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MAŠĪNZINĀTNE UN TRANSPORTS

QUALITY AND RELIABILITY
KVALITĀTE UN DROŠUMS

QUALITY MANAGEMENT, QUALITY ASSURANCE AND QUALITY CONTROL IN BLOOD ESTABLISHMENTS

KVALITĀTES VADĪBA, KVALITĀTES NODROŠINĀŠANA UN KVALITĀTES KONTROLE ASINS SAGATAVOŠANAS INSTITŪCIJĀ

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Introduction

On 27 January 2003, The European Union adopted Directive 2002/98/EC on setting the standards of quality and safety for human blood and blood component collection, testing, processing, storage and distribution. Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC set the technical requirements for blood and blood components, Directive 2005/61/EC of 30 September 2005 set the traceability requirements and notification of serious adverse reactions and events, and Commission Directive 2005/62/EC of 30 September 2005 set the standards and specifications relating to blood establishment quality system.

Terms such as “quality”, “quality system”, “quality management”, “quality assurance”, “quality control” have entered both our spoken language and the language of our official documentation. We can confidently answer in the affirmative to the question of whether the products we prepare (blood components) are qualitative, as the components are accepted for distribution and, therefore, meet the required quality standards. The question of what proves the quality of every single blood component unit is often answered by saying that the results of blood component quality control tests are good. However, do a technical quality measurements – **quality control** tests (a small part of the prepared blood component are tested) really indicate the fact that every unit meets the quality requirements?

Quality control for Processing of Blood Components and Aseptic Collection

Discussing blood components intended for transfusion, we are not talking about line production, as every single donation may be regarded as a separate line. 2004/33/EC directive, Annex V, part 2 defining quality measurements (Volume, Haemoglobin, Haemolysis, Leukocyte content, Platelet content, pH, Factor VIIIc etc. for corresponding blood components) state that the required **frequency** of sampling for all measurements shall be determined using **statistical process control (SPC)**. We are entitled to decide on both how often an how much measurement we take. We also determine various acceptable results for quality measurements.

The aim of quality control testing for bacterial contamination is to receive evidence that blood collection and processing comply with the defined requirements.

Statistical process control – what does it mean? Statistical process control is a tool which helps us to detect and to evaluate changes in the process and procedures, which monitors collected data over a period of time in **fixed conditions**. Accordingly, SPC became mandatory in 2005 for blood establishments in the European Union (Directive 2005/33/EC). SPC is a tool and only a tool for Quality Assurance of blood components. SPC is a good method for decision making process as well as for the changes in management in general [2].

