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Regulatory Trends in Regenerative Medicine in Japan

30 June 2015
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Pharmaceuticals and Medical Devices Agency, Japan
Introduction of PMDA

Pharmaceuticals and Medical Devices Agency (PMDA)

- an Incorporated Administrative Agency (IAA)

PMDA’s Safety Triangle

- **Review**
  - Reduction in risk
- **Safety**
  - Continuous risk mitigation efforts
- **Relief**
  - Relief measures for health damage caused by risk factors

Tokyo, JAPAN
Two Japanese Regulatory Authorities

- **Ministry of Health, Labor and Welfare (MHLW)**
  
  Planning basic policy, enforcement of administrative measures based on the law
  
  - Marketing authorization of pharmaceuticals and medical devices
  - Issue emergency safety information and direct product withdrawal
  - Safety measures for emergent and significant cases

- **Pharmaceuticals and Medical Devices Agency (PMDA)**

  Review, examination and data analysis

  - Scientific review, GMP/GLP/GCP inspection and consultation on the development of pharmaceuticals and medical devices for marketing authorization
  - Collection, analysis and dissemination of information relating to quality, efficacy and safety of pharmaceuticals and medical devices
Japan’s Performance on NDA Review

New active substance (NAS) median approval time for six regulatory authorities in 2004-2013

Japan has lagged its peers in bringing products to market

[The Number of Marketed Products & Products under Clinical Trials]

Europe (20 products)
Under Clinical Trials: 42 products
Bioseed-S (Autologous cultured derma)
Chondrotransplant (Autologous cultured cartilage)
Cellactive (Autologous cultured cartilage)
ChondroCelect (Autologous cultured cartilage)
Hyalograft (Autologous cultured cartilage)

Korea (14 products)
Under Clinical Trials: 42 products
Holoderm (Autologous cultured derma)
Articell (Autologous cultured cartilage)
Ossron (Autologous cultured bones)

U.S. (9 products)
Under Clinical Trials: 88 products
Epicel (Autologous, cultured skin)
Dermagraft (Allogenic cultured derma)
OrCel (Allogenic composition of cellular matrix)
Carticel (Autologous, cultured cartilage)

Other Markets (6 products)
Under Clinical Trials: 23 products
Chondrotransplant (Autologous cultured cartilage)
Cartogen (Autologous cultured cartilage)

Japan (2 products)
Under Clinical Trials: 4 products
JACE (Autologous cultured skin)
JACC (Autologous cultured cartilage)

< Comparison By Market >

As of Dec. 2012

【Disease Types】
Nerve: for Parkinson’s disease
Heart: ischemic cardiac disease
Vessel: arteriosclerotic obliteration
Pancreas: Type I diabetes

Pharmaceuticals and Medical Devices Agency
Regenerative medicine & cell therapy in Japan

**Medical care**

- **Clinical Research using human stem cells**
  - 108 protocols approved (as of November 2014 - before new legislation)
  - Cancer immunotherapies
    - Six types of therapy are currently provided in approved university hospitals as “advanced care”
    * Partially covered by national health insurance

**Commercial Product Marketing Authorization Purpose**

- **Cellular/Tissue based Products**
  - 2 marketed products
    - JACE (autologous cultured epidermis)
    - JACC (autologous cultured cartilage)
  - 21 clinical trials initiated (including 7 gene therapy products) (~June 2015)

**Pharmaceuticals and Medical Devices Act. (PMD Act.)**

**Academic Research Purpose**

- Covered by MHLW
- Covered by MHLW and PMDA

**Ex. Medical Care Act (MCA) = The Act on the Safety of Regenerative Medicine.**
# Approved Cellular/Tissue based Products

