NIHON KOHDEN

## ANVISA and INMETRO

# Challenges for further effectiveness

www.nihonkohden.com

**Nihon Kohden do Brasil**
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# Great Improvements

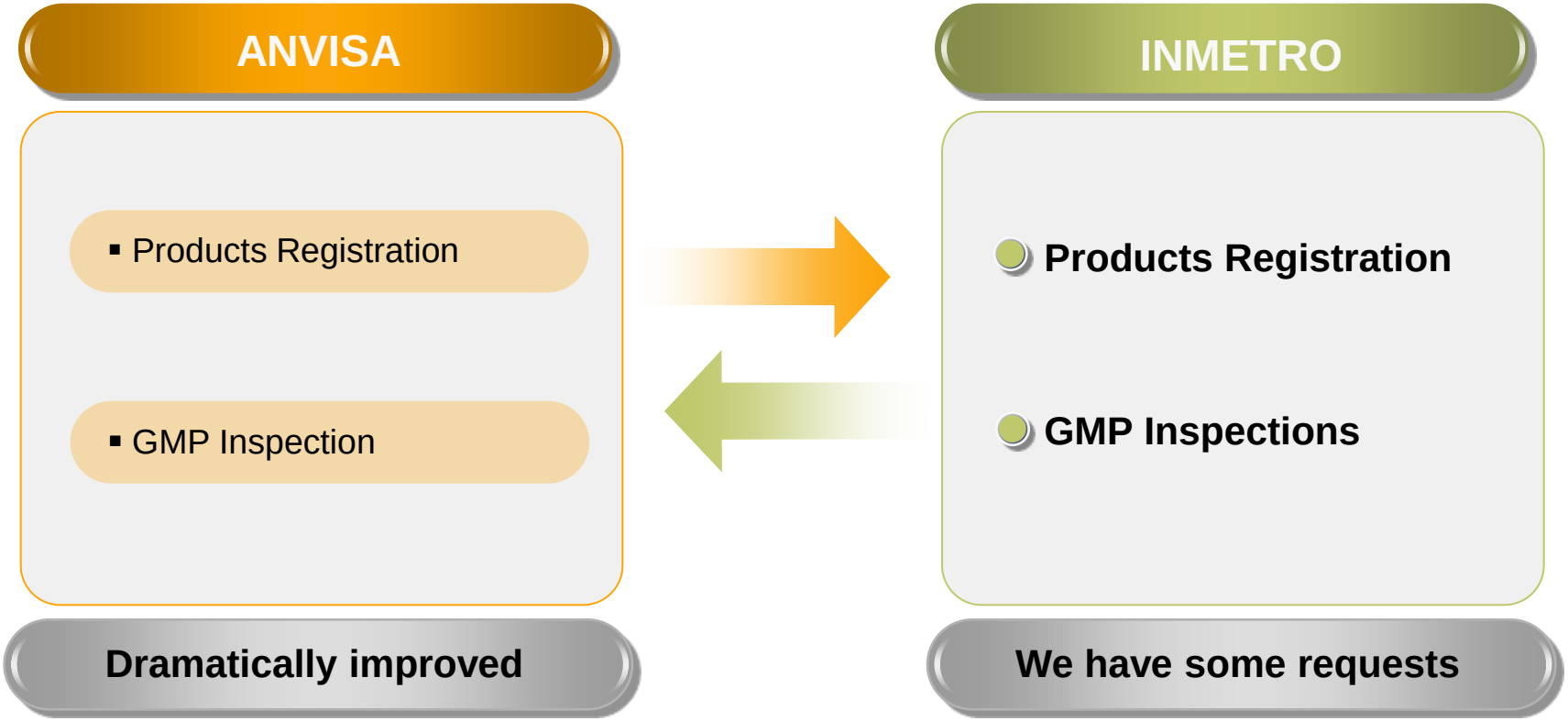
**Class I & II:**
From 6 – 8 to 2 – 3 months
**Class III & IV:**
From 12 – 18 to 6 months


From 35 to 20 days!

**Website Message Channel**
In a few days we will have answers

# ANVISA and INMETRO

**To adjust both ANVISA and INMETRO are hard tasks for us.**



# Introductions of Japan

**01**

**One QMS**

We only have one Quality Management System.