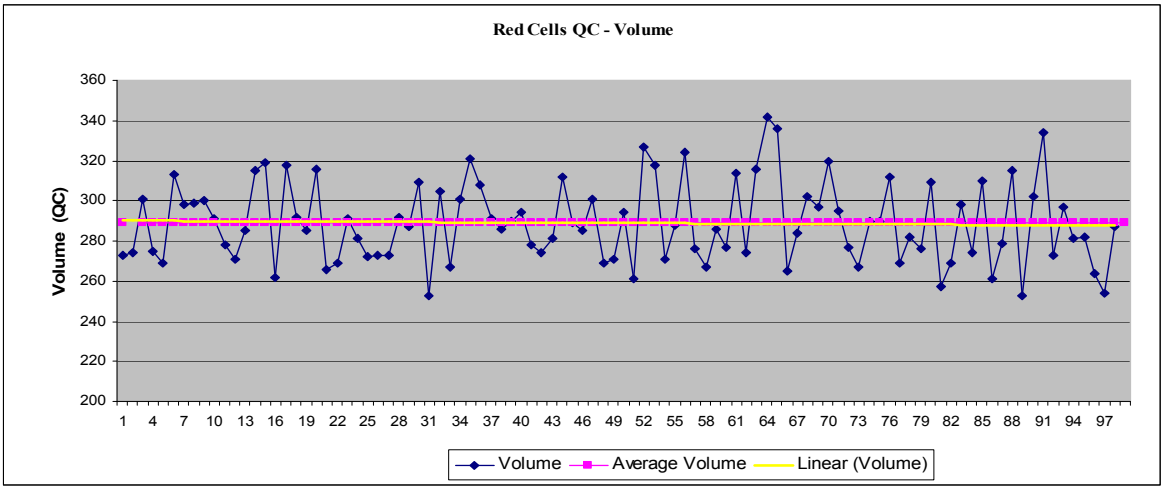

Fig. 1. Trendline and average volume is equal

Product Quality control

Screening tests for infectious disease markers and Blood Group serology testing are important parts of blood component quality parameters. The outcome of the testing precisely defines the quality/validity/compatibility status of every blood component unit. What else could be used as the product quality indicators? Blood component integrity, as well as labels with all required information are indicators of the product quality. Both of these indicators could be evaluated by the customer – hospital blood bank and could be ensured as relevant information / evidences.

Quality of Testing and Medical Laboratories

It is important for us that blood component unit and process quality control results are reliable. What are the ways of achieving the desired reliability? The quality aspect of all medical testing laboratory investigation results is affected by a wide range of factors.

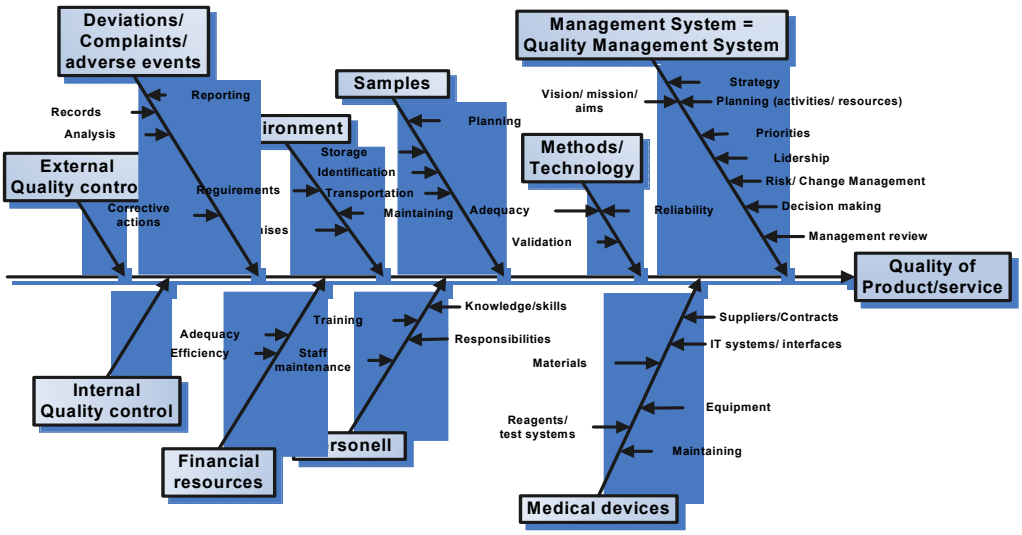

Fig. 2. „Fish bone" draft: What affects the quality of a laboratory product/service

Blood Service medical and testing laboratories successfully implement (or are capable of implementing) European and international standards in the formation and development of their management-quality assurance system. (EN ISO/IEC 17025:2005 /AC:2007 „General requirements for the competence of testing and calibration laboratories" and EN ISO 15189:2007 „Medical laboratories - Particular requirements for quality and competence".) The Quality Assurance system includes the internal and external quality control programs, as well as Quality management system. Quality Assurance System functioning results indicate compliance with the requirements of the corresponding standard, whereas Quality Management System functioning results indicate the uninterrupted laboratory work as well as improving effectiveness and efficiency[1].

