



ISPE®

Italy
Affiliate

Community of Practice

**Engineering changes
approaching the new draft
ANNEX 1 2020**

Kick Off - Presentation

03.09.2020

Main Purpose of the ISPE CoP:

Following the ISPE statements: “Connecting, Pharmaceutical, Knowledge”, the purpose of the CoP is to help the attendees in discovering and deepen contents of “new draft ANNEX 1 2020”.

Share Engineering Solutions and Case Studies to comply with new requirements.

Use the CoP for clarification of doubts and define common strategies to approach the most critical aspects coming from the new regulation.

Workstreams:

- 1. Differences between ANNEX 1 in force and NEW draft 2020 - identification of most critical changes**
- 2. Gap Assessment Approaches**
- 3. Case Studies: Engineering Solutions**

Frequency and Final Conference/Event on 2021:

**1. CoP meeting every two Months in Milan Area and Skype/Teams starting
from 2nd Oct 2020**

- BEFORE THIS 1ST MEETING WORKSTREAM CHOICE WOULD BE REQUESTED -

**2. Daily Conference / Event in Milan Area to be scheduled – tentatively 1st
or 2nd Quarter 2021**

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