

A photograph of a traditional Japanese stone well. The well is a shallow, oval-shaped basin carved into a large, flat stone slab. The water inside is still and reflects the surrounding environment. To the right of the well, a small, gnarled tree with vibrant green leaves stands on a bed of light-colored gravel. The background is a vast expanse of similar gravel, creating a minimalist and serene atmosphere. The text "Your next steps for Japan" is overlaid in white, sans-serif font across the center of the image.

# Your next steps for Japan

Keisuke Med Tech Consulting, LLC.

[Kaye.suzuki@outlook.com](mailto:Kaye.suzuki@outlook.com)

# JAPAN 日本 – a snapshot



## Positive Facts

- No. 2 market after US
- 1/3 of US population
- 1/4 is > 65 years of age
- Overall fair reimbursement
- Universal healthcare system
- Great therapy compliance
- Strong Brand Loyalty
- Westernized in lifestyle

## Open for Discussions

- Regulatory approval speed
- Quality demanding market
- Service oriented culture
- Risk adverse culture
- Socialist country
- Shrinking population
- Language barrier
- Japan is different from Asia



# How many “YES” 「はい」 do you have?

- Is your market share in Japan comparable to the States?
- Do you know the needs of the Japanese customers?
- Does your TOP 5 customers in Japan know you?
- Do you know your competitors on the ground?
- Is Japan visible in your day to day decision making?
- Are you happy with the results from Japan?
- Are your competitors operating the same way in Japan?

# Think Outside the Box!

Maximize Your Value Effectively



# Your BUSINESS, BRAND, PRODUCT

The key for success is fundamentally the same in Japan or US; It should operate based on:

- Your corporate culture
- Your way of running business
- Your business objectives
- Your priorities
- Your thought processes
- With local favors



# How different is Japan, really?

- 80% are fundamentally the same
  - Same but more Depths
  - Customers' expectation
- 20% are different
  - Risk adverse culture
  - Socialized government
  - Hunting versus Farming Society
- Inflation of the 20% differences
  - Preference, Practice or Perception
  - Who is inflating? Whose excuse?



# Reasons to go direct in Japan

- Your products are unique
- Your products could be appropriately valued
- Your growth opportunity is large
- Your projected ROI is relatively large
- You are direct in US and Europe
- Your product is not capital intensive
- You are committed to Japan as your No2 market



# Distributor to Direct: An Ideal Transition

1. Obtain new product Shonin/Ninsho under your ownership with distributor as DMAH
2. Hire country manager candidates and train in the States
3. Open entity and start Marketing with distributor
4. Obtain MAH license, keep distributor as Warehouse
5. Transfer old Shonin/Ninsho to your MAH
6. Register as Local Manufacturer and start distribution
7. Start dual channel sales activity
8. Take over full sales activities



# Transition in phases; Add one each year

	Distributor	Phase 1	Phase 2	Phase 3	Phase 4	Direct
Pre approval Regulatory	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Post approval Regulatory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Reimbursement	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Marketing	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Sales	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Logistics Manufacturing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Administration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

# Things to Consider

- Utilize JETRO (Japan External Trade Organization) services
  - Consultations
- Corporate Entity
  - Start with Representative Office until time to apply for MAH
- Office
  - Start with JETRO, then to Rental Office, such as Regus, hold on to expand until revenue
  - Need actual office to apply for MAH
- Accounting and Legal services
  - Use boutique service, not those expensive firms
  - Can always change to expensive firms later, wait until revenue
- HR matters
  - Start as a respectable company, Japan is about IMAGE, REPUTATION, PRIDE
  - Provide the same as US, if possible
  - The spouse and family can influence gaining good talents
  - Employee Handbook in Japanese is crucial to have

# Japan External Trade Organization

Non-profit, Japanese governmental funded organization to promote mutual trade and foreign investments into Japan

- Consultation on establishing business in Japan
  - Legal, Taxation, Regulations, HR, Office, Visas,
  - Partnership, Distribution, industry information
- Information library on doing business in Japan
- Temporary Office Space in Japan until establishment
- Offices in US
  - New York, Atlanta, Houston, Chicago, San Francisco and Los Angeles

