management to ensure the right people are assigned to the right positions throughout the Group, and provide growth opportunities for employees who actively take on challenges. In line with changes to the business environment, we also need to update our requirements for the type of people we seek. In position management, we will clearly define the roles and duties required for realizing our strategies and visualize the corresponding human resource requirements. This will facilitate operation in concert with talent management and accelerate the realization of our strategies.

Talent Management

Structuring Human Resource Development Plans with the Strong Commitment of Management

Since 2012, Chugai has been introducing and promoting a talent management system for developing individuals based on visualization of human resources and their capabilities. Each department held discussions on medium-to-long-term human resource development policies and formulated individual development plans. At the same time, we have created a talent pool of future management candidates. In addition, we clarified our succession plan by selecting successor candidates for a total of 94 general manager and department manager positions in Japan. The Company-wide plan, which includes medium-to-long-term career paths for each candidate, is being formulated and implemented through discussions by executive management and department managers to accelerate training of successor candidates.

Under IBI 18, we expanded talent management to a global scale, creating a new system that has enabled Chugai to systematically and continuously recruit, develop and promote people who can perform internationally. For key positions in strategy execution, in addition to internal candidates, we also consider hiring from outside the Company, whether in Japan or overseas, and candidate selection is under the direct supervision of the president. In IBI 21, we will review our training system to improve our ability to acquire, develop and deploy world-class human resources with the aim of identifying and training them more quickly.

Establishment and Enhancement of the Foundations of Human Resource Management

Promoting Diversity & Inclusion and Work-Life Synergy to Improve Productivity

Chugai has positioned D&I as a priority issue for the establishment and enhancement of the foundations of human resource management. We believe that D&I, which leads to the creation of a diverse workforce that works together with enthusiasm, is essential in order for employees to generate new value – in other words, diversity is necessary for generating innovation. As such, in 2010 we launched a working team led by the president, and in 2012 we established a dedicated organization that has since been conducting initiatives to promote diversity.

To promote gender diversity, we are actively providing opportunities for women to succeed. We set a target for 2018 of a 13 percent or higher female manager ratio, and have focused on career planning and development measures for women. With a female manager ratio of 13.3 percent as of December 31, 2018, we have achieved that target and are working for further advances. To promote the success of older employees and foreign employees in Japan, we are building awareness of their potential through training and other programs and creating environments including workplace systems to help them play active roles. Also, amid demands for more active participation by diverse human resources, managers play a key part in promoting D&I. We will aim to enhance their practical workplace skills through training in diversity management awareness, skills and behavior modification. Under IBI 18, we focused on leveraging D&I and presenting in-house case studies to encourage implementation by employees and vitalize the organization, thereby contributing to business success.

We also provide work arrangements and support systems so that all employees can benefit from work-life synergy that accommodates a variety of life events including but not limited to childbirth, child care

Chugai Diversity Promotion Forum: The Essence of Inclusion

and nursing care. With respect to "work style reform," which is currently a focal issue in Japan, studies and discussions between labor and management are under way with the goals of improving the work environment to enable employees to fully demonstrate their capabilities and promoting innovation by organically combining diverse knowledge.

Promoting D&I and work-life synergy is all about supporting the autonomy and growth of individuals to help realize an organization that generates innovation, which in turn contributes significantly to improving organizational productivity and increasing corporate value over the medium to long term.

