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QUALITY OF VMPS – UPDATE ON PICS

**REGIONAL WEBINAR –VMPS FOCAL POINTS
AFRICAN COUNTRIES, 23RD FEBRUARY 2022**

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Introduction



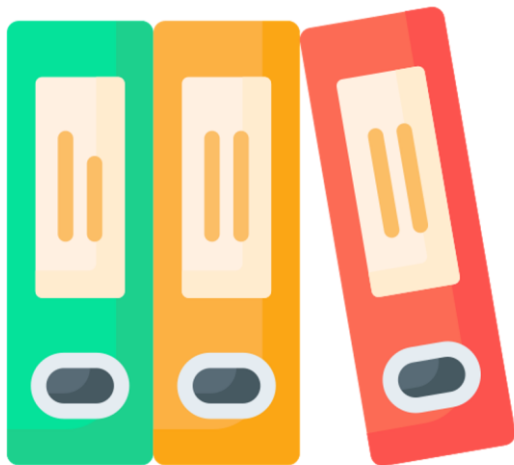
Introduction

Ensuring the Quality of Veterinary Medicinal Products (VMPs) is an essential and **basic requirement for the good governance of VMPs.**

Use of non good quality VMPs presents risks :

- For animal health : inefficient medicines
- For human health :
 - Risk of residues in food
 - Inefficient vaccines could have impact on zoonosis outbreak
- For environment : pollution

Marketing Authorisation dossier



Administrative Part : Summary of the dossier

Part 2: Pharmaceutical quality Part

Constituents, Manufacturing process, Control of starting materials, tests carried out at intermediate stages of the process, finished product ...

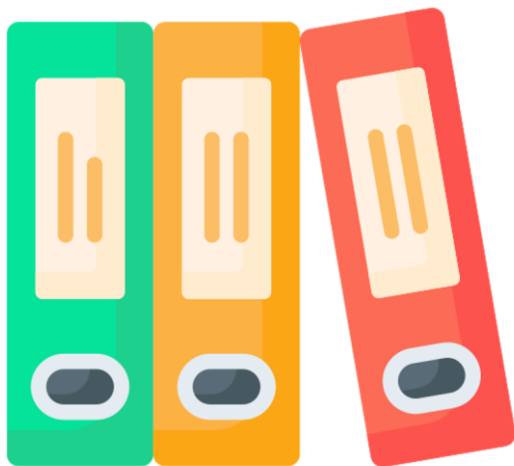
Part 3 : Safety and residues tests Part

Toxicology tests (single dose toxicity, repeat dose, effects on reproduction), user safety, environmental risk assessment ... (chemical products), administration of one dose, overdose, repeated administration, effects on reproductive performance... (immunological products)

Part 4 : Efficacy tests

Preclinical and clinical trials...