# Japan entity: KK versus GK

	PROS	CONS
KK	<ul style="list-style-type: none"><li>● Traditional</li><li>● Well known to public</li></ul>	<ul style="list-style-type: none"><li>● Disclosure of financial statement</li><li>● Board and Shareholder meeting</li><li>● Japan accounting standards</li><li>● Audit if capital is &gt; \$5M</li></ul>
GK	<ul style="list-style-type: none"><li>● Nondisclosure of financial statement</li><li>● Less regulated</li><li>● Tax benefit on the States side</li></ul>	<ul style="list-style-type: none"><li>● Still new</li><li>● Can not go public</li></ul>

- Lawyers and Accountants recommend KK as it will generate more business for them
- Apple, Cisco, P&G, Kellogg's and others have switched to GK from KK
- Transfer is simple and not expensive
- GK is simple and cheaper to start with



# HR matter – min. cost beside salary

- Health and Dental Insurance
  - 50/50 with employee, 9.97% to 11.52% of pay depending on age
- Mandatory Pension Plan
  - 50/50 with employee, 17.12% of pay
- Unemployment Insurance
  - 63% by employer, 1.35% of pay
- Worker's Compensation Insurance
  - 100% by employer, rate 3% to 7% of pay depending on business
- Severance Plan (voluntary)
  - Most respectable company has

# Own your Shonin/Ninsho

- Submit as a Foreign Manufacturer with DMAH
- Elect a DMAH (Designated MAH) who will represent you and conduct the post market vigilance
  - Exclusive distributor or a third party with MAH license
- Elect a local manufacturer who will work with DMAH to inspect, label and release the product for the Japanese market and store them prior to distributing into the market
  - Exclusive distributor or a third party with manufacturer registration
- Third party can be Emergo for DMAH and local logistic companies for manufacturer with storage space

# Shonin 承認 versus Ninsho 認証

## Shonin

- Class III and IV device
- No JIS or MHLW guidance
- No JMDN
- PMDA review
- Approved by MHLW
- Similar to PMA

## Ninsho

- Class II and III device
- JIS or MHLW guidance
- Notified body review
- Certified by notified body
- Similar to CE mark

# Transfer versus Renewal

	PROS	CONS
Transfer	<ul style="list-style-type: none"><li>● Limited impact on distribution</li><li>● Limited regulatory work</li></ul>	<ul style="list-style-type: none"><li>● Inherit the past</li><li>● Amendment is probably needed</li><li>● Monetary negotiation to transfer</li></ul>
Renewal	<ul style="list-style-type: none"><li>● A clean slate</li></ul>	<ul style="list-style-type: none"><li>● Significant impact on distribution</li><li>● Potentially new data necessary</li></ul>

- Obtain copies from MHLW thru Freedom of Information Act
- Monetary negotiation can be expensive, stressful and time consuming
- Due diligence is critical before transfer
- Ninsho (Accreditation) has less regulatory risk in selecting
- Shonin (Approval) needs careful consideration in selecting
- Product competitive strength, inventory and life cycle will influence



# Consider impact to distribution chain

- ✓ Approval number and approval name; if new and not transferred
- ✓ Product labels including package inserts (Tempubunsho)
- ✓ Re-registration on hospital accounting system
- ✓ Re-registration of Reimbursement code
- ✓ Approval name versus product name
- ✓ Changing distributors up to the hospital
- ✓ Establishing new account with present hospitals and distributors
- ✓ New pricing negotiation with distributors and hospitals
- ✓ Inventory control; audit of consignments

# Licenses and Registrations Needed

- MAH (Market release Authorization Holder) License
  - Responsible for the final market release of product
  - Product Shonin/Ninsho holder or in-country takecarer
- Manufacturing Registration
  - Design, main assembly, sterilization, storage (domestic)
  - Labeling can be done without registration if final release is done at domestic storage after labeling at registered site
- Sales and Rental - Needed at all sales offices to sell and store
  - Class III and IV - License
  - Class II – Register                      Class I – not necessary
- Repair – License
  - License per classification

