The Role of QC in the Pharmaceutical Industry

Kate Davies
Bristol-Myers Squibb
QC Roles

- Evaluation of quality throughout process
  - Raw materials and API
  - Drug Product
  - Packaging components
  - Reassay
  - Retains
QC Responsibilities

- Efficacy
- Safety
- Quality
- Compliance
  - FDA, MHRA, ICH
  - USP, BP, EP, JP
Raw Materials

- All Raw Materials are tested on site before use
  - Incoming identity
  - Full release testing
- Includes Excipients, Capsules, API
- Various techniques
  - Raman and IR Spectroscopy
  - Assay (HPLC and Titration)
  - Physical Tests
Packaging Components

- All packaging components tested if in contact with drug product
  - Bottles
  - Blister pack components
  - Cotton wool, Desiccants

- Range of techniques
  - Appearance
  - Spectroscopy
  - Loss on Drying
Finished Product (Release)

- Release into Clinic
- Mainly 2 techniques
  - HPLC
  - Dissolution
- Several tests
  - Assay
  - Content Uniformity
  - Dissolution
Finished Product (Reassay)

- Scheduled reassessment of released drugs
- Ensures continued efficacy
- Same techniques as Release
  - HPLC, Dissolution
  - Reduced testing for reassay
- Re assay schedule drug dependant
  - Comparators – manufacturers expiry
  - In house drugs – decided by formulator
Retains

- Sample of everything tested retained
  - Enough for full testing in duplicate
  - At label conditions
- Retain time determined by regulatory guidelines
  - Raw materials 12 Years
  - Finished products 10 Years
- All unsealed finished products inspected annually
Cleaning Verification

- All manufacturing equipment cleaned
- Subject Exposure Limit (SEL) set
- SEL converted to a Residue Limit (RL)
- Equipment swabbed
- Tested using HPLC
  - Std concentration made to RL
  - Swab concentration must be lower than std
- All surfaces must be validated
Future

- Process Analytical Technology
- Paperless laboratory
- Explore new uses of analytical techniques
  - NIR
  - IMS