Generic API Business of Eisai

May 18, 2016

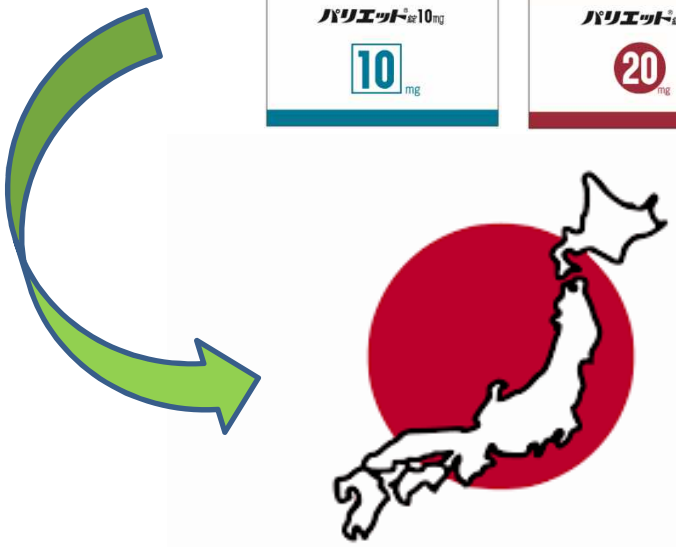
Tetsuya Oishi
Group Officer and Executive Director,
API Solutions
Eisai Co., Ltd.

