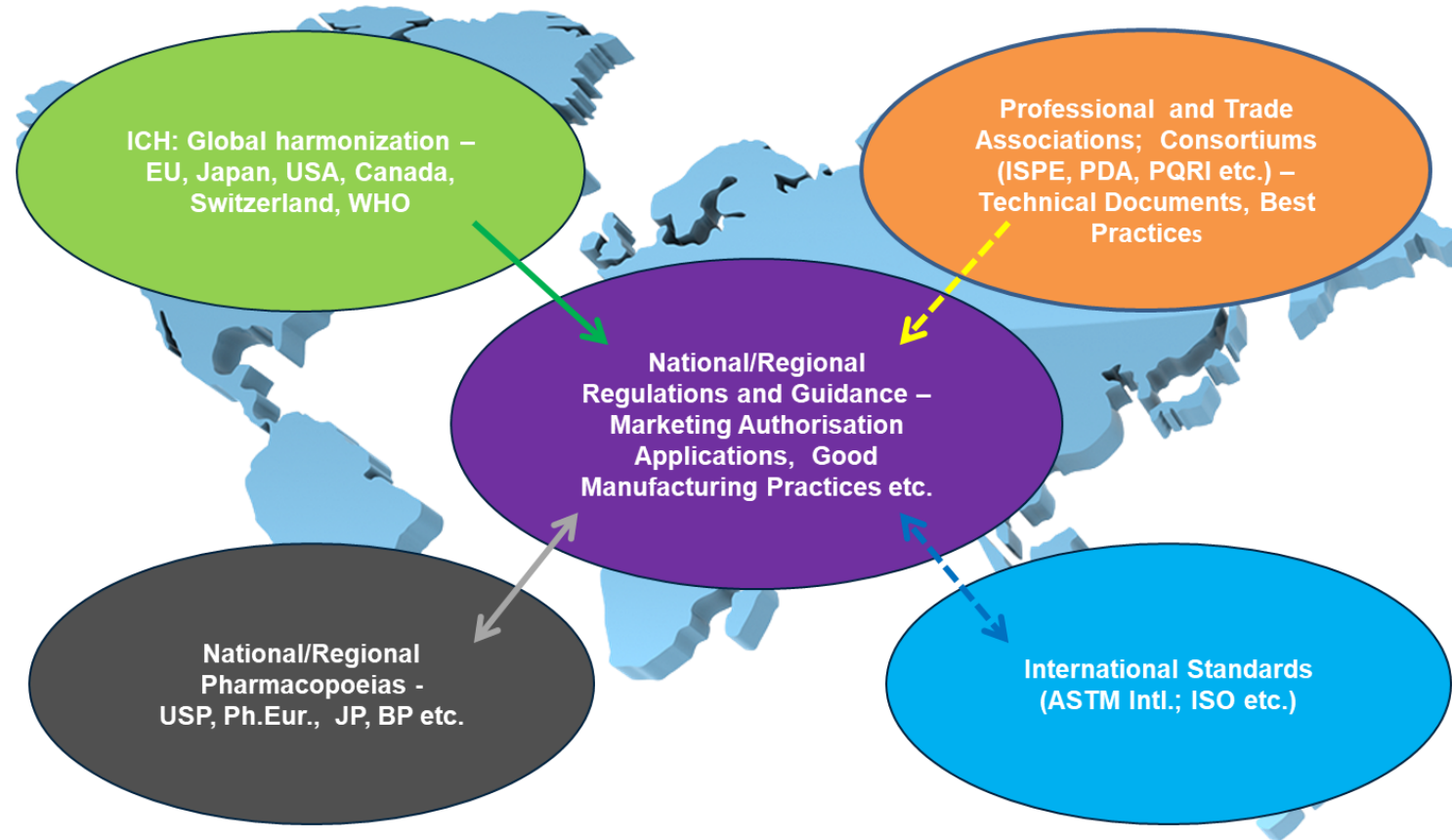


Regulatory Affairs Discussion

- Regulatory guidelines and consensus standard status
 - FDA & EMA & other national/regional regulatory bodies
 - ICH, USP
 - ASTM
 - NIIMBL, ISPE
- Ways of interacting with health authorities
 - ETP VS AMT?
 - QIG in Europe
- End user use cases/success stories?

