aqpa
Austrian Qualified Person Association

EU-GMP-Guide
Chapter 6: Quality Control

Revision published: 28 March 2014
Coming into operation: 1 October 2014

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- Sections „Principle“ and „General“: no changes
- Section „Good Quality Control Laboratory Practice“
  - 6.5: New text added: „Laboratory **equipment** should **not be routinely moved** between high risk areas to **avoid cross-contamination**. In particular, the **microbiological laboratory** should be arranged so as to **minimize risk of cross-contamination**.“

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- Section „Documentation“
  - 6.7: New requirement for laboratory documentation: „iv. A **procedure** for the **investigation** of **Out of Specification** and **Out Of Trend** results.“
  - 6.9: New requirement for trending: „Should“ instead of „Recommended“ (old version). „Any **out of trend or out of specification** data should be addressed and **subject to investigation**.“

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- Section „Sampling“
  - 6.12: New text added: „The **sampling plan** used should be appropriately **justified** and based on a **risk management approach**.“
  - 6.13: New text added: „They (**sample containers**) should be **managed** in a manner to **minimize the risk of mix-up** and to **protect the samples** from adverse **storage** conditions.“

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- Section „Testing“
  - 6.15: New text added: „A laboratory that is using a testing method and which did **not perform** the **original validation**, should **verify the appropriateness of the testing method**.“
  - 6.16: New text added: „Results of parameters identified as **quality attribute** or as **critical** should be **trended.**“
  - 6.17: New requirement for test records: „ix. Reference to the **equipment** used.“
  - 6.19: New text added: „The **level of controls** (quality of reagents, solutions, glassware, reference standards, culture media) should be **commensurate to their use** and to the available **stability data**.“

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- Section „Testing“ cont‘d
  - 6.20: New paragraph: „**Reference standards** should be established as **suitable for their intended use**. Their **qualification and certification** as such should be **clearly stated and documented**. Whenever **compendial reference standards** from an officially recognised source exist, these **should preferably be used as primary reference standards** unless fully justified (the use of **secondary standards** is permitted once **their traceability to primary standards has been demonstrated and is documented**). These compendial materials should be used for the purpose described in the appropriate monograph unless otherwise authorised by the National Competent Authority.“

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- Section „Testing“ cont‘d
  - 6.21: New requirement: **Solutions, reference standards and culture media** (old version: „laboratory reagents“) also marked with **preparation** and **opening date** and **signature**. **Expiry date for all reagents and culture media** (old version: „unstable reagents and culture media“)
  - 6.23: new paragraph: „**Culture media** should be prepared in accordance with the media **manufacturer‘s requirements** unless scientifically justified. The **performance of all culture media** should be **verified prior to use**.“
  - 6.24: new paragraph: „Used microbiological media and strains should be **decontaminated** according to a **standard procedure** and disposed of in a manner to **prevent cross-contamination** and **retention of residues**. The in-use **shelf life** of microbiological media should be **established , documented and scientifically justified**.“

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- Section „On-going stability programme“

  No changes

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- New Section added „Technical transfer of testing methods“
  - 6.37: New paragraph: „Prior to transfer … transferring site should **verify** that the … method(s) **comply with** … **MA** … . Original **validation** … should be **reviewed** to ensure compliance with **current ICH** … . A **gap analysis** should be performed and documented to identify any **supplementary validation** … **prior** to commencing the technical transfer process.“
  - 6.38: New paragraph: „The **transfer** … from one laboratory … to another … should be described in a detailed **protocol**.“

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- New Section added „Technical transfer of testing methods“ cont‘d
  - 6.39: New paragraph: „The **transfer protocol** should include, but not be limited to, …:
    - Identification of the **testing** … and the relevant **test method(s**)
    - Identification of the additional **training** requirements
    - Identification of **standards and samples** to be tested
    - Identfication of any special **transport** and **storage conditions** of test items
    - **Acceptance criteria** … based upon **current validation** study … and with respect to **ICH** …“
  - 6.40: New paragraph: „**Deviations** from the protocol … **investigated prior to closure** of the technical transfer process. … **report** should document the **comparative outcome** … and … identify areas requiring further test method **revalidation, if applicable**.“
  - 6.41: New paragraph: „Where appropriate, **specific requirements** described in **other** European Guidelines, should be addressed for the transfer of particular testing methods (e.g. Near Infrared Spectroscopy)“