INDUSTRY PERSPECTIVE – PHARMACOPOEIAL EVOLUTION

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IPEC FEDERATION

- 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

COUNCIL OF FOREIGN RELATIONS REPORT

- No single government regulator can support innovation and regulate products developed in facilities are the world
- 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 — Increases trust

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

WHAT'S NEXT?

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