



International Cooperation on Harmonisation of Technical Requirements
for Registration of Veterinary Medicinal Products



Japan's experience & VICH Training

Ken NODA, DVM PhD

National Veterinary Assay Laboratory,
Ministry of Agriculture, Forestry and Fisheries, Japan

> Topic 1 Japan's Experience

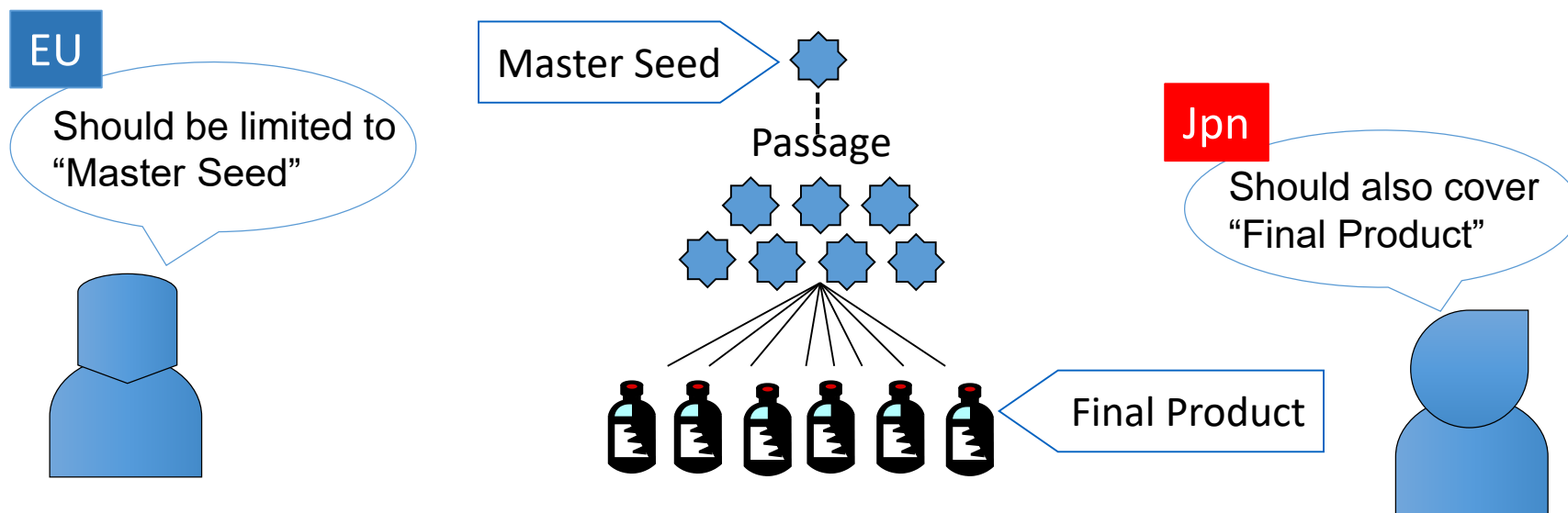
- How VICH modernized vet vaccine regulation in Japan ?

