QUALITY OF VMPS – UPDATE ON PICS

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Introduction

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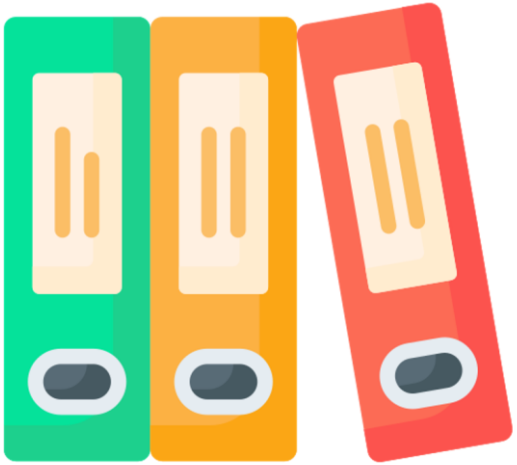
Ensuring the Quality of Veterinary Medicinal Products (VMPs) is an essential and **basic requirement for the good governance of VMPs.**

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 …

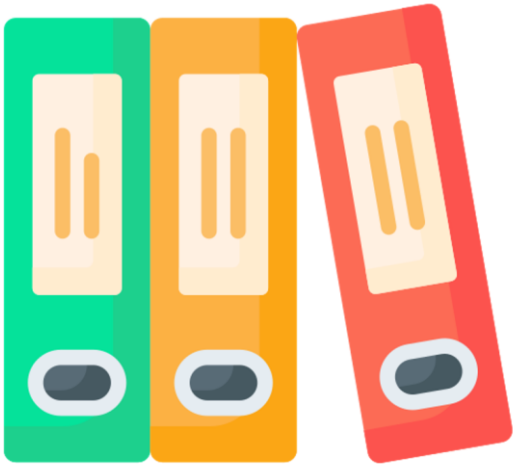
Part 3 : Safety and residues tests Part

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

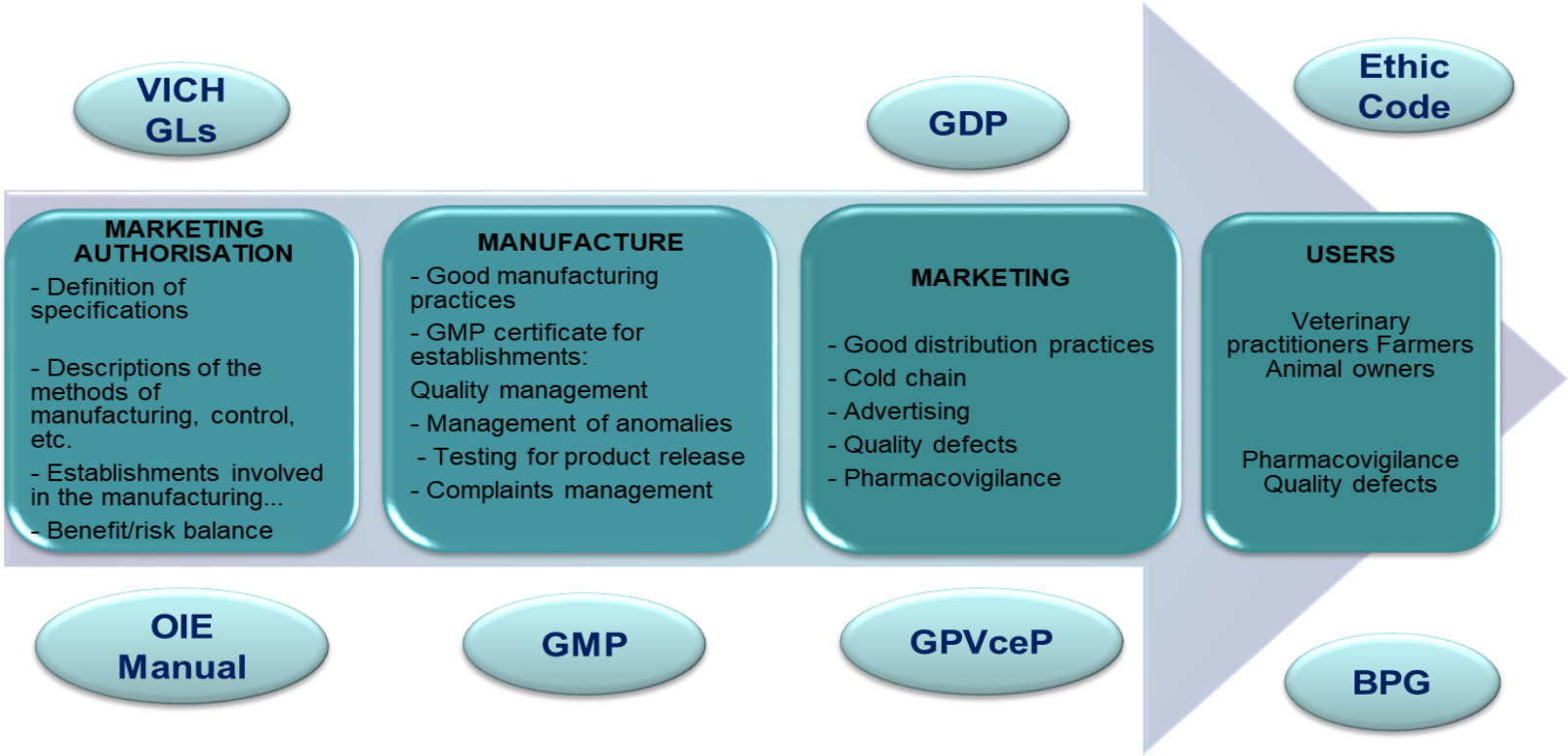
Preclinical and clinical trials…

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

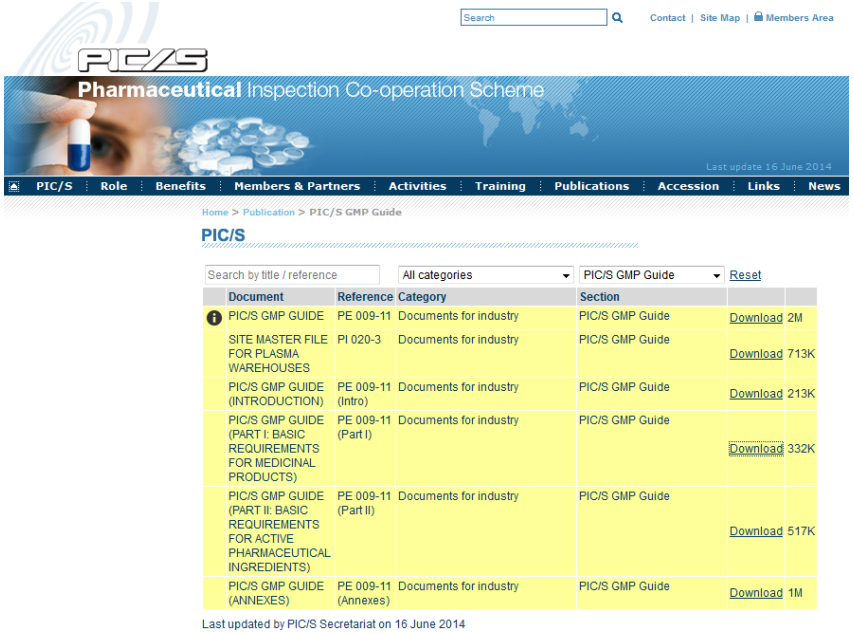
PHARMACEUTICAL INSPECTION
CO-OPERATION SCHEME

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."