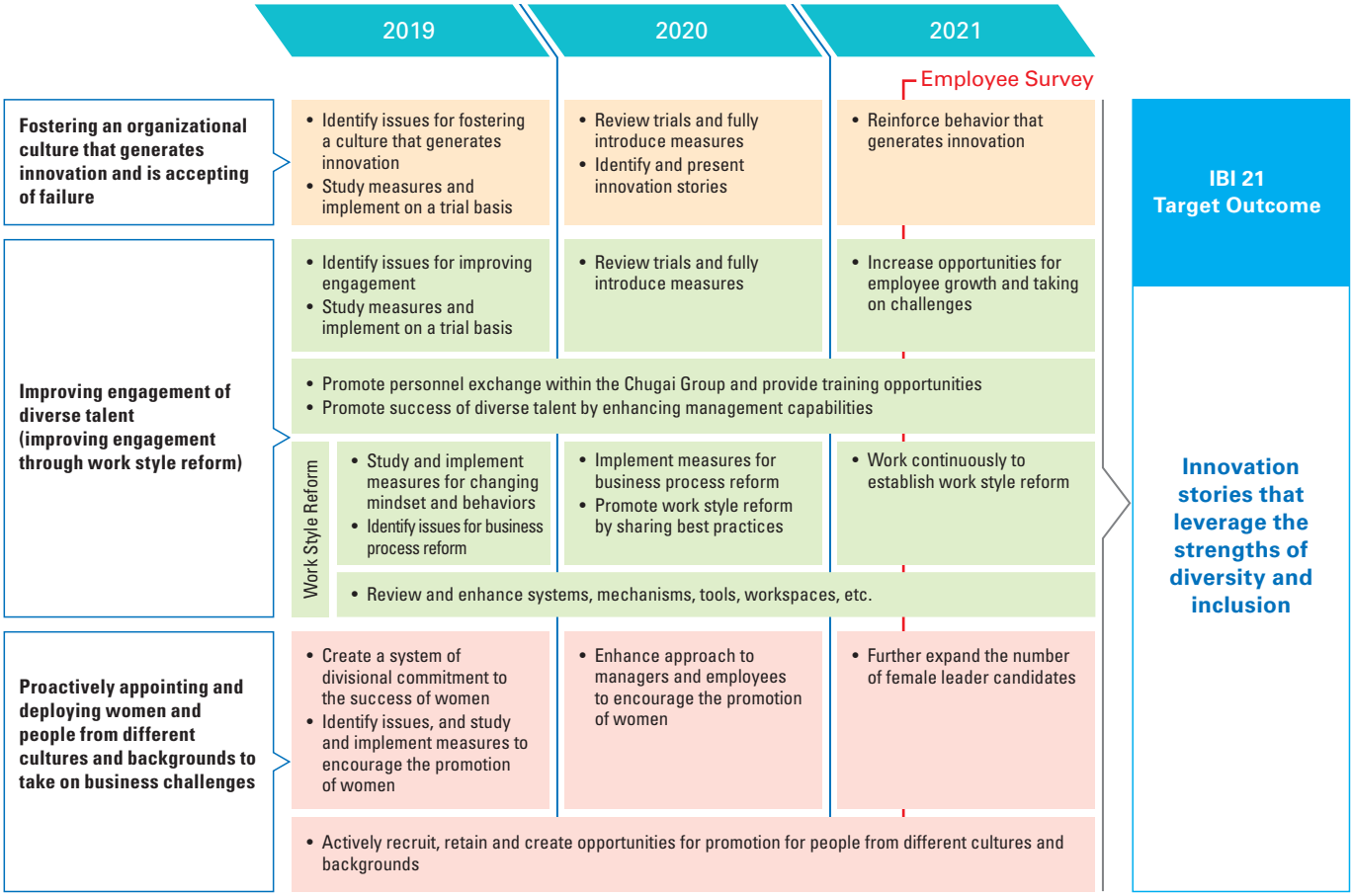
IBI 21 sets forth a target outcome of innovation stories generated by leveraging the strengths of D&I, and we have created a roadmap for expedited realization of our strategies. Based on respect for different values and ideas, we are working to address the following three issues in order to foster an inclusive organizational culture in which diverse human resources can succeed and pursue innovation.

1. Fostering an organizational culture that generates innovation and is accepting of failure
2. Improving engagement of diverse talent
3. Proactively appointing and deploying women and people from different cultures and backgrounds to take on business challenges

We are targeting a 16 percent or higher female manager ratio by the end of 2021, and will continue to focus on career planning and development measures for women.

For four years in a row since fiscal 2014, Chugai has been selected as a Nadeshiko Brand for its exceptional record in promoting the success of women.

D&I Roadmap for Promotion of IBI 21



Human Rights

IBI 18 (2016–2018)

- Conduct human rights awareness training
- Formulate a policy on respect for human rights
- Exchange opinions with third-party organizations

IBI 21 (2019–2021)

- Continue to conduct human rights awareness training
- Conduct human rights due diligence, including for suppliers
- Exchange opinions with third-party organizations to execute measures for resolving social issues

Continuation Evolution

Basic Approach

Chugai believes that a culture of respect for human rights is a cornerstone for a company to be recognized as a member of society and to earn trust. Therefore, we declare our respect for human rights in the Chugai Business Conduct Guidelines (Chugai BCG), which are based on our shared Core Values. In respecting human rights, we aim to realize workplaces that prize diversity, where each person values his or her own feelings and accepts the values of others – allowing everyone to fully demonstrate his or her abilities, based on an organizational climate of appreciation for oneself and others. People in such a workplace can work creatively with enthusiasm and engagement, thus increasing their achievements. Moreover, we believe that the actions of individuals who raise their sensitivity to human rights and show respect for others in such a workplace can also help to eliminate social discrimination and infringements of human rights in society in general through corporate activities and their private lives.

Today, companies are expected not only to conduct in-house initiatives regarding human rights, which have been increasing in importance as a social issue, but also to conduct business activities that respect human rights throughout the entire supply chain. With our deep involvement in people's lives and health as a member of the healthcare industry, we are promoting measures with a greater awareness of respect for human rights (see our website* for more details on our human rights policy).

* https://www.chugai-pharm.co.jp/english/csr/humanrights/

Issues and Initiatives

In previous initiatives toward respect of human rights, Chugai mainly focused on its employees in areas such as prohibition of workplace discrimination and harassment, respect for employee diversity, and safety and health. However, to conduct business activities in various regions of the world as a global company, we recognize that we need to address human rights issues throughout our entire supply chain, including labor-related rights at stakeholders involved in our business activities. Based on the United Nations' Guiding Principles on Business and Human Rights, we began preparations for drawing up a policy on respect for human rights and for conducting human rights due diligence.

