Dear Reader,

Regarding to the Draft - guidelines on the principle of good distribution practices for actives substances for medicinal products for human use -

Please find below my current questions and comments :

- Is there specific requirements for storage and distribution area ?
    - Microbiological testing at a frequency
    - Thermal & moisture mapping and validation
    - Continuous temperature and moisture monitoring

- As for manufacturing activities, distribution must be annually monitored (annual distribution review)?
  In order to produce supporting data of this process, to proof efficiency and improvement, can it be suitable to harmonize this good practice ?

- Paragraph 38 : “Only appropriately trained and authorised personnel should release active substances to be returned to stock.”
    - Is the authorised person a Qualified Person or can be a person with enough experience and appropriate training ?

Kind regards,

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