hhc
human health care

Eisai Vizag

Eisai Knowledge Center in India

Established in December 2009



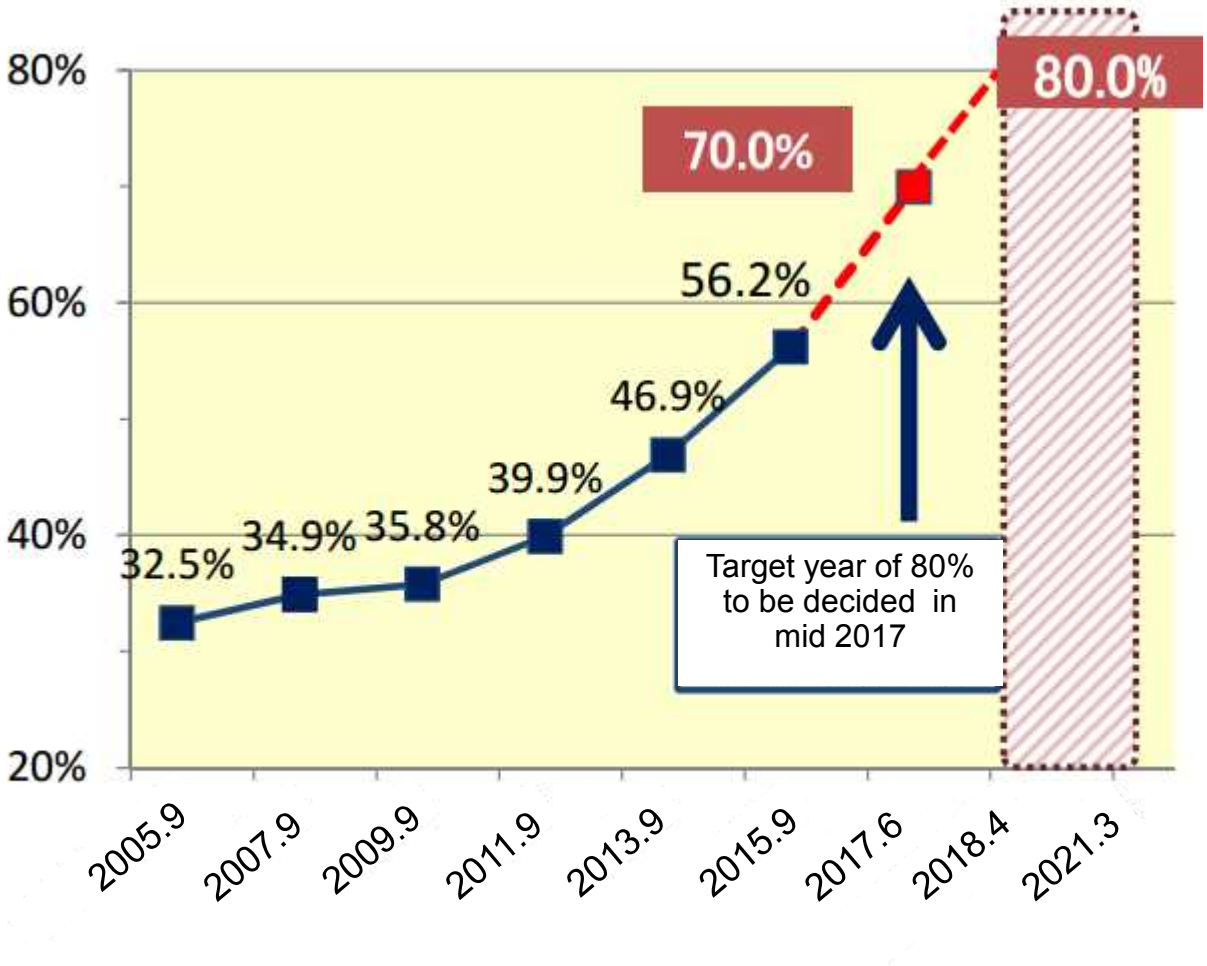
Agenda

Generic API Market and Issues in Japan

Our strengths

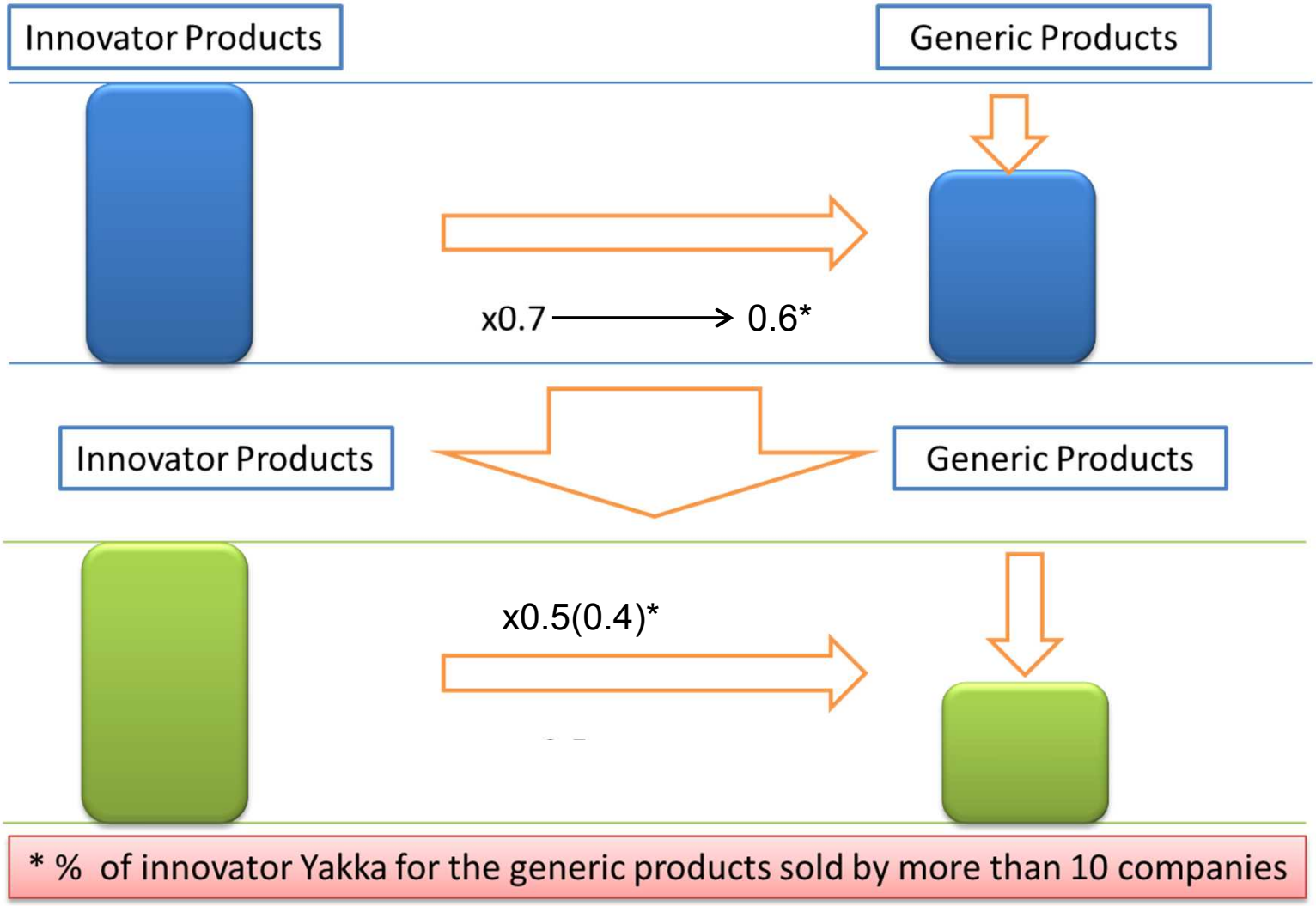
Proposals

New Target of GE Share in Japan by Government



Source: MHLW

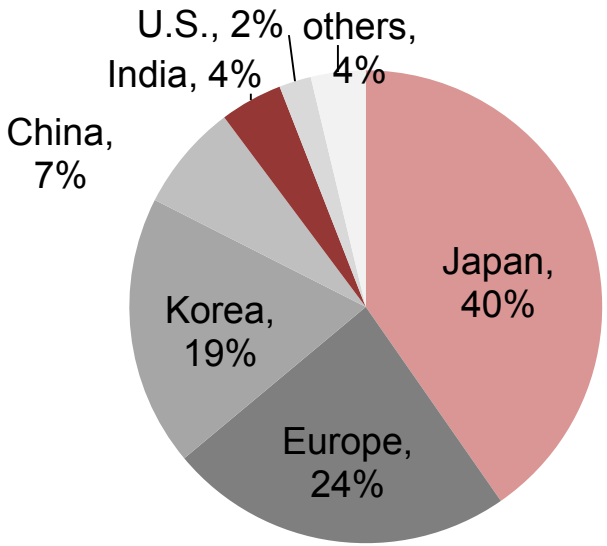
New GE Pricing System



Source: NuLink, Co., Ltd..

Market Analysis / API sources

Sources of Final API (on value basis)



Ratio of single-sourced API

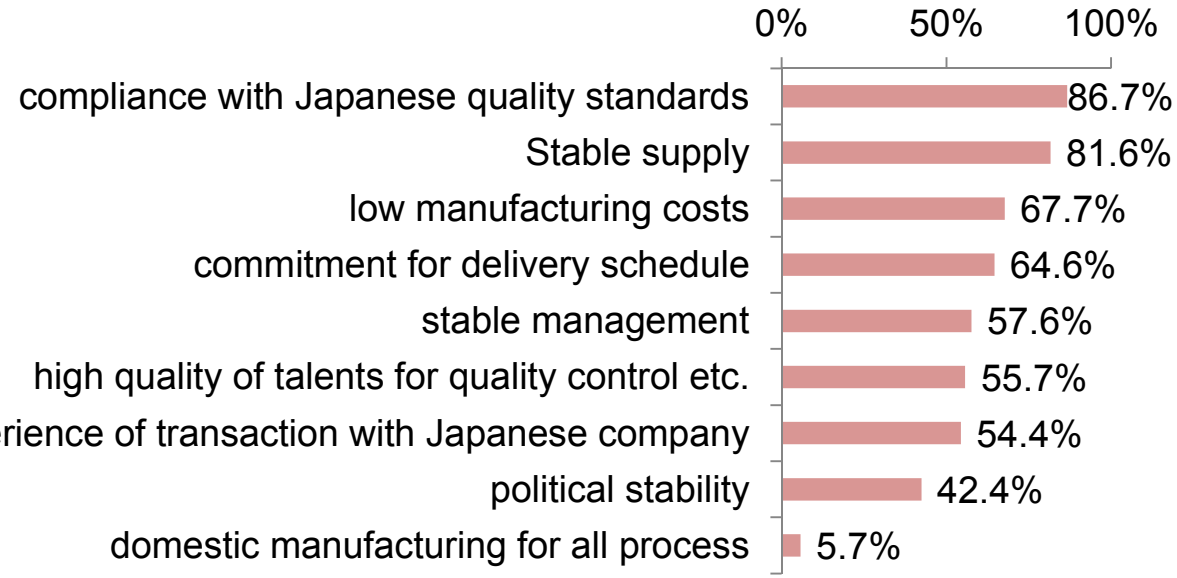
	Japan	Abroad	total
Single source	36%	41%	77%

source: MOH survey, March 2013, interview with trading companies

Issues in the GE API market

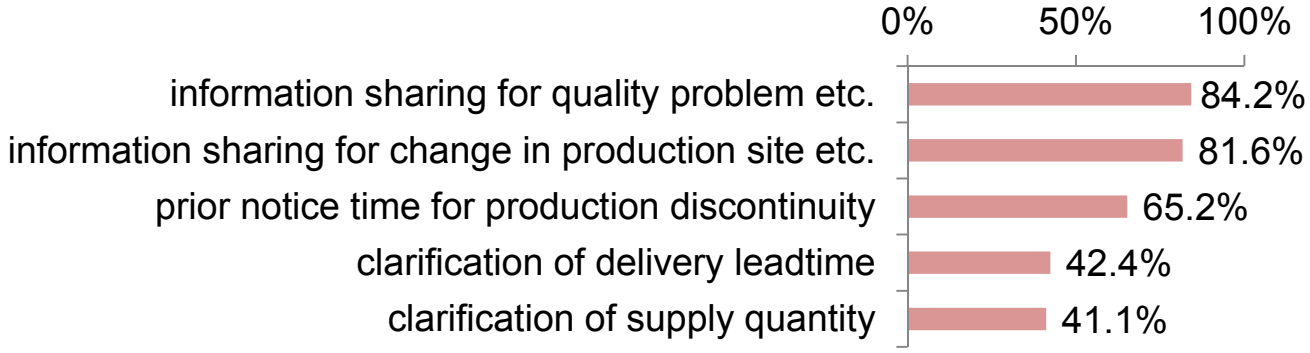
Criteria for supplier selection

(N=158)



Points when execute contracts with supplier

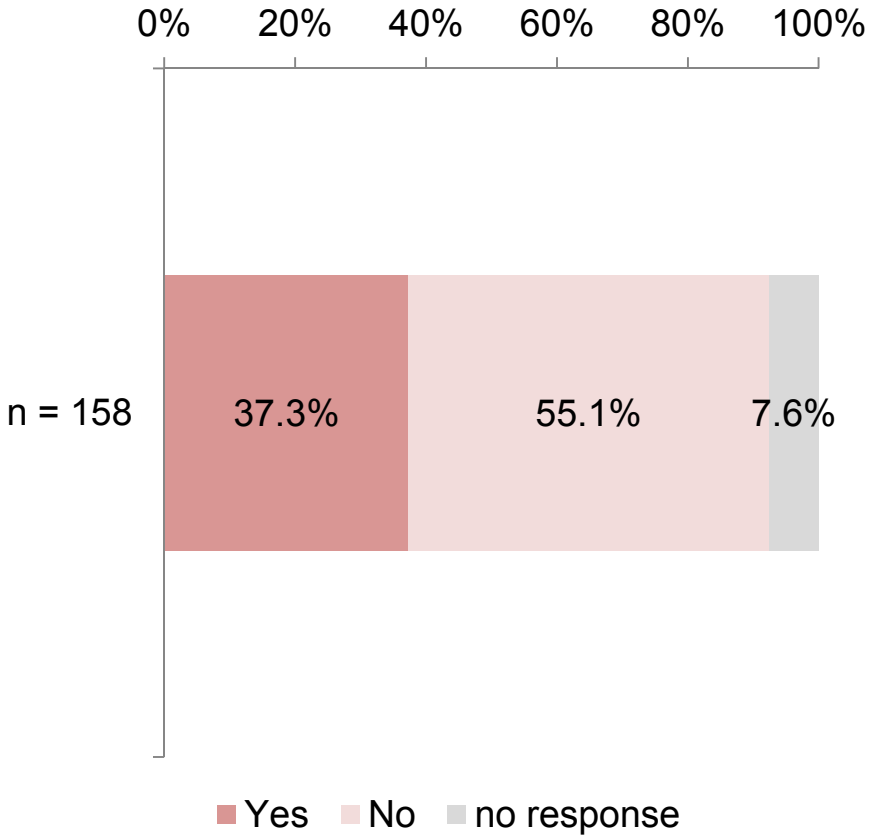
(N=158)



