

**THE ROLE AND IMPORTANCE OF THE QUALITY MANAGEMENT SYSTEM
IN THE PRODUCTION OF MEDICAL EQUIPMENT.**

Shavkatov Otabek Kozimbek Ugli

Andijan state technical institute

Metrology and light industry

Phd student

shavkatovotabek101@gmail.com

Annotation. Since medicine is a field that requires a high level of accuracy, all medical equipment, that is, from simple medical equipment to complex technological equipment - equipment for ultrasound examination, computed tomography, radiography - must strictly comply with certain technical parameters. This article analyzes the role of the quality management system in the production of medical equipment, its main principles, and practical significance. The role of quality management in improving the effectiveness, safety, and competitiveness of products based on international standards is also highlighted.

Key words: quality management, medical equipment, manufacturing, document control, internal audit, design control, maintenance, safety.

Introduction. The sphere of medical equipment production is directly related to human health, and the quality, reliability, and safety of products manufactured in this area are of paramount importance. Therefore, the introduction of a quality management system in the production process is an important factor at the level of modern requirements.

The production of medical devices requires strict control to ensure compliance with patient health maintenance and regulation requirements. At the center of this process are qualified individuals who play a decisive role in accreditation by ensuring compliance with quality standards, approving procedures, and confirming that each device meets established safety criteria. Qualified individuals can consistently highlight common standards, best practices, and key points.

The quality management system and its guarantees are of great importance in the processes of medical device manufacturing. A robust quality management system (QMS) forms the basis of accredited medical equipment production programs. The main components include:

Document Control and Storage: Maintaining clear, accessible records for audits and regulatory checks.

Internal audit and management reviews: Systematic evaluation and continuous improvement of the effectiveness of the SMS.

Supplier and Seller Management: Ensuring that outsourced processes and components meet the same quality requirements as domestic production.

Manufacturers must align processes with internationally recognized systems focused on design control, production, post-market monitoring, and corrective actions. The production enterprise assesses the quality indicators of the work carried out on its products through the following main elements: Dizayn nazorati: Mahsulot dizaynining barcha bosqichlarini hujjatlashtirish, ko'rib chiqish va tasdiqlashni ta'minlash.

Production and process verification: Verification that production processes consistently produce equipment that meets predetermined specifications.

Post-market monitoring: Monitoring the device's performance and reporting adverse events to identify trends and implement improvements.

Correction and Prevention Actions (CAPA): Eliminating inconsistencies and preventing recurrence through analysis of systemic root causes.



The Quality Management System (QMS) ensures not only product quality control but also continuous improvement at all stages of production.

A quality management system is a management system aimed at managing, controlling, and continuously improving the quality of products or services in a manufacturing organization. SMT in the production of medical equipment is based on the following basic principles:

- customer orientation
- process approach
- risk management
- continuous improvement
- fact-based decision-making

Customer orientation - in the production of medical equipment, the concept of the customer includes not only the end consumer (patient), but also doctors, medical institutions, and maintenance specialists. That is, identifying the needs of clients, fully understanding them, and offering them high-quality services or products. For example: tibbiy uskunaning ergonomik dizayni shifokorlar uchun qulay bo'lishi kerak

- the device interface should be simple and understandable.
- safety requirements must fully protect the patient's health.

As a result, products that meet customer needs are developed, which increases the manufacturer's reliability in the market.

A process approach is the management of an organization's activities not as separate units, but as a system of interconnected processes. The main processes in the production of medical equipment are:

- design
- procurement
- manufacturing
- quality control
- • Logistics & Delivery.

Advantages of the process approach: if a minor malfunction is detected in the production process, it is immediately eliminated without moving on to subsequent stages. This significantly improves the overall quality.

Risk-based thinking

Risk management in the production of medical equipment is one of the most important principles, since any mistake can cause serious harm to human health. Risk is a combination of the probability of an adverse event occurring and its consequences. Risk management includes the following steps:

- risk identification
- risk assessment
- development of risk mitigation measures
- monitoring and revaluation

As a result, the level of risk in the production process is minimized and product safety is ensured.

Continuous improvement

Continuous improvement is the process of continuous improvement of the organization's activities. This principle is often implemented through the PDCA (Plan-Do-Check-Act) cycle:

- Plan
- Do
- Check
- Act



As a result: product quality improves, costs decrease, and innovative development is ensured.

Fact-based decision-making

In modern quality management, decisions are based not on subjective opinions, but on accurate data and analysis.

This principle requires the following:

- data collection
- statistical analysis
- evaluation of results

For example, if the number of defects in a particular part increases, this is determined through statistical analysis and the root of the problem is found. As a result, correct and well-founded decisions are made, risks are reduced, and production efficiency increases.

Conclusion.

The process of producing medical equipment is a highly regulated, complex, and responsible activity that requires strict quality control and full compliance with international standards. The role of qualified specialists in this process is invaluable, as they ensure compliance with quality requirements at each stage of production and play an important role in the processes of documentation, validation, and accreditation. In the production of medical equipment, the quality management system is an important strategic tool. It not only ensures product quality, but also increases production efficiency and ensures competitiveness in the international market. In modern conditions, the implementation and improvement of the Quality Management System serves as an important factor in the sustainable development of the medical industry.

References.

1. Ministry of Health of the Republic of Uzbekistan. Technical regulations for medical equipment, 2023.
2. Resolution of the Uzbek Agency for Standardization, Metrology and Certification, Ministry of Health of the Republic of Uzbekistan. Tashkent-2017.
3. Joseph D. Bronzino, "Management of Medical Technology: A Primer for Clinical Engineers," Butterworth-Heinemann, 2014.
4. Shavkatov, O. (2025). Study of documentation for maintenance and repair of medical equipment. *Transport Bulletin*, 2 (2), 69-72.
5. Komilov, B., & Shavkatov, O. (2025). Quality management system in the healthcare system of developed countries. *Engineering*, 3 (2), 110-112.
6. Shavkatov O.K., & Tuxtasinov A.U. "Stages of Organization of Metrological Support and Maintenance of Medical Equipment." *International Journal of Science and Technology* 2.08 (2025): 7.