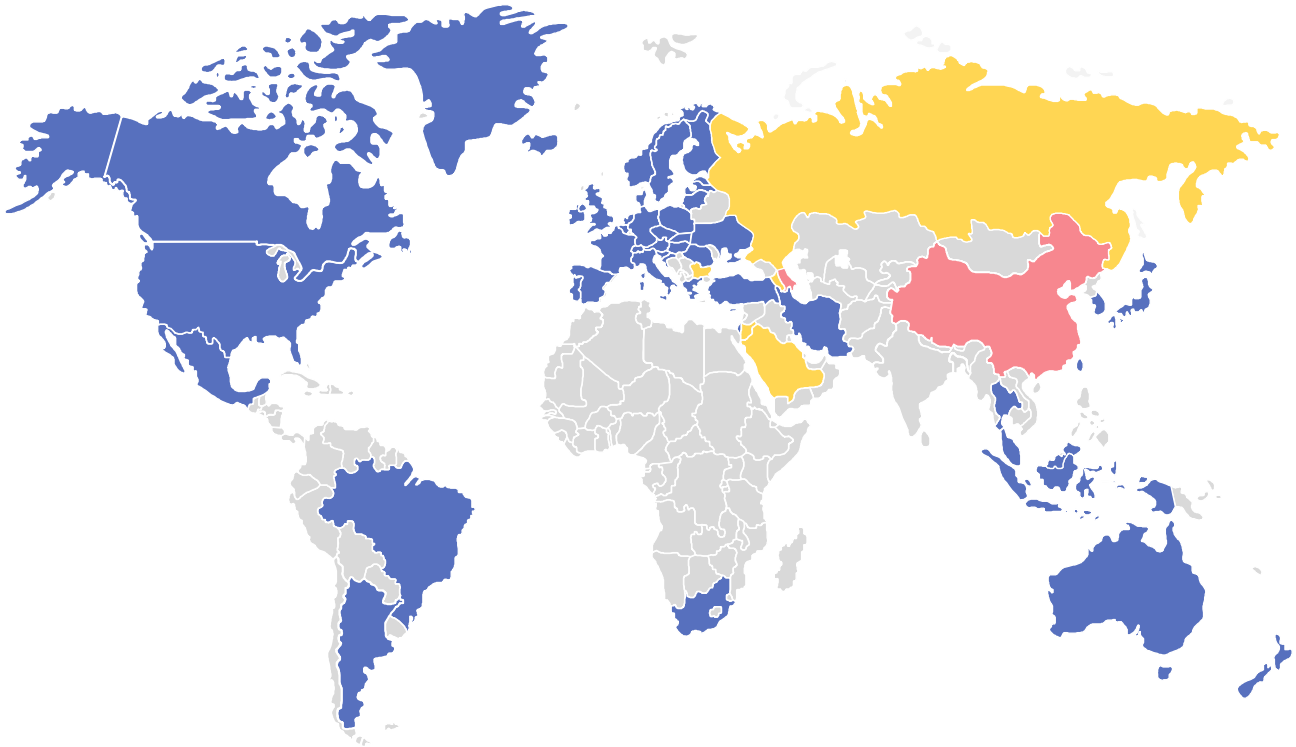
http://picscheme.org/



GOALS


PIC/S goals
Developing and promoting harmonised standards
Training of GMP and GDP inspectors
Facilitating the co-operation between authorities as well as with international organisations
Assessing GMP Inspectorates

