Marketing & Sales

“To contribute to the enrichment of quality of life around the world through the creation of innovative pharmaceuticals, and through the provision of pharmaceuticals addressing diverse medical needs.”

With this mission, Daiichi Sankyo Group operates in more than 50 countries.

Key Products Strategy

We have started its Third Mid-term Business Management Plan (FY2013-2017) aiming to establish itself as a “Global Pharma Innovator” capable of sustainable growth, while addressing diverse medical needs throughout the world. In fiscal 2007, when the Company started its combined business after merger of Daiichi Pharmaceutical Company and Sankyo Company Limited, a major challenge was to overcome patent cliff of its key products antihyperlipidemic agent pravastatin and the synthetic antibacterial agent levofloxacin, which the company successfully overcome by its blockbuster, antihypertensive agent olmesartan.

Now that olmesartan will be approaching maturity phase after growing throughout First & Second Mid-term Business Management Plans period (FY2007-2012), a major business challenge in the Third Mid-term Business Management Plan is going to be how smoothly we can offset olmesartan patent cliff by generating significant revenue from the next-generation antiplatelet agent, prasugrel, and anticoagulant drug, edoxaban, for sustainable growth.

● Olmesartan

In the Western markets, we are pursuing lifecycle management strategies focusing on a shift to combination products business. Especially in Europe, we are accelerating switchover to Sevikar and Sevikar HCT which not just provide significant patient benefits but also have extended market life and revenue opportunity.

There is still considerable room for growth in emerging markets. We are making attempts to increase market share of olmesartan by continually expanding our business in China following the successful launch of Sevikar.

In Japan, we are endeavoring to attract our potential customers’ attention to olmesartan’s well-established efficacy in the ARB class and its favorable safety profile. We are also going to emphasize olmesartan’s wide dosage range from low content of 5 mg to high content of 40 mg.

● Sales of Olmesartan (Local Currency Basis)

<table>
<thead>
<tr>
<th>Breakdown for Olmesartan</th>
<th>Japan: Olmetec, Rezaltas</th>
<th>U.S.: Benicar, Benicar HCT, Azor, Tribenzor</th>
<th>Europe: Olmetec, Olmetec Plus, Sevikar, Sevikar HCT</th>
</tr>
</thead>
</table>
● Prasugrel
We have conducted two Phase III trials of prasugrel in Japan, for treatments of ACS-PCI*1 patients and elective-PCI patients. Both trials in prasugrel group showed positive result in efficacy and the same level of bleeding ratio in safety, compared to the control group. We expect prasugrel to become a standard therapeutic drug for the treatment of ischemic heart disease undergoing PCI in Japan.

Based on these data, we applied for approval for an indication in the cardiac area in June 2013. Phase III trial for ischemic stroke patients is currently ongoing and expected to be completed in fiscal 2014.

In the global market, we are focusing more intensively on ACS-PCI patients with high risk of recurrence and aim to build growth in this area continuously based on the fact that we have obtained “class 1b” recommendation in the treatment guidelines of U.S. (AHA/ACCF/SCAI) and EU (ESC).

Also, we are going to actively expand our prasugrel business in emerging markets. Approval in China is expected by the end of fiscal 2013.

● Edoxaban
Edoxaban is an oral Factor Xa anticoagulant with excellent efficacy and a safety profile that requires only one dose a day, and is already marketed in Japan. We have conducted two global Phase III trials: Hokusai VTE trial aimed to acquire regulatory approvals for the indication of prevention of venous thrombosis (VTE), and the ENGAGE-AF TIMI 48 trial aimed to acquire approval for the prevention of stroke/systemic embolic events (SEE) among patients with (AF).

Regarding the indication for the prevention of stroke/systemic embolic events (SEE) among patients with (AF), we are aiming to get approval and launch by fiscal 2014 in Japan, U.S. and EU, and by fiscal 2015 or later in Asia and Latin America.

In addition, with regard to VTE, we are aiming to get approval and launch in Japan, U.S. and EU in fiscal 2014, and in Asia and Latin America in fiscal 2015 or later.

The group will also consider option to develop edoxaban business in emerging market through Ranbaxy.

● Sustainable Growth with Smooth Transition of Key Drivers

*1 Patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI).
Regional Strategy

We are currently pursuing marketing activities to address diverse medical needs in each region in an effort to achieve the target of the Third Mid-term Business Management Plan, i.e., “global sales of 1.3 trillion yen in fiscal 2017”. With our steady growth in the developed markets including the U.S., EU and Japan as a foundation, we are aiming to realize the sustainable and substantial growth in the emerging markets in India, China, Eastern Europe, the CIS countries and Africa over next 5 years.

The U.S.

In the U.S., we are engaged in three lines of business operations, i.e. Daiichi Sankyo, Inc. (DSI), Luitpold Pharmaceuticals, Inc. (LPI) and Ranbaxy Laboratories Limited. To address diverse market needs, we are aiming to grow through independent and flexible operations by making the most of the strengths of each line of operations in the U.S.

Since the exclusive marketing rights of Welchol and Benicar expire in fiscal 2014 and 2016 respectively, DSI will seek to offset the effect of LOE (Loss of Exclusivity) with prasugrel and edoxaban, as well as through complementary acquisitions or partnerships to boost sales performance.

LPI is aiming to maintain its leadership in the injectable iron segment by launching Injectafer in fiscal 2013, the next generation product to succeed Venofer. With entry into the gynecological medicine market within its sight, LPI is attempting to further develop its business in the U.S. iron preparation market where it has already secured the top share. LPI is also pursuing expansion of its multisource business by utilizing the new factory of former Pharma-Force that the company has acquired.

Ranbaxy is aiming to launch DS’s authorized generics*1 in the future in addition to the successful launch of FTF*2 products. Ranbaxy is also focusing on expansion of its branded business in dermatology. Products such as Absorica, which was launched at the end of 2012, are expected to become key drivers in our operation in the U.S. in the future.

Western Europe

Daiichi Sankyo Europe plans to improve the value of branded products as well as to maintain sales and profits by further shifting the promotion of olmesartan to combination products. Regarding prasugrel, the company is promoting use of the product in patients with high-risk ACS-PCI*3.

