Evaluation and quality assurance

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Quality

- Quality must be perceived broadly as it contains more components:
  - Stuctural
  - Material
  - Personnel
  - Result-oriented

- The principles of quality politics should be formulated in an active manner according to the „KISS-Principle“ (**K**eep **I**t **S**hort and **S**imple) – every employee should be able to repeat them at any time

Quality policy

- May consist of **early recognition** of potential areas of improvements and implementation of **suitable measures**
- Institution management is responsible for performing an **evaluation** of the quality
- The quality management nominee must ensure that all evaluations are performed **systematically** according to the stated directives, and that the results are **documented**
- All discrepancies (non conformities) have to be **corrected** within a given time period

Quality management system

- **QMS has to be modified** on the basis of changes that have occured (or are expected) in terms of organization, measures, equipment, employees, methods, activities or work load.
- The necessity to change the QMS can also be caused by the result of internal or external **control audit**, by the rernewed performance of reviews (by an accreditation body) or on the basis of **customer complaints.**
- All evaluations should be **documented** in the form of protocol including clear data about the measures that shuld be realized (i.e. who will realize them, in what time period, etc.)
- The documentation should be **easily accessible** and kept for suitable lenght of time

Quality assurance

- QA is a process of verifying or determining whether products or services meet or exceed **customer expectations.**
- QA is a process-driven approach with specific steps to help define and attain **goals.**
- This process considers: **design, development, production, and service.**

PDCA cycle

- The most popular tool used to determine quality assurance is the Cycle, developed by Dr. W. Edwards Deming.
- This cycle for quality assurance consists of four steps: *Plan*, *Do*, *Check*, and *Act*.
- These steps are commonly abbreviated as PDCA.

PDCA cycle

- PDCA is an effective method for monitoring quality assurance because it analyzes existing conditions and methods used to provide the product or service customers.
- The goal is to ensure that **excellence is inherent in every component** of the process. Quality assurance also helps determine whether the steps used to provide the product or service are appropriate for the time and conditions.
- In addition, if the PDCA cycle is repeated throughout the lifetime of the product or service, it helps improve internal company efficiency.

Quality Assurance

- Quality assurance demands a degree of detail in order to be fully implemented at every step.
- *Planning*, for example, could include investigation into the quality of the materials used, the actual assembly, or the inspection processes used.
- The *Checking* step could include customer feedback, surveys, or other marketing vehicles to determine if customer needs are being exceeded and why they are or are not.
- *Acting* could mean a total revision in the process in order to correct a technical or cosmetic flaw.

QA

- The quality of analytical data is a critical issue at each stage of a resource project, as the data are the basis for making key decisions throughout the project.
- The ultimate aim of a QA program is to determine if analytical data are representative and accurate within a framework of being ‘Fit for Purpose’.
- If traditional QC systems are difficult to use or produce non-standardised outputs, the ability to quantify levels of risk or identify key causes of error in a timely fashion is compromised. The end result is wasted time, money, and missed opportunities.

Quality Manager

- Most organizations have bookshelves of manuals and procedures that were written with good intentions but never really put into practice.
- A good manager must constantly monitor activities, no matter how much they are documented, to make sure they are executed properly.

Evaluation and quality assurance

- Evaluation and improvement process
- Assesment of user satisfaction and complaints
- Internal audit of examination process
- External quality assurance
- Status of preventive, corrective and improvement actions

Key features of QA

- Education and training
- Documentation
- Protocols
- Protocol and document controll
- Laboratory maintenance
- Testing
- External quality assurance programs

EQA

- Proficiency testing
- Assessing and maintaning the quality and standards of output
- Measuring the error rate and helps to identify underlying problems
- End point is an improvement performance and better quality control

Purpose of EQA

- Quantify the quality of a lab output
  - Analytical service
  - Interpretation provided by individual members of the lab staff
- Raise and harmonize standards
- Ensures that customers (patients and clinicians) receive the best possible service

External QA program

- Policy on EQA needs to include details of the EQA that the PGD laboratory uses, who in the PGD centre is responsible for doing the EQA and how the EQA is reported.
- Accreditation system cannot operate unless there is an EQA (or other equivalent scheme which can monitor performance)
- FISH - Cytogenetic European Quality Assurance (CEQA) www.ceqa-cyto.eu
  - Formerly worked for routine cytogenetics
  - Single blastomere PGD pilot EQA recently completed
- Molecular – UK NEQAS for Molecular Genetics www.ukneqas.org.uk
  - Established in 1991
  - Provide EQA for Molecular Genetics
  - Self funding, non-profitable scheme

Quality is „fitness for use“.

Juran, 1979

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