Dear Madam or Sir,

please find attached to this email the comments from Fresenius Kabi on the draft "Guidelines on the principles of GDP for active substances for medicinal products for human use".

The PDF has comments and changes.
Below we give our the rationals:

- Scope, 2: Clarification: The Scope section mentions that re-labelling is considered as part of manufacturing activities and thus falls outside the scope of these guidelines. In which case, we feel more clarification is required, for distributors, on what labelling can be applied as part of distribution activities and that any labelling they add must not cover, deface or remove any manufacturing ID and status labelling to ensure full label traceability is maintained.
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- Sect. 6. Clarification: Once the management representative has been appointed, this authority and responsibility should not be delegated.
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- Sect. 11. Clarification: The person responsible for the quality should approve the different operation procedures which may affect the quality of the active substances or of the distribution activity.
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- Sect. 12. Additional requirement: Life cycle plus five years minimum retention time for records, to be in line with current best practice.
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- Sect. 18. Change in requirement: Separation of API:s from other goods not a minimum requirement as long as the storage requirements in Part II of EU-GMP are fulfilled.
- Records should be reviewed by the person responsible for the quality (see sect 11 above)
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- Sect. 22. Change in requirement: Separated area not a requirement, if the separation can be made clear by other means (e.g. an administrative system), see storage requirements in Part II of EU-GMP
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- Sect. 23. The sentence/section is unclear, clarification needed.
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Kind regards,

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