Pharmaceutical Quality Part



Qualitative and Quantitative Particulars of the Constituents

Description of the Manufacturing Method

Control of Starting Materials

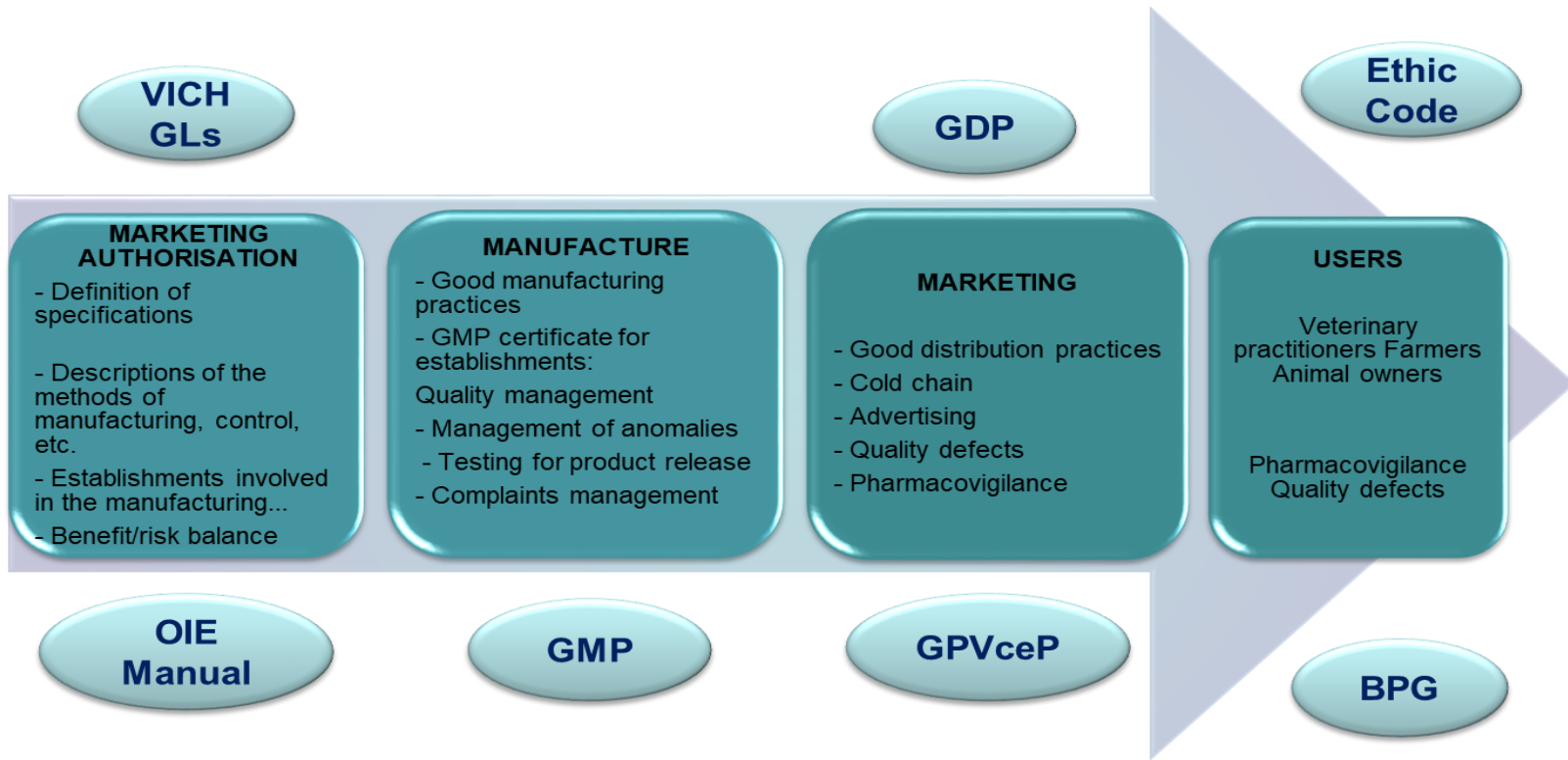
Control Tests Carried out at intermediate stages of the Manufacturing Process

Tests on the Finished Product

Stability Test

Other Information

Quality at all steps of VMPs life



PICS





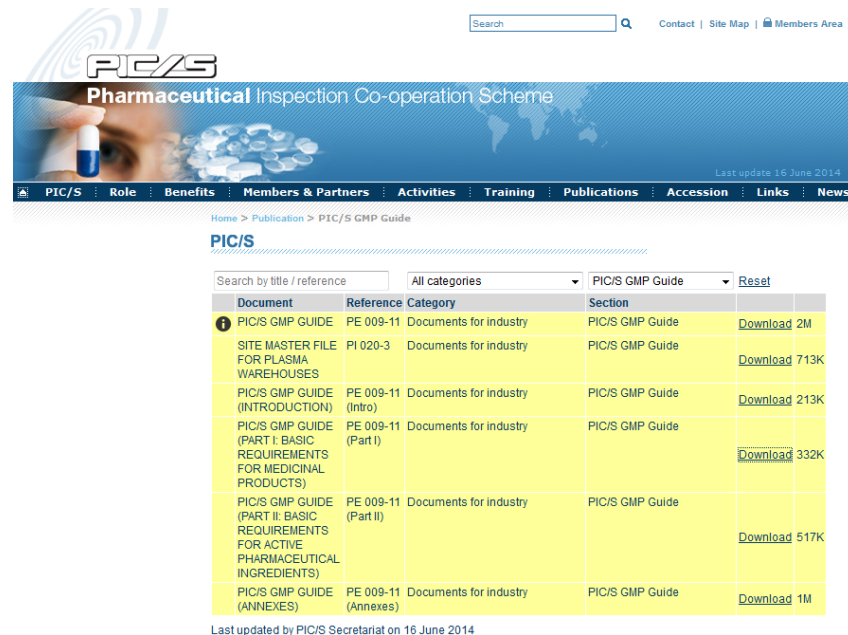
PHARMACEUTICAL INSPECTION
CO-OPERATION SCHEME

PICS : Organisation / Missions

The **Pharmaceutical Inspection Co-operation Scheme** is an **international instrument** between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of **GMP**.

