AG 8:

Qualifizierung und Validierung

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Treffen seit dem letzten GMP-Gesprächskreis

07.06.2011
bei der Artesan Pharma GmbH & Co. KG, Lüchow

27.10.2011
bei der Dr. Paul Lohmann GmbH KG, Emmerthal

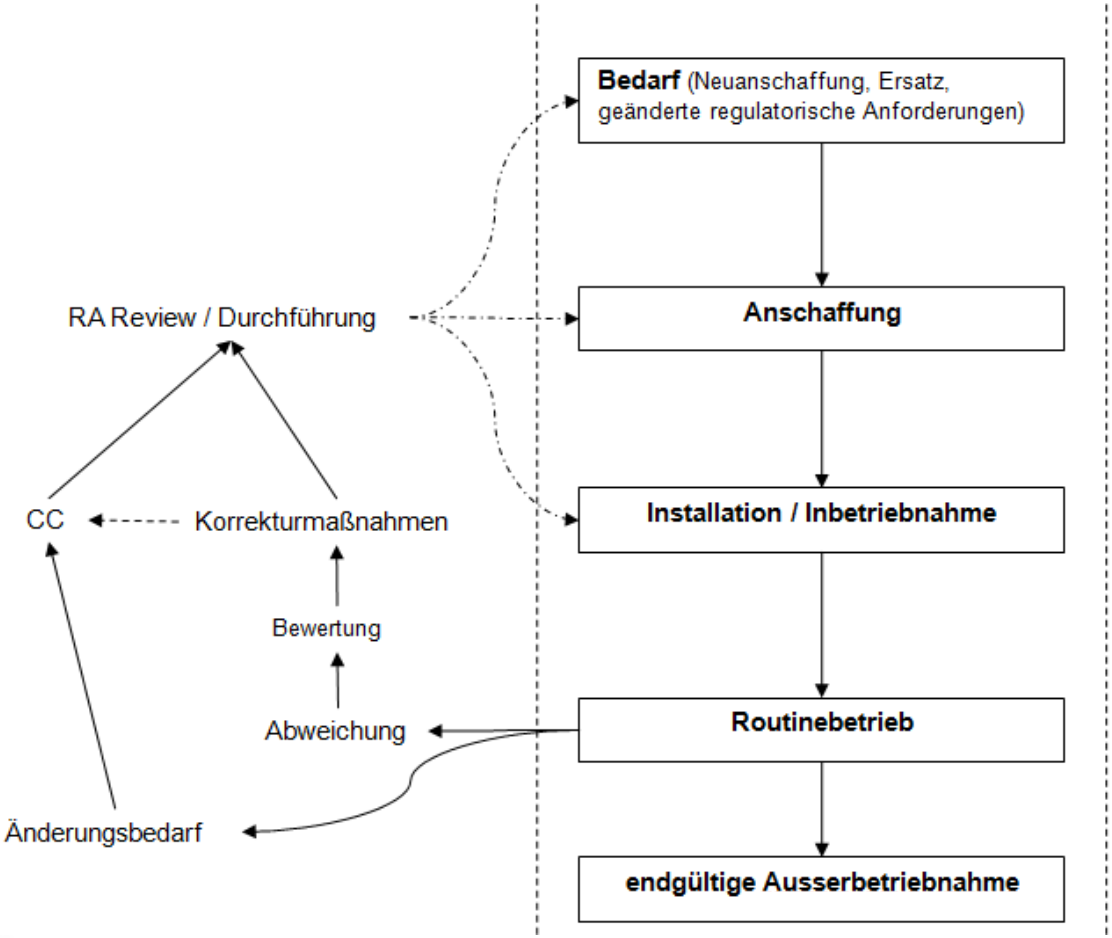
Danke an die Organisatoren und Gastgeber!