<table>
<thead>
<tr>
<th>Category</th>
<th>Brand Name (Company)</th>
<th>Approval Date</th>
<th>Target Organ</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autologous cultured epidermis</td>
<td>JACE (Japan Tissue Engineering Co., Ltd.)</td>
<td>Oct. 29, 2007 (submitted on Oct. 6, 2004)</td>
<td>Skin</td>
<td>Autologous cultured keratinocytes using Green’s technique in which keratinocytes derived from the patient’s own skin tissue are co-cultured with irradiated 3T3-J2 cells derived from mouse fetuses as a feeder to form a sheet in approximately three to seven layers thick. This is indicated for the treatment of serious large burns that cannot be provided with a sufficient area of donor skin for autologous skin grafting, and of burns in which the total area of deep second-degree (deep dermal) and third-degree (full-thickness) burn is 30% or more of the total body surface area.</td>
</tr>
<tr>
<td>Autologous cultured cartilage</td>
<td>JACC (Japan Tissue Engineering Co., Ltd.)</td>
<td>Jul. 27, 2012 (submitted on Aug. 24, 2009)</td>
<td>Bone/Cartilage</td>
<td>An autologous cultured cartilage to alleviate clinical symptoms by implanting it in the affected site of traumatic cartilage efficiency and osteochondritis disseccans (excluding knee osteoarthritis) in knee joints with a cartilage defective area of 4 cm² or more for which there are no other treatment options. Chondrocytes isolated from the non-load-bearing site of a knee joint of patients by taking a small amount of cartilage tissue are three-dimensionally cultured in atelocollagen gel to obtain this product. Clinical studies were conducted to evaluate the efficacy and safety of this product for patients with traumatic cartilage deficiency, osteochondritis dissecans, and knee osteoarthritis.</td>
</tr>
</tbody>
</table>
NEW REGULATORY SYSTEMS

Double track regulation:
Government policy

- Integrated support from basic to clinical research
- Development of infrastructure to promote regenerative medicines
- Support utilizing iPS cells as a drug-discovery tool

Regenerative Medicine Promotion Act (Enacted in May 2013)

**Goals for the next 6 years**

- Apply new drugs developed by iPS cells technology in clinical trials
- Increase the number of approved cellular therapeutic products
- Expand the target of illness in clinical trials
- Develop equipment or devices related to regenerative medicines

- Revision of the Pharmaceutical Affaires Law: The Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (PMD. Act)
- The Act on the Safety of Regenerative Medicine
New Legislative Framework

These two acts were promulgated in November 2013 by the Japanese Diet (Parliament) in line with the Regenerative Medicine Promotion Act, in order to reform the pharmaceutical and medical regulation related to regenerative medicine

- Revision of the Pharmaceutical Affaires Law: The Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (PMD. Act)

- The Act on the Safety of Regenerative Medicine

These two acts were enacted on 25 November 2014

Other related governmental policy:
- Healthcare and Medical Strategy Promotion Act (2014.5)
- Japan Medical Research Development Institution Act (2014.5)
# Human Cellular and Tissue based Products (hCTPs) regulations (comparison)

<table>
<thead>
<tr>
<th>Scope</th>
<th>Japan</th>
<th>Corresponding regulation</th>
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<tbody>
<tr>
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<td><strong>US</strong></td>
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</table>
| CTN for *clinical research* (other than product IND) and direct medical practices | *Act on the Safety of Regenerative Medicine* | ○ FDC Act. (IND/IDE) | ○ ATMP regulation  
□ Hospital Exemption ※ |
| IND for product R&D and NDA process | *Revised Pharmaceutical Affairs Law (PMD. Act)* | ○ FDC Act. (IND/IDE)  
○ PHS Act. Section 351 (biologics review)  
○ FDC Act (device review)  
□ Facility, cell collection, safety, manufacturing quality system (CFR 21 CFR1271) | ○ ATMP regulation  
□ IMP  
□ Product review |
Two Acts regulating regenerative medicine & cell therapy

MHLW process  ⟷  Regenerative Medicine  ⟷  PMDA process

* Two laws were enacted on 25 November 2014

All medical practices and researches using processed cells which safety and efficacy have not yet been established

The Act on the Safety of Regenerative Medicine

Production and marketing of regenerative and cellular therapeutic products by firms

The Act on Pharmaceuticals and Medical Devices (PMD Act)*

It may be similar to Hospital exemption of the EU or PHS 361 in the US
Rules for hospitals and clinics

High Risk (class I)

- Hospitals / Clinics
  - Plan submission
  - Certified special committee for regenerative medicine*
  - MHLW
  - Submission
  - Evaluation
  - Health Science Council
  - Provision (Within 90 days)
  - Change order (Within 90 days)

Middle Risk (class II)

- Hospitals / Clinics
  - Plan submission
  - Certified special committee for regenerative medicine*
  - MHLW
  - Submission
  - Evaluation
  - Provision