Quality of Blood Establishment management

Quality Assurance isn't possible without coordinated activities aimed at directing and managing a blood establishment with regards to quality, that is, without an appropriate Quality Management System. Management responsibilities include the vision, mission, quality goals, adequate planning for all groups of resources to achieve the constant aim - product and service quality improvement, cost reduction and meeting the demanding requirements

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[1] „Effectiveness- extent to which planned activities are realized and planned results achieved.; Efficiency – relationship between the result achieved and the resources used." (EN ISO 9000:2005)

The European Committee's recommendations refer to the principles of good practice and quality management, as described in the EU GMP guidelines and ISO 9000-series standards. According to these recommendations, the Quality System for blood establishments must include the following elements (these are minimum requirements) : **quality management** and process control; personnel and organization; premises, including mobile sites; equipment and materials; documentation; donor sessions; processing; storage and distribution; quality monitoring; **quality control**; contract management; deviations, complaints, adverse events or reactions, recall, corrective and preventive actions; self-inspection, audits and improvements.

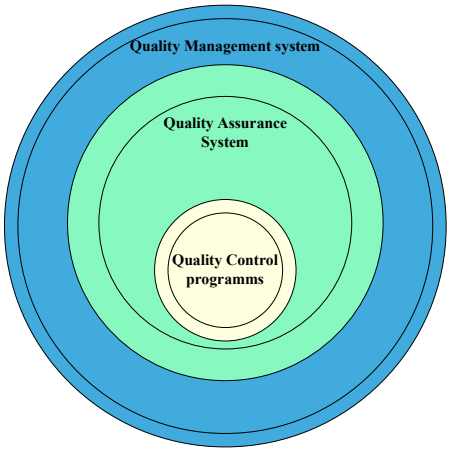

Fig. 3. Relationships between Quality Control, Quality Assurance and Quality Management system

According to ISO 9000, "system" means a set of interrelated or interacting elements, "management system" means a system that establishes policy and objectives which intend to achieve those objectives, "quality management" means coordinated activities set to direct and control an organization with regards to quality, and "quality management system" means a management system that directs and controls an organization with regards to quality.
In my opinion QUALITY PROGRESS could be achieved by increased abilities, continuing development, through preventive actions and by using ISO 9004 as guidelines for performance improvement.

The STABILITY OF QUALITY could be achieved by ensuring quality related requirements, by using monitoring and quality control data, corrective actions etc., as well as by using ISO 9001 and other related standards.

Conclusions

The quality of every blood component is closely connected with each donation sample medical investigation and testing [2].
Quality control results **do not indicate** every blood component quality, but they do attest the stability of blood and blood component processing level under the requirements determined. Quality control data (technical quality measurements) demonstrate that the **process** is in control. Quality control data dynamics are more important than individual quality control results.
SPC is a mandatory tool to define the requirements for Quality Control and Quality Assurance of blood and blood components processing.
We need Customer, Quality and Safety based Management system, which includes the Quality Assurance system, Quality Monitoring and Quality Control with the AIM: to make sure all the requirements are defined and fulfilled, that all the risks in the aspects affecting the Quality of our

products and services are minimized and will be minimized in the future by means of continuous improvement.
When we are speaking about the quality and safety of blood components for transfusion, *our standards can never be too high!*

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Bolbate N.. Kvalitātes vadība, kvalitātes nodrošināšana un kvalitātes kontrole asins sagatavošanas institūcijā.
Veikta kvalitātes jēdzienu un būtības analīze Eiropas Komisijas rekomendāciju skatījumā. Aprakstīta procesu un produktu kvalitātes kontroles būtība, kvalitātes nodrošināšanas mērķis. Pamatota kvalitātes sistēmas struktūra, kas ietver kontroli, kvalitātes nodrošināšanu un vadīšanu.

Bolbat N. Quality Management, Quality Assurance and Quality Control in Blood Establishments.
Quality terms and the roots of the matter are analyzed according to European Committee's recommendations. Essence of process and product quality control as well as essence of quality assurance is described. Quality system's structure including quality control, quality assurance and management is justified in the article.

Болбате Н. Управление качеством, обеспечение качества и контроль качества в учреждении заготавливающем кровь.
Проведен анализ терминов качества и их сущности в соответствии с рекомендациями Европейской Комиссии. Описана сущность контроля качества процессов и продуктов крови, с целью обеспечения качества. Обоснована структура системы качества, которая включает контроль, обеспечение и управление качеством.