In September 2018, Chugai participated in the 2018 Business and Human Rights Conference in Tokyo sponsored by Caux Round Table Japan, and engaged in dialogue with individual experts from overseas, receiving opinions and advice on putting the U.N.'s guiding principles into practice, including the formulation of a human rights policy. Through discussions of the Chugai Group's initiatives in the context of the principles, we received suggestions from these experts that will lead to more effective communication. They also expressed their expectations for us to incorporate and implement these principles in our business activities.

Dialogue with overseas experts

Based on these opinions, Chugai established its Policy on Respect for Human Rights in January 2019. In conducting human rights due diligence, we will also call on our business partners to comply with laws and social norms. In addition, we will work together with those partners in respecting human rights, with the expectation that efforts will take into account working conditions in ways including eliminating child labor and forced labor, prohibiting all forms of discrimination by race, gender or other attributes, respecting the dignity of individual employees and maintaining safety and health.

In addition, Chugai has established an Anti-Bribery Policy to help prevent bribery as part of the management of its corporate activities. In addition to setting standards for our own conduct, it prohibits our business partners from engaging in bribery of government officials, civil servants, corporate staff and other parties, whether corporations or individuals. We will continue our comprehensive efforts to prevent bribery.

We recognize Chugai's responsibility for respecting the human rights of all people involved in its business activities, and will work to fulfill it by ensuring that we do not infringe on the human rights of these people, and by responding appropriately with corrective action in the event of an infringement.

Initiatives to ensure respect for human rights must not be limited to employees, but should extend to all people affected by our business activities. We will convey the significance of such efforts through in-house training and foster understanding of their criticality among all links in our supply chain.

Emiko Mori
Senior Specialist, Business Ethics Group, Sustainability Dept.

Environment, Health and Safety

IBI 18 (2016–2018)

- Establishment of a promotion system for environment, health and safety (EHS)
- Formulation and execution of single-year goals to achieve mid-term environmental goals
- Formulation of priority items for health and productivity management, setting of targets and execution

IBI 21 (2019–2021)

- Establishment of a global EHS promotion system
- Achievement of mid-term environmental goals and formulation of new mid- and long-term environmental goals
- Execution of priority items for health and productivity management and reassessment of evaluation indicators

Continuation Evolution

Our Environmental, Health and Safety Functions

As a healthcare company, Chugai is engaged in many specialized scientific activities. One aspect of those activities involves handling antibodies and highly active pharmaceutical substances. Our responsibilities in environmental protection and health and safety are numerous, and we consider them an important foundation for all our business activities.

At the same time, the demands of society have grown more diverse and sophisticated. Integrated management of environment, health and safety is now required worldwide because of the close connection between "environmental protection" and "health and safety." Accordingly, Chugai has developed an integrated management system for EHS and implements the plan – do – check – act (PDCA) cycle based on a consistent policy Company-wide, from top management to each facility.

We consider EHS management to extend throughout the value chain, from the procurement of raw materials to the manufacture of products and their supply to patients and healthcare providers. Going forward, we intend to broaden our activities to cover the overall value chain in closer cooperation with customers and suppliers, partners and industry organizations.

To utilize the PDCA cycle effectively, we introduced health and safety risk assessment in 2014 and EHS risk assessment in 2017 to remove EHS risks in the workplace. Since 2008, we have implemented an assessment system throughout the Chugai Group to reduce the risk of occupational injuries from exposure to all substances handled, not only restricted substances.

Main Initiatives and Progress

Promotion and Progress of Environmental Protection Activities

Chugai's aims encompass not only its own sustainable development but also environmental protection in local communities and globally. We have set priority items to be addressed as well as medium-to-long-term targets.

Chugai designated climate change countermeasures, energy conservation,

Initiatives by Theme

Theme	Details of Initiatives
• Implementation of EHS risk assessment • Workplace safety measures	Create work environments that are free from unacceptable EHS risks.
• Climate change countermeasures • Energy conservation	Reduce greenhouse gas emissions by reducing energy consumption. Focus not only on reducing energy consumption at plants and laboratories, but also on promoting eco-friendly cars in the MR fleet and other Company-wide initiatives.
• Resource conservation • Waste management	Achieve zero emissions of waste by improving recycling ratio and further reducing landfill waste. Promote awareness of effective use of water resources by monitoring water consumption and wastewater discharge.
• Biodiversity protection • Prevention of environmental pollution	Curb destruction of the ozone layer by eliminating usage of specific CFCs. Prevent emissions of pollutants into the environment by observing laws, regulations, agreements and other rules for air, water quality and soil. In particular, focus on controlling emissions into water with whole effluent toxicity (WET) tests and other methods to protect the water environment.
• Improvement of environmental literacy	Circulate information on laws and regulations among related staff and raise awareness through ISO 14001 internal auditor training.
• Chemical substance management	Advance the establishment of a system for proper management of chemical substances, and promote safety and the prevention of environmental pollution. Continue risk assessments to prevent exposure to substances handled.
• Reduction of environmental risk	Ensure thorough compliance with environmental laws and regulations by conducting extensive environmental law checks through external consultants.
• Employee health management • Improvement of health literacy	Maintain a support system based on cooperation with the health management organization and related departments. Improve health literacy as the basis for all health and safety activities, and enhance awareness through various media and opportunities.
• Support for employees with cancer	Aim for early detection of cancer and provide enhanced support for continuing to work while undergoing cancer treatment.
• Measures to prevent and treat lifestyle diseases among employees	Recommend check-ups for high-risk individuals and provide health guidance to those diagnosed to reduce leaves of absence, job departures and accidents caused by lifestyle diseases.
• Measures for employees' mental health	Conduct a return-to-work program for employees on leave due to mental health issues and use the results of stress checks to improve working environments in cooperation with related departments.
• Measures to address employee presenteeism (working while sick)	Plan, implement and determine the effectiveness of measures based on health survey results.