PICS : Current members

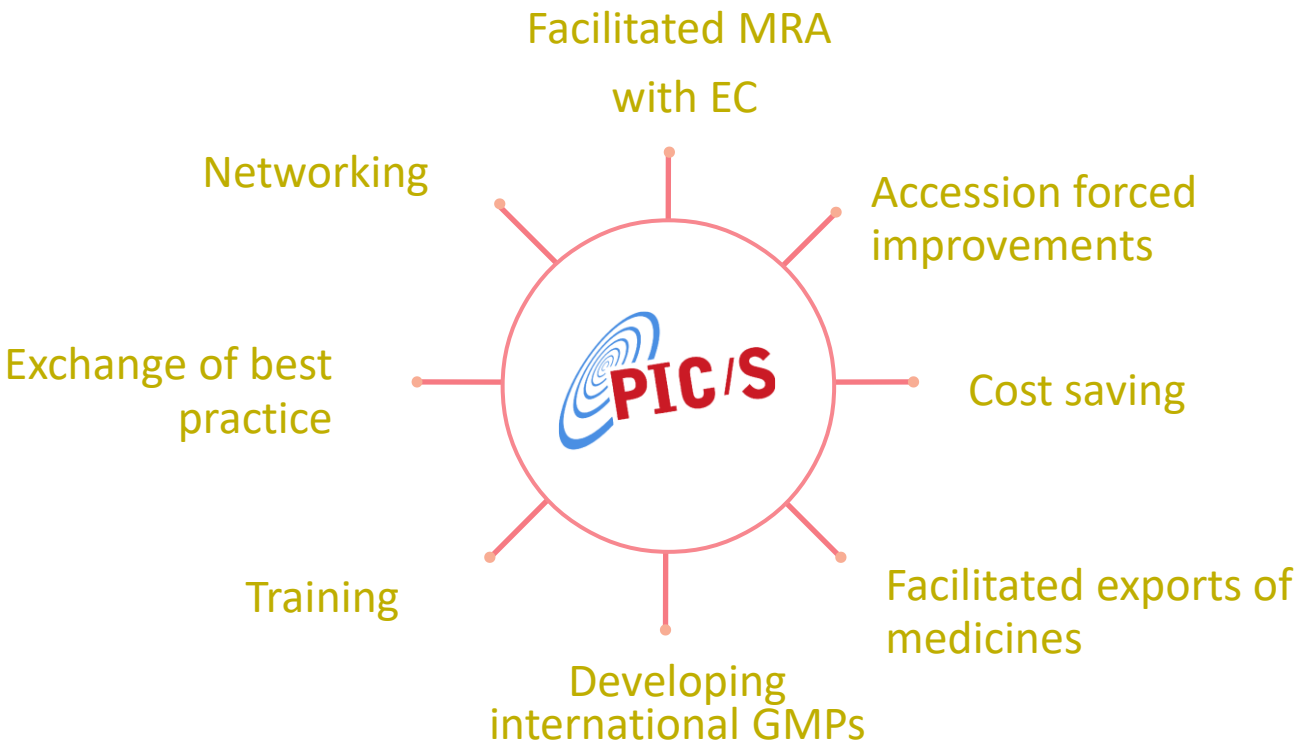


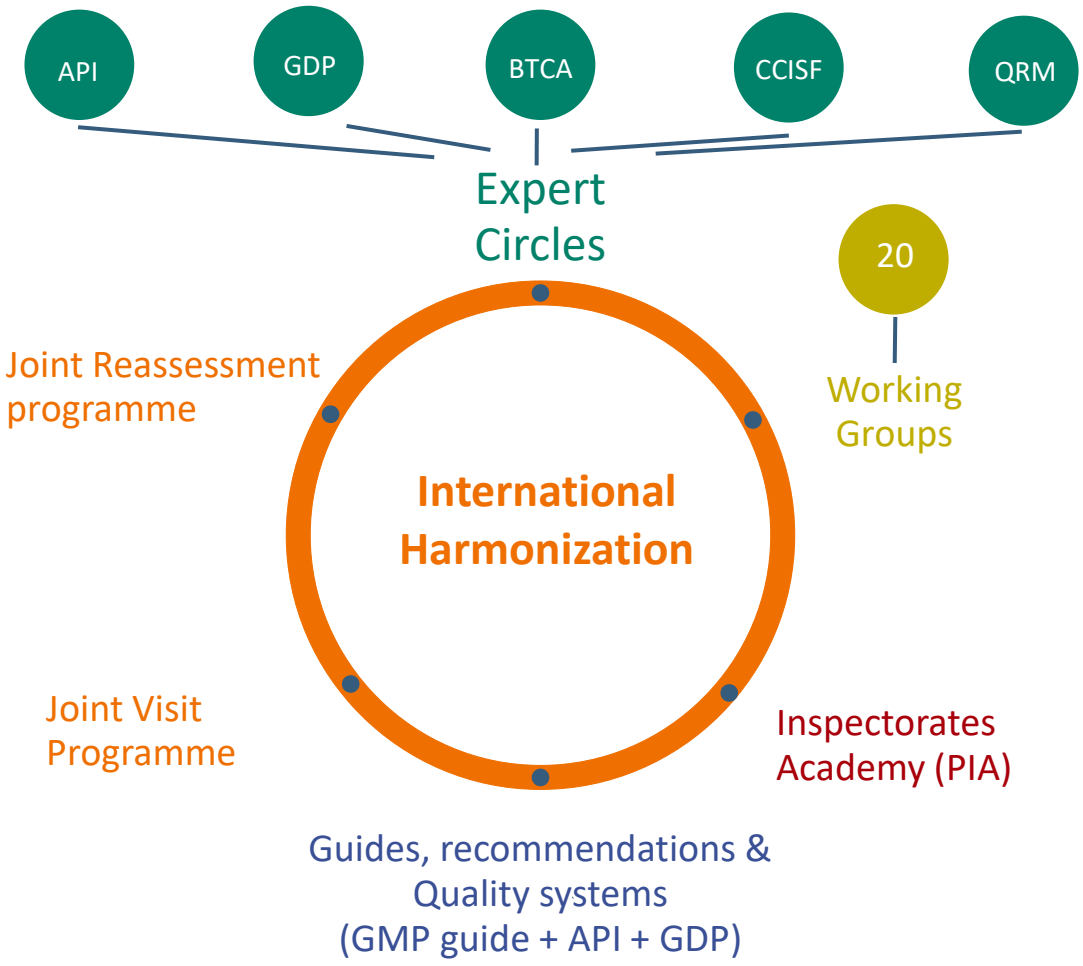
Member

Pre-applicant

Current applicants

Benefits of PICS members




API
GDP
BTCA
CCISF
QRM
Expert Circles
20
Working Groups
Joint Reassessment programme
International Harmonization
Joint Visit Programme
Inspectorates Academy (PIA)
Guides, recommendations & Quality systems (GMP guide + API + GDP)