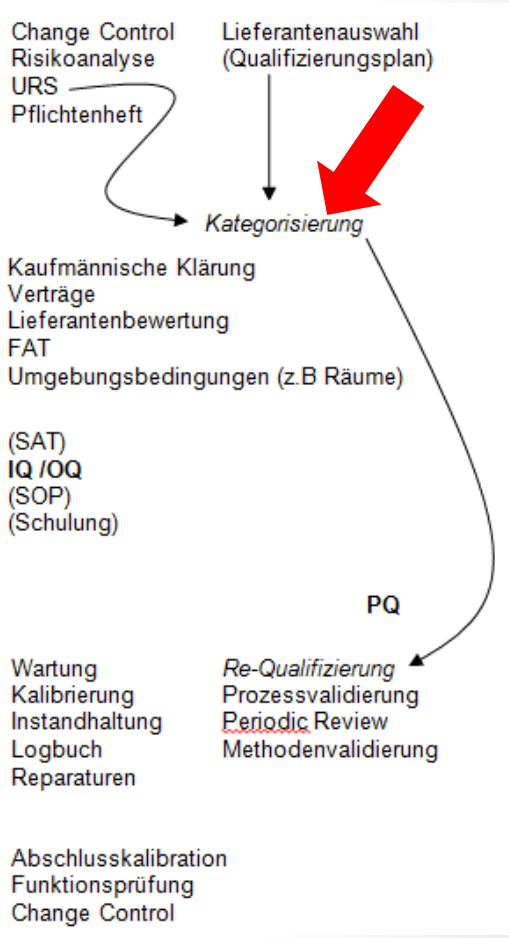
Womit befasst sich die Arbeitsgruppe? Womit wird sie sich noch befassen?

- Life Cycle Management
- Requalifizierung / -validierung

- Neue Technologien / Anforderungen
- Qualifizierung durch Externe
- Validierung computergestützter Systeme
- Qualifizierung von Prüfmitteln
- Reinigungsvalidierung
- „Mitarbeitervalidierung“
- Mängelstatistik der Behörden

Life Cycle Management





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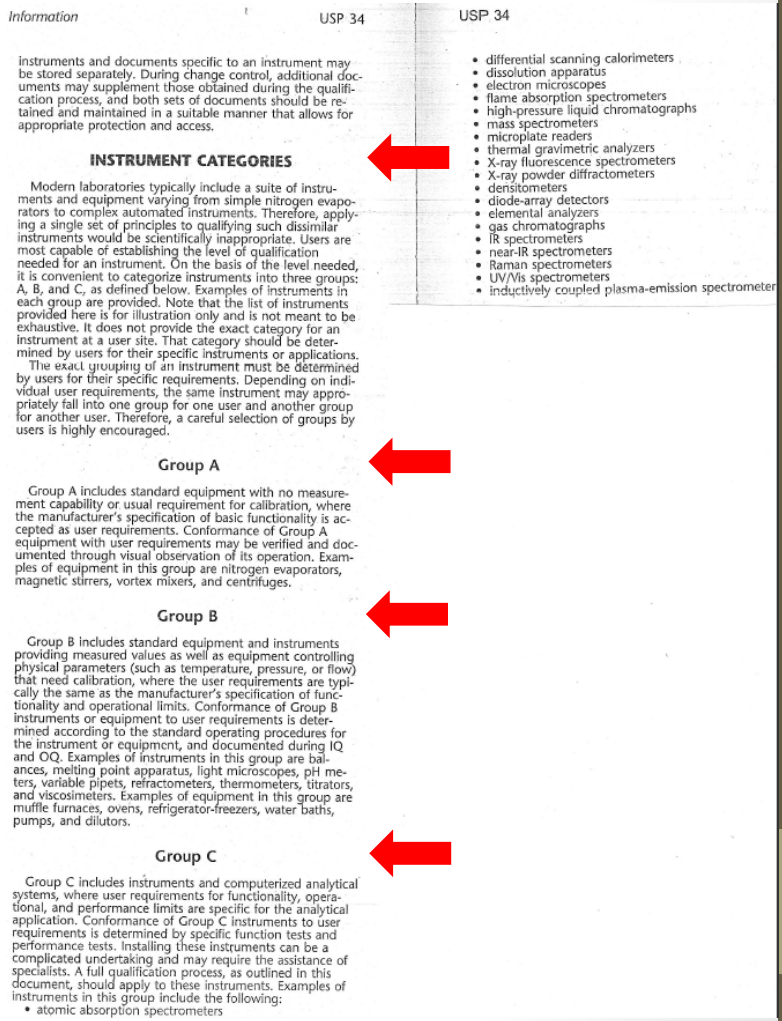
Analytical Equipment Qualification

- Das Kapitel enthält konkrete Vorgaben zur Qualifizierung
- Einfache Kategorisierung in drei Gruppen (A, B, C) ist die Grundlage für die Qualifizierung

→ Möglicher Ansatz auch für Maschinen, Geräte und Anlagen?



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instruments and documents specific to an instrument may be stored separately. During change control, additional documents may supplement those obtained during the qualification process, and both sets of documents should be retained and maintained in a suitable manner that allows for appropriate protection and access.

