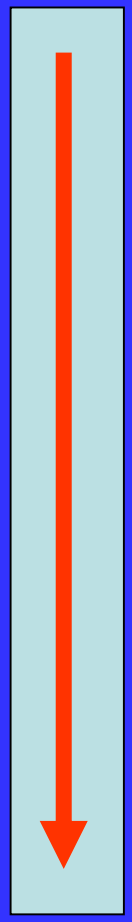
Quality management requirements for plasma for fractionation

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Basis for good quality management in “the plasma chain”

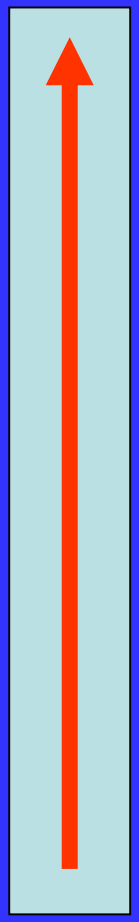


- If I would support supplying plasma for fractionation, then I need plasma which is of the best quality

- If I am selected to work within “the plasma chain” I will perform as one of the best

- If I need to perform as one of the best, I will keep my knowledge and skills up to date

- Making failures is human, but my intention is not to repeat failures neither by myself and by others



How do others address the quality and safety challenge…?

Oil industry, …. Airline industry

- Industries with experiences with competition on quality and on potential big risks
- Public considers them as safe working environments
- Both very active in the implementation and maintenance of quality and safety processes

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→ **They all have the same motto :**

Here you focus on quality and safety, … or you do not work here at all !

Quality management requirements for plasma for fractionation is equal to blood components

1. The inclusion of the complete transfusion chain.

- the recruitment of donors,
- collection of donations, either whole blood or source plasma
- processing of units,
- testing of blood samples,
- storage of final products,
    - distribution to hospitals,
    - (testing in the hospital laboratories),
    - handling in the hospital wards
    - administration to and follow-up of the patient.

2. The establishment of a quality system.

- in agreement with scientific principles
- facilitating and not hindering further improvement.

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Elements of this quality system

- evidence-based quality standards
- common critical quality system essentials
- education / training programs
- inspection / licensing
- quality audits / accreditation
- haemovigilance / pharmacovigilance



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Distinguish between

What we do know ?

What we think we know ?

What we don't know ?

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Basic requirements

- a well functioning organization,
- a documentation system,
- production,
- authorisation,
- accreditation and audits.

Basic requirements: Organization

- localization and premises
- responsible person
- management
- personnel
- authority
- education and training
- responsibilities

Responding to situations











Basic requirements: Documentation system

- quality master file or quality manual

- organization

- prescriptive as well as post-scriptive documents

- record keeping

- responsibilities

- equipment

- product identification and traceability

- Standard Operating Procedures (SOPs) with reference to published methods, guidelines, etc



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Basic requirements: Manufacturing

- identification of products
- contracts
- storage
- labeling
- provisions
- hygiene control
- proficiency testing
- internal and external quality control
- validation
- calibration
- incident - error - accident reporting and review









Basic requirements: licensing / authorization

- to get started and then maintained

- performed by the National Regulatory Authority

- based on the presentation previously made. Quality systems essentials presented in a quality master file or manual, and inspection

- maintained licensing could require accreditation



Basic requirements: Accreditation/Audits

- updated regularly by an accreditation body

- based on the previously described Quality System (recognized essentials)

- based on audits including compliance with the evidence based quality standard essentials as well as critical quality system elements

- correction of deviations and faults required to maintain accreditation (and licensing, where applicable)



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The 7 steps to Quality Management

- leadership
- process approach
- factual approach to decision making
- involvement of people
- continuous improvement
- customer / deliverable focus
- Mutually beneficial supplier relationships



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Step 1 : Leadership

- establish unity of purpose and direction
- create and maintain the internal environment
- assign clearly the accountability in the organization
- organise QM not only in directing the system but also in creating sufficient support / input from clinics and hospitals
- promote the importance of QM, formulate the quality policy, support the development of a quality system and provide resources for quality
- promote the need for meeting quality for the benefit of donors and patients, on regulatory requirements for complying with the law, and on statutory requirements, because functioning QM is essential for optimal clinical blood transfusion practice
- carry out the quality planning by formulating the quality objectives and plans of the quality management system.

