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Investigation.-Examine the new FDA "attitude" that is being taken with non-sterile product.-Identify the OOT and OOS regulatory concerns in a cGMP environment.

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Microbiology laboratories should be separated from production areas and have an air handling system separated from the production areas. Microbiology laboratories should be

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designed and have sufficient space to suit the operations carried out in them and to avoid mix ups, contamination and cross contamination. If necessary,

## ~~Guidance for Industry: Microbiology Laboratories (Version 1.0)~~

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-Examine the new FDA "attitude" that is being taken with non-sterile product. -Identify the OOT and OOS regulatory concerns in a cGMP environment. -Review the microbiological issues that may occur within Incoming Raw Materials, In-Process and API phases.

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