On the other hand, being in the highly competitive market environment, the company has already started business productivity improvements including organizational restructuring, and is aiming to transform itself to a more resilient organization that is capable of sustainable growth.

*1 The generic medicine which is entitled to use the patents and made using the completely same ingredients and manufacturing method with the original medicine.
*2 An abbreviated name for First to File. The U.S. system to ensure 180-day market exclusivity for the first company which files a patent application for generic drugs.
*3 Patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI).
Emerging Countries (ASCA)

In the ASCA (Asia, South and Central America) regions, due to the diversity in terms of demographics, economic growth, economic disparity, medical insurance systems, distribution systems, and use of medicines, differentiated strategies and tactics suitable for the market characteristics of each country is essential for sustainable growth.

In such an environment, we are first aiming to launch new products such as prasugrel and edoxaban, in China, while further expanding our olmesartan business.

We are also aggressively working on promotion of the hybrid business in collaboration with Ranbaxy and utilization and acquisition of external resources to achieve rapid growth during the implementation of the Third Mid-term Business Management Plan.

(Ranbaxy)

Ranbaxy is a key component of Daiichi Sankyo Group’s hybrid business model. We are striving for sustainable growth by promoting its products with high quality and profitability in the global market.

We are aiming to grow further as a leading company in India by further leveraging Ranbaxy’s brand.

We are focusing on development of competitive and differentiated products and market them through Ranbaxy’s global sales network. Regarding the business development in the emerging countries in Eastern Europe and Africa, we are promoting acquisition of external resources while strengthening business foundation in the regions.

In addition, we will implement Consent Decree agreed by the U.S. FDA (Food and Drug Administration) in December 2011, to resolve the AIP*1 (Application Integrity Policy) and import alert on certain manufacturing facilities in India. Daiichi Sankyo is appropriately overseeing the quality of Ranbaxy’s products. We will continue to strengthen the foundations to establish organizational structure to support growth strategy.

During the Third Mid-term Business Management Plan, we are further evolving the “hybrid business model”, which has been promoted by Ranbaxy ever since they joined the Daiichi Sankyo Group., Daiichi Sankyo group’s innovative drugs such as olmesartan and others are going to be promoted in the emerging countries by Ranbaxy.

At the same time, we will expand Ranbaxy’s generic products and differentiated products through Daiichi Sankyo’s network in Japan as well as global market.

Furthermore, we are aiming to develop authorized generics of Daiichi Sankyo’s innovative medical drugs right after the expiration of LOE (Loss of Exclusivity).

We are exploring cost reductions by sharing part of DS’s olmesartan and edoxaban production processes with Ranbaxy.

*1 An abbreviated name for Application Integrity Policy. An AIP is invoked against a facility by the U.S. Food and Drug Administration (FDA) when questions arise concerning the integrity and reliability of data submitted in its drug applications.
Japan Innovative Pharmaceutical Business

We contribute to medicine in Japan by providing a reliable source of information and the pharmaceuticals that Japanese patients need on a daily basis.

The products launched during Daiichi Sankyo’s Second Mid-term Business Management Plan (FY2010-2012) period are all pharmaceutical products that will become even more important as the population of Japan continues to age. These products include Rezaltas, an antihypertensive; Memary, a treatment for Alzheimer’s disease; and Nexium, a proton pump inhibitor for treating reflux esophagitis and other problems.

The product lineup will be enhanced even further as part of the Third Mid-term Business Management Plan. PRALIA, a new treatment for osteoporosis, was launched in June 2013. In fiscal 2014 new indications are planned for Lixiana (edoxaban), a direct oral factor Xa inhibitor, and in the same year we plan to launch Prasugrel, an antiplatelet agent. Both products have the potential to aim for positions in Japan as standard treatments for thrombosis and embolism. For diabetes drugs, in addition to Tenelia which is manufactured by Mitsubishi Tanabe Pharma Corporation and was launched in fiscal 2012, we also plan to jointly market Canagliflozin, which was submitted for marketing approval by MT Pharma in May 2013.

The power of reflecting the strength of product lineup surely in the acquisition of prescriptions - the massive volume of details*1 gathered by 2,300 MR*2 and the high quality of information are the unique features of Daiichi Sankyo.

After going through the integration period of the First Mid-term Business Management Plan and then building a strong base for rapid progress with the Second Mid-term Business Management Plan, Daiichi Sankyo’s Japanese Sales & Marketing Division has built up trust from those in the medical field. By using this business base we have built so far and carrying out the Third Mid-term Business Management Plan with speed and passion, we will contribute to both medical advancement in Japan and growth of the Daiichi Sankyo Group.

Although the growth rate of the Japanese prescription drug market has been slowing, it is

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*Ryoichi Kibushi
Senior Executive Officer
Head of Sales & Marketing Division, Japan Company
Daiichi Sankyo Co., Ltd.

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*1 Provision and collection of medical information
*2 A medical representative (MR) is primarily responsible for visiting medical professionals to compile and provide information on the safe and effective use of pharmaceutical products in order to ensure that the products are used appropriately.
still expected to reach an annual value of 10 trillion yen.

In particular, with the aging population, prescription drugs for lifestyle-related diseases such as Renin-Angiotensin type hypertension, lipids and diabetes will continue to be a major market. With cancer still the leading cause of death, anticancer drugs are seeing significant growth, and Japan’s preventive health care policies have also contributed to growth for vaccines. On the other hand, the promotion for the use of generic medicines will be enhanced upon the fact that the national medical expense is increasing in excess of the growth of the national income. In addition, the introduction of Transparency Guidelines and tightening of the Promotion Code are examples of how conditions for marketing activities have become stricter.

The circumstances surrounding the medicines have been changed from moment to moment in accordance with the medical needs which have been diversified. In flexibly responding to the changes of circumstances, and in increasing the number of products on which we need to focus, we will start approaches via various channels such as promoting new products and those listed for a long time, by utilizing almost 100% (based on the amount) distribution coverage of Japan’s sales channels of medical and pharmaceutical products, building the relationships with health insurance pharmacies, hosting lectures, advertising online, and enlightening diseases in order to perform efficient information services (Multi-Channel Approach). We aim for sustainable growth by being a reliable partner. We do this by continuing Daiichi Sankyo’s original MR Crosswise Structure*, which combines medical representatives (MRs) responsible for meeting the overall needs in medical facilities, with highly specialized MRs assigned to specific therapeutic areas, and collaborating with Group companies.