resource conservation and waste management, biodiversity protection, prevention of environmental pollution and improvement of environmental literacy as its priority items. In 2010, we set four mid-term environmental goals focusing on management of energy consumption and waste from a medium-term perspective, with 2020 as the final year. We are implementing the PDCA cycle and conducting initiatives to meet these goals.

As measures to conserve energy, we are reducing energy consumption by introducing highly energy-efficient facilities, switching fuels, introducing eco-friendly cars, and conducting an energy conservation program in daily business activities while curbing greenhouse gas emissions,[1] which is the key to combating climate change. To prevent environmental pollution, we are also working to reduce the use of CFCs and HCFCs to halt the destruction of the ozone layer, and to prevent the leakage of environmental pollutants.

Water is an important raw material in pharmaceutical manufacturing, and it is also a crucial global resource. Chugai therefore considers risks related to procurement and water damage to be water-related risks. Although Chugai's procurement-related risks are low at present, it monitors the volume of water it uses and the wastewater it discharges each year, and is building awareness of the effective use of water resources. At the same time, Chugai conducts countermeasures for the risks to stable supply caused by water damage. In waste management, we aim to increase the waste recycling ratio and further reduce landfill waste to achieve zero emissions of waste, and our initiatives are yielding results.

Moreover, from the standpoint of protecting biodiversity, we began conducting WET tests[2] in 2013 to ascertain the ecological impact of wastewater discharged from our facilities. In 2018, we conducted WET tests once at all plants and research laboratories, and confirmed that there were no problems.

1. We received independent verification of our 2018 greenhouse gas emissions associated with energy consumption, leakage of CFCs and HCFCs, use of aircraft for business travel, and industrial waste generated.
2. Whole effluent toxicity test: A method for comprehensive evaluation of the safety of wastewater and the aquatic environment by determining the impact on crustaceans *(Daphnia)*, algae and fish *(Oryzias latipes* and others*)* immersed in diluted wastewater

Mid-Term Environmental Goals	• Energy consumption per employee: 20 percent reduction compared with 2010 • Discontinuance of the use of chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs) • Zero emissions of waste:[2] Three facilities • Average fuel efficiency of MR fleet: 16 km/L or higher
Environmental Goals for 2018	• Energy consumption and greenhouse gas (GHG) emissions: Reduction of 2 percent or more compared with the previous year • Ratio of eco-friendly cars:[3] 60 percent or higher; average fuel efficiency of MR fleet: 16 km/L or higher • A recycling ratio of 80 percent or higher and a final disposal ratio of 2 percent or lower • On-site verification of 100 percent of waste disposal contractor facilities over a three-year period • Plain paper copier (PPC) paper purchased: Less than the previous year; recycling ratio of 80 percent or higher
Mid-Term Health and Safety Goals	• Cancer screening participation rate[4]: 90 percent or higher • Percentage of employees at high risk for lifestyle diseases: 2 percent or lower by 2020 • Awareness of Company programs: 90 percent or higher • EHS risk assessment: Conduct at each site at least once every three years

2. A waste recycling ratio of 99 percent or higher
3. Includes hybrids and fuel-efficient vehicles
4. Screening rate for lung, breast, gastric, colon and cervical cancer

Promotion and Progress of Health and Safety Activities

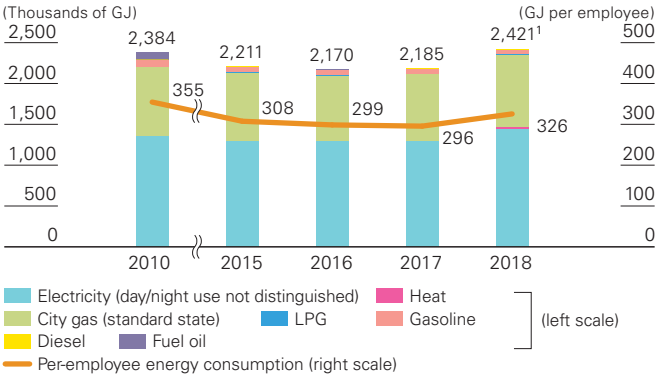
Chugai engages in health and safety activities as one aspect of its health and productivity management, in the belief that sound employee physical and mental health and a satisfying and rewarding work environment where all employees can do their jobs with enthusiasm are the foundation for growth.

Climate Change Countermeasures

(2010 is the base year for per-employee energy consumption and CO_2 emission mid-term environmental goals.)