# License and Registration Requirements

LICENSE	KEY REQUIREMENTS
MAH	<ul style="list-style-type: none"><li>● Market Release General Manager</li><li>● Safety Manager</li><li>● Quality Manager</li><li>● SOPs (PAL, GVP, QMS, GPSP ordinances compliant)</li></ul>
Manufacturing	<ul style="list-style-type: none"><li>● Responsible Manager – Domestic</li><li>● Responsible Engineer per site – Domestic</li><li>● Responsible Manager per site – Foreign</li><li>● SOPs (QMS ordinance compliant)</li></ul>
Sales/Rentals	<ul style="list-style-type: none"><li>● Manager per site</li><li>● Facility requirements</li><li>● SOPs (PAL compliant)</li></ul>
Repair	<ul style="list-style-type: none"><li>● Responsible Technician per site</li><li>● Facility requirements</li><li>● SOPs (PAL compliant)</li></ul>

# Concurrent Scheme for MAH

- Class I MAH (Class III and IV device)
  - GM and Quality Manager (QM); min 2 qualified managers
- Class II MAH (Class II device)
  - GM and QM or Safety Manager (SM); min 2 qualified managers
- Class III MAH (Class I device)
  - GM, QM and SM; min 1 qualified manager
- MAH and Manufacturing (Storage) on same address
  - QM and Responsible Manager or Responsible Engineer



# MAH versus Designated MAH

	PROS	CONS
MAH	<ul style="list-style-type: none"><li>● Local entity owns Shonin/Ninsho</li><li>● MAH activities completes within Japan</li></ul>	<ul style="list-style-type: none"><li>● Less ownership by foreign entity (FE)</li><li>● Japan is TBD during R&amp;D</li></ul>
DMAH	<ul style="list-style-type: none"><li>● Foreign entity owns Shonin/Ninsho</li><li>● Japan less likely to be TBD during R&amp;D</li><li>● Easy to switch DMAH</li></ul>	<ul style="list-style-type: none"><li>● MAH activities is joint effort</li><li>● Less ownership by Japan entity</li><li>● More regulatory responsibility on FE</li></ul>

- MAH license is necessary to become DMAH
- Requirements for Japan entity is same for either MAH or DMAH
- Can be decided on product base
- Distributor or third party can be your DMAH
- Easy to change DMAH

# Repair station classifications

## 18 class (9 x 2); Specified and Unspecified

1	Diagnostic Imaging System	X ray, MRI, lithotripter, hyperthermia, contrast media injector,
2	Monitoring System	ultrasound, defibrillator, thermography, oxymeter,
3	Therapeutics & Facility	Pacemaker, electric cautery, surgical equipments, anesthetic, respiratory
4	Artificial Organs	Excluding pacemaker
5	Optical	laser, scopes, tonometer
6	Physical Therapeutics	photo, frequency, ultrasonic, thermo massaging
7	Dental	
8	IVD	scintillation counter, RIST, BGA, microtome
9	Instruments and Home use	surgical instruments, massage chair