Sales of prescription drugs for fiscal 2012 in Japan included the increased sales of Memary and Nexium, with the aggressive promotions described as above after the removal of the limitation on dosage period, for a 9.6% increase year-over-year to ¥459.9 billion. Trends and future strategies for major products are given below.

- **Olmesartan Family (Antihypertensive)**
  Olmetec is widely recognized for its strong efficacy in reducing blood pressure putting it in a position where it can aim for the top share of the ARB mono therapy market in Japan. In fiscal 2013 we are focusing on providing information so that Olmetec will be prescribed to a wider range of patients. We have Calblock, a long-acting calcium channel blocker with hopes for its cardioprotective and renoprotective effects, and Rezaltas, combination products of Olmetec and Calblock. The Daiichi Sankyo Japanese Sales & Marketing Division has positioned these three products as the olmesartan family, and will propose them as treatments that can meet the needs of a variety of different conditions.

- **Memary (NMDA Receptor Antagonist Treatment for Alzheimer’s Disease)**
  We are attempting to penetrate the Japanese market with Memary as a new treatment for Alzheimer’s disease. We promote proper use so that dementia patients and their families can enjoy peaceful daily life, as part of a comprehensive approach including patient education with the goal of prescribing Memary and Donepezil jointly to new patients.

- **Nexium (Proton Pump Inhibitor)**
  Achieving status as No.1 new prescription once the dosage period restriction was lifted, shares of sales have increased rapidly. With joint promotion of Nexium together with AstraZeneca K.K and recognized as being very effective at regulating gastric acid secretion, our goal is to quickly gain the top share in the proton pump inhibitor market in Japan.

*1 A structure that links MRs who call on certain medical facilities and regional areas with MRs supplying specialized data in specific medical and therapeutic fields, ensuring the provision of high-quality information.
Japan  
Generic Business

We will bring about a new standard of generic drugs utilizing the quality and innovation that are unique to Daiichi Sankyo brands.

The government has reinforced the promotion of the use of generic drugs in order to inhibit the increase of the medical costs with Japan’s rapidly aging society. In April 2013, the Ministry of Health, Labor and Welfare announced a generic usage promotion plan to raise the existing target level and aim for the volume-based penetration rate of 60% or over by the end of fiscal 2017 based on the new calculation system. Under the circumstances, Daiichi Sankyo Espha steadily increased the line of generic drugs and the sales in fiscal 2012 reached 10.9 billion yen, a 20.3% increase compared to the previous year (prior to consolidated adjustment).

Based on the trust that the Daiichi Sankyo Group has established as a brand-name drug manufacturer, Daiichi Sankyo Espha has been creating and providing high value-added generic drugs with an aim to become the first choice of patients who need generic drugs. Particularly on “quality” aspects, we used techniques such as laser printing of the name of the drug/company on both sides of the tablet and printing a barcode on the back of the PTP sheet of each tablet in order to make it easy to take and to avoid misuse of our medications. We are committed to setting new standards for generic drugs and meeting unmet needs by enhancing the value of generic, which will help us meet the expectations of the society and offer more options for the Japanese healthcare system.

In fiscal 2013, one of our key strategies is to seek a larger market share of the generic drug Donepezil that was put on the market in fiscal 2011. Since January 2013, we have strengthened the sales cooperation with the Sales & Marketing Division of Daiichi Sankyo that owns the treatment of Alzheimer’s disease Memary that can be taken in combination with Donepezil. We will contribute to establishing the Daiichi Sankyo brand in the area of AD (Alzheimer’s disease).

In addition to this, we will strive to strengthen the relationships with health insurance pharmacies and wholesalers to ensure the top share of two items in generic ARB drugs which will become off-patent in 2014. We will also try to secure the No.1 domestic share of the product that would become the first drug developed jointly with Ranbaxy and thus create synergies for the Daiichi Sankyo Group.

Hiroto Yoshiwaka  
Representative Director, President  
Daiichi Sankyo Espha Co., Ltd.
Japan ● Vaccine

We make a contribution to improve public health and medical economic efficiency while preventing infectious diseases and child life-threatening diseases.

A movement to foster the increased use and access of vaccines is currently growing in terms of preventive care in Japan. As a result of the amended Preventive Vaccination Act enforced in April 2013, 3 vaccines for haemophilus influenza type b (Hib), pediatric pneumococcus and cervical cancer were added to the list of routine immunization as essentially free of charge. To combat potential pandemic threats, Daiichi Sankyo initiated operations of Japan Vaccine Co., Ltd. (Japan Vaccine) as a joint company with GlaxoSmithKline K.K. (GSK) in July 2012 and the vaccine business has been further expanded since then.

Daiichi Sankyo is engaged in research, early-phase clinical development, and distribution for vaccines. In addition, the company also pursues the creation of vaccines to serve important medical needs of patients, and ensures their stable supply through its relationship with Kitasato Daiichi Sankyo Vaccine Co., Ltd. specialized in production/CMC*1 and Japan Vaccine specialized in distribution and late-phase clinical development. The basic strategy for the Third Mid-term Business Management Plan (FY2013-2017) is described as below.

- Establish Daiichi Sankyo as a leading vaccine company
  In addition to combination vaccines, we will develop new concepts such as an intradermal administration vaccine by leveraging our device technology. For distribution, we will enhance our product line-up by adding GSK vaccines.

- Enhance the manufacturing/CMC structures and improve manufacturing efficiency
  Prior to PIC/S*2 affiliation in Japan, Kitasato Daiichi Sankyo Vaccine will proceed to secure the global standard quality and enhance production efficiency through working with PIC/S GMP*3 at an early point.

- Join national plan for human influenza pandemic
  Through "The project maintenance for new influenza vaccine development/production system" by the Ministry of Health, Labour and Welfare, we will proceed to secure a vaccine development/production system and a rapid supply system at the time of the occurrence/prevalence for a new strain of influenza.

*Takeshi Ogita Ph.D.
Member of the Board, Senior Executive Officer Head of Vaccine Business Intelligence Division, Japan Company Daiichi Sankyo Co., Ltd.