**02**

**Compatibility test to QMS**

With condition of having ISO13485, the most of tests are done by Writing Report.

**03**

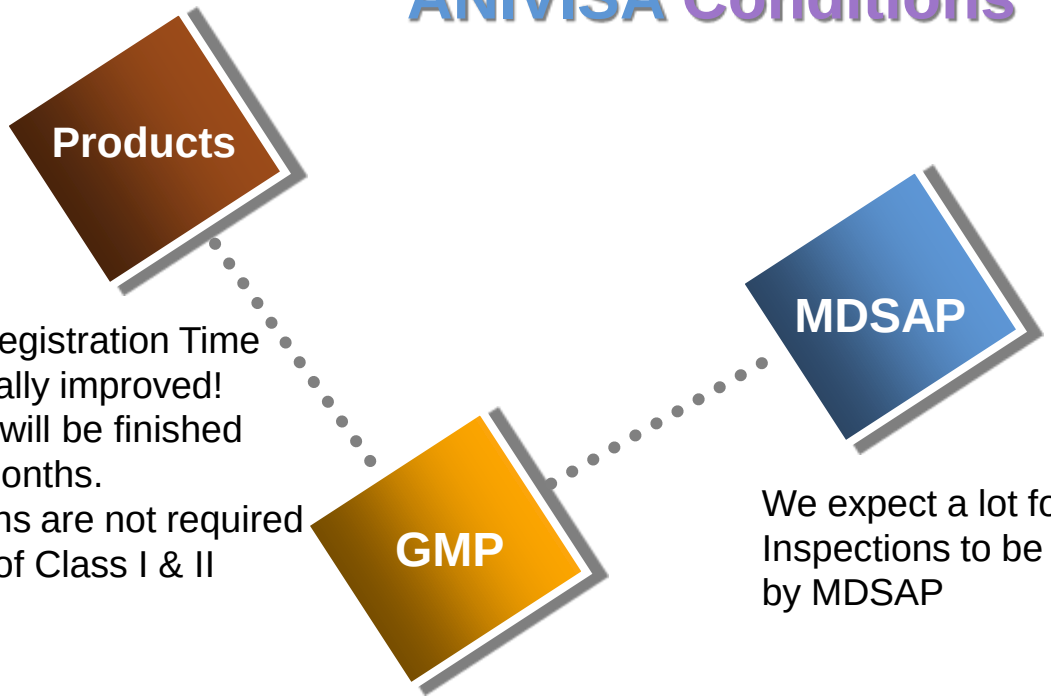
**Compatibility to international QMS**

With conditions of test laboratory holding ISO17025, the certificate of compatibility can be used instead of test report

**Our challenges are to keep high level quality management system with simplified procedures**

# ANVISA

## ANIVISA Conditions




Products Registration Time is dramatically improved! Basically it will be finished around 3 months.
Registrations are not required for Renew of Class I & II products.

We expect a lot for GMP Inspections to be simplified by MDSAP

Waiting lines for GMP Inspections are around 3 years.
Costs became higher around 3 times.

# Requests for ANVISA

01

**Shorten Waiting lists for GMP**

It takes around 3 years to have GMP inspections. This period is getting entry barrier to Brasil.