source: MOH survey, March 2013

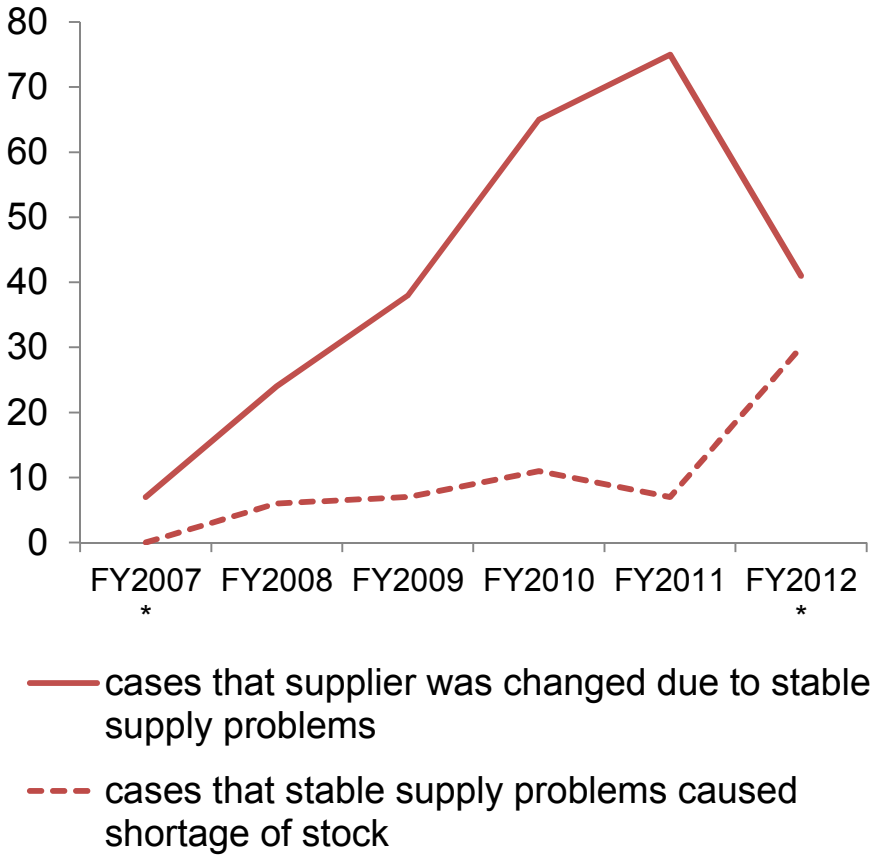
Issues in the GE API market

Companies experienced supply problems



source: MOH survey, March 2013

Numbers of supply problems



* FY2007: Oct-Mar, FY2012: Apr-Dec

Our Strengths

As a Japanese pharmaceutical company that has already achieved Japanese quality in India, Eisai:

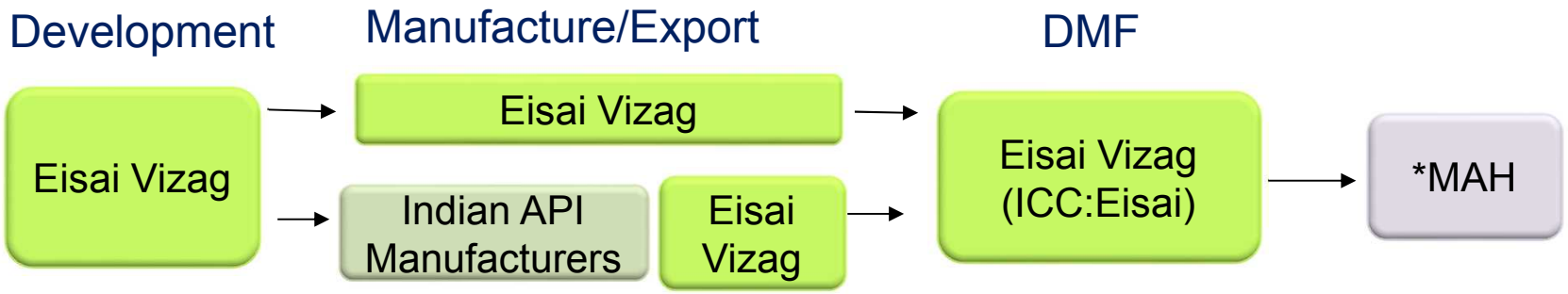
1. can provide high quality and low cost APIs to Japanese MAHs who are particularly stringent in their own quality requirements beyond JP either by in-house manufacturing or utilization of local partnership.

2. can provide "total package solutions" to Japanese MAHs by utilizing our existing capabilities, such as R&D, manufacturing, quality control, patent analysis, inspection/audit, etc.

Proposal 1

1 Supply GE APIs with high quality and competitive price taking advantage of Eisai Vizag and its vast local partnership in India

1. Molecules developed and manufactured in Eisai Vizag



2. Molecules developed and manufactured by other API manufacturers

*MAH: Marketing Authorization Holder

Role of Eisai Vizag in Partnership

1. Execute supplier search based upon Global Supplier Qualifications Policy of Eisai
2. Provide technical support to Indian suppliers based upon our own experience and know-how to meet with stringent specifications of Japanese MAHs beyond JP, which is critical to do business in Japan
3. Provide endorsement for quality of API by evaluating pre-shipment samples from suppliers
4. Support for effective and smooth communication between Indian suppliers and Japanese MAHs after commercialization
5. Support for supplier inspection/audit by Japanese MAHs in cooperation with ICC

Proposal 2

2

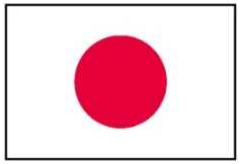
Create a new segment in the generic API market by providing “total package solutions” to MAHs

Possible Contributions…

Becoming a bridge between India and Japan for promoting collaboration of two countries in the pharma industry

Contributing to the reduced cost of healthcare of Japan without compromising quality by utilizing advanced and cost-effective pharmaceutical technology of India

Contributing to the economic growth of both countries by integrating knowledge exists in the Indian pharma companies and Eisai



どうもありがとうございます。

Thank You

Eisai

hhc

human health care

Note: All stock photos in the presentation are property of istockphoto.com

MEDREICH

Activities of Meiji/Medreich Group and expectation on Bilateral Cooperation

May 18, 2016

@India Habitat Centre / IHC New Delhi

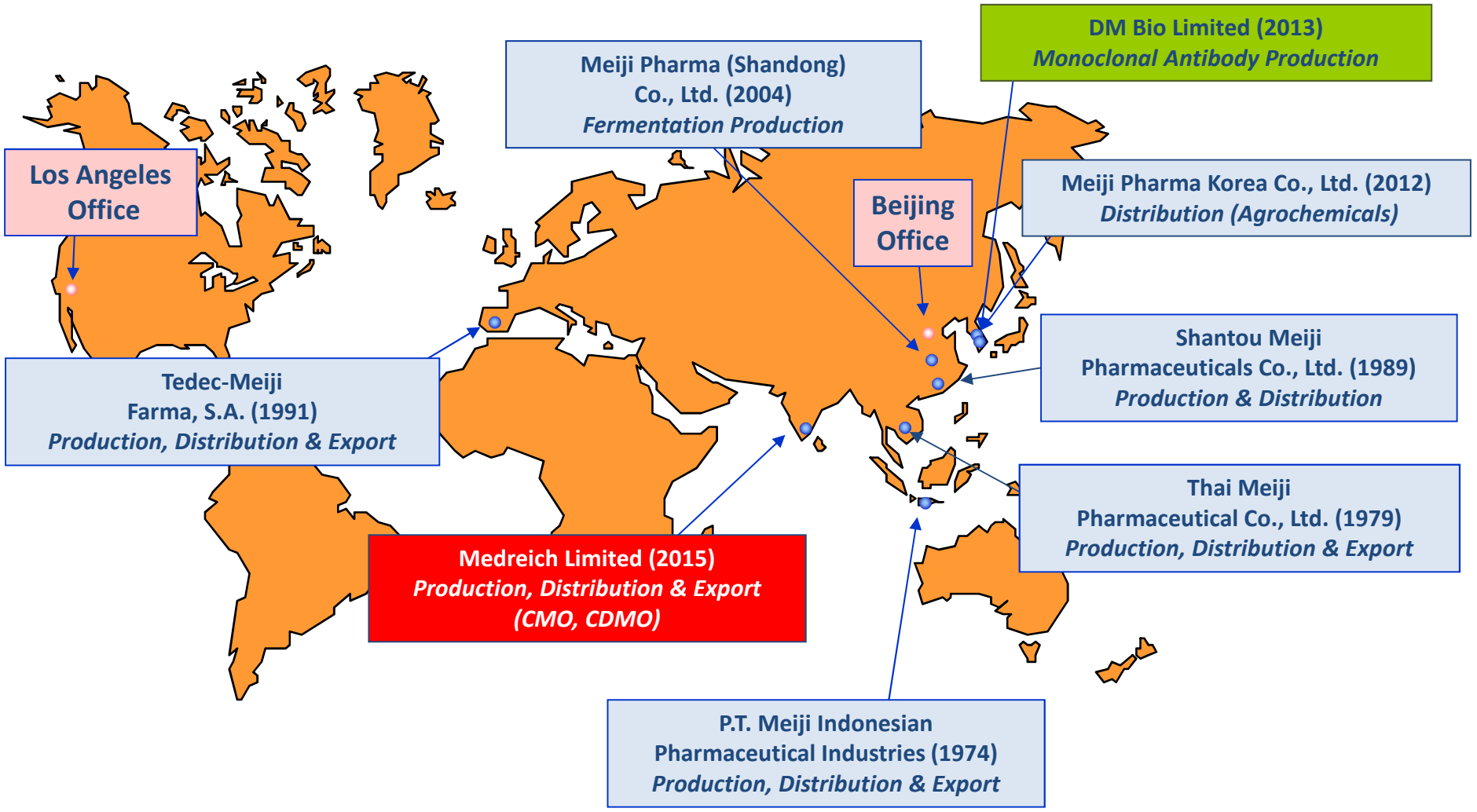
by Makoto SHIGEMITSU, Executive Board and DMD of Medreich Ltd.