PIC/S' mission is "to lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products."

<http://picscheme.org/>



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PICS
Pharmaceutical Inspection Co-operation Scheme

Last update: 16 June 2014

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PICS

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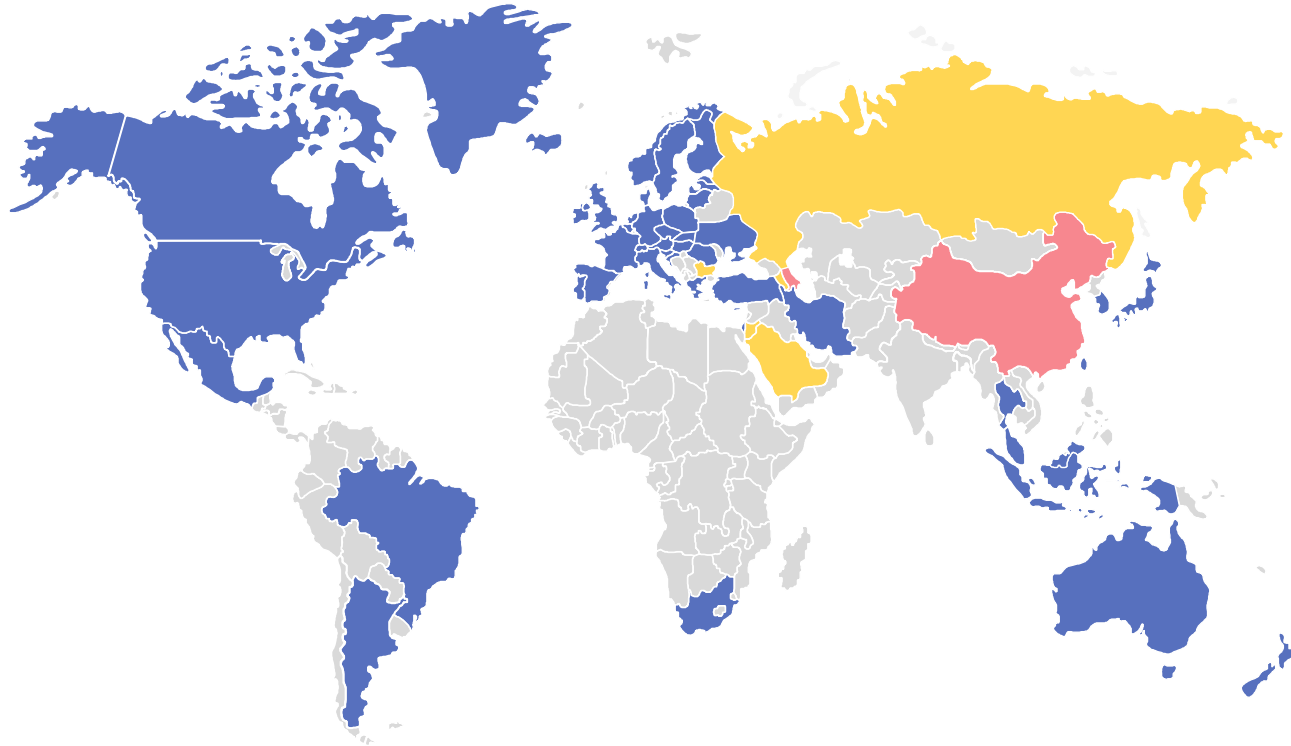
Document	Reference	Category	Section		
 PIC/S GMP GUIDE	PE 009-11	Documents for industry	PIC/S GMP Guide	Download	2M
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PIC/S GMP GUIDE (ANNEXES)	PE 009-11 (Annexes)	Documents for industry	PIC/S GMP Guide	Download	1M