02

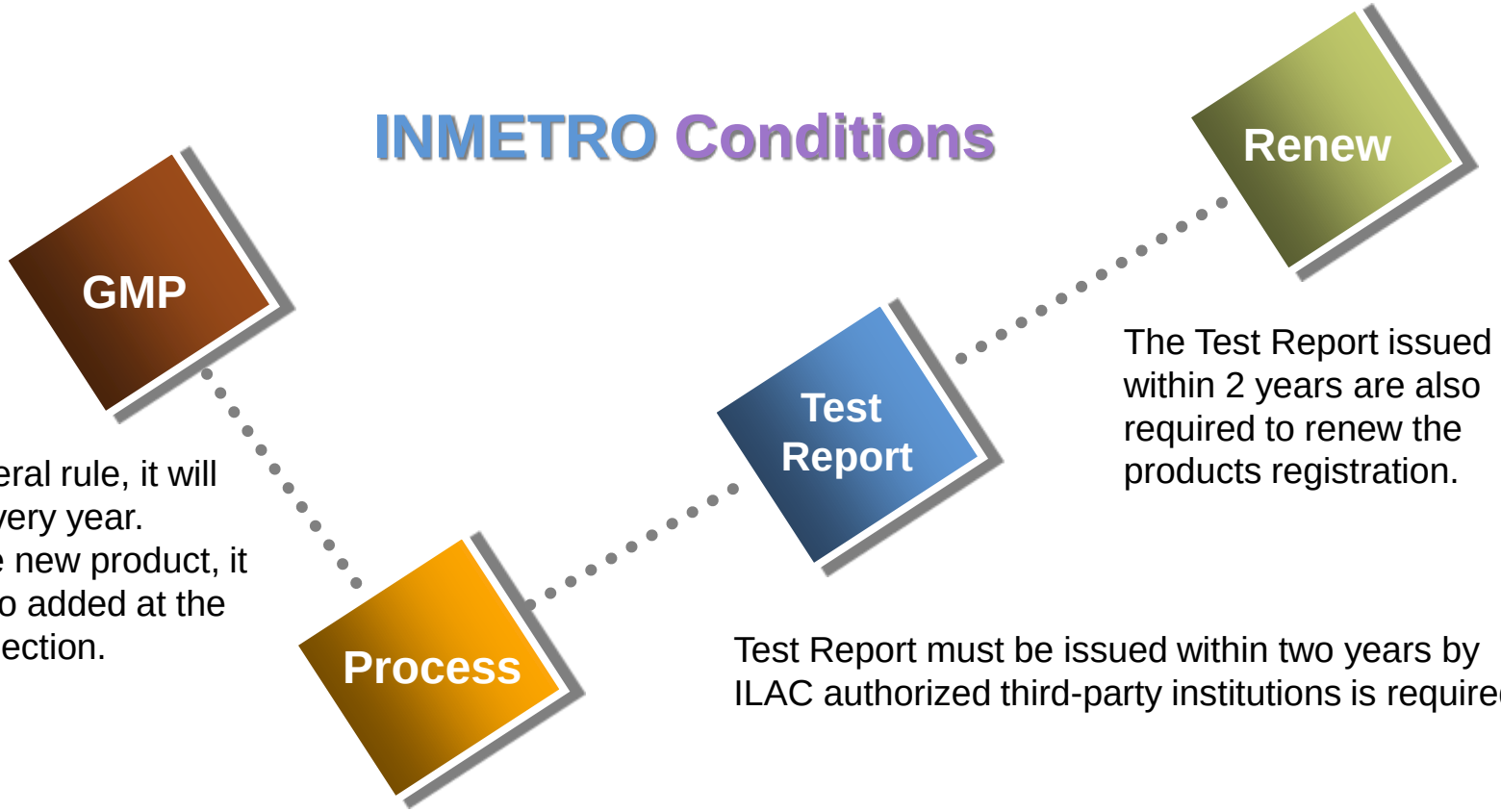
**Exemptions of GMP with conditions**

With MDSAP, we expects GMP inspections will be exempted with some conditions

**Products registration has been dramatically improved.**
**Now we hope GMP inspections will be simplified a little more.**

# INMETRO

## INMETRO Conditions




As a General rule, it will be held every year.
If we have new product, it will be also added at the GMP Inspection.

GMP is done by following ISO13485 – Quality Management system

Test Report must be issued within two years by ILAC authorized third-party institutions is required.

The Test Report issued within 2 years are also required to renew the products registration.

# Requests for INMETRO

**01**

**Exemption of GMP inspections**

With conditions of holding ISO13485, we expect to exempt GMP inspections. Requirements of INMETRO and ISO13485 are similar

**02**

**Test Report within two years**

Test report must be issued within two years. We expect to remove or extend. This is too short.

**03**

**Test Report for Renew Products**

Request not to require it for renew. Compatibilities for IEC are being maintained after product release.

