the future of excipients is in our hands

IPEC EUROPE

PHARMACOPOEIAL REVIEW & HARMONISATION
A STRATEGY FOR MULTICOMPENDIAL COMPLIANCE
SO WHAT?

Why action is necessary?

- Excipients makers & users continue to be CHALLENGED BY NON VALUE-ADDED TESTING to ensure regulatory compliance.
- Pharmacopoeial harmonisation has not achieved its goals as even more compendia publish DIVERGENT MONOGRAPHS.

Where are we now?

- Companies have INTERNAL PROCEDURES TO CROSS-VALIDATE PHARMACOPOEIAL STANDARDS which some pharmacopoeias have accepted but there is NO STANDARDISED INDUSTRY APPROACH.

What do we need?

- Our industry NEEDS A BEST PRACTICE which enables companies to align their internal procedures achieving compliance with multiple compendia.
- Such an approach will NEED TO BE ACCEPTED BY REGULATORY AUTHORITIES.

How do we get there?

- Understand the regulatory framework to DEVELOP A STATEMENT OF INTENT for a best practice
- CREATE A TASK FORCE to deliver a best practice, composed of members who are:
  - Knowledgeable of method development and validation;
  - Experienced in compendial matters;
  - Have a breadth of understanding of analytical techniques.

What's in it for you?

- The opportunity to DESIGN AN INDUSTRY STANDARD.
- EXCHANGING AND BENCHMARKING on industry approaches with KEY STAKEHOLDERS.
- ENGAGING WITH COMPENDIA AND IPEC SISTER ASSOCIATIONS to align with our proposal.

What's expected of you?

- Two face-to-face meetings.
- Teleconferences as needed.

What's the proposed timeline?

- Launch the TASK FORCE IN OCTOBER 2019.
- BEST PRACTICE deliverable date in MARCH 2021.

Interested?

- Contact the IE Secretariat (info@ipec-europe.org) **by 31 August**.

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