INSTRUMENT CATEGORIES

Modern laboratories typically include a suite of instruments and equipment varying from simple nitrogen evaporators to complex automated instruments. Therefore, applying a single set of principles to qualifying such dissimilar instruments would be scientifically inappropriate. Users are most capable of establishing the level of qualification needed for an instrument. On the basis of the level needed, it is convenient to categorize instruments into three groups: A, B, and C, as defined below. Examples of instruments in each group are provided. Note that the list of instruments provided here is for illustration only and is not meant to be exhaustive. It does not provide the exact category for an instrument at a user site. That category should be determined by users for their specific instruments or applications.

The exact grouping of an instrument must be determined by users for their specific requirements. Depending on individual user requirements, the same instrument may appropriately fall into one group for one user and another group for another user. Therefore, a careful selection of groups by users is highly encouraged.

Group A

Group A includes standard equipment with no measurement capability or usual requirement for calibration, where the manufacturer's specification of basic functionality is accepted as user requirements. Conformance of Group A equipment with user requirements may be verified and documented through visual observation of its operation. Examples of equipment in this group are nitrogen evaporators, magnetic stirrers, vortex mixers, and centrifuges.

Group B

Group B includes standard equipment and instruments providing measured values as well as equipment controlling physical parameters (such as temperature, pressure, or flow) that need calibration, where the user requirements are typically the same as the manufacturer's specification of functionality and operational limits. Conformance of Group B instruments or equipment to user requirements is determined according to the standard operating procedures for the instrument or equipment, and documented during IQ and OQ. Examples of instruments in this group are balances, melting point apparatus, light microscopes, pH meters, variable pipets, refractometers, thermometers, titrators, and viscosimeters. Examples of equipment in this group are muffle furnaces, ovens, refrigerator-freezers, water baths, pumps, and dilutors.

Group C

Group C includes instruments and computerized analytical systems, where user requirements for functionality, operational, and performance limits are specific for the analytical application. Conformance of Group C instruments to user requirements is determined by specific function tests and performance tests. Installing these instruments can be a complicated undertaking and may require the assistance of specialists. A full qualification process, as outlined in this document, should apply to these instruments. Examples of instruments in this group include the following:

- atomic absorption spectrometers

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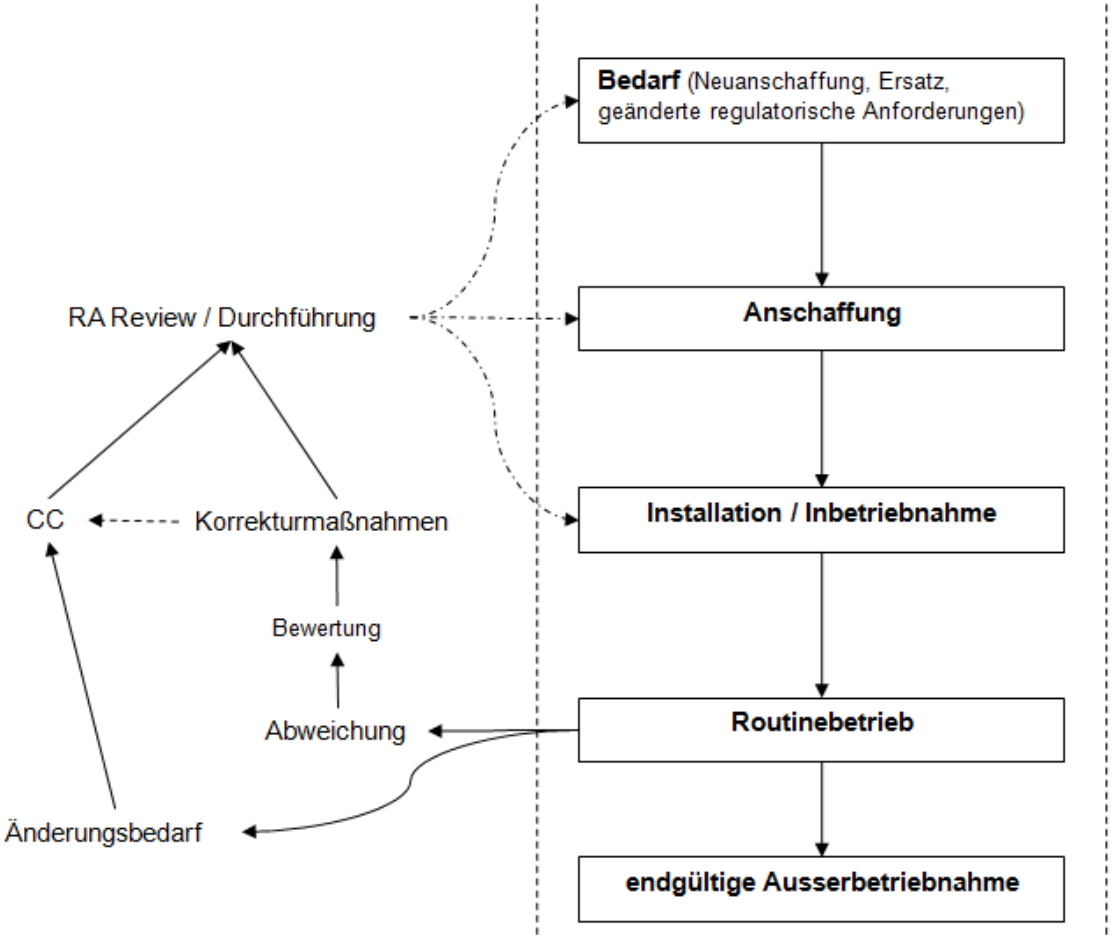
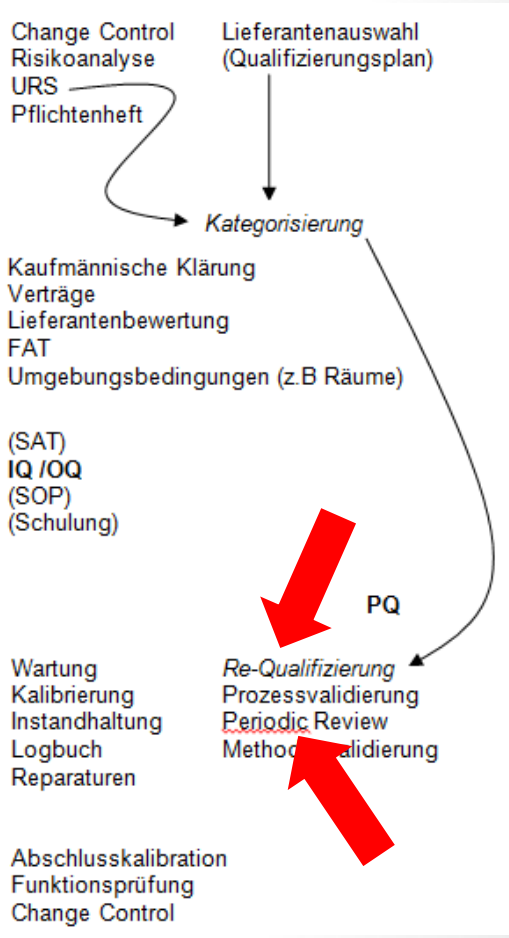
- differential scanning calorimeters
- dissolution apparatus
- electron microscopes
- flame absorption spectrometers
- high-pressure liquid chromatographs
- mass spectrometers
- microplate readers
- thermal gravimetric analyzers
- X-ray fluorescence spectrometers
- X-ray powder diffractometers
- densitometers
- diode-array detectors
- elemental analyzers
- gas chromatographs
- IR spectrometers
- near-IR spectrometers
- Raman spectrometers
- UV/Vis spectrometers
- inductively coupled plasma-emission spectrometer

Kategorisierung von Produktionsanlagen

- Einordnung beispielsweise nach Auswirkung auf die Produktqualität („Direct Impact“)
- Qualifizierung / Requalifizierung: Hoher Aufwand für kritische Anlagen, geringerer Aufwand für weniger kritische Anlagen
- Grundlage für Intervalle und Aufwand zum Erhalt des qualifizierten Zustandes

Life Cycle Management





Periodic Review als Schlüsselelement zum Erhalt des qualifizierten Zustandes

- Regelmäßige Begehung der Anlage vorsehen
- Regelmäßiger Dokumentenreview (Changes, Abweichungen, Dokumentation von Wartungen/Kalibrierungen)

- Intervall zur Begehung auf Basis der Gerätekategorie
- Aufwand wird bei Erstqualifizierung festgelegt
- Kann das Maß einer Requalifizierung drastisch herabsetzen

AG 8: Ausblick für anstehende Treffen

- Konkretisierung der gewonnen Erkenntnisse
- Nähere Betrachtung des Life Cycle Managements (z.B. CC, Abweichungen)
- Einbindung in Vorgaben aus ICH Q9 und Q10

Die Arbeitsgruppe freut sich über weitere Mitglieder!

Danke für Ihre Aufmerksamkeit!