meiji

Corporate Profile

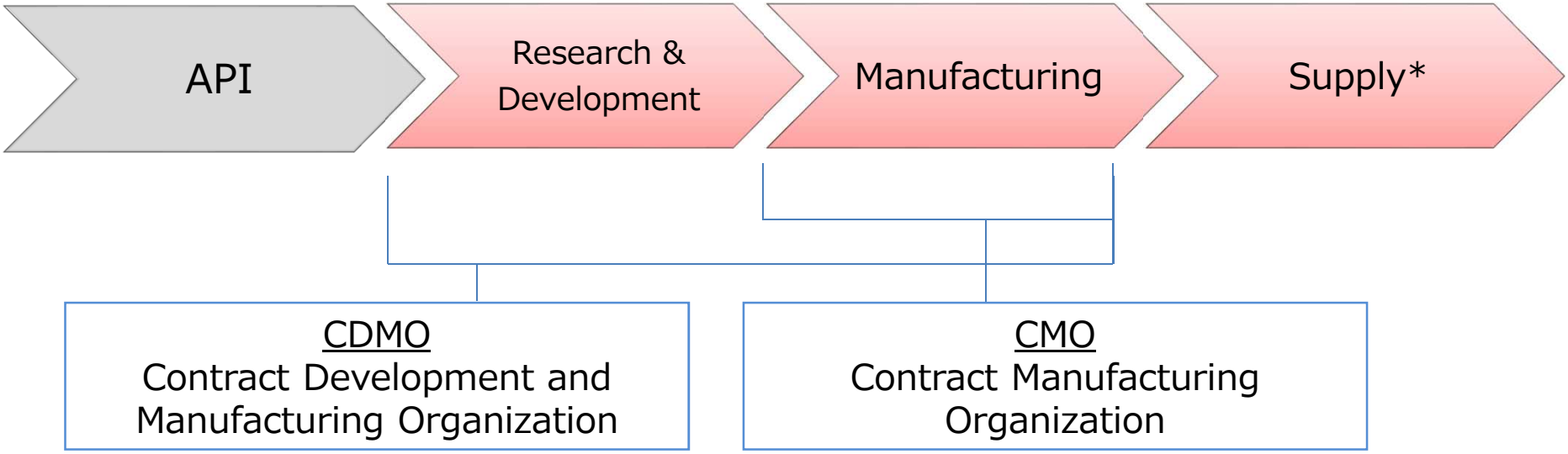
Company Name	Medreich Limited
Main businesses	☐ CMO and CDMO in finished product ☐ Branded Generics manufacturing and sales
Headquarters	Bangalore, India
Group employees	About 3,000 *FY 2015-16
Manufacturing site	8 in India（7 in Bangalore, 1 in Hyderabad）
Shareholder	Meiji Seika Pharma Co., Ltd

meiji Group – Meiji Seika Pharma -



CMO/CDMO Business

Value chain



*Medreich Group has its own sales organization in some countries

Dosage form for CMO / CDMO

- Tablets : plain/ film coating / enteric/ sugar coated
- Hard gelatin capsules : powder/ pellets/ tablets
- Dry powders : syrups/ suspensions
- Liquid orals : syrups/ powder/ suspensions

◆ Features of each business segment

CMO

- Capacity of about 18 billion units *
- About 170 products portfolio
- Dealing with Multi National Companies over 20 years

*incl. tablets, capsules, and bottles in 2016

CDMO

- More than 60 products pipeline
- Regulatory approvals in over 50 countries (EU, Asia, Oceania, and Africa)

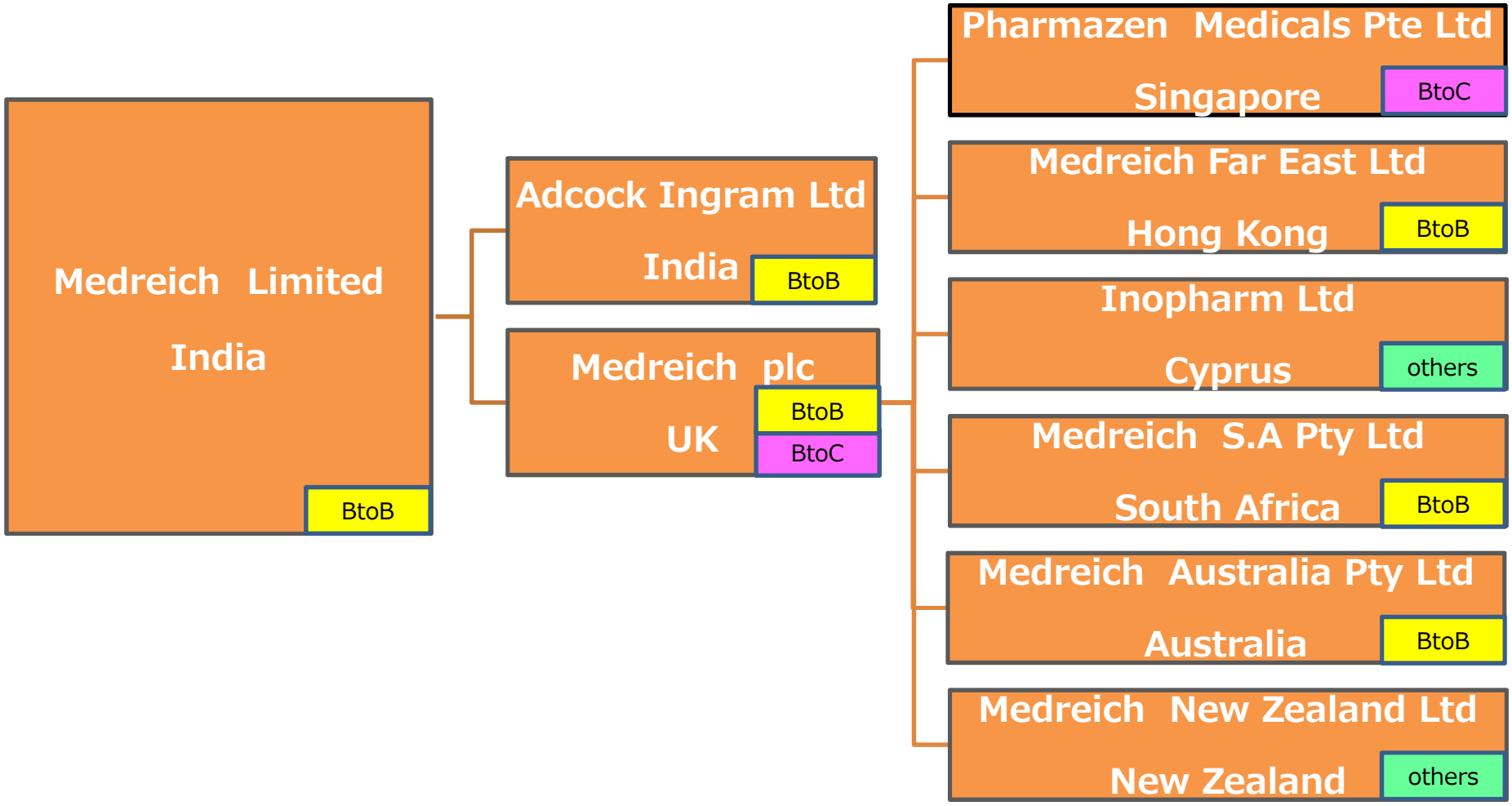
Branded Generic

- Sales of β-lactams etc. in 8 countries

Special Features of Medreich

- **Large Capacity**
- **Low-cost operation**
- **Regulatory approvals around the world**
- **Quality accepted by Multi National Companies**

Structure of major group companies



◆ Research & Development

R & D | Manufacture | Supply

- About 130 research staffs
- More than 60 products pipeline (planned to be expanded)

- About 30 walk-in chambers for stability
- Stability study in each condition under ICH guideline

- Experienced regulatory team members
- Over 1,200 global registrations

Staff and facility with expansion plan

Manufacturing Site

R & D | **Manufacture** | Supply

Number of site	8 sites (3 for β-lactams / 5 for general)
Capacity	About 18 billion (in 2016)
Dosage forms	Tablet / Capsule / Dry Syrup / Liquid
Key approvals	MHRA(UK), ANSM(France), TGA(AUS), UNICEF etc.