**To keep High Level QMS must be the first priority,**
**So put on strict “conditions” might be keys for simplifying procedure**

# Requests for INMETRO

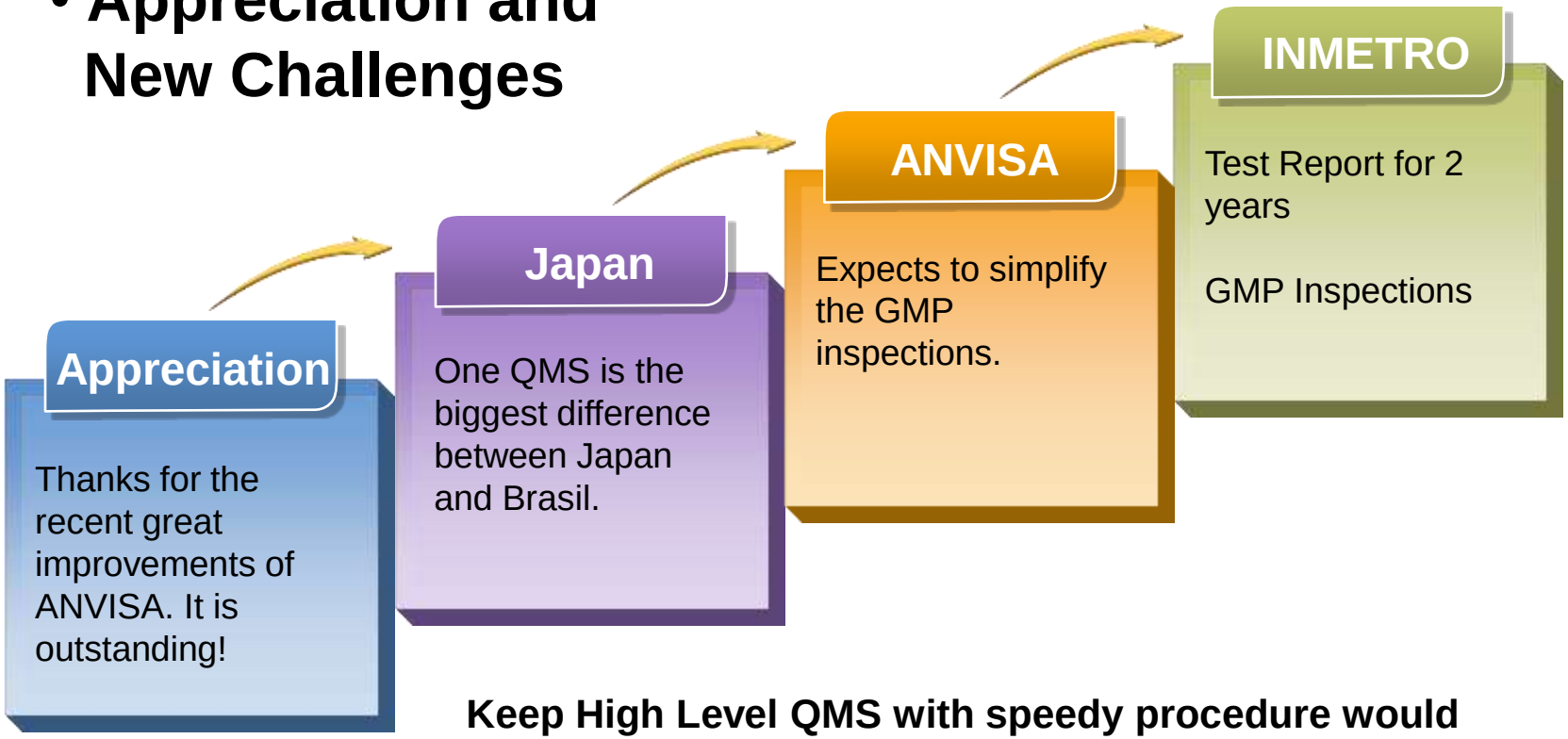
04

## Test Report

With conditions of test laboratory holding ISO17025, we expect the certificate of compatibility can be used instead of test report

# Summary

- **Appreciation and New Challenges**




**Keep High Level QMS with speedy procedure would be our common goal!**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Thank You!
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