Total and Per-Employee Energy Consumption

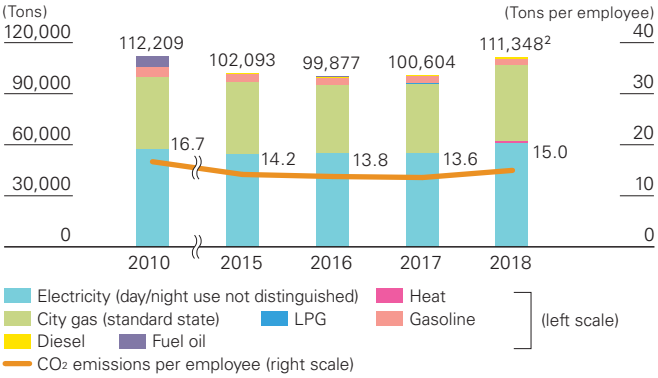
The Chugai Group's energy consumption in 2018 increased 10% over the previous year. The main reason was the newly constructed UK3 manufacturing plant for handling high-mix, low-volume biological API production within the Ukima Research Laboratories in Kita-ku, Tokyo.



1. Includes 40,000 GJ of overseas consumption (electricity, heat)

CO_2 Emissions and CO_2 Emissions per Employee

Total CO_2 emissions increased 11% from 2017 to 111,348 tons. CO_2 emissions per employee increased 1.4 tons. The main reason was the newly constructed UK3 manufacturing plant for handling high-mix, low-volume biological API production within the Ukima Research Laboratories in Kita-ku, Tokyo.



2. Includes 1,947 tons of overseas emissions (electricity, heat)

To create such an environment, we established a Company-wide health and safety promotion framework in 2017, based on a policy of cooperating with the health insurance society and the labor union in simultaneous pursuit of both individual and organizational health. We also established six priority items: support for employees with cancer, measures to prevent and treat lifestyle diseases among employees, measures for employees' mental health, measures to address employee presenteeism (working while sick), improvement of health literacy and workplace safety measures. We set mid-term health and safety goals for the underlined items and are conducting activities to achieve them. We are also working to improve organizational health using the results of an organizational analysis of stress checks in collaboration with relevant departments.

Of course, in addition to these preventive measures, we continue to conduct our existing programs to support employees during cancer treatment and after they return to work, as well as mental health awareness activities.

GHG Emissions

Scope 1: 49,486 tons

Direct emissions from fuel combustion: 49,240 tons

Plants: 31,017 tons
Research labs: 13,996 tons
Overseas: 0 tons

Branches: 4,203 tons

Head Office: 24 tons
Distribution: 0 tons

Fugitive emissions

Fluorocarbons, etc. from business activities

248 tons
Japan: 248 tons
Overseas: 0 tons

Scope 2: 62,108 tons

Indirect emissions from the generation of purchased energy (electricity), heat

Plants: 31,842 tons
Research labs: 26,030 tons
Overseas: 1,951 tons

Branches: 1,111 tons
Head Office: 558 tons
Distribution: 617 tons

Scope 3: 4,583 tons

Indirect emissions other than Scope 1 and 2

Category 5 (Waste materials)
Industrial waste generated by business activities
302 tons
Japan: 277 tons
Overseas: 25 tons

Category 6 (Business travel)
By aircraft
4,281 tons

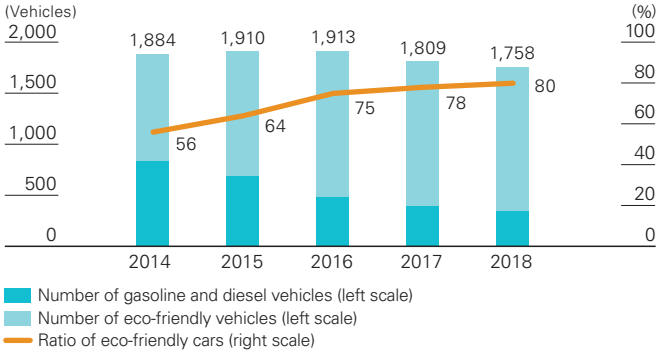
To achieve our 2020 environmental goals, we have introduced a system for visualizing energy use, conducted data analysis, and created an energy conservation plan. In 2019, we will implement energy-saving measures according to plan, bringing us closer to achieving our environmental goals for 2020.

Masatake Takei
Formulation Research Group 2,
Production Engineering Dept.

Resource Saving and Waste Reduction

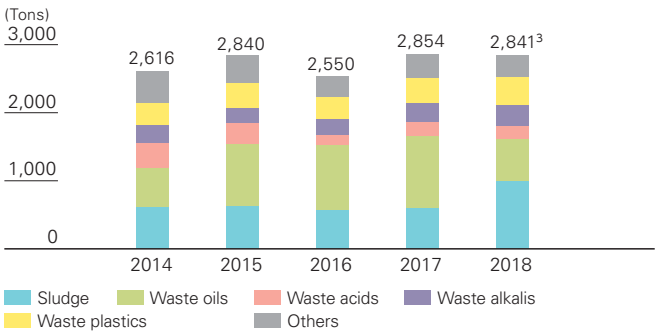
Ratio of Eco-Friendly Cars

As of December 31, 2018, Chugai had introduced a cumulative total of 1,415 hybrid and fuel-efficient vehicles in its MR fleet. The ratio of eco-friendly cars was 80 percent, remaining above the target of 60 percent.