Last updated by PIC/S Secretariat on 16 June 2014

GOALS



PICS : Current members

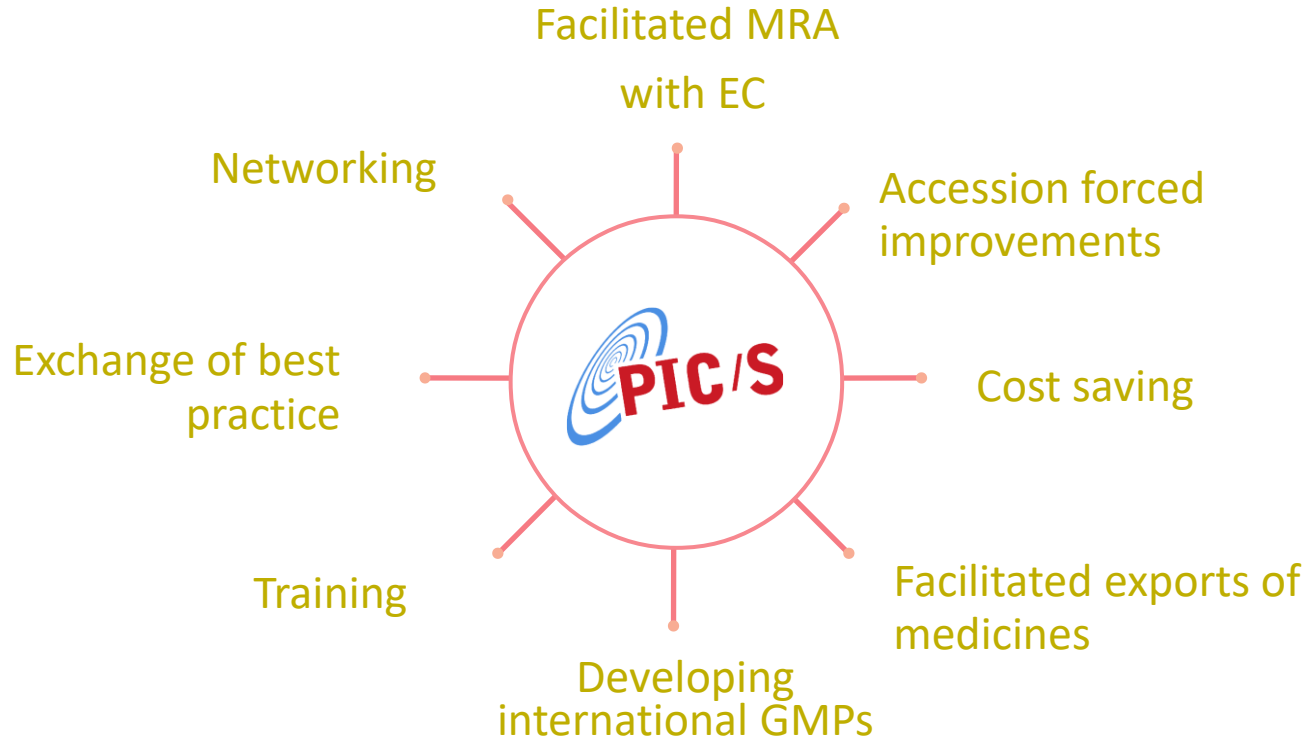


■ Member

■ Pre-applicant

■ Current applicants

Benefits of PICS members





Expert Circles

Aim:

Develop draft guidance documents & Training in specialised field



- ✓ APIs
- ✓ Controlling Cross Contamination in Shared Facilities
- ✓ Human Blood, Tissues, Cells & ATMPs
- ✓ Quality Risk Management
- ✓ Good Distribution Practices