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

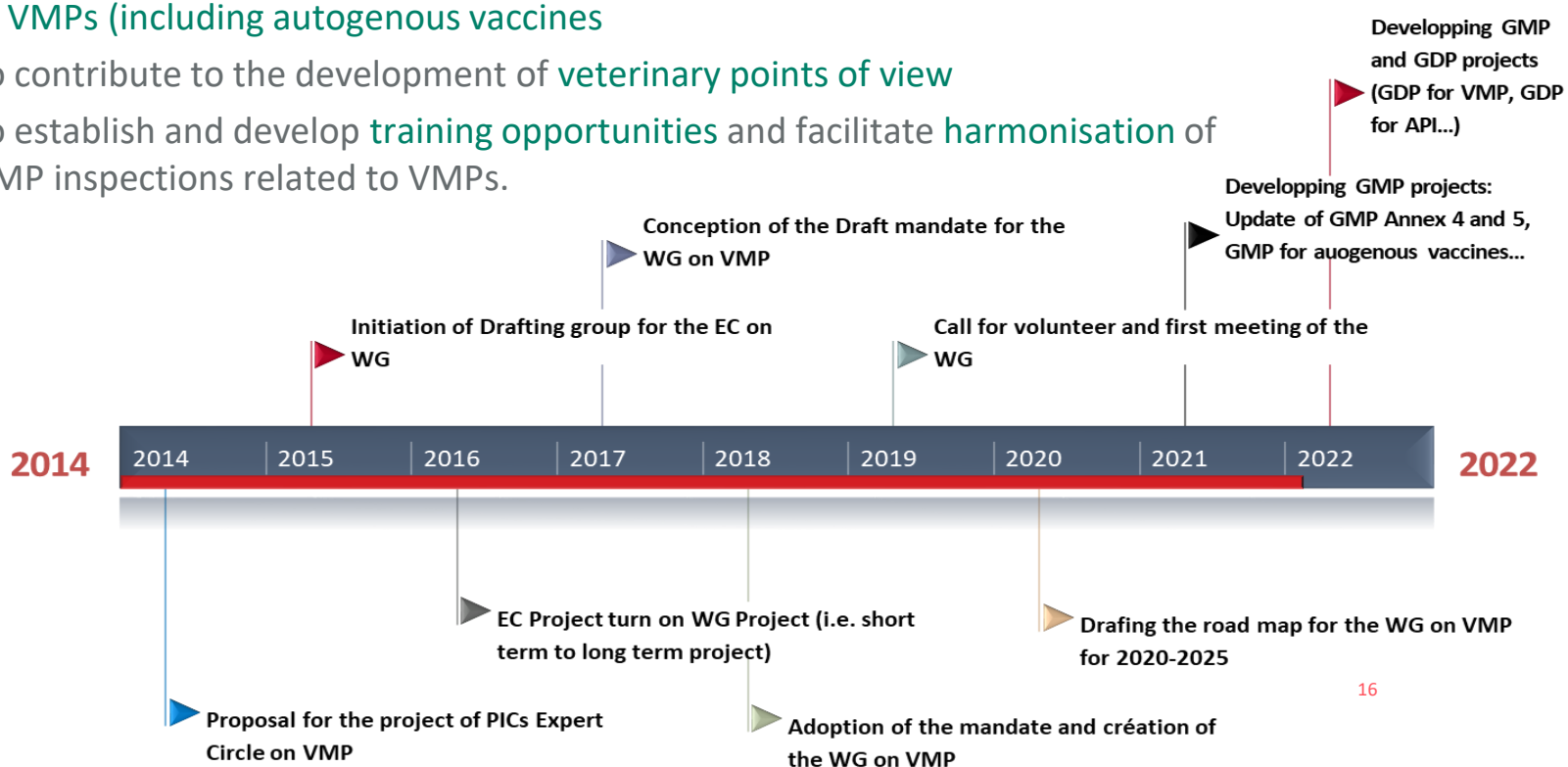
Working Groups