Industrial Waste

The amount of industrial waste generated increased 13 tons from 2017 to 2,841 tons. Sludge increased due to higher production volume, but waste oil decreased substantially. The main reason for the decrease was that the Fujieda Plant, which had generated the largest amount of waste oil, was able to treat most of the waste oil as water by enhancing its wastewater treatment facilities.



3. Includes 9 tons of overseas waste

Social Contribution

IBI 18 (2016–2018)

- Cultivation of human resources to handle next-generation scientific technologies
- Contribution to health through disease awareness-raising activities
- Understanding of diversity through para-sports

IBI 21 (2019–2021)

- International contribution in the field of global health
- Contribution to health in local communities
- Promotion of understanding of diversity to achieve a society of co-existence

Continuation → Evolution

Chugai's Social Contribution Activities

As a responsible pharmaceutical company in healthcare, we work to raise awareness of diseases.

In the area of welfare, in conjunction with our business activities in the renal and bone and joint areas, we conduct ongoing donations of specially equipped para-transit vehicles as we understand the importance of transportation assistance services for people who require in-home nursing care. Regarding education, as a company that deals with leading-edge science we conduct activities to raise awareness of science and medicine among students, from elementary school children to university students, as well as among adults.

Moreover, we cooperate with local communities and engage in disaster preparedness education, mainly in areas where our research laboratories and plants are located. We also support para-sports to help create a society where everyone can participate in sports. Please see our website[1] for more details on Chugai's basic stance on social contribution.

1. https://www.chugai-pharm.co.jp/english/csr/community/

Main Initiatives

Disease Awareness

Chugai participates in a variety of activities to support cancer patients and their families. One such activity is Relay For Life Japan, an awareness support campaign that forges ties in the fight against cancer. This event, a 24-hour walk-a-thon in which cancer patients, their families and supporters participate as relay teams, was held in 48 locations throughout Japan in 2018. Chugai employees have participated as volunteers in Relay For Life Japan since 2007. A total of 500 employees took part as "Team Chugai" at 27 locations in 2018.

This year, we conducted the awareness raising activity of screenings with the "Try! Scope," which uses a fiberscope, and participants in various locations enjoyed the experience. As Team Chugai members provided explanations, participants experienced a simulated endoscopy, gaining an understanding of the importance of screening and early detection and treatment. We also promoted understanding of the importance of screening by using "Try! Scope" in health events hosted by local governments.

Initiatives for Generation AYA

Chugai launched the website AYA Life[2] for young cancer patients in March 2017 and has been continuously updating the contents. The term "AYA" (an abbreviation of Adolescents and Young Adults) was relatively unknown in Japan at the time of the launch, but recognition has grown with the inclusion of "Generation AYA Cancer" in the Japanese government's Third-Term Basic Plan to Promote Cancer Control Programs in March 2018. However, as the AYA generation ages, it will be dealing with a wide range of issues including higher education, employment and marriage. As a leader in the area of oncology, Chugai cooperates with academic and patient organizations to spread knowledge of generation AYA cancer patients' individual concerns and social issues to create an environment where they can receive treatment with peace of mind.

2. https://aya-life.jp/ (Japanese only)

Promotion of Measures against Locomotive Syndrome

Locomotive syndrome is a condition in which muscles, bones, joints, cartilage, intervertebral discs and other parts of the musculoskeletal system become impaired and motor function declines. The progression of the syndrome is highly likely to impede daily life. The Japanese Orthopaedic Association proposed it as a concept in 2007 and has been working to prevent the syndrome, establish measures for coping with it, and improve awareness. In cooperation with the prefectural chapters of the Japanese Clinical Orthopaedic Association, Chugai holds the Musculoskeletal Disorder/Bone and Joint Forum 10 or more times a year to deliver the latest information to healthcare providers. We will continue helping to promote healthy life expectancy through this activity.

Support for Para-Sports

Chugai co-sponsors the Japanese Para-Sports Association (JPSA) as an official partner, and cooperates in activities to help realize the JPSA's philosophy of "creating a vital and inclusive society." The main activities Chugai conducted in 2018 are as follows.

Dispatch of Volunteers to Competitive Sports Events

Chugai held the Chugai Pharmaceutical 2018 Wheelchair Softball Tournament in Tokyo as the title sponsor and provided support by sending 25 employee volunteers to assist with set-up, event management, English interpreting and other matters.

Raising Awareness of Para-Sports

- Co-sponsorship of a chair ski school for parents and children held by the Japan Chair Ski Association
- Support for a wheelchair tennis camp for children
- Operated a booth for experiencing wheelchair tennis and chair skiing at local community events and other venues
- Presentation of the para-sports-related webpages "Another Sport" and "ATHLETE MOTHERS" on the Chugai website (Japanese only)

Parent and child enjoying chair skiing class

Initiatives for Employees and Their Families

To deepen understanding of para-sports and people with disabilities, Chugai held a hands-on event for experiencing blind sports in cooperation with the Yokohama City Special Support School for the Visually Impaired. There were 18 participants from Chugai, including employees and their family members.