*1 CMC stands for Chemistry, Manufacturing and Control. It means any information concerning chemistry, manufacturing and control of drug substances and drug products in application documents.
*2 PIC/S stands for Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme. It is an unofficial framework for interauthority cooperation in the field of medicinal products. EU, the U.S. FDA, and many other countries have joined it.
*3 PIC/S GMP is GMP (Good Manufacturing Practice) that PIC/S establishes.
Japan  OTC Business

To respond to various patient needs, our OTC products help to promote beauty and health.

In order to maintain and enhance the public health, OTC drugs1 with new functions and switch-OTC drugs with converted medical compositions have been increased in Japan. On the other hand, the competitions are becoming severe because of diversified distribution channels in the market. In 2012, the Japan OTC drug market was 97.8% (based on store sales) of the previous year.

In an intensely diverse market in 2012, Daiichi Sankyo Healthcare had a 2.8% increase in sales compared to the previous fiscal year which comes to a total of 47.1 billion yen. This growth was due to the sales expansion of antipyretic-analgesic Loxonin S and the growth of the functional skincare/oral care category.

During the Third Mid-term Business Management Plan, the Company will focus on the following fundamental strategy to meet the various needs of people.

- Increase sales by focusing on selected brand and improve P&L structure

While enhancing sales by concentrating resources on more competitive brands, optimization of direct sales expenses will be applied to other brands. We will actively expand our investment for brands such as Lulu, Loxonin S, Daiichi Sankyo gastrointestinal drug, and Transino. For Loxonin S in particular, we will maximize the brand value by encouraging the promotion for proper use as well as providing useful counseling information to pharmacists.

- Expand skin care direct marketing business

For the mail-order business, which started in 2012, we will build upon our foundation by enriching the product line-up in terms of aging care brand Derma-energy in the growing skincare market, as well as expanding to new customers.

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*1 Over-the-counter (OTC) drugs are pharmaceutical products that can be purchased without a prescription from a doctor.
## Major Products

### Global products

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>Olmesartan</strong></td>
<td>Anti-hypertensive agent</td>
</tr>
<tr>
<td><strong>Prasugrel</strong></td>
<td>Antiplatelet agent</td>
</tr>
<tr>
<td><strong>Edoxaban</strong></td>
<td>Anticoagulant</td>
</tr>
</tbody>
</table>

### Innovative pharmaceuticals in Japan

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Memary</strong>®</td>
<td>Treatment for Alzheimer’s disease</td>
</tr>
<tr>
<td><strong>Nexium</strong>®</td>
<td>Treatment for reflux esophagitis, etc.</td>
</tr>
<tr>
<td><strong>Inavir</strong>®</td>
<td>Anti-influenza treatment</td>
</tr>
</tbody>
</table>

### Generic pharmaceutical

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Donepezil</strong></td>
<td>Treatment for Alzheimer’s disease</td>
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</table>

### Vaccine

<table>
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<tr>
<th>Product</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ActHIB</strong>®</td>
<td>Haemophilus b conjugate vaccine</td>
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### OTC Drug

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>Loxonin</strong>® S</td>
<td>Analgesic and anti-inflammatory drug</td>
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Innovation and Openness Leads the Way to "Global Pharma Innovator"

Glenn Gormley, MD, PhD
Senior Executive Officer, Head of Research & Development
Daiichi Sankyo Co., Ltd.

The Environment Surrounding the Pharmaceutical Industry and the Challenge for Daiichi Sankyo Group

The pharmaceutical industry is facing dramatic challenges in our business environment. Three major challenges include: 1) a decrease in the number of approved new molecular entities, 2) a shift from small molecules to biologics, and 3) a marked increase in R&D expenditures. As an innovative organization, we must continuously address challenges to our business and be prepared to change, or redirect, how we do business. For Daiichi Sankyo R&D, this means we must improve our productivity while making efforts to reduce costs.

We continue to focus on developing first in class products to bring innovative treatments to the patients who need them. One of our key focus areas during the Second Mid-term Business Management Plan (FY2010-2012) was to globalize the R&D organization – which has allowed us to harmonize our procedures and systems. As a global organization, we are able to access expertise from around the world, allowing for quicker decision making and enhanced collaborations across the globe. We have had many successes but we still have room to improve. As an innovative organization, continuous improvement is a must. Scientists by nature are always looking to improve upon things and it is this innate quality of our R&D organization that keeps us looking for better ways to do things.

The Daiichi Sankyo R&D Culture

To have a highly efficient organization, we must be willing to change how we work and how we behave. In this regard, there are several things I want us to focus on:

- challenge respectfully;
- empower employees at every level;
- proactively engage stakeholders;
- take calculated risks.

Respectful and timely debate is a foundation of our decision-making and key for enhancing person-to-person relations, developing technical capabilities and evolving
Way to “Global Pharma Innovator”

our organization. Therefore, I encourage active debates throughout the organization, regardless of level. I also encourage risk taking, particularly in the planning and execution of our clinical programs. Of course, risk taking still requires us to be committed to quality and compliance, but it does provide opportunities to challenge the status quo, or to approach a problem in a different way. I am committed to establishing a diverse organization, where different ideas and backgrounds come together to find new solutions to familiar problems.

Establishing this organizational climate will contribute to enhancing collaboration with our outside partners and will enhance the corporate value of our group through developing productive partnerships in order to deliver truly innovative medicines quickly to our patients.

Aiming For an Organization That Will Stimulate Innovation

I am very proud of the R&D Unit in Daiichi Sankyo, and I believe that it is a very innovative organization. By continuously challenging ourselves to do more, and to do better, we will overcome many barriers to innovation. There are many patients who are counting on us to find treatments for their illness, so I push myself every day, and that is what I expect of everyone in R&D.

An example of continuous improvement is the recent formation of our internal Venture Science Laboratories, which is comprised of a small number of scientists who are empowered to make decisions quickly based on their own judgment without the need for lengthy reviews. They will aggressively establish partnerships and relationships with external organizations and drive innovation in different ways.

Never Sacrifice Quality or Compliance

Our commitment within the 5-year Business Plan (FY2013-2017) is to increase productivity, speed up timelines wherever possible, and expand our portfolio rapidly. But the most fundamental necessity of R&D lies in maintaining quality and compliance.

