System suitability tests verify that the analytical equipment will perform according to the criteria laid down in the analytical procedure.

3.8 User Requirement Specification - (URS)

Documentation, which defines the functionality required from analytical equipment by the user.

4 Responsibilities

4.1 R&D Line Management

Line Management, as defined in local procedures, is responsible for:

- Authoring local SOPs regarding analytical equipment qualification.
- Ensuring that analytical equipment qualification is carried out, documented, technically reviewed by someone sufficiently competent in the equipment and approved prior to use in GMP activities, including seeking QA review/approval where required.
- Ensuring that there is an up to date record of equipment qualification.
- Reviewing with R&D QA any qualification report where the work/results are not in line with the plan.
- In conjunction with R&D QA assuring, by assessment, the capability of suppliers to provide, validate and maintain equipment as suitable for GMP use.

4.2 R&D QA

R&D QA is responsible for:

- Assuring that an appropriate documentation for analytical equipment qualification is in place prior to use in GMP activities.
- Approving local SOPs regarding analytical equipment qualification.
- Approving qualification protocol/plan and modifications as required.
- Approving qualification reports where actual work/results are not in line with the plan.
- In conjunction with R&D involvement in all stages of qualification for critical equipment. This involvement shall be decided on a case-by-case basis and defined in the qualification plan.
- In conjunction with R&D assuring, by assessment, the capability of suppliers to provide, validate and maintain equipment as suitable for GMP use.

5 Guideline

5.1 Qualification

There are four critical components involved in the generation of reliable and consistent analytical data. The diagram below shows these components as

The extent of OQ testing any particular analytical equipment undergoes depends on the intended application and the type of equipment. Therefore, no specific OQ tests are cited here. As a guide to the type of tests to be considered during OQ the following are examples of tests, which may be undertaken for an HPLC system:

- Pump Flow
- Gradient Linearity
- Detector wavelength accuracy, linearity, drift and noise
- Injector repeatability

The successful completion of the operational qualification will normally be sufficient to confirm the correct operation of any installed operating software as indicated in GAMP 4.

As already stated in Section 5.5 a single operational qualification plan may be used for multiple purchases of the same type of equipment. The amount of qualification tests for subsequent purchase of the same type of equipment may be reduced. The option to carry out reduced testing must be included in the original plan. However, if modifications are required to an already approved plan, then a reduced document outlining the changes must be produced and approved by R&D QA as stated in section.

5.5.4 Performance Qualification (PQ)

Performance qualification provides documented verification that the analytical equipment function as intended and produce results repeatedly and reliably.

For commercial off the shelf equipment PQ may be satisfied by calibration, system suitability tests and the routine maintenance of the analytical equipment (GAMP categories from A to E)

For more complex equipment (GAMP Category F) more detailed PQ testing (e.g. a PQ program recommended by the system vendor) may be appropriate. In these circumstances it may be appropriate for scheduled preventative maintenance of the system to comprise full or partial execution of the PQ program.