Facility with expansion plan

◆ Overseas presence of meiji group

Region	Country	Company name	Production*	BtoB	BtoC
Asia	China	Shantou Meiji Pharmaceuticals Co., Ltd.	FP	-	○
	China	Meiji Pharma (Shandong) Co., Ltd.	API	○	-
	Hong Kong	Medreich Far East	-	○	-
	Thailand	Thai Meiji Pharmaceuticals Co., Ltd.	FP, API	○	○
	Indonesia	P.T. Meiji Indonesian Pharmaceutical Industries	FP, API	○	○
	India	Medreich Limited	FP	○	-
	Singapore	Pharmazen Medicals Pte Ltd.	-	-	○
Oceania	Australia	Medreich Australia Pty Ltd.	-	○	-
Europe	Spain	Tedec-Meiji Farma, S.A.	FP	○	○
	UK	Medreich plc	FP	○	○
Africa	South Africa	Medreich SA Pty Ltd.	-	○	-

*FP: Finished Products / API: Active Pharmaceutical Ingredient

Expansion of overseas presence by acquisition of Medreich Group

Meiji Seika Pharma's history

1916	Tokyo Confectionery Co., Ltd. (the predecessor of Meiji Seika) was established.
1946	The pharmaceuticals business was launched with the commencement of penicillin production.
1958	Japan's first world-class antibacterial drug "KANAMYCIN" (Kanamycin) was introduced.
1974	P.T. Meiji Indonesian Pharmaceutical Industries was established.
1979	Thai Meiji Pharmaceuticals Co., Ltd. was established.
1981	Antibacterial drugs "FOSMICIN"(Fosfomycin) was introduced.
1989	Shantou Meiji Pharmaceuticals Co., Ltd. was established in China.

1991	Entered into capital participation in Tedec-Meiji Farma, S.A. .
1994	Antibacterial drug "MEIACT" (Cefditoren Pivoxil) was introduced.
1998	Generic Development Department was established and full-fledged entry to the generic drug market is commenced
1999	The antidepressant "DEPROMEL" (Fluvoxamine) was introduced.
2003	Meiji Pharma (Shandong) Co., Ltd. was established.
2011	Meiji Seika was renamed as Meiji Seika Pharma Co., Ltd. .
2015	Medreich Group joins Meiji Group

*International business

Meiji have long term experience as "**Specialty & Generic Pharma**" and have engaged in **international business for more than 40 years**.

Our challenge to produce Japan Quality Product

- Based on experience of long history in MEIJI (Indonesia, Thai, China, Spain and INDIA)
- Partnership, Mutual-understanding
- Specification and quality-design
- Quality of What (Document, Facility, Product, QMS, Products …)
- Understand Infrastructure and Culture
- Difference between INDIA/JAPAN
- Market needs in JAPAN (price, quality(≠spec.), info., reliability)
- Japan technology (innovative technology, JPN quality, efforts to get common understanding, maintenance)
- KAIZEN, PDCA, Improvement/ Innovation, Change Management

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Our Expectation (India – Japan)

R & D | Manufacture | Supply

R & D PV/RA

- Global R&D (India, Japan, Spain, etc)
- Products pipeline (Mutual application)
- INDIA : People/Facilities/IT
  JAPAN : People/Key tech/IP/MA

Mnf./ Quality

- Global SCM
  (API ~ Formulation ~ Pack ~ Market)
- Right Quality (Global Policy / Region Fitting)
- INDIA: Facilities/IT/Cost
- JAPAN: Quality/Technology/KAIZEN

Eg.; "Make in INDIA" and Sell in Japan

Supply

- Marketing: Global Synergy
- JAPAN: contribute to "GE 80% Gov. Strategy"
- MEIJI/MEDREICH: Market Presence (B to B/B to C)
- Patient-Medicals Friendly

Close relationship with regulators

To be a Good Model of Realization of Modi/Abe Initiatives in Pharmaceuticals

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◆Expectation to Regulators/Industries

INDIA

- Infrastructure (R&D, Facility)
- Supply chain (Traffic, Cold chain, etc)
- Import/Export (GST, IT-application, etc)
- Investment Backup

JAPAN

- Global Regulatory Cooperation (PIC/S, MOU, etc)
- Training of “Module 1 – Regulations” for Engl.-countries
- Pharmacopoeia harmonization

Industries /Academia

- Tie-up across different areas (IT, Medical Device, Trading, RM/PM)
- Japan Quality to globalize
- Mutual Understanding : INDIA/JAPAN
- Cooperation between Academia/Industry (training, internship, etc.)

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Thank you

MEDREICH

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Industries' Activities related to Pharmaceutical Regulation and Expectation on Bilateral Cooperation

India -Japan Medical Products Regulation Symposium May-2016

Sriram A V Ph.D.

Vice-President

Quality and Regulatory

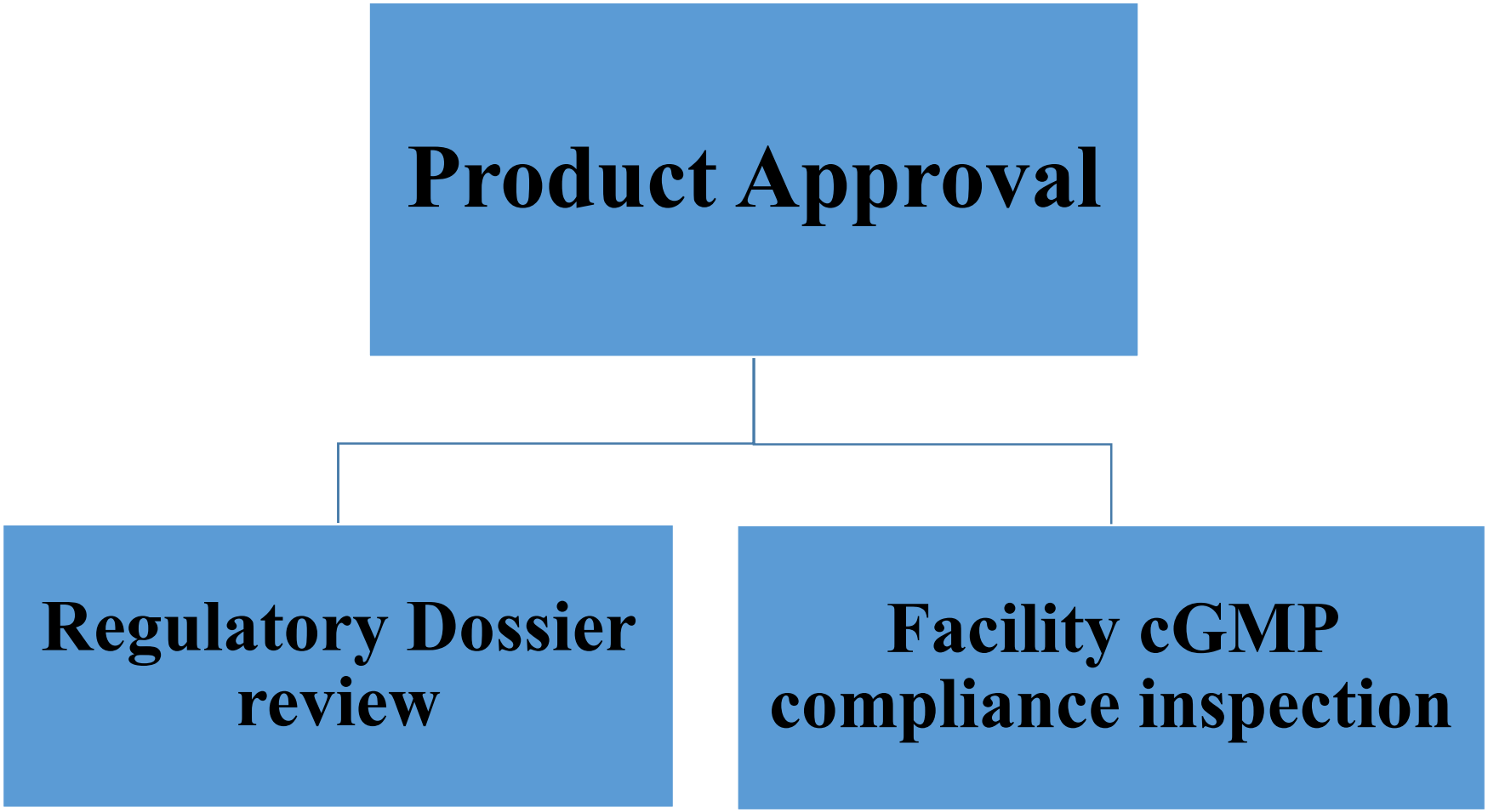
Outline of presentation

- **Partnership Overview-Biocon-Japan Company**
- **Regulatory Aspects**
- **Compliance Audits**
  - ✓ Pre-Audit Preparedness
  - ✓ PMDA GMP compliance Audit
- **Conclusion**

Partnership Overview: Biocon- Japan Company

- **Relationship started in 2012**
- **Biocon was responsible for CMC and non-clinical development**
- **Japan company was responsible for performing local clinical trials and registration**
- **Biocon-Japan partner together met PMDA on multiple occasions to discuss and finalize regulatory and development strategy**
- **Approval received in Mar 2016**