> Topic 2 VICH Training

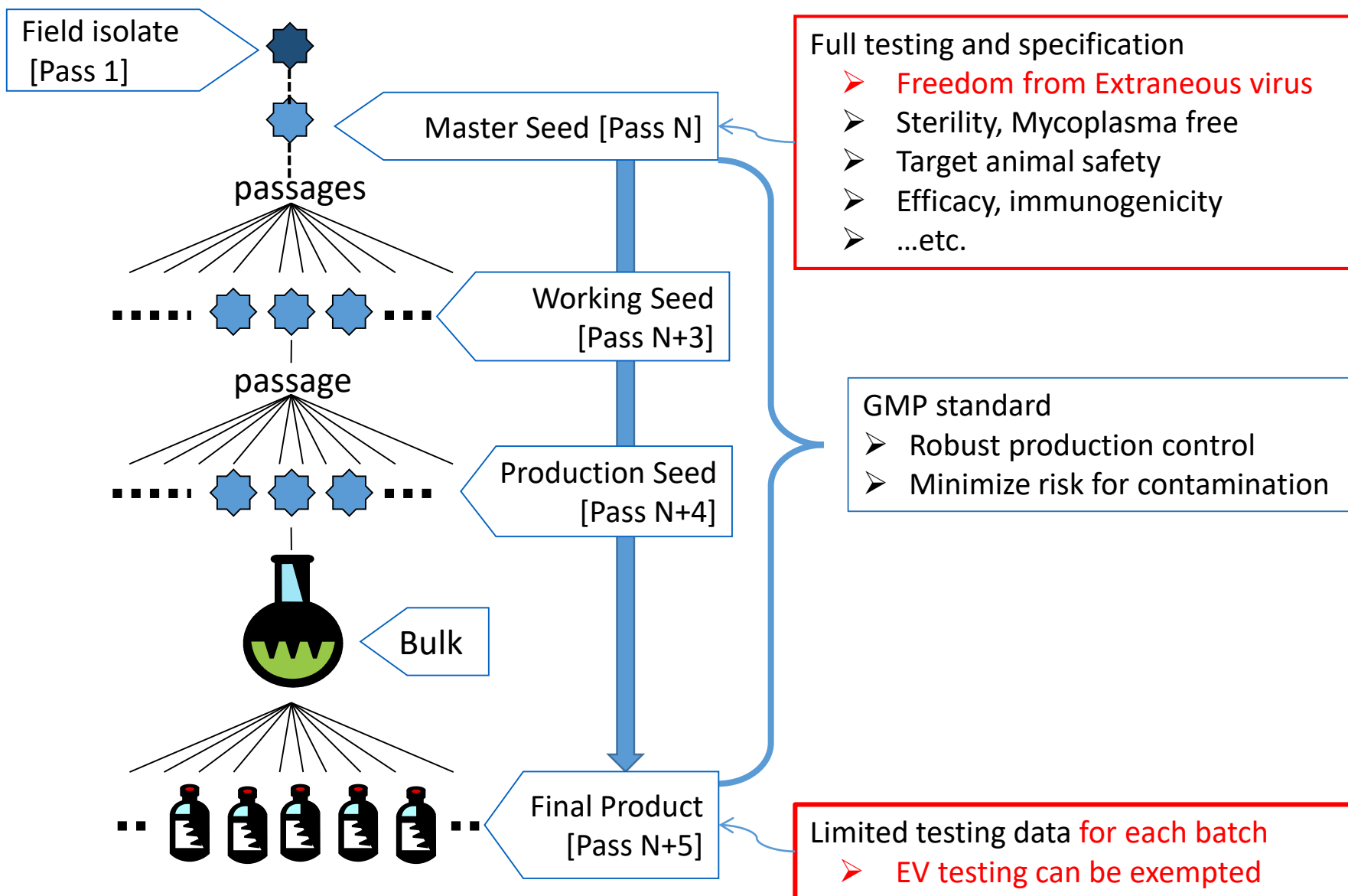
- Concept, Achievement and Materials



- > 1961: Pharmaceutical Affairs Act enacted in Japan
- > 1996: VICH established
- > 2004: 14th SC in Tokyo,
 - Harmonized GL on Extraneous Virus (EV) testing proposed
 - Caused big argument on scope of the GL



EU proposal make sense when Seed-lot system and GMP already adopted



- > OIE recommended standardized manufacturing process (Seed-lot system and GMP)
- > Already adopted in EU and USA, but not in Japan
- > Contribute modernization of vaccine production
- > Promote the harmonization of the international standard.