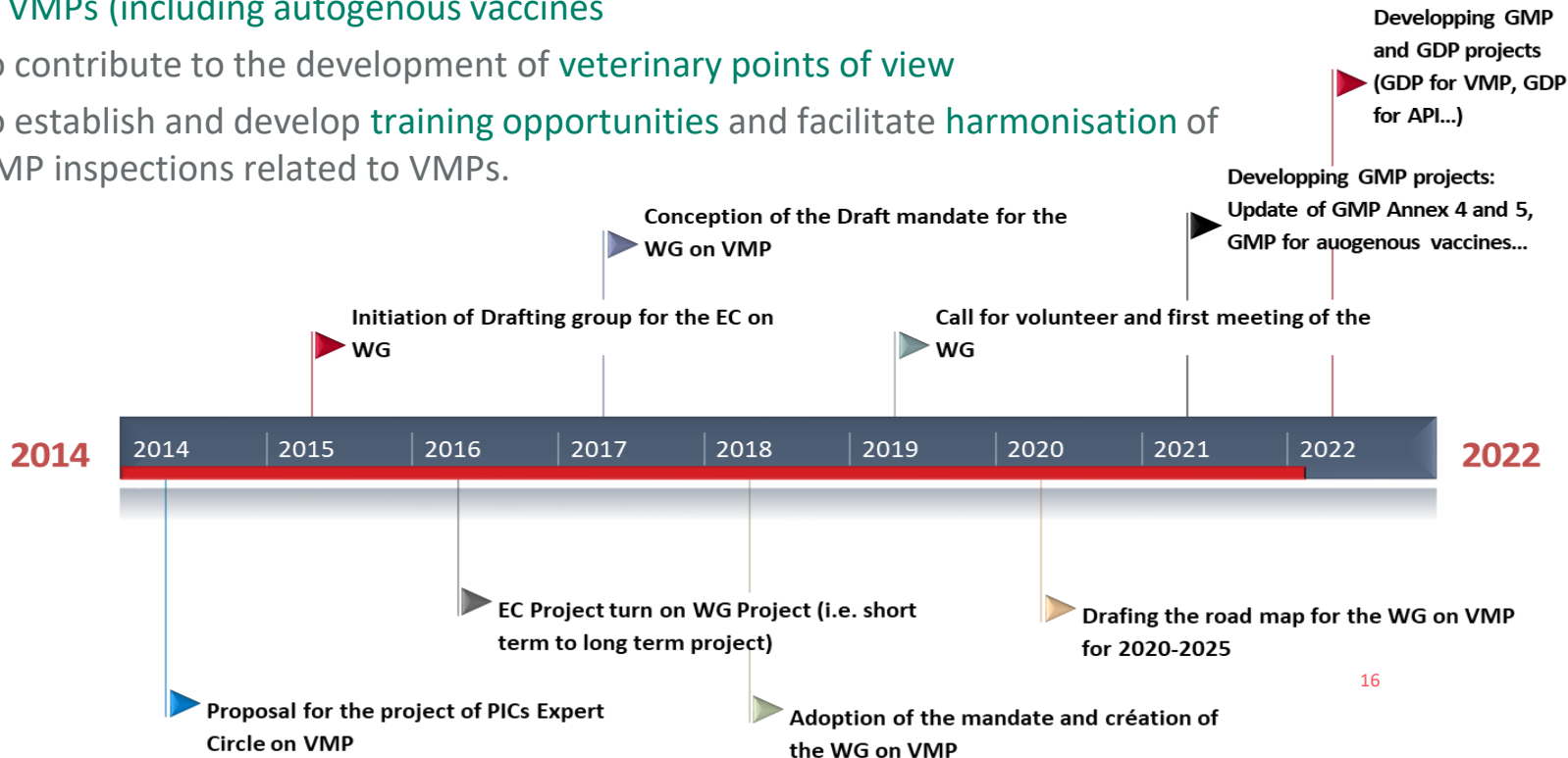
Working Groups

1. Revision of Annex 1 (joint WG with EMA and WHO)
2. Revision of Annex 2
3. Harmonisation of Classification of Deficiencies
4. Data Integrity
5. Controlling Cross-Contamination in Shared Facilities
6. GCP & GVP
7. Revision of PI 006
8. Unique Facility Identifiers (UFI)
9. Inspector Travel Safety
10. Veterinary Medicinal Products
11. Quality Defects
12. Informants
13. Revision of Blood guidance documents
14. Aide Memoire on Tissues and Cellular Therapy Products Inspections
15. Computerised Systems
16. Revision of Accession Guidelines and related documents
17. Third Party Funding
18. Revision of the PIC/S Aide Memoire on QRM Implementation
19. ICH Q12 Training Material
20. PIC/S Inspection Reliance
21. Remote Assessment

PIC/S and Working group on VMPs

A new Working Group on VMP launched in 2018 :

- ❖ To determine and to analyse **potential issues** in connection with **GMP inspection of VMPs (including autogenous vaccines)**
- ❖ To contribute to the development of **veterinary points of view**
- ❖ To establish and develop **training opportunities** and facilitate **harmonisation of GMP inspections** related to VMPs.