Our R&D division has established a close relationship with the compliance organization. Allan Welsher, who leads the Global Quality Assurance Department, and I meet regularly to discuss issues and share ideas. At every level of the organization there is a clear commitment to maintain quality and compliance. It is a very clear principle.

Contributing to Global Health and Becoming a True “Global Pharma Innovator”

The mission of Daiichi Sankyo is to bring innovative new treatments to patients who need them. That is at the heart of R&D. We are always looking for ways to bring new medicines to patients anywhere in the world.

We often develop medicines that are useful to a large number of people. But sometimes we identify products, or even technologies, that can be used to treat small groups of patients – such as orphan indications. Being able to provide a treatment to any patient is a great accomplishment, but particularly for patients with a rare disease when many companies may not want to invest in the research and development, it is very satisfying.

We continuously monitor the activities of R&D to ensure we are focusing on priorities. By setting clear goals, we will create a competitive pipeline, deliver innovative products, and enhance our commitment for improved global health.
Research and Development

Realizing Innovation

Global Research System

At Daiichi Sankyo, our research facilities around the world work closely together to identify novel treatments. In Japan, Daiichi Sankyo’s Research Laboratories lead innovative R&D activities of Daiichi Sankyo; Daiichi Sankyo RD Novare plays a role as the discovery platform for R&D and Asubio Pharma focuses on basic research to preclinical study activities – the core of discovery function. In Europe, U3 Pharma is actively developing new antibody drugs as potential cancer treatments while in the U.S., Plexxikon has built a promising pipeline of small molecules and technical research platform. The Daiichi Sankyo Life Science Research Centre in India (RCI) and Tissue and Cell Research Center Munich (TCRM) function as the strength to identify innovative new medicines.

Establishment of Venture Science Laboratories

Daiichi Sankyo established Venture Science Laboratories in April 2013 to enhance an innovative organization. It is comprised of a small number of scientists who are empowered to challenge various kinds of development through new approaches freely with their special authorities and budgets. The venture spirit has already started their very innovative R&D activities.

Open Innovation

Daiichi Sankyo has supported the TaNeDS® (Take a New challenge for Drug diScenary) collaborative drug discovery project since FY2011. This project solicits applications for funding from researchers at universities in Japan and public research centers in Japan. In FY2013, we began to actively seek new products and/or technologies being developed outside of Japan, including in Germany, Austria and Switzerland which will contribute to future research and development activities.

The logo mark of TaNeDS
The logo mark of TaNeDS symbolizes “a hope growing up by partnership.” The twin leaves, which also appear as two people holding hands, represent collaboration needed to nurture the seeds of hope.
Reinforcing the research function of biomedical drugs

To reinforce the basis of biopharmaceutical research, we have established the new Biologics Oversight Function, which integrates biopharmaceutical functions that have been traditionally dispersed throughout the research centers. Within the Biologics Oversight Function, the Biologics Pharmacology Research Laboratories was created for target-based drug discovery and pharmacological evaluation of next generation biopharmaceuticals. This group is also responsible for the development of Biosimilars in Japan to provide lower cost and highly effective biologics as they reach the end of their patent life. Additionally, the manufacturing technology development function of biopharmaceuticals was transferred from the Pharmaceutical Technology Division into the R&D Division.

In order to protect the intellectual property

It is important for Daiichi Sankyo to maintain a variety of intellectual properties such as the idea of overcoming the challenges of science and technology (patent, utility model), the easy-to-use design (design), and the brand to promote a choice for consumers (trademark). We, Daiichi Sankyo Group, strive to create excellent pharmaceutical products and contribute to the improvement of global health*1 through properly protecting our intellectual property.

We have substance patents for protecting the active ingredients, and also a portfolio of patents protecting production methodologies and formulation technologies. We recognize that the tools and biomarkers necessary for research and development and other basic technologies necessary for production are key to our business model in order to support the expanding business strategy while protecting the intellectual property of our own as well as respecting the intellectual property rights of others even in the area of biotechnology-based pharmaceuticals, well-established pharmaceutical substance, biosimilars, vaccines, etc. We are also globally dealing with intellectual property issues to meet the global business expansion. We are expanding the countries to ensure intellectual property rights, placing the intellectual property personnel in Japan, the U.S., Europe and India, taking into account the characteristics of the area in an accurate and timely manner. We are working closely with the research and development department in order to adapt the latest science and technology to the research and development of pharmaceutical products, and establishing a cooperative relationship with outside agencies of open innovation and open development.

Voice

We will speed up on developing biopharmaceuticals, one of the future key industries of Japan.

Junichi Koga, Ph.D.
Corporate Officer, Global Head of Biologics Biologics Oversight Function, R&D Division
Daiichi Sankyo Co., Ltd.

Biopharmaceuticals constitute a market that has a potential to become one of the key industries of Japan. It is an area that will grow as a platform for drug discovery contributing to addressing unmet medical needs. In addition to our acquisition of U3 Pharma, a bio-venture based mainly on antibody drugs, we have gained the most valuable experiences concerning biopharmaceuticals through the development and distribution of Denosumab, our first major antibody drug.

First, we hope to succeed in biosimilar development, which will also benefit patients. Then, we can link the experience to third generation biopharmaceuticals development. We created the “Biologics Oversight Function” in order to raise the level of biopharmaceutical research, integrating biopharmaceutical functions dispersed throughout the research centers. It is important that offices work closely with each other at a global level while maintaining independence.

*1 Global health refers to the issues concerning health and health-care across borders.
For Enhancing the Productivity in R&D

Global decision making and Effective investment of resources

Our culture within Daiichi Sankyo R&D has been to ensure we can have robust discussions about science. We want the data to drive our decisions, and we expect that our internal experts challenge conventional thinking. Our highest decision making bodies are TR-GEMRAD (Translational Research–GEMRAD) for the decision in the early phase of development and GEMRAD (Global Executive Meeting of Research and Development) for the decision in the late phase of development. The discussions at the GEMRAD and TR-GEMRAD meetings include expertise from across the organization, including Quality and Safety Management, Product Portfolio Management and Business Development, so we can ensure we are investing our resources to develop the right medicines for patients.

