Quality Assurance

- Describe what you are doing !
- Document that you did what you described !
- Traceability !
- Validate your method !
- Participate in ring trials !

History

- In december 1994 the decision was taken to establish a QA system
- In 1999, the first analysis was accreditated by DANAK according to the EN/ISO 17045.
- Today, 38 analysis in the house are accreditated, and more on it’s way…
- ”MIC with Sensititre” since March 2002.

QA at the National Food Institute

DS/EN ISO/IEC 17025

Institute – 1 head of QA: ”The QA handbook”

↓

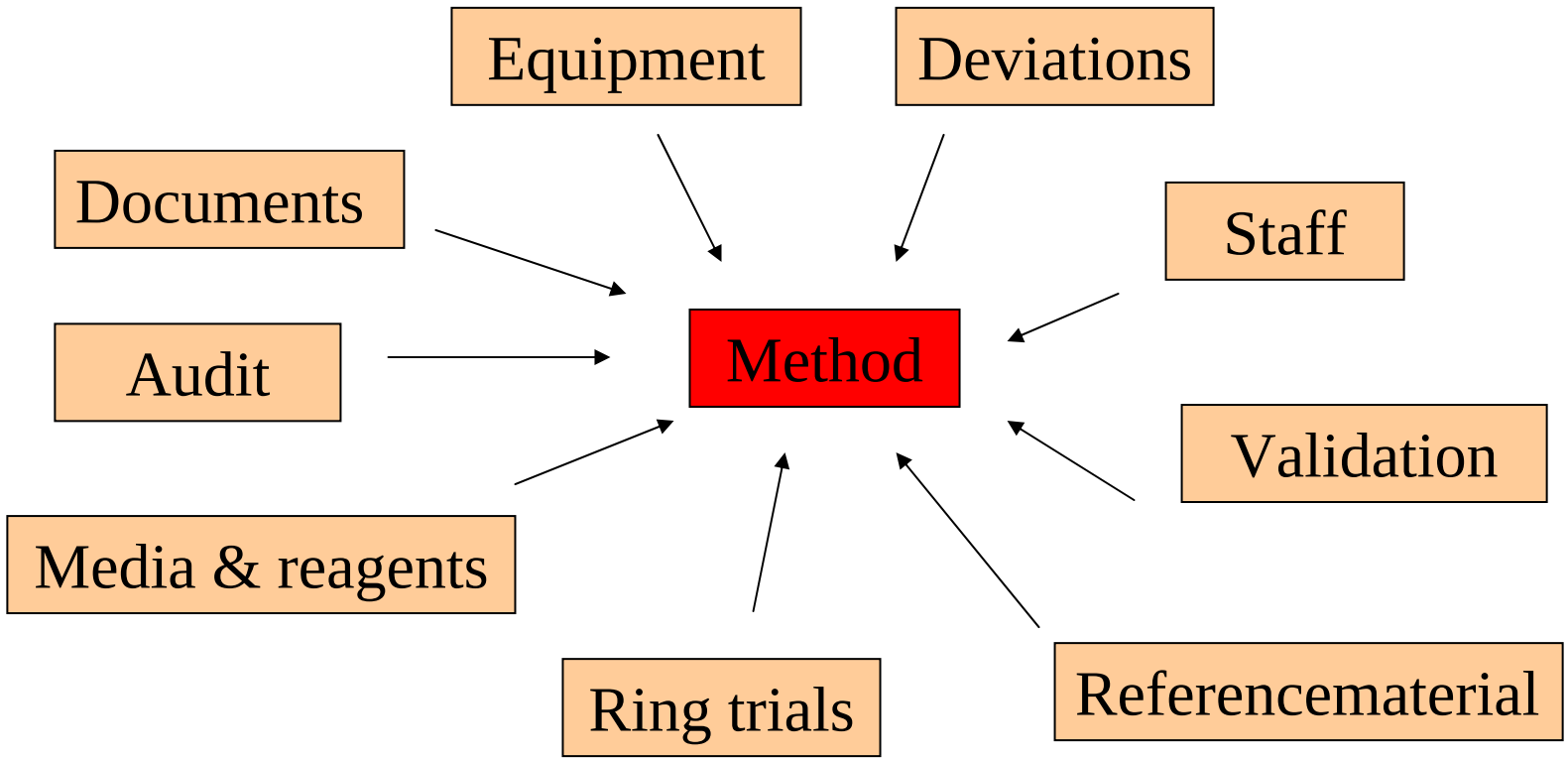
Department – 1 Quality Coordinator: ”Dept. SOP collection”

↓

Section – Quality Co-workers – individual analysis

”Standard Operational Procedures”

QA for each analysis



Staff

- Training
- Documentation for the training
- Define areas of responsibility
- CV and description of working areas

Documents

- Maintaining the documents (SOPs etc)
- Distribution of the documents (SOPs etc)
- Traceability…when was the SOP approved for use etc…

Equipment

- Manual for use
- Traceability all the way – ”who did what”
- Logbook for use, repair etc
- Test/validation before use
- Procedures for regularly maintaining and calibrating.
- Define acceptable deviations
- Software is also equipment !
- For incubators, freezers etc:

  - Daily control of the temperature

  - Regular validation of the temp. in 24 hours and in different places inside the equipment.

Media and reagents

- Description of how to produce the media
- Procedure for testing each new lot
- Accept criteria for each new lot
- Description of how to maintain and store
- Traceability….

  - which lot of media/reagent was used

Ring trials

- Participate in relevant ring trials
- Define accept criteria for your performance
- Evaluate the results
- Document any corrective actions
- Traceability…. – ”who did what”.

Deviations and Audit

- Procedures when deviations appear
- State if the results are influenced
- Deviation reports with corrective actions
- Internal audit system (once a year).
- External audit by DANAK (once a year).
- Traceability….

Validation and referencematerial

- Need for validation depends on the method.
- MIC/DD – use of international standards = validation already done for you!
- Referencematerial for susceptibility testing: The QC referencestrains (ATCC strains)
- Procedure for maintaining the QC referencestrains.

QC testing on MIC

- Each new lot of broth
- Each new lot of MIC-panels
- Weekly QC in the lab with all the ATCC strains in use on all panels in use.
- Daily QC for campylobacter !

QC testing in the lab

- Daily performance is needed if the lab do not have any routine or experience in MIC-testing. After a longer period (CLSI states 30 days) of QC testing without any deviations, weekly QC testing would be okay.
- The number of QC referencestrains to use varies, but if testing Salmonella and Campylobacter, the minimum QC testing should include the ATCC *E. coli* strain and the ATCC *C. jejuni* strain.
- QC acceptable ranges are not defined for all antimicrobials. In house reference values can be used instead.

QC testing in the lab

- The QC referencestrain *Ps. aeruginosa* is recommended because it reveals if the cationic concentration in the broth (or agar) is not appropriate (the results for tetracycline and aminoglycosides would be affected).
- The QC referencestrain *E. faecalis* is recommended because it reveals if the antagonist content of the broth (or agar) is not appropriate for testing trimethoprim and sulphonamides

QC - Troubleshooting

If QC results are out of the acceptable range…..

- Switch of strains ?
- Contamination ?
- Growth weak or inoculation wrong ?
- Incubation temperature and -time ?
- New lots of broth or other media/reagents ?
- Use of expired disks, broth, MIC-panel or other reagents ?
- Etc….

Action on QC deviations

- Re-testing (after subcultivation)
- One dilutionstep outside the acceptable QC range can be accepted, but….
- …if the same deviation appears over time or for other QC strains too, you have to take action !
- Welcome to contact CRL for advice….