PIC/S and Working group on VMPs

Main topics of the 2020-2025 road map for the WG on VMP:

Update GMP
Annex 4 on
Manufacture of
Veterinary
Medicinal
Products other
than
Immunological
Veterinary
Medicinal
Products

Update GMP
Annex 5 on
Manufacture of
Immunological
Veterinary
Medicinal
Products

Develop
concept paper
on GMP for
autogenous
vaccines

Develop
concept paper
on GMP for
novel therapy
veterinary
medicinal
product

Develop GDP
for veterinary
medicinal
products

Develop GDP
for active
substances
used in
veterinary
medicinal
products

Quality System requirements

Aim:

Adopt a common standard for quality system requirements – to ensure consistency in inspection standards between National Pharmaceutical Inspectorates.

In return this facilitates mutual recognition of those Inspectorates.

- Quality Improvement & Corrective / Preventive Action
- Complaints
- Issue & Withdrawal of Licences and GMP certificates
- Handling Suspected Quality Defects & Rapid Alert System

- Quality Manual
- Administrative Structure
- Organisation and Management
- Documentation and Change Control
- Records
- Inspection Procedures
- Inspection Resources
- Internal Audit

PIA : Inspectorates Academy



- A unique virtual tool for proposing harmonised training material and qualification process for GMP inspectors
- A system defined by inspectors for inspectors
- Containing training modules validated by experts belonging to PIC/S Participating Authorities
- With a regular update on its contents
- Available 24h/ 24, 365 days a year



Web based educational centre

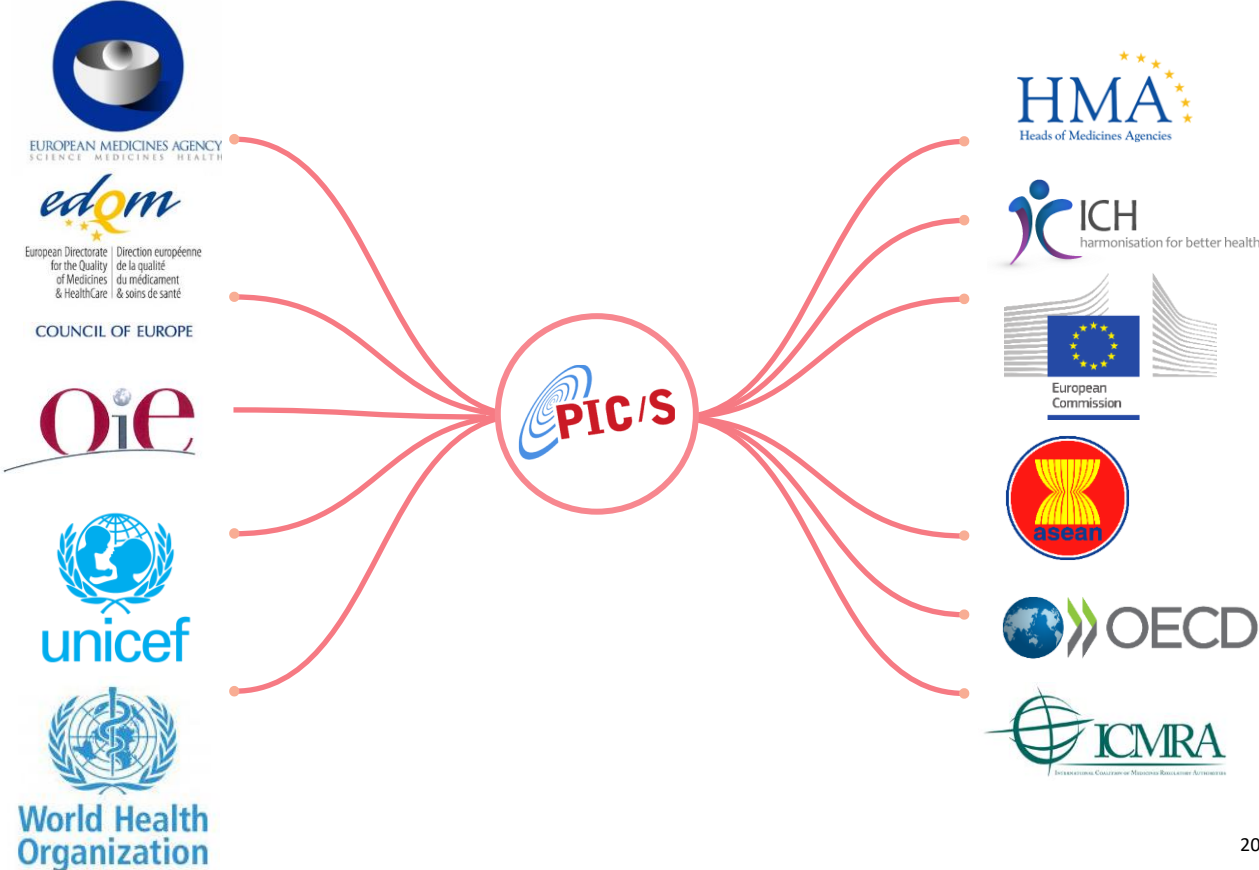
Standardises GMP training at international level – recognised qualification