Innovation of methods of work and action

All R&D members are expected to demonstrate strong leadership and contribute to the success of our company. Each person is empowered to play a leading role in the different areas of expertise and make a quick decisions whenever possible in order to obtain a world-class technological innovation capability.

In order to be truly innovative, our work requires brave ideas beyond a conventional way of thinking. It is an expectation of each member of R&D to engage our internal and external stakeholders to help test our thinking.

Research and development management with the clear setting of the goal

We have set clear and aggressive – yet achievable goals for the R&D organization in the Third Mid-term Business Management Plan. For example, launching of 2 new medicines for major indications, advancing 4 projects into late phase clinical trials after POC and 9 projects into phase 1 new clinical trial are set as important goals every year. By achieving these goals we can create a competitive pipeline while delivering innovative pharmaceutical products to patients quickly and continuously to meet unmet medical needs.

Collaboration with outside partners

In order to rapidly and continuously deliver new drugs, we not only develop our company’s products together with partner companies having excellent expertise, but also we are actively engaged in the license alliance that incorporates the research results of other companies including bio-venture companies in our company.

Major License/Alliance Partnerships Related to R&D from 2010 to 2012

<table>
<thead>
<tr>
<th>License/Alliance</th>
<th>Business Partner</th>
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<tbody>
<tr>
<td>AMP-110, B7-H4 fusion protein (autoimmune diseases)</td>
<td>Amplimmune</td>
</tr>
<tr>
<td>Comprehensive Research Alliance</td>
<td>National Cancer Center</td>
</tr>
<tr>
<td>Etanercept rPTD-protein (autoimmune diseases)</td>
<td>Coherus BioSciences</td>
</tr>
<tr>
<td>Rituximab monoclonal antibody (malignancy)</td>
<td>Biosimilar business in Japan and Asia</td>
</tr>
<tr>
<td>Collaborate to Discover and Develop Innovative Therapeutics</td>
<td>NRM Biopharmaceuticals</td>
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<tr>
<td>Narcotic Analgesic Hydrochloride Hydrochloride (cancer pain)</td>
<td>Mundipharma</td>
</tr>
<tr>
<td>Establishment of Japan Vaccine Co., Ltd Strategic Alliance (Vaccine Business)</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>Methylthioninium chloride Solution for Injection for Methaemoglobinemia</td>
<td>Provepharm</td>
</tr>
<tr>
<td>Therapeutic Collaboration to Develop Anticalin® Therapeutics</td>
<td>Pieris</td>
</tr>
<tr>
<td>Biological Drug Development Program</td>
<td>Biowa/Lonza</td>
</tr>
</tbody>
</table>

*1 POC, which stands for Proof Of Concept, is to confirm the predicted features concerning the effectiveness and safety of new medicines through clinical trial.
To Meet Unmet Medical Needs

We are promoting the development of Anti-thrombosis therapeutic medicines while we maintain a competitive edge in the portfolio of medicines for high-blood pressure, infectious diseases and hyperlipidemia. Our research teams also focus on the areas of oncology and cardiovascular-metabolics to increase our competitiveness in these areas with significant unmet medical needs.

“Priority” Areas

In research and early development, Daiichi Sankyo focuses on the categories of oncology and cardiovascular-metabolics, where there are significant unmet medical needs. In these categories, Daiichi Sankyo, together with subsidiary organizations such as Plexxikon (U.S.) and U3 Pharma (Germany) have been taking the initiative in research. U3-1287 is an anti HER3 antibody developed by U3 Pharma. HER3 is highly expressed in various cancer cells. PLX3397 is an oral kinase inhibitor developed by Plexxikon being investigated for applications in both solid and liquid tumors.

“New” Areas

We are also proceeding with the research beyond our traditional therapeutic areas. We are collaborating with Amplimmune, Inc. to develop “AMP-110”, the B7-H4 fusion protein for autoimmune diseases. “AMP-110” is being investigated with the potential to become a first-in-class medicine with a novel mechanism of action that works by blocking inflammatory T cell differentiation. We have started an early phase clinical trial in the first half of 2013. Daiichi Sankyo and Amplimmune will also collaborate on basic research related to AMP-110 including biomarker discovery.

Edoxaban
(Anticoagulant: oral factor Xa inhibitor)

Two global, phase 3 clinical trials of Edoxaban were recently finished. The trials of ENGAGE AF-TIMI 48 have been underway for the prevention of thromboembolism caused by atrial fibrillation in collaboration with 21,000 patients. The trials of HOKUSA-VTE have also been underway for the treatment and prevention of recurrence of deep vein thrombosis (DVT) and pulmonary embolism (PE) in collaboration with more than 8,200 patients.

Prasugrel
(Antiplatelet Agent)

Since launched as a treatment for cardiac disease in Europe and the U.S. in 2009, Prasugrel has been approved in more than 70 countries in the world. In Japan, Daiichi Sankyo has been developing the drug for several indications including ischemic heart disease who need percutaneous transluminal coronary angioplasty (PCI).
In order to meet the diversifying medical needs and to provide pharmaceutical products with high customer satisfaction, we will continue to create and realize innovative pharmaceutical technology as "A Solutions Innovator."

The vision of the Pharmaceutical Technology Unit

"A Solutions Innovator" - The vision of the Pharmaceutical Technology Unit in the Daiichi Sankyo Group is to create and to realize innovative pharmaceutical technology.

The needs for pharmaceutical products are ever evolving. In order to meet these changing demands, our role is to improve our pharmaceutical technology and realize innovative "solutions," thereby providing pharmaceutical products with high customer satisfaction.

To fulfill our role, we have set numerous strategic goals in the last six years, and attempted to improve our pharmaceutical technological capabilities. Along with new technology development and high value-added pharmaceutical products using new devices, the Pharmaceutical Technology Unit was able to respond in a timely manner to the Great East Japan Earthquake in March 2011, and was able to minimize the impact of this disaster.

With several challenges found in the past six years, we will use the lessons learned from them and intend to grow further in the Third Mid-term Business Management Plan.

Three strategic objectives in the Third Mid-term Business Management Plan

There are numerous situations surrounding recent pharmaceutical technology, including the growing needs for lower cost pharmaceutical products due to the medical expenditure reduction policies taken by various nations due to the global economic downturn, and the resulting increase in the low-cost generic pharmaceutical products as well as the increase in the volume of counterfeit medicine.

