

# REGULATIONS PROCEDURE OF THE INTERACTION WITH CONSUMERS DURING THE FORMATIVE QUALITY MANAGEMENT SYSTEM

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**Introduction.** One of the key principles of modern Quality management is a focus on customers. From the standpoint of principle, which is also implemented with the requirements of ISO 9001:2015, top management of the organization should demonstrate leadership and commitment on targeting consumers by ensuring that:

- a) the requirements of customers and applicable statutory and regulatory legal requirements identified, understood and consistently met;
- b) risks and opportunities that may affect the conformity of products (goods and services) the requirements, as well as the ability to increase customer satisfaction, identified and addressed;
- c) the focus is improving customer satisfaction.

Today almost every profitable company that wants to compete and grow their business critical condition for achieving sustainable success is adherence to this principle.

**Aim.** The aim of our study was to investigate the scientific literature, the requirements of ISO 9000 and excellence for production companies in the world applied recommendations concerning the regulation of interaction with customers as part of the Quality Management System (QMS) that can be applied to domestic pharmaceutical companies.

**Materials and methods.** In the course of our work examined different approaches to establishing a system of feedback and increase customer loyalty in enterprises of various fields and traced change the standards for quality management system and analyzes the typical violations of the requirements observed in the domestic pharmaceutical enterprises.

**Results and discussion.** We offered must regulate activities related to the interaction with consumers of feedback. If such a process is identified as one of the processes of the QMS, it is advisable to describe his performance in the documented procedures (DP) for PDCA Cycle ("Plan-Do-Check-Act"), which makes it possible to order the planning of such a process, the terms of its performance indicators, criteria and means of checking the effectiveness and directions and measures for continuous improvement of this activity.

In practice, these actions are not often described in the documents of the reasons why the procedure contains important elements and cannot regulate and perform activities that could significantly affect the outcome of the process. For example, the lack

of description of the performance evaluation process of interaction with consumers (and any other process) makes it impossible to accumulate measurable results of assessments and track them over time, analyzing trends and patterns. In addition, the lack of data makes factual basis for the development of corrective and preventive actions needed for continuous improvement process.

The same can be said about the importance of regulated planning phase of the process, because proper planning any activity largely determine its outcome.

Information communication with customers, described documented procedure should include:

- a) provide information about products/services;
- b) processing requests, contracts or orders, including their changes;
- c) provide feedback on products and services from consumers, especially for claims, complaints or claims of consumers;
- d) handling or property management customers;
- e) establish special requirements for actions taken in unforeseen circumstances.

The organization has always define the requirements established customer, including requirements related to delivery and subsequent maintenance, if applicable to the products. In addition, should also be determined by the requirements not stated by the customer but necessary for specified or intended use, where such knowledge.

**Conclusion.** We believe that organizations often make the mistake of only limited documentation of direct regulatory or customer requirements, without describing those that are not obvious. Description action claims and complaints - one of the key elements DP QMS regarding interaction with customers. This element should include ways and means of receipt of such information, as well as enough detailed sequence of actions in such situations - from receipt, registration and consideration of complaints, to develop appropriate solutions and actions to eliminate the causes of complaints and minimize the negative consequences for the customer and its information. These actions may be summarized in a separate document, such as standard operating procedures, SOP).

Documented procedures also describe the monitoring data relating to customer perception of the degree of their needs and expectations. It is necessary to determine the methods for monitoring and analyzing this information. For example, this may include consumer surveys, reviews of products delivered / services rendered, meetings with customers, market share analysis, and thanks for warranty claims and dealer reports. Also organization shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the organization shall consider statutory and regulatory requirements; the potential undesired consequences associated with its products and services; the nature, use and intended lifetime of its products and services; customer requirements; customer feedback. Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.