Regulatory and consensus standard – Complex Ecosphere Which Needs to be Understood



ICH 'Q' guidelines

- Q means they only cover product quality and things that impact product quality
- The primary ICH guidelines that address or mention PAT are as follows:
 - **ICH Q8 (R2) - Pharmaceutical Development.**
 - **ICH Q9 - Quality Risk Management.**
 - **ICH Q10 - Pharmaceutical Quality System.**
 - **ICH Q11 - Development and Manufacture of Drug Substances.**
 - **ICH Q12 - Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management.**
 - **ICH Q7 - Good Manufacturing Practice (GMP) for Active Pharmaceutical Ingredients (APIs)**
 - **Plus others....**

Other Relevant Guidelines

- **FDA Guidance for Industry: PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance (2004)**
- **USP General Chapter <1037> - Pharmaceutical Applications of Process Analytical Technology**
 - Published in *USP's Pharmacopeial Forum* on May 1, 2025, for public comments.
 - Objective is to establish a comprehensive guide that aligns with current scientific and regulatory standards
 - Provide clear direction for the implementation of Process Analytical Technology (PAT) within pharmaceutical companies.
 - Comprehensive guidance on PAT, ensuring the continued advancement and quality of pharmaceutical manufacturing.

Not all USP chapters are 'equal'

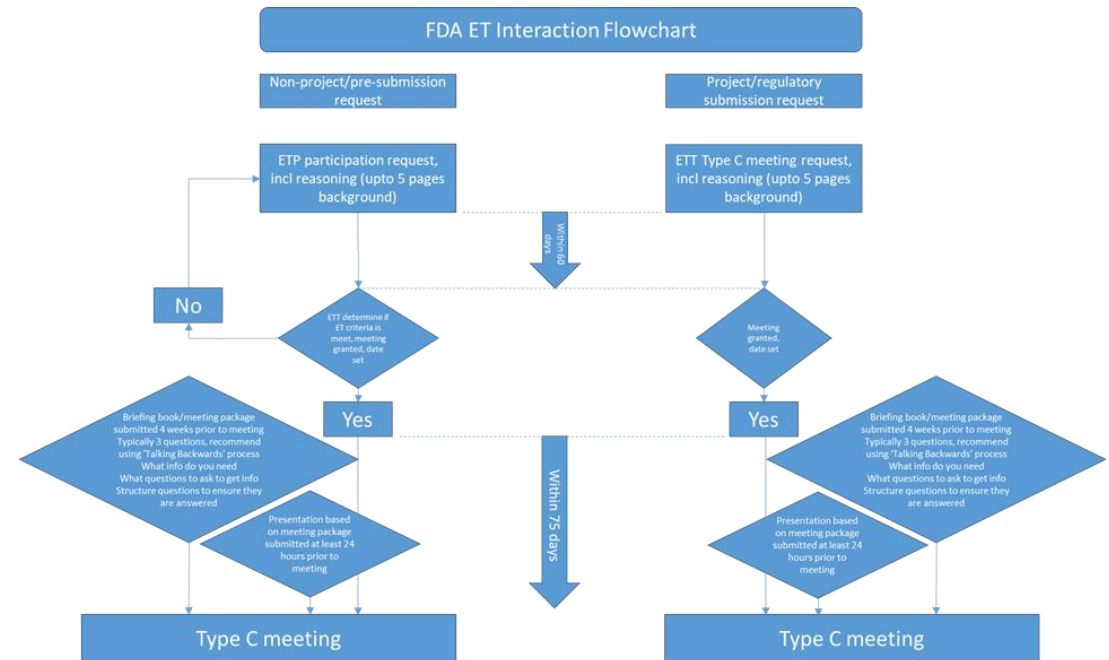
For example, USP chapters covering 'Raman'

- USP Chapter

- | | | |
|----------|-------------------------------------|------------------------|
| • <857> | Raman spectroscopy | Primary |
| • <1857> | Theory/practice of Raman | Informational |
| • <197> | ID tests, Raman allowed | Mandatory when applied |
| • <1118> | PAT monitoring, Raman referenced | Contextual |
| • <1207> | Packaging integrity, Raman possible | Contextual |

Interacting with health authorities

- Scientific Advice request?
 - Steps involved
- Participation request?
- But what about the rest of the world? QIG in EU, PMDA in Japan, etc etc



End user use cases/success stories?