Low Risk (class III)

- Hospitals / Clinics
  - Plan submission
  - Certified committee for regenerative medicine
  - MHLW
  - Submission
  - Evaluation
  - Provision

*Certified special committee for regenerative medicine is required to have highly specialized screening expertise and third-party characteristics (roughly 10 to 15 certified special committees for regenerative medicine across the country)
Overview of the Act on the Safety of Regenerative Medicine

I. Obligate hospitals and clinics to submit plans

II. Enable commissioning cell processing to licensed enterprises

III. Obligate CPCs to notify or obtain licence

Notification (Hospitals / Clinics) or Application for a license (Firms)

Cell processors

Hospitals / Clinics

Certified committee for regenerative medicine

Certification

Minister of Health

Cell processing

Provision of regenerative medicine
Two acts regulating regenerative medicine & cell therapy

MHLW process  Regenerative Medicine  PMDA process

All medical technologies using processed cells which safety and efficacy have not yet been established

The Act on the Safety of Regenerative Medicine

Production and marketing of regenerative and cellular therapeutic products by firms

The Act on Pharmaceuticals and Medical Devices (PMD Act)*

* Two laws will be enacted in November 2014

Commercial IND and product approval system
Revision of Pharmaceutical Affairs Law

◆ **Revisions of Drugs and Medical Devices Articles**
  - Relevant party’s obligations are specified to ensure quality, safety, and efficacy of drugs and medical devices.
  - MAH’s obligation to notify labeling and its revision, reflecting the latest findings

◆ **Revisions of Medical Devices Articles**
  - Independent Chapter for “Medical Devices”
  - Expansion of Third party certification system to higher risk devices
  - Quality Management System (QMS) adherent to ISO 13485
  - Other revisions related to medical devices

◆ **Additions for Regenerative Medical Products**
  - Definition and independent chapter for Regenerative Medical Products
  - Introduction of conditional/time limited approval system
Definition of “Regenerative Medical Products” in Japanese Legislation

- **Regenerative medical products** are defined as **processed live human/animal cells** that are intended to be used 1) for either (1) the reconstruction, repair, or formation of structures or functions of the human body or (2) the treatment or prevention of human diseases, or 2) for gene therapy.

Under the Revised PAL (=Pharmaceuticals and Medical Devices Act. (PMD Act.))

.||.

Cellular and Tissue based Products and Gene therapy Products

.||.

**Advanced-therapy medicinal products (ATMPs)**

Regulation (EC) No 1394/2007
Scope of Manipulation ("Processed cells") to be regulated

(Definition)

1. **Manipulation to be regulated**
   - Artificial proliferation and differentiation of cells and tissues
   - cell lines
   - drug treatment for the purpose of activation
   - biological properties modification
   - combination with non-cellular components
   - genetic engineering modification
   - Isolation/separation of specific cell by biological and chemical treatment with agents
   - Cells for non-homologous use

2. **Minimal manipulations** such as, treatment with antibiotics, washing, freezing, The gamma ray sterilization, simple isolation/separation without biological and chemical treatment are **not covered by the new regulation**

   Blood transfusion (blood products), Hematopoietic stem cell transplantation, Assisted Reproductive Technology, except those derived from genetic engineering, iPS cells, are also excluded from the scope of the regenerative medicine regulation.
How to expedite R&D and review for cellular and tissue based product

• Designed for unmet needs under the present treatment: limited number of patients available for CT
• Difficult to conduct controlled study to demonstrate “true end point” of clinical benefit
• Heterogeneity of Quality affected by source materials

Would it take long time for CTs and review if regulator pursues the conventional drug pathway too much?
Benefit and Risk Balance Assessment

• Discussion of acceptable level of clinical effectiveness vs. patient access to the new therapy
• Weighing acceptable risk against expected benefit
• Based on regulatory sciences in terms of social responsibility for public health
To what extent probability of effectiveness is to be pursued before Marketing authorization?

Question is “What is the socially and scientifically acceptable level of effectiveness for approval?”

For:

• A new product for life threatening disease, which is affected by the timing of access

• Breakthrough therapeutics for present unmet medical needs, longing for treatment, while paying particular attentions to the safety
The Pharmaceuticals and Medical Devices Act (PMD Act)

- Separate category and definition of “regenerative medical products”

Difficult to gather and evaluate the data for efficacy of regenerative medical products in a short time due to heterogeneity of cells.