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

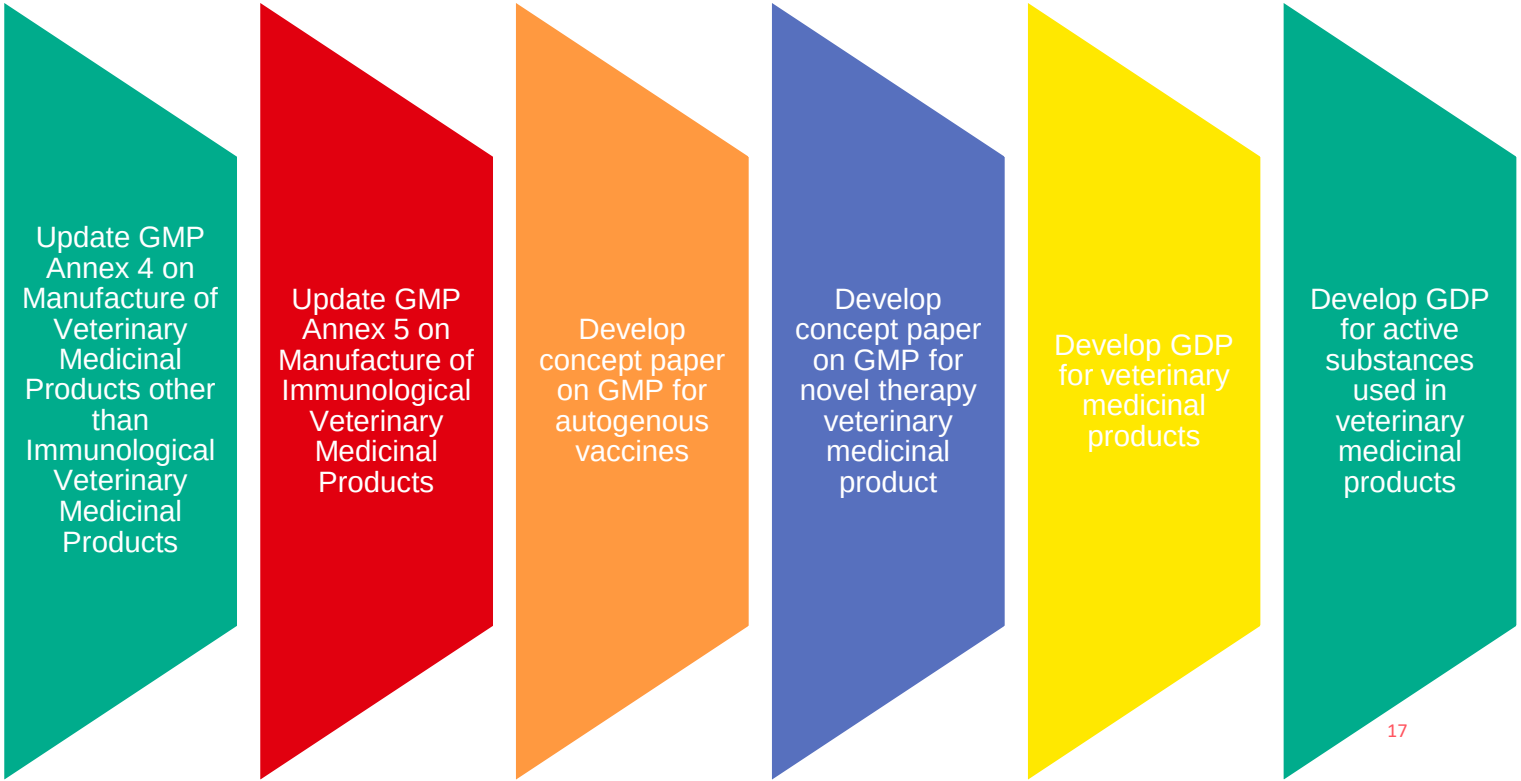
A new Working Group on VMP launched in 2018 :

