EU-GMP-Richtlinie – Kapitel 6 «Quality Control»
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Kapitel 6 – Quality Control
Übersicht

- Termin zur Stellungnahme: **18. Juli 2013**
- Bisher: 5 Seiten, 3 Abschnitte und 4 Unterabschnitte (in Kraft seit 1. Juni 2006)
- Entwurf: 6 Seiten, 3 Abschnitte und 5 Unterabschnitte
- **Grund der Änderung**
  Inclusion of a new section on **Technical transfer of testing methods** and **other items** such as **out of specification** results.
- **Betroffene Abschnitte**
  - Keine Änderungen in den Abschnitten “Principle” und “General”
  - Nur Änderungen im Abschnitt “Good Quality Control Laboratory Practice”
    - Insbesondere im Unterabschnitt “**Testing**”
    - Neuer Unterabschnitt “**Technical transfer of testing methods**”

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Änderungen bei Good Quality Control Practice

- **Good Quality Control Laboratory Practice**
  - 6.5 In particular, the **microbiological** laboratory should be arranged so as to minimize risk of **cross-contamination**. Laboratory equipment should not be routinely moved between high risk areas to avoid accidental cross-contamination.
- **Documentation**
  - 6.7 Procedure for the investigation of **Out of Specification** and anomalous results
  - 6.7 Procedure for **qualification** of instruments
  - 6.9 Any **out of trend** or **out of specification** data should be addressed and subject to **investigation**

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Änderungen bei Good Quality Control Practice

- **Sampling**
  - 6.12 **Samples** should be representative of the batch of materials or products from which they are taken. Other samples may also be taken to monitor the most stressed part of a process (e.g. beginning or end of a process). The sampling plan used should be appropriately justified.
  - 6.13 They should be managed in a manner to **minimize the risk of mix-up** and to protect the samples from adverse storage conditions.
- **On-going stability programme**
  - Keine Änderungen

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Änderungen bei Testing

- 6.15 A laboratory that is using a **testing method** and which did not perform the original validation (e.g. the use of a compendial method), should **verify the appropriateness** of the testing method.
- 6.20 **Reference standards** should be certified, qualified and verified as suitable for its intended use.
- 6.21 **Culture media** should be prepared in accordance with the manufacturer's requirements unless scientifically justified. The performance of all culture media should be verified prior to use
- 6.22 The **expiry date** of unstable reagents and culture media should be indicated on the label, together with specific storage conditions. In addition, for volumetric solutions, the last **date of standardisation** and the last current factor should be indicated.
- 6.25 **Microbiological media** and strains should be decontaminated and disposed of in a manner to prevent the cross-contamination and retention of residues. The in-use shelf life of microbiological media should be established, ~~and~~ documented and scientifically justified.

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Neu – Technical transfer of testing methods

- 6.37 Prior to transferring a test method, the transferring site should verify that the test method(s) comply with those as described in the **Marketing Authorisation** or the relevant technical dossier. The original **validation** of the test method(s) should be **reviewed** to ensure compliance with current ICH/VICH requirements. A gap analysis should be performed and documented to identify any supplementary validation that should be performed, prior to commencing the technical transfer process.

- 6.38 The transfer of test methodology from one laboratory (transferring laboratory) to another laboratory (receiving laboratory) should be described in a **written protocol**.

- 6.39 The **protocol** should include, but not be limited to, the following parameters: Test method(s), training requirements, standards and samples, special transport and storage conditions of test items, testing to be performed and the acceptance criteria

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Neu – Technical transfer of testing methods

- 6.40 **Deviations** from the protocol should be investigated prior to closure of the technical transfer process. The technical transfer report should document the comparative outcome of the process and should identify areas requiring further test method revalidation, if applicable.

- 6.41 Where appropriate, **specific requirements** described in others European Guidelines, should be addressed for the transfer of particular testing methods (e.g Near Infrared Spectroscopy).