- > Japan decided to introduce Seed-lot system and GMP,
- > Asked VICH SC to wait until the adoption in Japan, then to resume discussion



> 2005

- GMP for Veterinary Vaccine

> 2005-2007

- National project for development of veterinary vaccine
Seed-lot system

> 2008

- Implementation of Seed-lot standard for virus and cells



Quality Vaccine and Proper Use



Production



Distribution



Usage



Monitoring

Pillar	Purpose	Measure/System
Production	✓ Quality/Safety/Efficacy	<ul style="list-style-type: none"> • License for Manufacturing • License for Marketing Authorization Holder (MAH) • Pre/Post-marketing evaluation • National Assay • Seed-lot system • GMP
Distribution	<ul style="list-style-type: none"> ✓ Proper storage/transport (cold chain) ✓ Proper retailing ✓ Sales by vet. oversight 	<ul style="list-style-type: none"> • License for Retailing • Prescription
Usage	<ul style="list-style-type: none"> ✓ Vet. consultation ✓ Responsive Use 	<ul style="list-style-type: none"> • Prescription • Code of practice
Monitoring	<ul style="list-style-type: none"> ✓ Adverse effect ✓ Vaccine break 	<ul style="list-style-type: none"> • Pharmacovigilance

Moisture testing (VICH GL26)

Residual formaldehyde testing (VICH GL25)

Mycoplasma contamination testing (VICH GL34)

Target animal safety testing (VICH GL44)

Waiver of Target Animal Batch Safety Testing for Inactivated vaccine (VICH GL50R)

Waiver of Target Animal Batch Safety Testing for live vaccine (VICH GL55)

Waiver of Laboratory Animal Batch Safety Testing (VICH GL59)

TABST/LABST GLs are applicable where Seed-lot system, GMP and Pharmacovigilance are in place!



> **Topic 1 Japan's Experience**

- **How VICH modernized vet vaccine regulation in Japan ?**

> **Topic 2 VICH Training**

- **Concept, Achievement and Materials**



- > Provide basis for wider international harmonization of technical registration requirements,
- > Raise awareness of VICH in Collaboration with OIE
- > Promote acceptance of VICH GLs
- > Communication and Training to raise awareness of the benefits of VICH

- Brunei, April, 2017
 - back to back with the 4th meeting of the ASEAN National Focal Points for Veterinary Products (ANFPVP)
- Participants
 - VMP regulators in seven ASEAN countries
Brunei, Cambodia, Malaysia, Philippine, Singapore, Thailand, Vietnam
 - ASEAN secretariat
 - OIE sub-regional Representation for South-East Asia.
- Speakers
 - VICH delegate from JMAFF
 - Thailand DLD veterinary official



- VICH GL27
 - Guidance on pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance
- VICH GL50
 - Harmonisation of criteria to waive Target Animal Batch Safety Testing for inactivated vaccines for veterinary use
- Related information
 - Introduction to VICH
 - Antimicrobials regulation
 - Vet vaccine regulation



- Trial was quite valuable for VOF members
 - Strong wish for modernizing VMP regulation through VICH activity
- On-site training seminar complement the lack of information and miscommunication
- It was proposed to invite VICH training seminar also to the next ANFPVP meeting in Cambodia, 2018
- The delegate explained “beneficiary-payment principle”



> Cambodia, April 2018

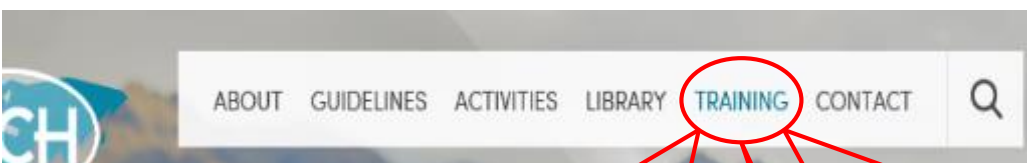
- back to back with the 5th meeting of the ANFPVP

> Program Focus

- Introduction to VICH (structures, GL, website, training materials)
- Q&A brainstorming
- Planning a VICH workshop in April 2019; potential topics, logistics and funding
- Pharmacovigilance; The Essentials; Development systems, GLs
- Global Resource Center