Delivers general or advanced GMP training

Is a platform for discussion / sharing among regulators

A single point of access to all PIC/S training

Partners



PICS Contact

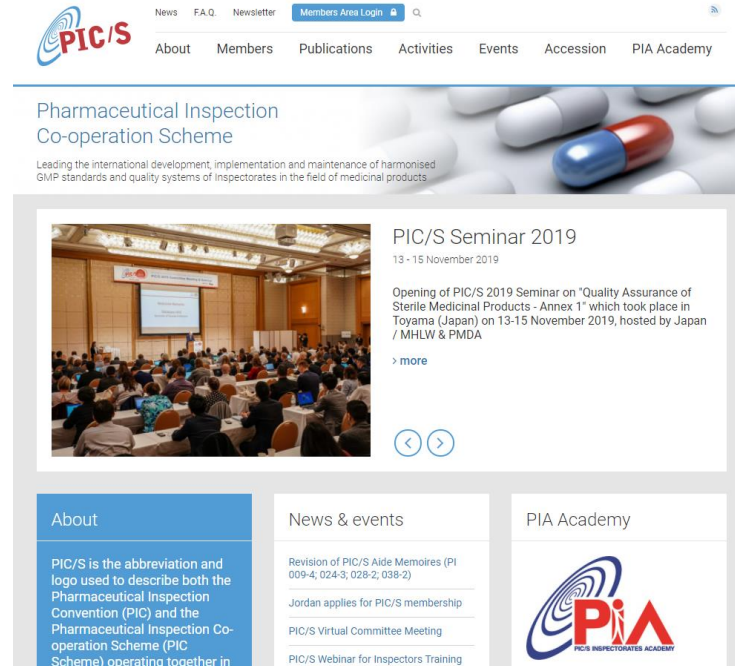


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The screenshot shows the PIC/S website homepage. At the top, there is a navigation bar with links for News, F.A.Q., Newsletter, Members Area Login, and a search icon. Below this is a main menu with links for About, Members, Publications, Activities, Events, Accession, and PIA Academy. The main content area features a header for 'Pharmaceutical Inspection Co-operation Scheme' with a background image of pills. Below the header is a sub-header 'PIC/S Seminar 2019' with a date '13 - 15 November 2019' and a description: 'Opening of PIC/S 2019 Seminar on "Quality Assurance of Sterile Medicinal Products - Annex 1" which took place in Toyama (Japan) on 13-15 November 2019, hosted by Japan / MHLW & PMDA'. There is a '> more' link and navigation arrows. At the bottom, there are three columns: 'About' (describing PIC/S as the abbreviation and logo used to describe both the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) operating together in...), 'News & events' (listing 'Revision of PIC/S Aide Memoires (PI 009-4, 024-3, 028-2, 038-2)', 'Jordan applies for PIC/S membership', 'PIC/S Virtual Committee Meeting', and 'PIC/S Webinar for Inspectors Training'), and 'PIA Academy' (with the PIA logo).

Conclusion



Conclusion

- ***Ensuring quality of Veterinary medicinal products is essential.***
- ***Appropriate legislation and Staff (trained inspectors, laboratory capacities) are needed.***

- *Efficient systems of Authorisation (VMP and companies)*
- *Transparency and communication*
- *Efficient Inspectorate body with appropriate power*
- *The possibility to survey both the legal and illegal market*

are essential as well as :

The capacity of prosecution and recalling products