In addition, upon the fact that the level of quality assurance has been tighten than ever because of the enhanced regulations for medical and pharmaceutical products, we, at the Pharmaceutical Technology Unit, have identified the following three strategic objectives which we will implement in the Third Mid-term Business Management Plan.

The first objective is differentiation through superior formulation technology and the "creation of high added value" by providing solutions to new business needs. The next objective is the "improvements to productivity" by acceleration of development speed, quicker launch to market, and efforts to lower cost. Finally, contributions to the global market including Japan, U.S., Europe and ASCA*, as well as effective global utilization of operating resources including the Ranbaxy Group, in other words "collaboration," can be realized.

By implementing these strategic objectives into our action plans, we can further improve our innovative pharmaceutical technology, and we will aim to become the innovator which can provide "solutions." It enables medical care which the patients and their families, as well as the medical professionals hope for.

*1 Abbreviation of Asia, South and Central America. This is internal terminology indicating markets outside Japan, the United States and Europe.
The main approach

- **Creation of high value-added pharmaceutical products through cutting-edge technology**

We are actively developing and applying new technology which can contribute to pharmaceutical product development to meet the diverse needs for pharmaceutical products. For example, the application of oral dispersing (OD) tablets\(^1\) to major products, which are increasingly in demand due to its ease of consumption. Product name printing on tablets is applied to major products to avoid mix-ups in the consumption of medicine. Extended release formulation technologies\(^2\) are being applied to narcotics. We will make every effort to improve the health and quality of life of the patients.

We emphasize the employees’ physical visit of medical fronts, such as hospitals, to thoroughly search all the needs addressed by medical professionals dealing with medicines. With the pharmaceutical platform technology of the Pharmaceutical Technology Unit, we will move forward to the realization of unique and innovative ideas ever and the provision of patient-friendly highly-value-added pharmaceutical products.

Additionally, as a precaution against counterfeit medicine, we have started investigating the introduction of identification tags that use highly advanced technology on top of existing cutting-edge technology that can identify counterfeit medicine.

- **Organization structure that can match the global market strategy**

Since the environment surrounding pharmaceutical products is becoming more globalized and diverse, our Pharmaceutical Technology Unit has implemented an optimum operation structure that can match the global market strategy, and continuously improve and optimize operation processes with our global group companies, as well as conduct global technological collaboration. For example, investigational medicinal products used for global clinical studies are being manufactured locally in an attempt to lower cost and improve operation efficiency. We also will attempt to obtain and protect intellectual property in the establishment of the manufacturing methods, taking mutual advantage of the strength of our group companies.

Additionally, we have been hosting internal SC-CMC Technology Meetings with the Supply Chain Unit as part of our technology collaboration. The first of these meetings, held in fiscal 2012, was attended by a large number of employees, and was proven to be a very fruitful event. We plan to continue holding this meeting after fiscal 2013, as a place to actively exchange ideas.

The cultivation and deployment of human resources that can work globally are important strategies, and various measures will be taken. Starting with support for professional knowledge and language development, we will also aim for solid organization that utilizes individuals’ strength while mutually covering their weaknesses, and also develop an environment that will promote cooperation.

- **Decrease in the odor by developing the new blister package sheet films**

The odor from Olmetec Tablets is absorbed by the odor absorption material added to the package sheets. The odors dissipated when taking the tablets out of the sheets have decreased significantly compared to previous package with this improvement. Also, we are working to change our design to a more easily understandable, highly discernible one.

*1 Tablets that dissolve quickly by saliva when administered intraorally, so that neither water nor swallowing is necessary.

*2 Tablets that are manufactured to dissolve gradually, avoiding sudden increase in the blood concentration, and consequently has the advantage of reducing the number of medication.
Supply Chain

Amid the current rapidly changing environment, it is necessary to change to a quick and flexible supply chain, and we will fulfill this need.

Ensuring quality targets and achieving stable supply

Currently, the environment surrounding the pharmaceutical industry is changing rapidly. Increased globalization of markets has led to expanded sales areas and handling higher numbers of products (including the rise of generic pharmaceuticals), and with these factors supply chains have become more complex. With the need to meet the requirements of Corporate Social Responsibility in addition to the importance of stable supply and quality assurance for pharmaceuticals, it has become a critical issue for companies to deal with all aspects of their supply chain, from procurement of raw materials to production and sales.

It is because of the current rapidly changing environment that changing to a quick and flexible supply chain is necessary. We have a clear vision to ensure quality requirements, low costs, and to ensure a supply chain system that is capable of providing a stable supply of products.

Enhancements to supply chain technology

In order to ensure quality and a stable supply, it is important to control the optimal supply structure using supply chain technologies in manufacturing and management. As part of our mid-term policy and strategy over the next 5 years, first I would like to mention adopting a new mindset to reduce initial costs by having a broader perspective. We will continue activities to reduce initial cost on a global level, from decreasing costs through global procurement to optimizing transport methods and optimizing manufacturing sites. The foundations for a global supply chain structure taking full advantage of the resources of each region will be built and optimized in order to create results. By implementing these strategies, we will work towards achieving our goal of a supply chain structure that is efficient, stable, low-cost and high-quality.

Improving individual observation skills

What is the best way to achieve high quality results in a rapidly changing era? In addition to obvious assets such as personnel, funding and resources, ensuring the entire organization is thinking along the same vectors is also important. We will work on building an organization in which, based on knowledge and experience, each individual is constantly improving their skills in order to catch subtle changes and abnormalities and work towards the greatest quality possible.
The main approach

- **Pursuit of Quality, Cost and Delivery (QCD) by enhancement of supply chain technologies**

Supply chains consist of many steps, from procurement of raw materials to manufacturing and logistics. And for pharmaceutical products where people’s lives are on the line, the key duties include ensuring the product reaches patients and that urgent requests can be met quickly. In order to make it possible for doctors to treat their patients appropriately, it is necessary to strategically manage inventory, including those products with lower demand. Therefore, it becomes necessary to improve technologies and skills throughout the supply chain, from planning and calculating initial costs to proposals of manufacturing plans and inventory management. By switching over to production methods based on advanced technologies and lowering costs by cooperating with partners to use cost competitive ingredients, we will continue to pursue quality, cost and stable supply simultaneously.

