INDUSTRY PERSPECTIVE – PHARMACOPOEIAL EVOLUTION

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Over 1,200 excipients in use
Can represent up to 95% of the formulation
Patients consume more excipients than active ingredients
Serve important functions in formulations
Harmonisation of individual monographs is Critical, but cannot occur without harmonization of general test chapters

Harmonisation has been proven to be slow and challenging

Harmonisation is politically difficult

Pharmacopoeial Harmonisation has been limited to PDG & original ICH countries

PDG expansion is not an option

ICH does not want to reopen ICH Q4B
RISKS???

- Is there a true risk to patients (quality & safety) from EU or Japan visiting the USA, and then taking a medicine that was tested only to the USP requirement (or vice-versa)?

- Is there a risk on that basis alone?

BENEFITS OF A NEW APPROACH

- Provides industry, regulators and patients with a single standard
- Coordination of resources (regulators/pharmacopoeias/industry)
- Clarity and consistency in quality testing
- Supports global filings and inspections
- Supports the complex supply chain
- Facilitates the procurement process
No single government regulator can support innovation and regulate products developed in facilities worldwide.

There are approximately 300,000 facilities worldwide in over 150 countries.

Fragmented standards and regulations make it easier for less scrupulous healthcare product participants to gain entry to markets.

Uniform quality standards across global markets can mitigate this.

**FUNCTIONAL EQUIVALENCE**

**What is it?**  
- Performs the same function and provides the same utility.

**How is it used?**  
- Allows recognition of standards where they are focused on public health, safety, quality.

**Opportunities**  
- All compendia are focused on public health and safety.
EVOLUTION OF REGULATORY SYSTEMS

QUALITY RISK MANAGEMENT (ICHQ Q9)

MUTUAL RECOGNITION AGREEMENTS

ICH EXPANSION

PIC/S EXPANSION

ICMRA (INTERNATIONAL COALITION OF MEDICINES REGULATORY AUTHORITIES)

IPRP (INTERNATIONAL PHARMACEUTICAL REGULATORS PROGRAMME)

PIC/S (PHARMACEUTICAL INSPECTORATE COOPERATION SCHEME)

Harmonisation of GMP/GDP is fundamental to PIC/s

Pharmacopoeial compliance/ testing is fundamental to GMP

Common standards are necessary to accept inspection results
Industry supports / encourages establishing a process for engagement with the global pharmacopoeias to continue collaboration and discussions.

Addition of Functional Equivalence of Pharmacopoeias into the strategic framework.