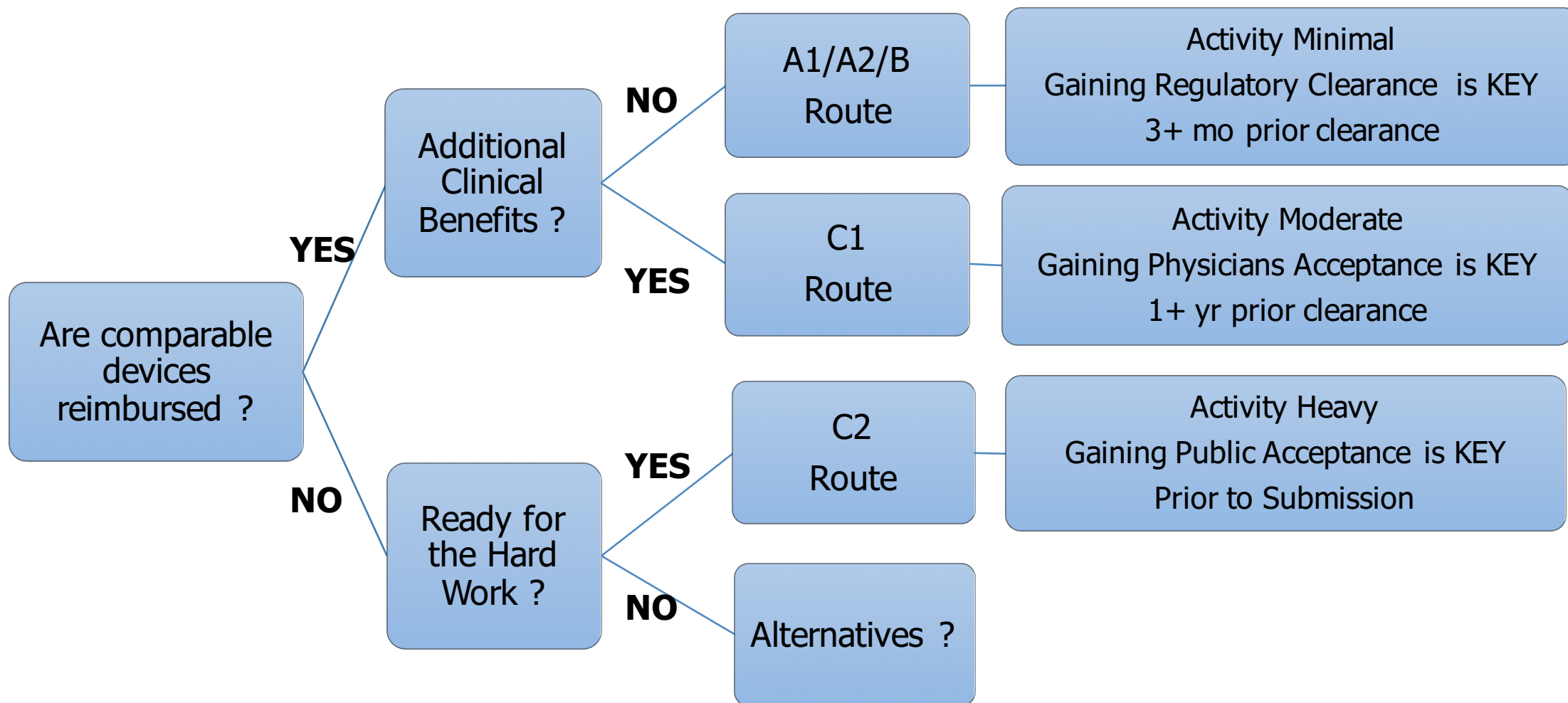
# No Reimbursement = No Sales

- Product Approval (Fact base)
  - Pharmaceutical Affairs Law
  - Approval based on Quality, Safety and Efficacy
- Reimbursement Approval (Political)
  - Health Insurance Law
  - Central Social Insurance Medical Council (No direct access to Industry)
  - Approval dependent of Availability, Acceptability, Assurance, Appropriateness, Awareness and Affiliation

# Reimbursements Categories

Category	Definitions	Examples
A1	Inclusive to any Treatment Code	sutures, disposable syringes, gauges
A2	Medical Device with Specific Treatment Code (included)	X rays, CT-scans, endoscopes
B	Individually Reimbursable Medical Materials based on defined functional categories (separate from Treatment Code)	dialyzers, pacemakers, artificial joints, stents
F	Not Applicable	home use thermometers
C1	Applicable Treatment Code exist but device improved and/or modified from present A2 or B	DES
C2	Totally new device with no applicable Treatment Code	implantable artificial hearts, stent grafts

# Reimbursement Path





# Reimbursement Drives Regulatory

		Regulatory Categories					
		Class 1	Class 2		Class 3 & 4	ALL	
			Guidance	NA	Similar	Modified	New
		Notification	Certification	Approval			
Reimbursement Path	F	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	A1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			
	A2		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	B		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	C1					<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	C2						<input checked="" type="checkbox"/>

# Japanese Customers



Great!

- Strong Brand Loyalty
- Willing to pay for quality and originality
- Willing to help you improve your quality

Challenges

- Intolerant of complacency and careless mistakes
- Quality and service demanding

# Customers 顧客 are Always Right

Japanese Customers' Expectations	Expected Behaviors from YOU
Commitment	Attention to details
Trustworthy	Deliver your commitments
Innovation	Sense of Urgency
Understand their needs	Flexibility to modify your products
Deal directly with the source	Face to Face communication
Modesty	Perseverance
Devotion	Appreciative
Reliability	Compliant
Consistency	Sensitivity



