



# IPEC Federation

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# IPEC\* Federation

- ▶ Represents: excipient suppliers, distributors & pharmaceutical manufacturers
- ▶ Develop, implement, and promote voluntary guidance for excipients
- ▶ Encourage adoption of scientifically appropriate regulatory and compendial standards
- ▶ Assist, educate, and cooperate to advance public health

*\*IPEC: International Pharmaceutical Excipient Council*



# IPEC Federation

- ▶ Recognizes that the drug market is global, including excipient sourcing
- ▶ Monitors regulatory developments from multiple perspectives and geographies
- ▶ Represents an industry speaking as ‘one voice’ for common global issues
- ▶ Builds on IPEC’s unique set up: users, producers and distributors of excipients sharing the same quality and safety vision to benefit patients

# IPEC Federation

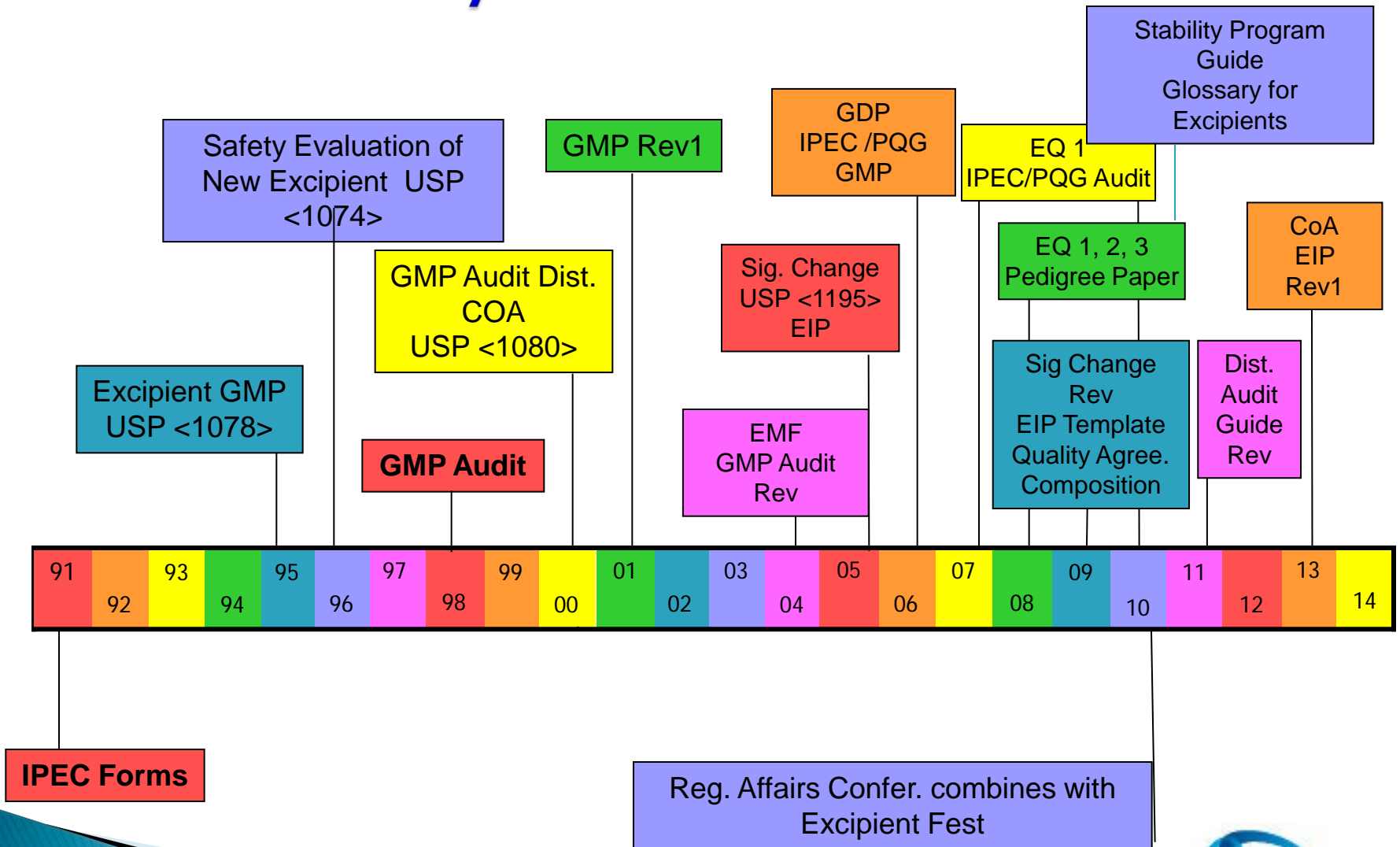
- ▶ Established 2009 from TriPEC
  - Not for Profit, based in Belgium
- ▶ Formalize interactions
- ▶ Provide a mechanism for developing consensus based positions across regions
- ▶ Set priorities for issues that interest/affect globally
- ▶ Full Members
  - IPEC–Americas, IPEC Europe, IPEC Japan + IPEC China (2008)
- ▶ Associate Members
  - Brazil (*Partnership with SindusFarma*)
  - IPEC India (*Forming*)