Disaster Relief

Support for Children in Stricken Areas

Chugai once again participated in the global charity event Roche Children's Walk conducted by Roche to support children in need. In this annual initiative, Chugai matches the total amount of funds raised by its employees, with half of the total amount donated to Malawi and other countries and the remainder donated to an organization in an earthquake-affected area in Japan. In 2018, the recipient organization was the non-profit organization Chobora, a cooperative facility for disabled children and adults in Iwaki City, Fukushima Prefecture.

Charity Sale

As part of its support for recovery from the 2011 Great East Japan Earthquake and heavy rain in Western Japan in July 2018, Chugai held a charity sale at its Head Office and Kamakura Research Laboratories. As employees at each location handled the goods and conversed with the sales staff, they renewed their hopes and prayers for the restoration and recovery of the affected areas.

Para-Transit Vehicle Donation Program

Chugai's program to donate specially equipped para-transit vehicles began in 1985 as part of activities to commemorate the Company's 60th anniversary. The program marked its 34th year in 2018. A total of 253 vehicles have been donated since the start of the program, including the five donated in 2018.

Securing the means for senior citizens and disabled people living at home to go to places such as hospitals, day service centers and day care centers and for staff from these facilities to visit homes to perform in-house care, is significant from the viewpoint of enhancing welfare services.

The para-transit vehicle donation program is conducted in cooperation with the Japan National Council of Social Welfare and Central Community Chest of Japan, and through it vehicles have been donated to recipients in all of Japan's 47 prefectures.

Initiatives for Global Health

As international contributions in the area of global health, Chugai participates in the Global Health Innovative Technology Fund (GHIT Fund),[3] which aims to conquer infectious diseases in developing countries, and Access Accelerated,[4] which conducts measures for people in low and middle-income countries who are living with noncommunicable diseases (NCDs). Please see our website[5] for more details on Chugai's basic stance on global health initiatives.

3. For details, see the GHIT Fund website (http://www. ghtfund.org/en).
4. For details, see the Access Accelerated website (http://www.accessaccelerated.org/).
5. https://www.chugai-pharm.co.jp/english/csr/globalhealth/

GHIT Fund

Jointly established in April 2013 with funding from Japanese pharmaceutical companies, the Japanese government (the Ministry of Foreign Affairs and the Ministry of Health, Labour and Welfare), the Bill & Melinda Gates Foundation and the United Nations Development Programme, the GHIT Fund is Japan's first public-private partnership to support and promote research and development of drugs, vaccines and diagnostics for infectious diseases in developing countries.

In December 2014, Chugai announced its participation in the GHIT Fund and contributed capital. It has also been promoting efforts using its innovative discovery technologies and research resources, including a program to develop drugs to prevent and treat dengue fever. As a partner in the GHIT Fund, Chugai expects that furthering the development of new medical technologies will go beyond fulfilling its basic social responsibility, leading to the promotion of health and sound economic growth in developing countries.

Access Accelerated

Access Accelerated was established in January 2017 by 22 global pharmaceutical companies including Chugai at the World Economic Forum Annual Meeting held in Davos, Switzerland. In partnership with the World Bank Group and the Union for International Cancer Control (UICC), Access Accelerated is working to achieve the U.N. Sustainable Development Goal 3 target of reducing premature deaths due to NCDs by one-third by 2030.

In addition to collaborative programs with other member companies, Chugai is conducting its own project to promote safer childbirth and maternity healthcare in Myanmar in partnership with AMDA-MINDS (AMDA-Multisectoral and Integrated Development Services). Through participation in Access Accelerated, Chugai will help to improve access to healthcare in low and middle-income countries.

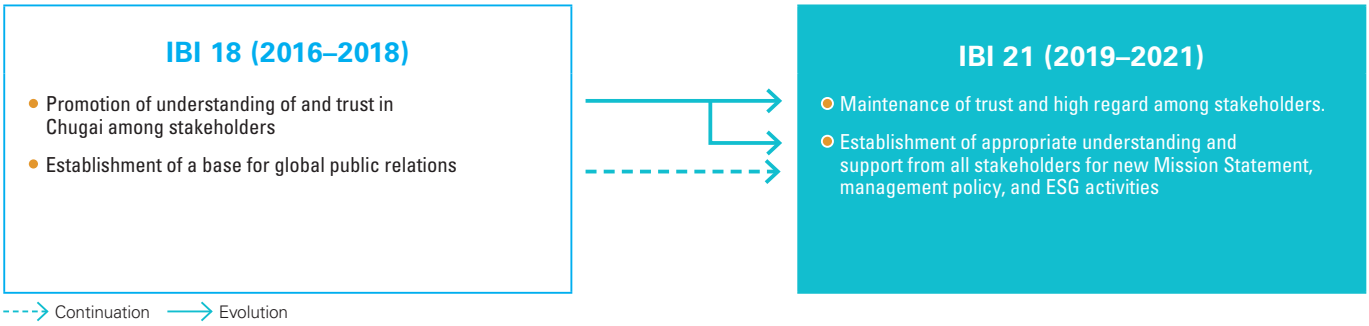
Main Initiatives and Progress

- Conducted awareness-raising and support activities for para-sports (served as title sponsor of a sporting event, provided training facilities, and operated a booth for experiencing para-sports)
- Donation of para-transit vehicles to provide transportation for home welfare services: Total of 253 vehicles over 34 years (1 vehicle each to 5 organizations in 2018)
- Number of locations in which Chugai employees participated in the 24-hour charity event Relay For Life Japan: 27
- Biology lab classes for children at the Japan Science Foundation's Science Museum: 130 participants in 12 labs
- Endowed courses at Waseda University: 2
- Number of employees who took volunteer leave: 45