# Group versus Individual



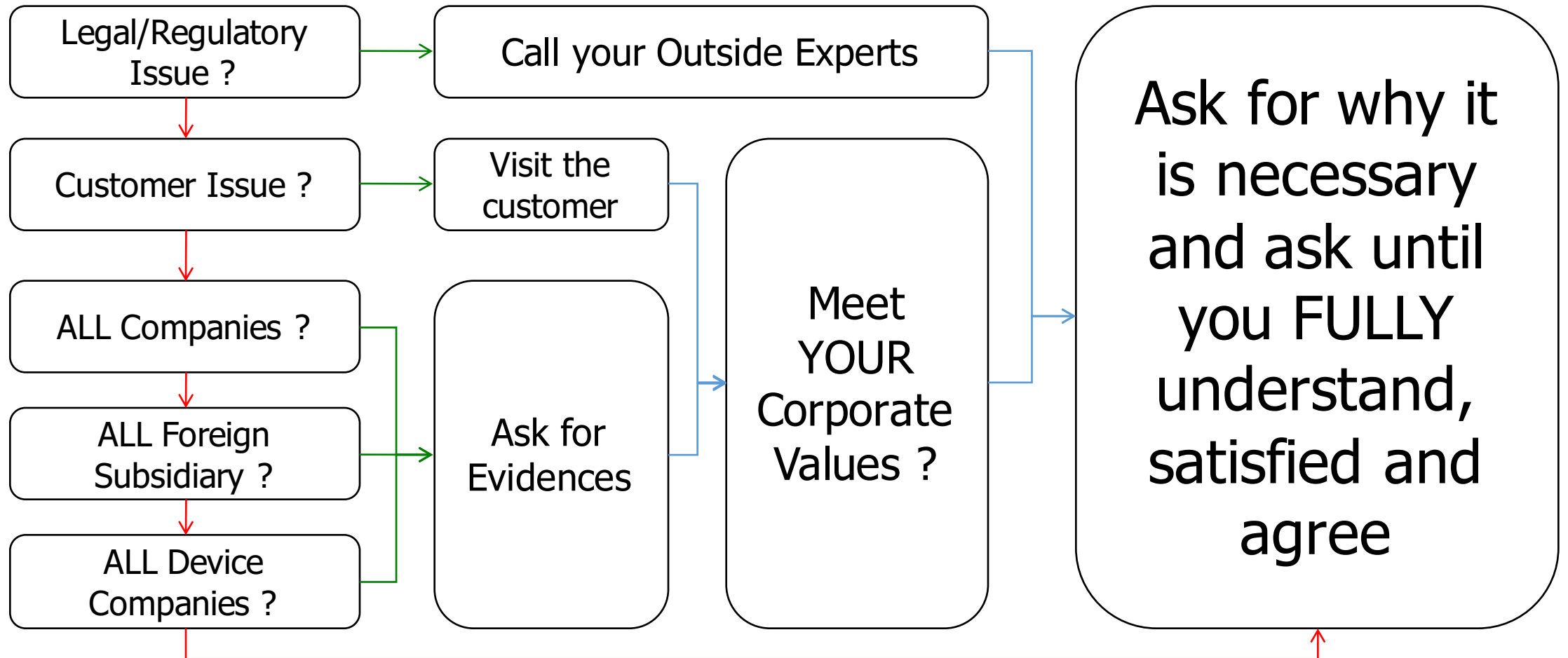
## Common Behavior in Japanese

Consistent	Risk Adverse	Loyal	Dependence
Reliable		Committed	
Obsessed in details		Conform	
Consider all options		Dedicated	
Conservative		Hierarchy	
Group decision		Humble	
Slow		Perseverance	

# Is this a cultural issue or an excuse?

COMMON PHRASE	ISSUE	HOW TO MANAGE
"Hai!" does not mean "Yes!"	Social & Cultural	<ul style="list-style-type: none"><li>• "I hear you, but I have not agreed"</li><li>• Ask for the meeting memo in English on what was agreed on</li></ul>
"Japan is different"	Foreign Capital Company	<ul style="list-style-type: none"><li>• "I do not agree or do not want to"</li><li>• Ask if Sony and Honda are doing the same thing?</li></ul>
"Japanese laws & Regulations say"	Foreign Capital Company Issue Regulated Industry	<ul style="list-style-type: none"><li>• "I do not want to and my excuse is based on my interpretation"</li><li>• Ask for the specific Laws &amp; Regulations and discuss</li><li>• Ask for the specific regulator who said so and be willing to meet</li></ul>

# Pin Point the fact!







# Thank you

Building Quality is Developing People