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Step 2 : Process approach

- a desired result is achieved more efficiently, when activities and related resources are managed as a process
- ‘process owners’ i.e. persons who carry the responsibility on the executing of parts of the process need to be established
- responsibilities and authorities should be clarified and communicate to the organization
- use competent personnel and ensure that the personnel have the right experience, the right education, the right training and the right skills
- establish a process map with input, output and handover specification by providing the quality infrastructure
- implement a structured procedural documentation that is easy to maintain
- take care of good communication in the quickly changing business and process environment.

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Step 3 : Factual approach to decision making

- effective decisions are based on the outcome of analyses of data and information
- as basis for analyses, quality indicators or key performance indicators and key compliance indicators need to be created, including a process of performance metrics
- it should be defined on how non-conforming should be identified and handled.

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Non-conforming should be identified and handled…..



Step 4 : Involvement of people



- People are the essence of any organization
- in order to create this backbone of safety, a trainings plan on QM for all staff
- means every employee is fully aware of the fact that his or her contribution is essential

Step 5 : Continuous improvement

- Quality Plans
- management – quality system oversight and decision forum need to be in place
- pro-active process risk assessments
- systematic selection / development and qualification / validation of computer systems
- results that the preventive actions achieve should be recorded and the effectiveness examined.

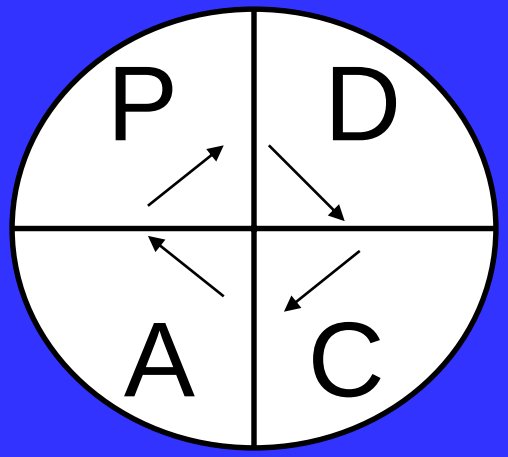
Deming Q cycle

- Plan

- Do

- Check

- Act



Step 6 : Customer / deliverable focus

- organisations depend on their customers and therefore should understand the current and future customer needs
- meet the customer requirements and strive to exceed the customer expectations
- an excellent relation between plasma supplier and fractionator is paramount
- a good feed back system functions as a linking pin between the plasma supplier and the fractionator



Step 7 : Mutually beneficial supplier relationships.

- organisation and its clients are interdependent
- clear contracts that specify exact deliverables, quality levels and quality management system expectations
- successful approach is partnering with your clients



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Legal framework

- Quality management in blood transfusion medicine should be in line with the requirements as been set by the regulatory authorities
- The specifications and quality parameters subject to a formal process of regular review and update at timely intervals
- process is conducted by qualified experts in the relevant areas of transfusion practice
- subject to inspection by the national competent body.







not the goal…….

- to pinpoint on mistakes, failures and faults in an atmosphere of blaming the actors.



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Summary

- Quality management requirements for plasma for fractionation aims for a way of working which is based on:

  - confidence
  - planning and control,
  - for a better way of working together,
  - for better and safer plasma,
  - for good and clear communication,
  - for partnerships in order to get the overall best results.

- The best quality management should not be searched at the “other side”, but at each of the partners themselves.

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Quality is an attitude,
is certainly
a fantastic attitude



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