We are supporting para-sports, healthcare, welfare and disaster relief efforts with the goal of creating a society in which everyone has the opportunity to flourish. We will continue to work on a broad range of issues based on social needs, contributing to the creation of a sustainable society in the process.

Megumi Sakai
Social Contribution Group,
Sustainability Dept.

Corporate Communications



Functions

Chugai is strengthening communication activities for internal and external stakeholders with the aim of securing their support and trust and sustainably increasing corporate value. In addition to clearly, fairly and continuously transmitting information on activities related to the creation of shared value with society, as well as our business activities, we emphasize two-way communication.

As a result, Chugai is well regarded externally. Chugai was chosen for inclusion in all four ESG indices selected by the Japanese Government Pension Investment Fund (GPIF), and has been selected as a component of DJSI Asia Pacific for the fourth time. (See page 2 for more details on external evaluation of our ESG initiatives.)

Disclosure Policy

Under new mid-term business plan IBI 21, we have identified "strengthen sustainable platforms" as a Group-wide strategy. Accordingly, we will strive to further develop communications as we believe that enhancing the platforms through dialogue with stakeholders will support our quest for innovation. To this end, in April 2019 the IR Committee was reorganized as the Corporate Communications Committee and shifted its focus from considering information disclosure policies for capital market participants to considering corporate communication strategies encompassing a wider array of stakeholders.

The Corporate Communications Committee is a corporate management committee composed of the CFO and general managers of the Corporate Communications Department, the Corporate Planning Department, the Finance & Accounting Department, the Sustainability Department and the General Affairs Department. The committee holds regular meetings and is responsible for the establishment, revision and internal dissemination of the Disclosure Policy, and for the management and promotion of information collection, disclosure and other related activities. Top management, including the CEO and key executive officers, has primary accountability for disclosure. In addition, the Corporate Communications Department takes the lead in coordinating with relevant departments, using various tools to communicate promptly and effectively.

Note: For further details on the Company's policy for disclosure to shareholders, investors, securities analysts and other capital market participants, please refer to the Chugai website (https://www.chugai-pharm.co.jp/english/ir/policy/disclosure.html).

Communication with Shareholders and Investors

Chugai's policy for disclosing information to shareholders and investors is to make timely, appropriate and fair disclosure of information in accordance with the Financial Instruments and Exchange Act and relevant rules of the stock exchange on which Chugai's shares are listed in order to receive fair valuation in capital markets. In addition, as a means to ensure transparency, we disclose information simultaneously in Japanese and English in principle, to allow easy access to disclosed information.

The 108th Annual General Meeting of Shareholders was held on March 28, 2019, and all agenda items were approved and passed by a majority. Moreover, in addition to quarterly investor presentations and conference calls to explain operations, we also conducted "R&D conference calls" to present and answer questions about information of great interest to investors. Furthermore, to improve communication with individual shareholders and investors, we hold production site tours and conduct investor presentations at securities company branches and via the Internet. Senior management also hosts visits by overseas institutional investors, and each year the president holds informal discussions with investors and analysts as an opportunity to speak directly in small groups.

Due to the introduction of the Principles for Responsible Institutional Investors (Japan's Stewardship Code) and Japan's Corporate Governance Code, greater dialogue between companies and shareholders is required. Chugai has proactively established forums for ongoing discussions between investors and the management team to ensure a fuller exchange of opinions. We will continue measures to enhance face-to-face IR with management.

Communicating Information to a Wide Range of Stakeholders

We emphasize proactive communication of information that is easy to understand in order to gain the support and trust of a wide range of stakeholders. Chugai takes an active approach to media relations through methods including press releases, various types of information meetings and informal discussions with management. We also use our website and a variety of other tools to promote understanding among the general public of the broad range of activities through which our businesses contribute to healthcare, the environment, human rights, society, human resource development and other areas. We plan to strengthen communication activities because we believe they help to enhance corporate value.

Main Initiatives and Progress

- Media and IR information events: 15
- Security analysts and institutional investors worldwide with whom individual meetings were held: 407
- Briefings for individual investors and shareholders: 8
- Attendees at the General Meeting of Shareholders: 414
- Second Prize, Nikkei Annual Report Award 2018
- 3rd place, Pharmaceuticals Category, 2018 Awards for Excellence in Corporate Disclosure, The Securities Analysts Association of Japan
- 2nd place, The 2018 All-Japan Executive Team Rankings, *Institutional Investor* magazine
- ESG website newly created