- 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:



Quality System requirements

Aim:

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

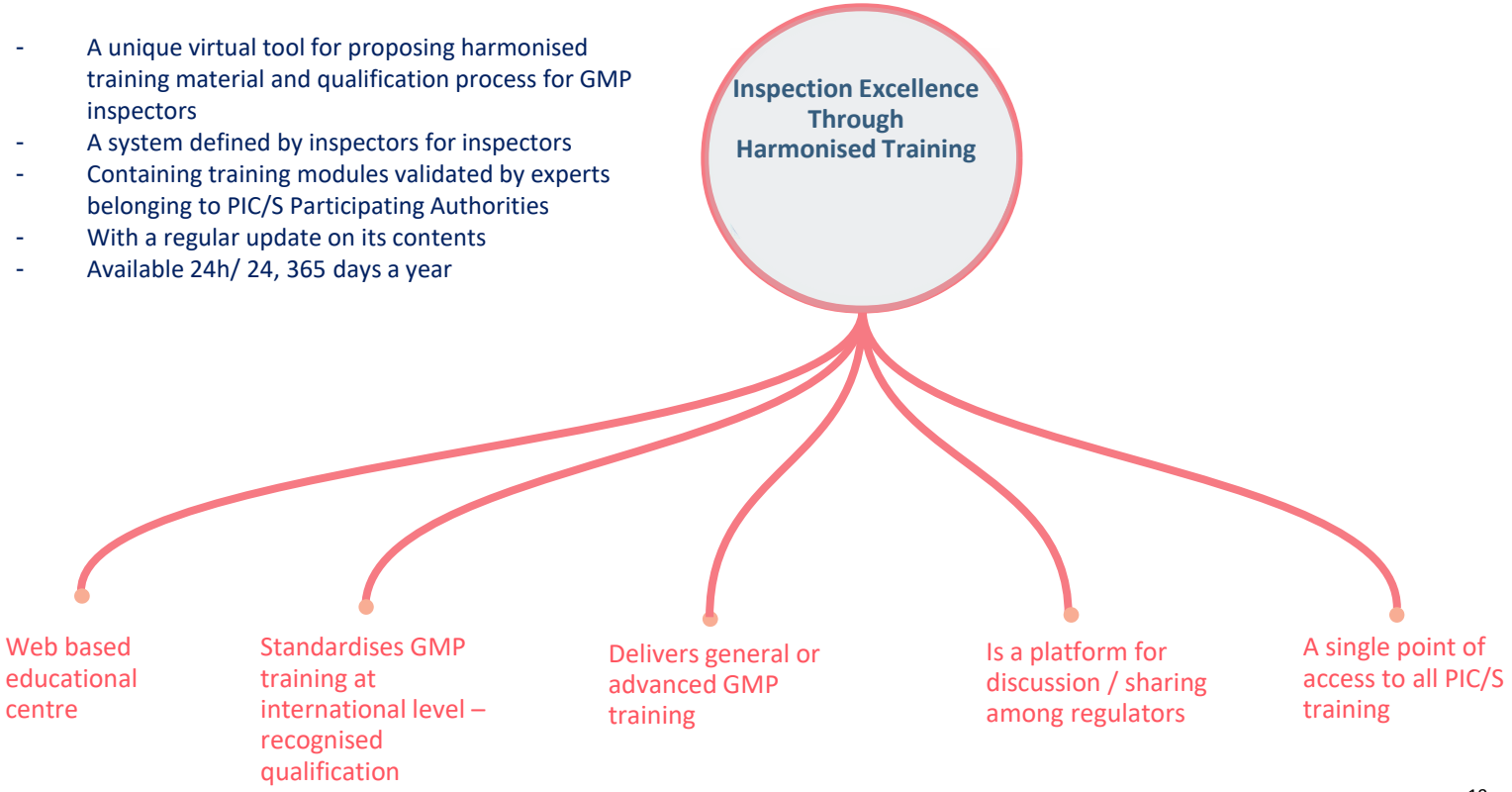
In return this facilitates mutual recognition of those Inspectorates.