- **Maximized use of global resources to optimize supply chain**

With the globalization of our business, we have been building and optimizing a global supply chain that uses the resources of each region to their maximum potential. Specifically, we are looking at optimum manufacturing sites considering the lifecycle of each product through collaboration between Japan and Ranbaxy (Please refer to the diagram below concerning global commodities). We also plan to optimize domestic manufacturing structures, looking at possible structural inefficiencies among manufacturing and logistic affiliates.

- **Seamless management and personnel exchange**

The supply chain unit has adopted a barrier free supply chain unit in regards to the organization, country and area when it comes to information coordination and communication. In other words, in our management, the key word is “seamless.” As part of this, a variety of personnel are rotated in and out. Exchanges are carried out periodically not only for Pharmaceutical Technology Unit, Quality & Safety Management Unit, but also with domestic manufacturing and logistic affiliates. At the global level, we have exchanges ranging from 3 months to several years, which have proven very beneficial to both the employees and Daiichi Sankyo. We will continue to work towards training personnel who can seamlessly share the vision of the affiliate companies involved in the exchange.

- **Supply route for global products**

The diagram below illustrates the supply route for global products.

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**Diagram of Supply Route**

- **Daiichi Sankyo Group Value Report 2013**
Reliability Assurance

Since the quality and safety are the foundation of pharmaceutical products, we aim to assure optimal reliability wherever we conduct businesses, with no room for compromise.

Quality assurance optimized for the field

We make pharmaceuticals that are proven to have good safety and efficacy profiles, industrialize them using our superior pharmaceutical technology, reproduce consistent quality in our production process, and deliver them to customers. It is our mission and our number one priority as a life-science oriented company to create safe and high quality pharmaceuticals. We are confident that the quality and safety control structure of the Daiichi Sankyo Group meets the global standards. Increasing levels of globalism as well as stricter quality assurance and safety standards have demanded that we continuously meet even higher levels of quality and efficiency.

The policy of the Quality & Safety Management Unit is to "carry out operations to ensure high safety control, quality assurance, and reliability assurance levels, as well as improvements to the productivity for the whole Daiichi Sankyo Group." We will respect the culture and customer needs of the local region, and assure optimum quality and safety while carrying out and enforcing policies to maintain regional competitiveness, and aim for quality assurance structure that we can be globally proud of.

Future essential measures

We plan to establish reliability in the data to be used to apply for the approval of the oral factor Xa inhibitor Edoxaban, while also taking necessary safety steps to deliver safe and trustworthy products to the patients as soon as possible. We will further enhance the safety measures for PRALIA, a novel treatment for osteoporosis which became available to patients in Japan in 2013, and seek continuous improvement in our safety control structure of all of our innovative pharmaceuticals. Additionally, we will improve the coordination channels between all product related divisions including research and development, supply chain and pharmaceutical technology, whilst executing appropriate product quality assurance steps in the life cycle management (LCM) measures for our new and existing products.

We will also modify and strengthen the organizational structure of the whole Quality & Safety Management Unit at various levels, in order to maintain the foundation of the company to meet stricter regulations of each nation. We will work to improve the operational standards of quality assurance and safety control not only in Japan but also of the whole group at the global level. Accordingly, we will provide effective assistance/support for group companies such as rotation of personnel with required skills and knowledge, considering the strengths and challenges of each company.
The main approach

- **Quality assurance structure for the whole product life cycle**

We will operate under the global structure following the GxP*1 and receive inspections by the regulatory agency in each country for the whole product life cycle. We will also conduct internal audits to make sure that GxP is being followed from a global standpoint, and use them to improve our operations. We will further conduct objective system audits on our group companies, ensure appropriate standards for all assurance levels, and provide active support when necessary.

We will enhance our structures to enable stable supply of high quality pharmaceutical products, and make every effort so that patients and medical professionals can reliably use our products.

- **Enhancing the safety control operation**

In order to enhance and increase the efficiency of our safety control operations, we are working with different departments in our group to construct systems for the successful operation of the global safety database, the IPOS (Integrated Pharmacovigilance Operations System) within fiscal 2013. The goal is to standardize and optimize the safety control operations, collect safety data from all sites, and improve the transparency and the flexibility through increased coordination between sites, all at a global level. We plan to move this system into stable operation in the year 2014. We will unify safety evaluation operations globally, improve the quality and efficiency of such operations, and analyze the global data to take quick and solid steps against safety risks.

- **Review of the Quality & Safety Management Unit structure**

The structure has been reviewed since April 2013 due to the globalization and diversification of the business as well as stricter regulations. This has involved emphasizing the unification between quality assurance and safety control within the structure of the Quality & Safety Management Unit, so that they can now move strategically towards a common goal.

The unit will be managed so that the management cycle is always being conducted, and sound achievements are being made.

Through the process of quality assurance, we will contribute to the creation of innovative pharmaceuticals and the supply of pharmaceuticals that meet the diverse medical needs.

### Quality Assurance and Safety Management System

<table>
<thead>
<tr>
<th>Notification of clinical trial</th>
<th>Application/review, approval/launch</th>
<th>End of life cycle</th>
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<tbody>
<tr>
<td>Research</td>
<td>Non-clinical</td>
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<tr>
<td>Standard for effectiveness/safety</td>
<td>GLP</td>
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<td>Candidate compound production</td>
<td>Investigational drug production</td>
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<tr>
<td>Quality standard</td>
<td>Pharmaceutical production, storage, transport</td>
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</tbody>
</table>

GLP: Good Laboratory Practice, standard for pharmaceutical safety related to non-clinical test execution
GCP: Good Clinical Practice, standard for the execution of clinical trials of pharmaceuticals
GMP: Good Manufacturing Practice, standard for production control and quality control of pharmaceuticals
GVP: Good Vigilance Practice, standard for post-marketing safety control of pharmaceuticals
GPSP: Good Post-Marketing Study Practice, standard for post-marketing surveillance and trials of pharmaceuticals
GQP: Good Quality Practice, standard for quality control of pharmaceuticals and others
GDP: Good Distribution Practice, standard for the logistics of pharmaceuticals

*1 Standards set by governments and public organizations to assure safety and reliability.