

International Experiences in Implementing the PIC/S System

Recommendations for Vietnam:

A Dual-Path Strategy for DAV and
Industry

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The Dual-Path Imperative

DAV REGULATORY AUTHORITY

Mission: Demonstrate Inspection Capability

- Recruit 20+ GMP inspectors
- Develop PIC/S procedures
- Conduct EU/PIC/S inspections
- Achieve ASEAN LIS status
- Submit PIC/S application

IND MANUFACTURERS

Mission: Upgrade to EU/PIC/S Standards

- Implement Annex 1 compliance
- Invest in barrier technology
- Establish data integrity systems
- Provide facilities for DAV training
- Support DAV assessments

DAV cannot demonstrate capability without compliant facilities. Industry cannot access markets without PIC/S. Neither succeeds alone.

EU GMP Annex 1 Revision (Aug 2023)

First major revision since 2008. Mandatory for EU/PIC/S market access.

1. Contamination Control Strategy

DAV: Train to assess CCS | **IND:** Develop comprehensive CCS

2. Barrier Technology (e.g. RABS)

DAV: Understand requirements | **IND:** Invest \$500K-2M per line

3. Environmental Monitoring

DAV: Verify continuous monitoring | **IND:** Zero CFU tolerance

4. Quality Risk Management

DAV: Assess risk quality | **IND:** Cultural shift to proactive

5. Data Integrity (ALCOA+)

DAV: IT audit expertise | **IND:** Validated systems with trails

Critical Reality: **Vietnam** must leapfrog from WHO to EU Annex 1. No incremental path exists.

ASEAN LIS: Mandatory Gateway

Register of approved inspection authorities.

Current members: Singapore, Malaysia, Indonesia, Thailand and Philippines.

Three-Phase Sequential Pathway

Phase 1 (2025-27): Foundation.

Phase 2 (2027-29): ASEAN LIS.

Phase 3 (2029-30): PIC/S Member.

Key Enablers: Three Pillars

Pillar 1: Facility Readiness (Industry).

Pillar 2: Inspection Capability (DAV).

Pillar 3: Continuous Improvement.

Philippines Case Study

Timeline:

2013-2019 preparation,

2019 ASEAN LIS,

2023 PIC/S application.

Total: 13-14 years.

DAV & Industry Collaboration

DAV transformation roadmap.

Industry pilot facility program.

Coordinated training and support.

Critical Risks & Mitigation

Six key risks:

1. Inspector capacity,
2. Facility upgrades,
3. Funding,
4. Timeline,
5. Coordination,
6. Premature application.

Quantified Benefits & ROI

Investment:

\$5-10M over 5 years. (3-5 IND) – \$10-25M over 5 years. (5+ IND)

Returns: \$200M-400M+ annual exports by 2030+

ROI: 2000%+

Call to Action: Q1 2026

MOH/DAV: Establish steering committee, engage consultants.

VCCI: Form advisory committee, identify pilots.

References & Resources

Key documents: EU Annex 1, PIC/S Guide, ASEAN MRA. (Mutual Recognition Arrangement or Agreement)

Support experts: Bob Tribe, Dr. Revithi and Stuart Sutton.