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

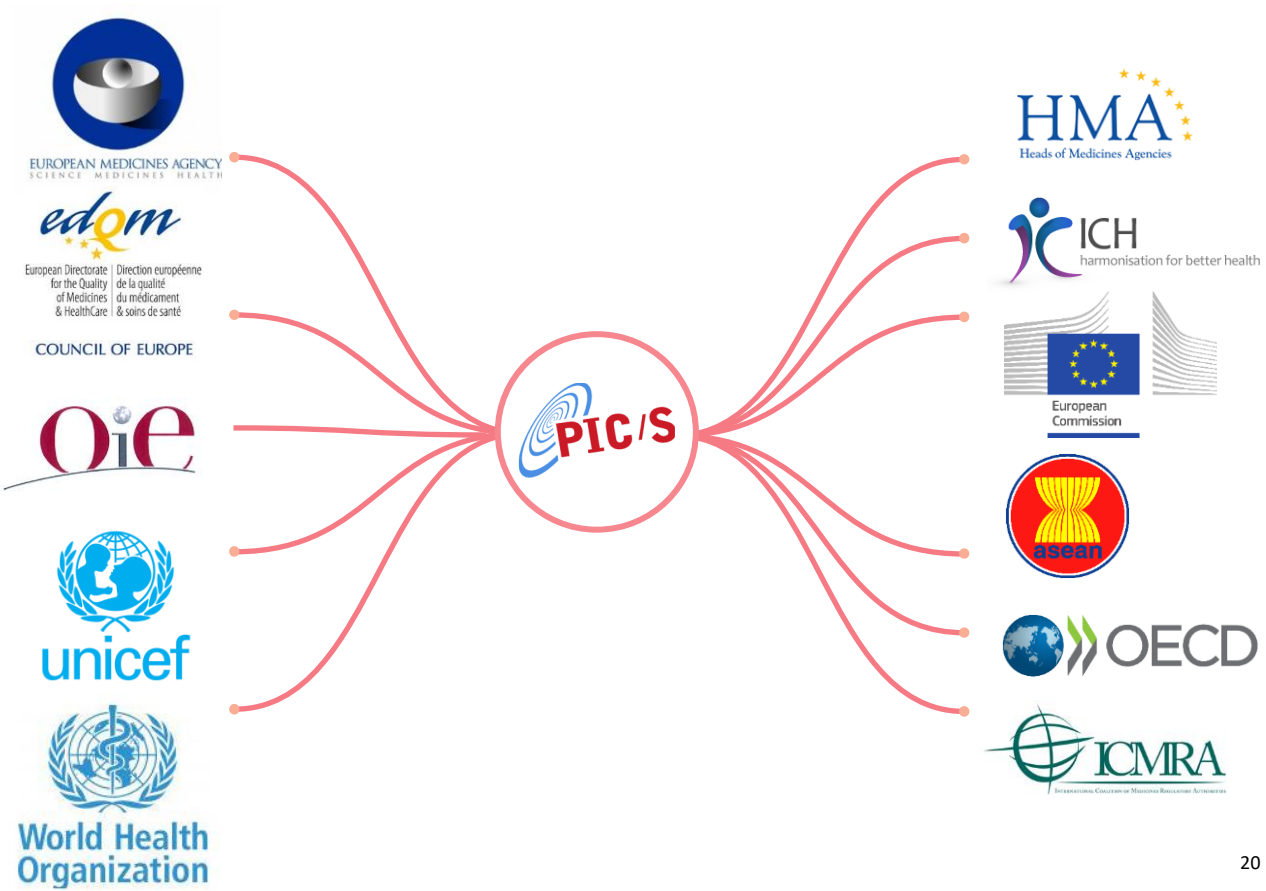
- Quality Manual
- Administrative Structure
- Organisation and Management
- Documentation and Change Control
- Records
- Inspection Procedures
- Inspection Resources
- Internal Audit

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



Partners


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé
COUNCIL OF EUROPE
OIE
unicef
World Health Organization
PIC/S
HMA
Heads of Medicines Agencies
ICH
harmonisation for better health
European Commission
asean
OECD
ICMRA

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Conclusion

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- ***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