# IPEC Federation Key Objectives

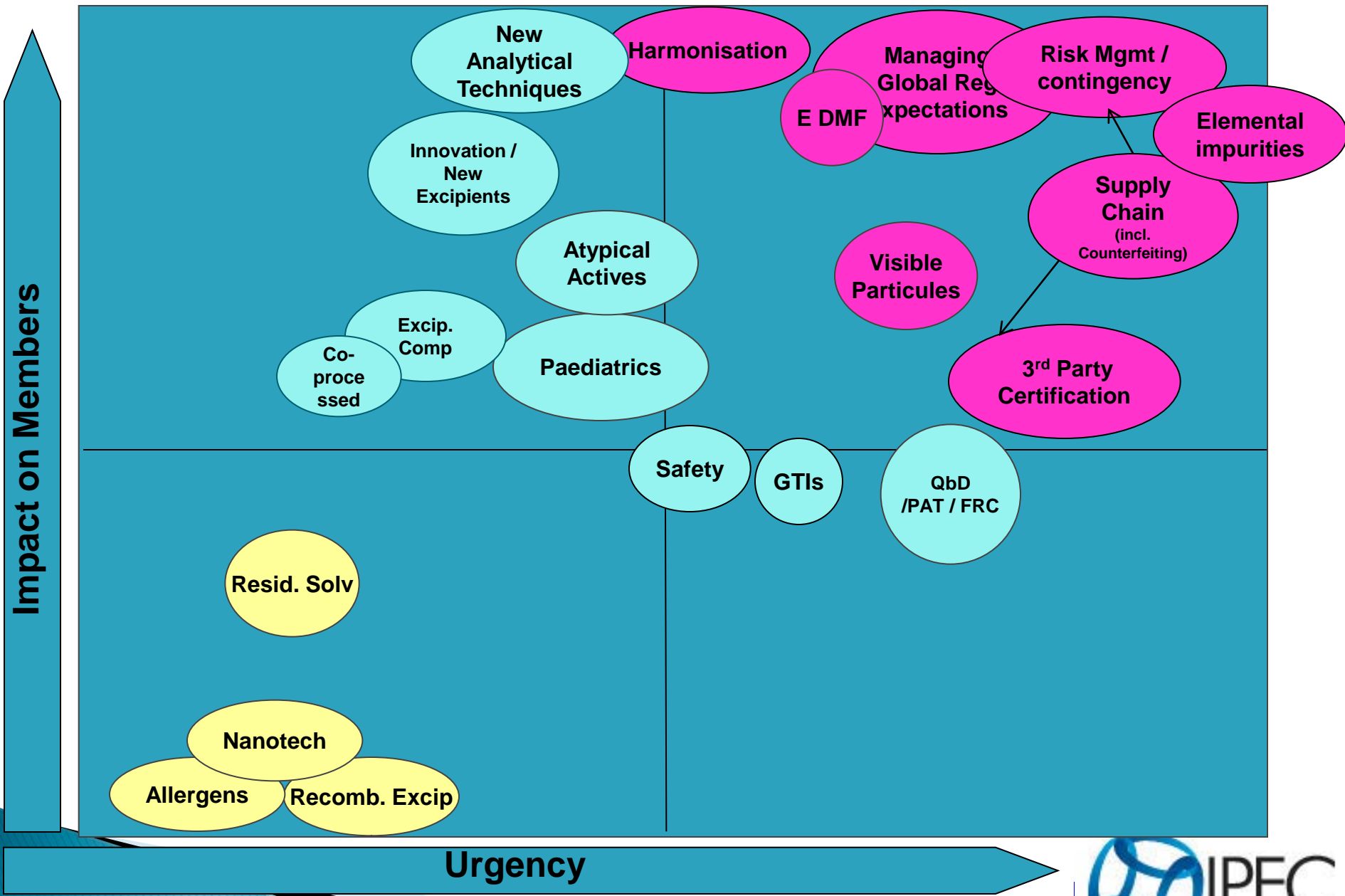
- ▶ Managing global regulatory expectations
  - Identify emerging regulations impacting excipients
  - Establish position papers on any relevant advocacy activity
- ▶ Harmonization of standards
  - Work with PDG\* to continue the harmonization process of pharmacopoeial monographs
  - Develop harmonized voluntary industry guidance for global use
- ▶ Promoting supply chain security
  - Excipient risk management
  - Third party GMP certification

\* PDG is made of EP (European Pharmacopoeia), JP (Japanese Pharmacopoeia), USP (United States pharmacopoeia)

# IPEC History & Guidance Documents



# IPEC Federation Priorities



# Resources

- ▶ IPEC

- [www.ipecamericas.org](http://www.ipecamericas.org)

- ▶ Download IPEC Guidance documents

- Available for free (do need to register)

- <http://www.ipecamericas.org/public/registrationform2.php?94,30>