

## Roundtable Session 2 – Table 3 – Lifecycle Management of Reagents and Equipment

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Roundtable #3 Session 2:

Lifecycle Management of reagent & equipment

1. How do GxP requirements and expectations affect selection of reagents and equipment, and at what stage do they become important?
  - Supply for critical reagents is difficult
  - You need enough buffer
  - Ideally at least 2 vendors
  - External vendor doesn't have to inform
  - Extension of expiration dates
    - Statistical tool for trending compares data to initial qualification data
    - Scientific rational for extending expiration dates
  - Critical Reagents
    - Secondary antibodies
    - Primary antibodies
    - Serum
    - Cells
    - Growth factors
    - Lot to lot variation
  - Contact to CQC
    - PPQ – Play
    - 1 year before PPQ starts
    - Harmonized equipment allows for faster transfers
  - IT
    - Security Software
  - Different signals with diff plate readers
    - How to compare is calculations are the same, don't worry
  - Inventory
    - Using the same name would be helpful

- Cell lines
  - Licenses
  - ATCC also fees for clinical testing or lot-release assay
  - In house produced cell lines problem: lack of documentation
- Shipping of cells/serum
  - Difficult
  - Country specific requirements
  - Use serum-free freezing
- Reference standard
  - Primary RS in liquid N working RS @ -80°C
  - In order to detect decreases in RS & internal control