> Spekaer

- VICH delegate from HealthforAnimals



General training material

- **REVISED** PowerPoint presentation: VICH General Principles and current update of VICH Outreach Forum current activity (27 June 2016)
- **REVISED** VICH/10/008 - Revision 2 - 20 September 2016 - VICH and its role in providing harmonised data requirements to support the authorisation of veterinary medicinal products

VICH Workshop - General Information (Tanzania, 24 June 2015)

- 1 - Introduction to VICH
- 2 - Role of VICH and VICH guidelines in the approval process for veterinary medicinal products
- 3 - Introduction to the VICH Outreach Forum
- 4 - How to get involved in VICH?
- 5 - How can I get more information on VICH??
- 6 - VICH - development of PhV systems

Module 6 - Pharmacovigilance

- PowerPoint presentation "Pharmacovigilance: Development of PhV systems and processes"
- PowerPoint presentation "How to - VICH PhV final" (given at the ASEAN national focal point for VPs training in Cambodia, April 2018, and at VOF 10 Bruges, June 2018)

Module 2 - Quality

- VICH Guidelines on Stability: Overview (English) - Vue d'ensemble (French)
- VICH GL3 (R) & 4 - Stability testing of new veterinary drug substances and medicinal products + Annex GL4 - Requirements for new dosage forms
- VICH GL5 - Photostability testing of new veterinary drug substances and medicinal products
- VICH GL8 (R) - Stability testing for medicated premixes
- VICH GL10: Impurities - GL on Impurities in new veterinary drug substances
- VICH GL11: Impurities: GL on Impurities in new veterinary medicinal products
- VICH GL18 (R): Impurities: Residual solvents in new veterinary medicinal products, active substance and excipients
- VICH GL45 (R) - Bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products
- VICH GL51 - Statistical evaluation of stability data

Module 3 - Efficacy

Bioequivalence GL52: Blood Level Bioequivalence Study training presentation (June 2018)

Module 4 - Safety

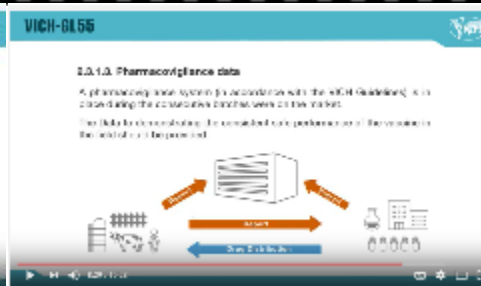
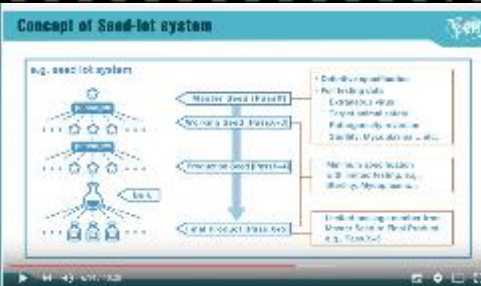
- VICH Residue Guidelines (VICH GL46 to 49, 56 and 57) - Data Requirements for setting Withdrawal Periods
- Presentation from ASEAN Training on VICH, 26-27 April 2017, Brunei
- a) Brief Introduction for Approval System of Antimicrobials in Japan
- b) VICH GL27: Guidance on Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food Producing Animals with Respect to Antimicrobial Resistance


Module 5 - Biologicals

- Presentation from ASEAN Training on VICH, 26-27 April 2017, Brunei - GL50 Waiver of TABST
- Training presentation for VICH TABST GL 50(R) & GL 55
- **NEW** Training video for VICH guidelines 50 & 55 on criteria to waive the target animal batch safety testing for inactivated vaccines



<https://youtu.be/uqbLNoZzWbM>



The background of the slide is a photograph of a vast, rolling landscape. In the upper middle section, a large flock of white sheep is gathered on a green grassy slope. The hillsides are covered in a mix of green grass and golden-brown crops, possibly corn, which are in various stages of growth. The lighting suggests a bright, sunny day, with long shadows cast across the terrain.

Thank you !
ありがとうございました

www.vichsec.org