Product Approval Process



Regulatory Aspects

- **Drug Substance (DS)**
  - Biocon owned MF in Japan through In Country Caretaker (ICC)
  - DS review queries were handled directly by Biocon
- **Drug Product (DP)**
  - Japan partner filed NDA
  - DP queries:
    - CMC, non-clinical query response were handled by Biocon with Japan partner
    - Clinical queries were handled by partner primarily by Japan partner with help from Biocon where needed
- **Biocon appointed a local regulatory consultant who was instrumental in aligning the expectations between Biocon, Japan partner, ICC and PMDA**

Quality Audits-Pre-Audit Preparedness

- **Self assessment and gap analysis**

- **Audit by Japanese consultant- Ex-PMDA inspectors (facilitated by Japan Company)**
  - **Consultant Audit date :** October -2014
  - **Observations :** Few, Non critical
  - **Consultant audit provided confidence on facility and process compliance**

- **Japan company audit**
  - **Audit date :** March-2015
  - **Observations :** Few, Non-critical

Quality Audits- PMDA GMP compliance Audit

Audit Month

- **October 2015- DS**
- **October 2015- DP**

Audit Focus on

- **Article 14, para 6- Law for ensuring quality, efficacy and safety of drugs and medical devices - guideline GMP compliance**
- **In-depth process details**
- **Analytical details and product quality**
- **Quality Systems**
- **Hygiene & cleanliness**
- **Pest control**

Audit Outcome

- **Few Observations**
- **Receipt of Audit Report - Nov 2015**
- **Audit Response by Biocon- Dec 2015**

Final Certification

- **PMDA issued on 1st Mar 2016 (< 5 months from date of inspection)**

Conclusion

- **Collaboration between Indian and Japanese companies**
- **Continuous interaction throughout the development**
- **Timely feedback and advise from Regulatory Authority**

Demonstrated successful Industry activities related to Pharmaceutical Regulation and Bilateral cooperation

Thank You all

Sriram.Akundi@biocon.com

Indo Japan Manufacturing Relationships

Srinivas Lanka

Credentials
- Speaker

- Srinivas Lanka has dealt with Japan Pharma since a long time
- Two of the Top 5 companies in trade value terms with Japan were led by the speaker
- Executive Director of Sun Pharma. Director of Aurobindo Pharma. Vice Chairman of Ramky Group. Relationships with Japanese companies were built.
- As a member of CEPA negotiations, had interfaced with Japanese delegates on behalf of Ministry of Commerce. Government of India.

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India's pharma exports to Japan – 2% of global pharma trade

- India's pharma exports to Japan
  - US $ 287 mio of Advanced Intermediates/ APIs
  - US $ 35 mio of Formulations

- US $ 322 mio . Approximately 2% of India's exports of US $ 17 bio to world

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India's Manufacturing Capabilities
- over one third of DMFs/ANDAs/CEPs in US/EU

- India's manufacturing capabilities
  - ~ 4000 US DMFs; ~ 3500 ANDAs; ~ over 700 facilities registered with US FDA
  - ~ 2000 EU Marketing Authorizations; ~ 1400 CEPS; over 600 facilities with EU GMP
  - ~ one third of DMFs/ANDAs/CEPs are filed by Indian companies
  - India is 2nd largest exporter of formulations global trade by quantity

    (No 1 is Germany) both branded and generics together. (~ 13%)
  - India is 5th largest importing partner of USA in terms of value in Formulations
  - Well developed manpower in science/engineering/infrastructure

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Top exporters, products and importers

1. Top Exporters include Dr Reddys, Aurobindo, Smilax, Mylan, Jubilant in APIs/Advanced Intermediates
2. Top Products include Antivirals, Antibiotics, Anti-hypertensives
    1. Valacyclovir
    2. Clarithromycin, levofloxacin
    3. Valsartan, Losartan, Sartans Intermediates
    4. Clopidogrel, Clopidogrel Intermediates
    5. Sertraline, Itraconazole, finasteride
3. Top Importers
    1. CBC, Chori, Diato, OG corp, DKSH, Summit, Koa Shoji, Kenko, Nippon, Towa, Otsuka, Fujikawa

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What led to just 2% share in the 2nd largest pharma mkt with ~ US $ 100 bio

1. India develops ANDAs for USA and reaches other markets. The dosage strengths used in Japan vary. A no of Japanese molecules are prescribed in Japan, which are not in the portfolio of US market. Often a mismatch of Indians portfolio and Japanese requirements
2. India develops dossiers with universally accepted bioequivalence studies and dose linearity concept. However Japan requires local bioequivalence studies. And full study of each dosage strength. Hence most portfolio of Indian companies can not be registered .
3. In Japan, convincing doctors becomes essential. Hence most companies are unable to promote beyond certain therapy areas.
4. Profit in selling branded products is far higher compared to generics - resistance in Japan trade.
5. The price realization by Indian generic company is very low and the cost of product dossier is several times high leading to viability issues.
6. Japan requires API DMF to be first accessed by a Formulator. Where as in USA, one can file a portfolio of DMFs and look for attractive partners later.

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Manufacturing / Research Alliances – the opportunities for Japanese Corporates

1. Japanese Manufacturers Associations can sign up for Pharma Parks and house their manufacturing in India. Many states like Andhra Pradesh, Telangana etc will readily support
2. Japanese Manufacturers can select various DMF approved sites for contract manufacturing and reduce their advanced intermediates / APIs sourcing costs.
3. Initially OTC/ Neutraceuticals/ Dietary supplements/ pharmaceuticals can be manufactured in FDA/EU approved sites and reduce their sourcing costs. Bulk packs can be strip packed in Japan.
4. India has emerged strong in Complex chemical reactions - Hydrogenations, Chiral reactions, Catalysis, Halide reactions etc. Japan can outsource these complex steps and have reliable supply chain management.
5. Japan can outsource Formulation development, API synthesis, Drug intermediates synthesis, developing novel routes, monoclonal antibodies development etc and can enhance success.

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Manufacturing / Research Alliances – the opportunities for Japanese Corporates

6. A generic equivalence to innovator/ dose linearity concept may be accepted like in US/EU. Japan can get many generic equivalent options and reduce health cost burden. US has saved an estimated 2 trillion dollars by developing these generic concepts.

7. Normally Japanese companies don't share required specifications and analytical methods. Slightly changing this philosophy will move projects very fast.

8. Japanese patents are less understood by Indians due to language issues. Sharing the patented routes and concepts of infringement will speed up developing novel routes.

9. Indians can chase targets fast with lateral thinking and the above can help a lot to improve the success between partners

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What leads to successful alliances tips to Indian Manufacturers

1. Build High Quality Manufacturing Infrastructure. Prevent risks through high precision equipment. clean room areas even to process advanced intermediates.
2. Develop JP compliant manufacturing process with out many purifications. Then only send sample.
3. Invest on sophisticated Quality control infrastructure which can support real time manufacturing. Budget of qc+qa = production in manpower/investment. Detection ability of analytical methods & equipment should be the best.
4. Play open book & share details on capacities and r&d capabilities. Stick to timelines.
5. Every Japanese relation lasts very long and once trust develops, a lot of input arrives.
6. Decision making process is elaborate. Representing should remain same and should be authentic. Meet twice a year. Never reschedule. Don't Push. Keep 4 to 6 yrs time frame to gain credibility.

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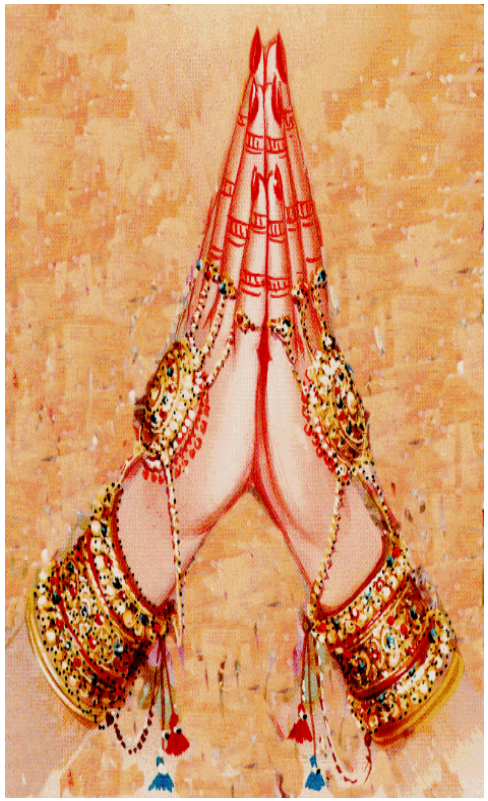
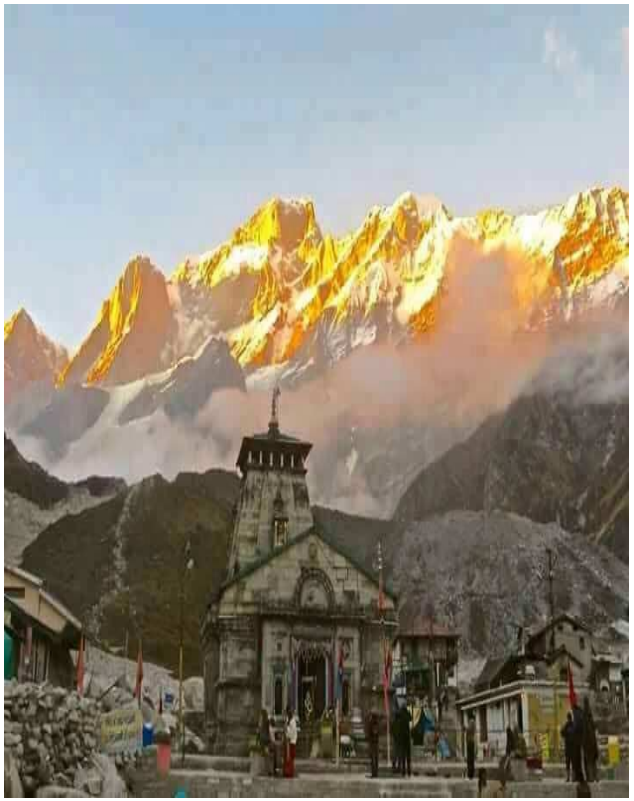
Thank you
Arigatou Gozaimashita
Namaste