To secure timely provision of safe regenerative medicines, a new regulatory framework is needed.

Expedited approval system for regenerative medical products

After the safety is confirmed and the results predict likely efficacy, the product will be given conditional, time-limited marketing authorization in order to enable timely provision of the products to patients.
Pharmaceuticals and Medical Devices Agency

Expedited approval system under PMD Act

< Drawback of traditional PAL approval system >
Long-term data collection and evaluation in clinical trials, due to the characteristics of cellular/tissue-based products, such as non-uniform quality reflecting individual heterogeneity of autologous donor patients

[Traditional approval process]

Clinical study → Phased clinical trials (confirmation of efficacy and safety) → Marketing authorization → Marketing

[New scheme for regenerative medical products]

Clinical study → Clinical trials (likely to predict efficacy, confirming safety) → Conditional /term-limited authorization → Marketing (Further confirmation of efficacy and safety) → Re-application within a period (max. 7 years) → Marketing authorization or Revocation → Marketing continues

Post-marketing safety measures must be taken, including prior informed consent of risk to patients

Pharmaceuticals and Medical Devices Agency
Likely to predict efficacy (clinical benefit)

• To approve products based on the limited data, such as surrogate endpoints in exploratory study.

• Similarity to accelerated approval of USFDA * The product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit (ref.)

• We have experiences in the orphan drug drug area.

Ref.) USFDA--Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses (57 FR 58958, Dec. 11, 1992)
Public no-fault Indemnity system for patient injuries associated with products approved under PMD Act.

<table>
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<th>Regenerative medical products</th>
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Private Insurance products will be available for clinical studies under the Act on the Safety of Regenerative Medicine
Product review
Quality of human cellular and tissue based products (hCTPs)

Beyond bio-pharmaceuticals regulation

- Live Cells
- Difficulty in identifying quality attributes to describe product efficacy and safety
- Heterogeneity, lot-to-lot quality consistency
- High variability of test methods
- No appropriate reference material (like potency assay)

How is the quality of a hCTP assured?
Quality concept of hCTPs

Bio-pharmaceuticals

- Source materials, process variability
- In-process control
- Characterization
- Specification

hCTPs

- Source materials, process variability
- In-process control
- Characterization
- Specification

- Difficult to cover every aspect of quality by specification
- Limited information can be obtained from characterization and specification
- Much more rely on in-process control to control quality
Can ICH guidelines be applicable to every case of hCTP development?

Most of the conventional biologics regulatory framework, including ICH biologics guidelines (Q5A, Q5D, Q5E, Q6B, S6, S7A), is even appropriate for hCTPs, however;

• ICH-S6 (safety) :
  ✓ How to determine exposure of hCTP?
  ✓ What are the appropriate animal species over the species difference?
  ✓ Can impurity safety assessment be made for the matrix?

• ICH-S7A (safety pharmacology) :
  ✓ Are there appropriate animal models to demonstrate hCTP’s MOA?

• No ICH guidelines for tumorigenicity assessment
Safety and Efficacy evaluation of limited number of subjects in the trial for conditional approval

• Challenge on new designs and statistical methodologies for small population

• How to secure evidence level
  • Design : controlled? / blinded? possibility?
  • Clinical endpoint (efficacy) : clinical significance, objectiveness, surrogacy, etc.

• At least, Maximize the information from a single subject in terms of safety and efficacy.

• Post-marketing study, further confirmatory study?
Regulatory Challenges of early access scheme

• **Clinical study in post-marketing**: RCT may be difficult for confirmation in some cases (single arm study with pre-agreed threshold or observational case / control study) in the postmarketing settings
  - monitoring, collection and use of real-world data, post-authorisation, as a complement to RCT data (**Adaptive pathway**)

• **Reimbursement**: Question on consistency with regulatory approval and on acceptance of clinical data for HTA payers (predicted effectiveness vs. confirmed effectiveness)

• **Quality data**: limited qualification of bio-products in early stage and quality control under GMP/GCTP (validation, scalability, comparability)
Overall picture of CMC development

**Typical Development**

- **Non-Clinical Study**
  - Phase 1
  - Phase 2

- **Clinical Study**
  - Early access review timeline

- **Approval**
  - Post-Approval

**Control Strategy**

- **Target Product Profile**
  - Establishment of Design Quality and Product Quality by CMC study

- **Quality Attributes**
  - CQA

- **Process Parameters**
  - CPP

**Consistency**

- Knowledge Control / Quality Risk Management

**Equivalency**

- Investigational Product GMP

- GMP
Two of the new products applications under the new regulation (on-going)

• According to the news released by the sponsor companies, in September and in October 2014, two new product applications for marketing authorization were filed by PMDA.