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Bridging the Gap

India & Japan

…….a different perspective

Durgesh Sharma
CBC Corporation India Pvt Ltd

CBC GROUP
Dream Together - Grow Together

Profile of the Speaker – Durgesh Sharma

- Chemistry Graduate (University of Rajasthan)
- MBA (University of Lucknow & IIM – Calcutta)
- 18 years of experience in Pharmaceutical Industry
- Working with CBC Co Ltd, Japan since last 3 years
- Currently **Managing Director - CBC India**
- Experience of the Global Pharmaceutical Industry
- In the past
  - Over 6 years in Dr. Reddy's managed
    - European CRAMS business of Dr. Reddy's (based at Cambridge, UK)
    - Head of North Asia & **Country Manager – Japan (based at Tokyo for 4 years)**
    - Head of Asia Pacific (based at Hyderabad, India)
    - China and Russian Business (based at Hyderabad, India)
  - GVK Biosciences (1 year) – Global Head of Sales & BD
  - Orchid Chemicals & Pharmaceuticals Ltd. (4 years) – Head of Asia Pacific
  - Wockhardt Ltd. (4 years) – Head of Middle East, SAARC & Eastern Europe

Am here is to talk about my experience, having worked/working for

- An Indian & a Japanese company
- In Japan for 4 years as Country Manager & Dr Reddy's India's representative
- In India for 3 years as CBC Japan's representative

CBC GROUP

Dream Together - Grow Together

"The reasonable person adapts himself to the world, while the unreasonable one persists in trying to adapt the world to himself."

-George Bernard Shaw

CBC GROUP

Dream Together - Grow Together

What is Culture…….

It is a term that has various meanings. However, the word "culture" is most commonly used in three basic senses:

- Excellence of taste in the fine arts and humanities, also known as high culture.
- An integrated pattern of human knowledge, belief, and behavior that depends upon the capacity for symbolic thought and social learning.
- The set of shared attitudes, values, goals, and practices that characterizes an institution, organization or group. (even Country)

Culture creates Image, Impressions & can be a Brand in itself

Minor things - Major Impact

Greeting - Japan

- Formal and Ritualized.
- Traditional form – Bow, Bend depends upon relationship and situation.

Gift Giving

- India – not very crucial, not expected to open in front of giver.
- Japan – very crucial, wrapping is even more important.
- Opening the gift in front of the giver and praising is good.

Meetings and Negotiations

- India - Time flexibility is accepted, Agenda is not strictly fixed, Meetings are frequent.
- Japan – Time punctuality very important.
- Japan - Group consensus is important.

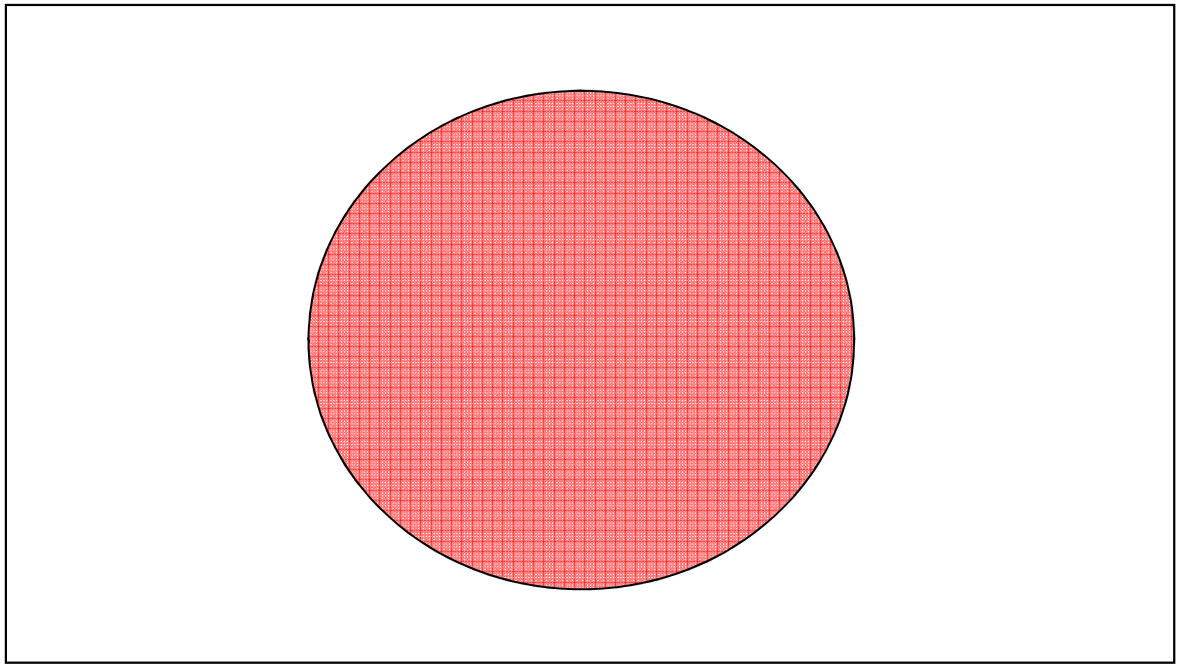
Focus is on Building Relationships
&
trying to understand other side better

Culture of Quality in daily lives

- Products in Japan - good packaging, no dust, smudging of ink, crumpled/de-shaped packs, nice carry bags (quality of the product inside is a given)
- Culture of cleanliness, keeping things in order is prevalent everywhere (children taught at school to clean classrooms/desk from Kindergarten)
- Packaging is extremely important because Image is important.
- Japanese are very service oriented (service is the pillar of Japanese business culture).
- Japanese society is very polite, well mannered & reserved (highly formal, even after years of association).
- Consumer's attitude is very sensitive, claims can come quickly for simple reasons (from non-Japanese perspective).
- Every sector in Japan is highly regulated (regulation is a pre-requisite)
  - Barber – graduates from a school and has to take a license. Only then qualified to cut hair
  - Taxi – knowledge of routes/maps, take a test and never overcharge
  - Courier - if the delivery is requested at 9 PM, the delivery will happen around 9 pm
- All businesses provide in time and expected quality, these are the circumstances Japanese are living & this is the expectation by the customer

Quality of medicines is only one example,
The quality is visible in normal life, in day to day things

Japan is a large potential market……..



…….& it is growing fast

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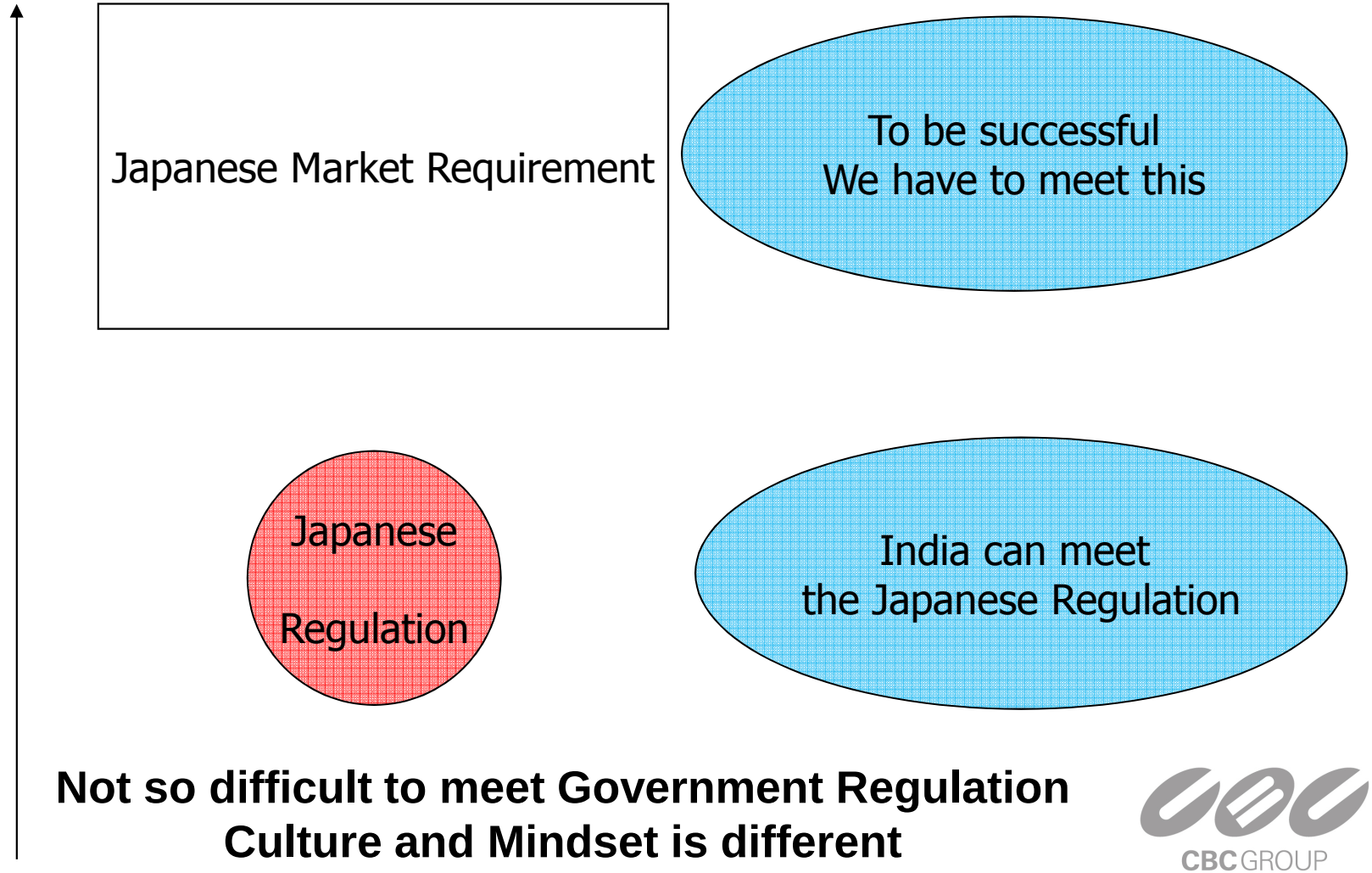
Regulation is important……

but is something more important?



Not so difficult to meet Government Regulation
Culture and Mindset is different

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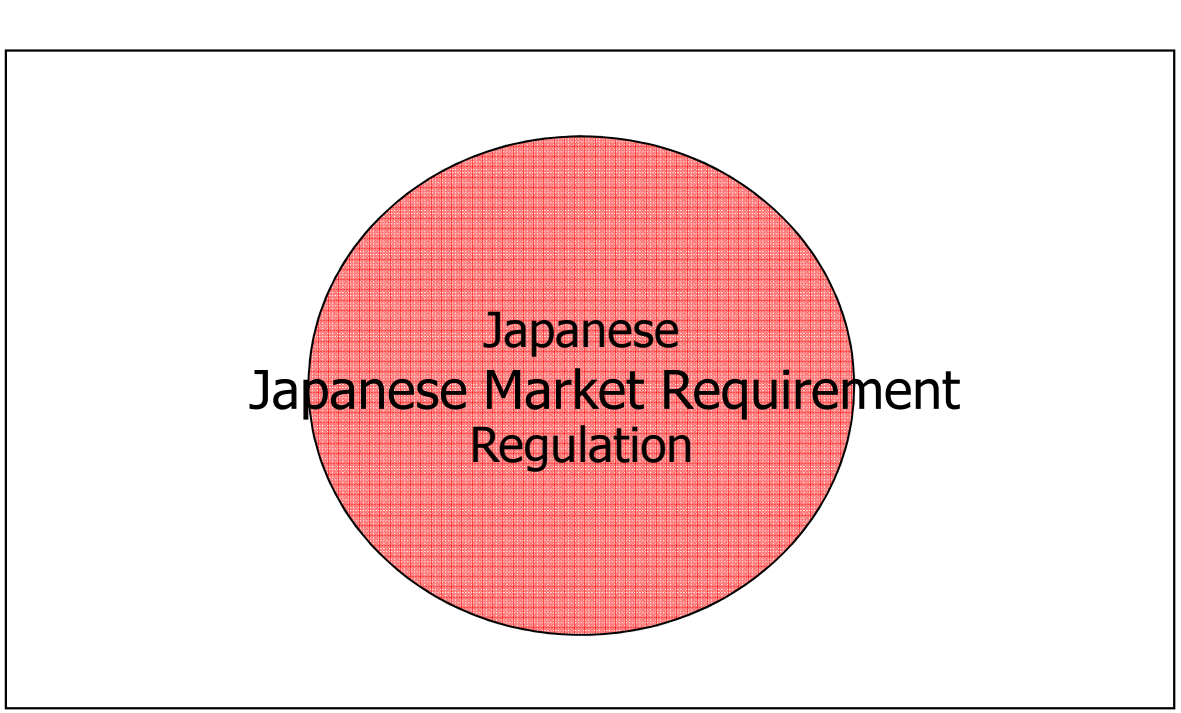
Regulation is a subset of Universal Set



Regulation is the minimum requirement
Customers (Hospitals, Doctors, Pharmacies, Patients)
require much above the minimum requirement
To be successful we have to meet Both

To summarize……..

- Japanese need high level of quality & stable supply (Build Image & in turn the Brand)
- Confidence is built over a period of time (Patience & Effort is important)
- Very stringent visual quality check of the product & product's packaging
  - Machine Error – Easy to correct; Human Error – takes time to correct (culture & attitude comes in here)
- Excessive quality of product comes from culture & market requirement (not only from Government regulation)
- Regulation is the minimum requirement
- Customer expectation/market requirement (Hospitals, Doctors, Pharmacies, Patients) and competition is much above (has to be met)
- Japanese feel all businesses provide **in time & expected quality without any trouble**, this is the circumstance that they are living in & this is the expectation
- Brand Image is important, have to build a "good Brand image"
- People working for the Japanese market have to be made sensitive to this (attitude/culture)
- Change has to be top down, the Owners/MDs/CEOs/Key Stake Holders have to be involved from the beginning (right message)

ご清聴ありがとうございました。

Thank You for your kind attention.

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May 18, 2016, Delhi

Observations & Expectations

For Mutually Beneficial Cooperation between India and Japan

Tsutomu Une, Ph.D.
Daiichi Sankyo, Japan

Ranbaxy Events

- US FDA's message at the import ban & Consent Decree designated to ensure compliance with GMP
  - Cultural Issue
  - Cannot see the wood for the trees

Cultural Issue?

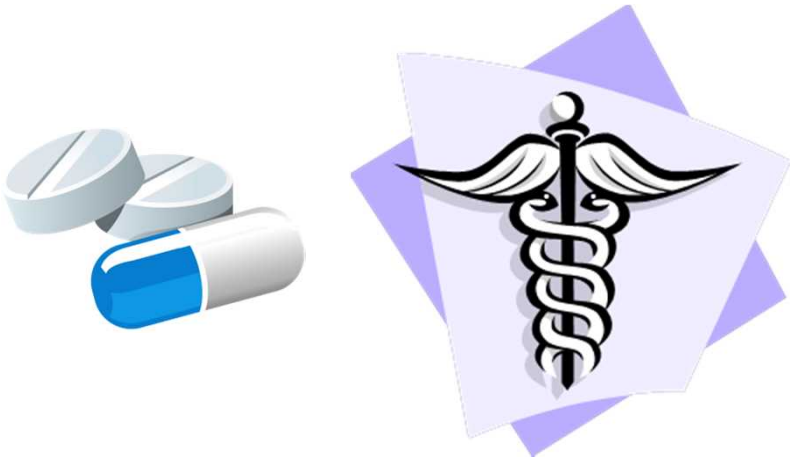
- Outcome-focused operation
  - Profit-first even beyond integrity
  - Cutting corners
  - Fabricated data
- "Silo" operation
  - Prevents cross-functional cooperation
- Remote management

Nature of Pharma Business

- Products are not always safe or effective, *even if they satisfy regulatory requirements*
- Need traceability, and hence to stay on process and not cut corners

Expectation I

- Commitment to Integrity
  - Essential in pharma
  - Most critical element for successful collaboration between India and Japan



Expectation II

- Higher regard for the "shop floor"
- Instill greater sense of responsibility across the organization

Expectation III

- Make it Branded
  - Currently no truly global, "flagship" Indian products
  - Go beyond the minimal requirements
  - Create branded/trusted YET still affordable

Conclusion

- Integrity & Affordability