• On-going review process to be goaled in 2015 ????

1. Bone marrow mesenchymal stem cells (MSCs) for GVHD
2. Skeletal myoblast sheet for serious heart failure due to ischemic heart disease

Note: Figures quoted from the company press release docs
Quality System
GXPs (Quality system requirement) = GCTP

- Broader term of Good Tissue Practice (GTP) is aimed at requirement for source material handling such as:
  - Source material selection, Donor eligibility
  - Personnel, procedure
  - Facility, Equipment, process control (Contamination prevention / sterility)
  - Validation
  - Record keeping, traceability
  - Storage, shipment, distribution
  - Reporting

- In cellular product manufacturing, the downstream of GTP regulation may be included in GMP type regulation
Consistent parts of the two Acts

Medical technologies using processed cells (except clinical trials under PMD Act.)

The Act on the Safety of Regenerative Medicine

- Manufacturer (Licensed)
- Outside hospital
- Cell processing
- Cell collection
- Hospital
- Transplant
- GCTP

Regenerative Medical Products

- PMD Act. (revised PAL)
- Manufacturer (Licensed)
- Obtaining Cell
- Cell Processing
- Delivery of cell product
GCTP Quality System Structure

Management & Supervision System
(release, deviation, change control, self-inspection, Training/education, complaint management, recall)

Product quality review

Quality control system (labo. system)

Supplier control system

Validation / Verification

Manufacturing control system
(operational performance of process, Sterility assurance, Product quality monitoring)

Facility & equipment system
(qualification, calibration, maintenance)

Document management system
(Product master file, specification, statement, SOPs, record)

Reflecting product marketing authorization documents

Quality Risk Management/ Knowledge management
Key Consideration

**Quality System Requirement** for regenerative medical technologies/products, considering the characters of these products; such as raw materials that cannot be sterilized

- Quality Risk Management
- Manufacturing Control (Sterility assurance, Prevention of Cross-contamination..)
- Quality control (Verification/validation, Quality review)
- Facility requirements

It is necessary to consider whether the risk is manageable,
- not only from the facility point of view,
- but from the effects of the manufacturing operation, such as the evaluation of performance.
Quality Risk Management

- Significance and essence of QRM
  QRM will promote understanding of products and processes, so that you will obtain stronger ability to assure quality of products manufactured, leading to more robust quality assurance.

- Risk cannot be eliminated
- Recognize the risk
- Predict, prevent and manage the risk
Quality Risk Management Process (ICH Q9)

in a series of manufacturing processes

Quality Risk Assessment
Risk identification
Risk Analysis
Risk Evaluation

Quality Risk Control
Acceptance of risk
Risk reduction
Balance with profit, risk and resources
New risk caused by controlling specified risk

Quality Risk Review
Build in review and monitoring system
Review risk acceptance level
Risk based approach

• Evaluation of risk in the quality, based on scientific knowledge, ultimately should be consequences to patient protection.
GMP in each stage of development

Human subject protection

Investigational product

Exploratory Trial

Confirmatory Trial

Development stage

In an early development phase, acquired knowledge is limited, so that implementable assurance level may be lower, however, risk based flexibility is needed to keep higher level of assurance.

In the development phase, quality is also under development. It would be unreasonable to apply GMP of the commercial product level. Flexible risk based approach would be more appropriate.
1. Validation or verification

The purpose is to “validate” the facility and equipment and procedure at the manufacturing site are giving the expected result, or to “verify” they have given the expected result.

The documentation of validation or verification is intended to allow constant manufacturing of quality compatible products.

⇒ After identified variables, normally the sponsor validates “three lots” of manufacturing control and quality control methods give the expected results. (prospective validation)

2. Verification

The implementation of process validation is difficult manufacturing process

• Manufacturing experience is limited
• Quantitative limitation of the specimen due to ethical reasons,
• technical limitations

To verify and document manufacturing procedures have given the expected results for each product for each lot number or batch number
Facilitate Development
Barrier (Valley of Death) for Practical Application

- **Basic Research**: Discovery of target and Seeds (Discovering logic/knowledge on disease)
- **Applied Research**: Exploratory Research (Research towards practical application)
- **Non-clinical Study**: Optimization Research (Quality/Pharmacology, Toxicology/PK)
- **Clinical Trial**: Phase I-III

**Regulatory Science**

- **Academia**: Venture
- **Industry**: Shortage of funding for R&D, Lack of human resource, Inadequate understanding of regulation, Lack of intellectual property strategy, Lack of development strategy in consideration of marketability

**Approaches (e.g.)**
- Translational Research Network Program
- Network to support drug discovery
- Promotion Program for Practical Use of Innovative Pharmaceuticals, Medical Devices, and Regenerative Medicines

- **Pharmaceutical Affairs** Consultation on R&D Strategy

Need studies and manufacturing processes in compliance with Pharmaceutical Affairs Act and related standards.
Pharmaceutical Affairs Consultation on R&D Strategy

Valley of Death
- Shortage of funds, Knowledge on Regulation and developmental strategy

Consultation on quality and battery of pre-clinical, including examining tumorigenicity, biological ingredient safety

Consultation on endpoints or sample size of early clinical trial

Flow of Strategy Consultation
- Introductory Consultation (744)
- Pre-Consultation (900)
- Face-to-Face Consultation (258) (7/1/2011 – 9/30/2014)
Related Guidelines for Products Evaluation

Guidelines on Ensuring Quality and Safety of Products Derived from Processed Cell/Tissue
- Autologous (2008)
- Allogeneic (2008)

Guidelines on Ensuring the Quality and Safety of Products Derived from Processed Human Stem
- Autologous Somatic Stem Cells (2012)
- Autologous iPS-like Cells (2012)
- Allogeneic Somatic Stem Cells (2012)
- Allogeneic iPS-like Cells (2012)
- Embryonic Stem Cells (2012)

Points to Consider for the Evaluation of Specific Products
- Cell sheet for heart failure (2010)
- Corneal epithelial cell sheet (2010)
- Corneal endothelial cell sheet (2010)
- Articular cartilage repair (2010)
- Cell sheet for periodontal tissue regeneration (2011)
- Autologous induced pluripotent stem cells-derived retinal pigment epithelial cells (2013)
- Allogeneic induced pluripotent stem cells-derived retinal pigment epithelial cells (2014)

The Science Board Report. PMDA.
- Current Perspective on Evaluation of Tumorigenicity of Cellular and Tissue-based Products Derived from induced Pluripotent Stem Cells (iPSCs)* and iPSCs as Their Starting Materials (2013)
Support for Innovation Implementation via Science Board

Universities/ institutes/ medical institutions
Researchers with superior knowledge, experiences in drugs/medical devices, and with superior research achievements, who are taking active part in the front line.

Collaboration with academia

Take initiative in putting cutting-edge technologies into practical use based on regulatory science

Rotation of Personnel

Science Board

Exchange opinions between top-class researchers in Japan and PMDA reviewers on assessment methods of cutting-edge technologies

Pharmaceuticals and Medical Devices Agency
Outcome of the Science Board of PMDA

Further to the discussion in the last term, in the present term following immediate discussion is on-going to support scientific consultations and reviews of PMDA:

- **Cellular & Tissue-based Products**
  - Current Perspective on Evaluation of Tumorigenicity of Cellular and Tissue-based Products Derived from iPSCs and iPSCs as Their Starting Materials (Aug. 21, 2013)
  - Manufacturing and quality of cellular products during the early development in cell processing facilities (2015, to be released soon!)
PMDA for the world
-To create society to receive the essential forefront medicines-

Swift approvals of innovative products

Convey Japanese technology to the world

Cooperate with all agencies in the world

Full measures by use and application of medical information

Swift relief for occurred health damage

Japanese citizens

Safety

Relief

Regulatory Science

Contribute to the world’s medicine
Thank You for your attention!

Daisaku Sato, Ph.D.
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Thanks to my colleagues of Office of Cellular and Tissue-based Products

Literature available in English:
