

МІНІСТЕРСТВО ОСВІТИ І НАУКИ УКРАЇНИ  
MINISTRY OF EDUCATION AND SCIENCE OF UKRAINE

НАЦІОНАЛЬНИЙ ТЕХНІЧНИЙ УНІВЕРСИТЕТ  
«ХАРКІВСЬКИЙ ПОЛІТЕХНІЧНИЙ ІНСТИТУТ»  
NATIONAL TECHNICAL UNIVERSITY  
«KHARKIV POLYTECHNIC INSTITUTE»

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**МЕТОДИЧНІ ВКАЗІВКИ**

до практичних занять

з дисципліни «Управління якістю»  
для студентів галузі знань 07 «Управління та адміністрування»

**A MANUAL FOR PRACTICAL CLASSES  
ON COURSE “QUALITY MANAGEMENT”**  
for students in the field of knowledge **07 – Management and Administration**

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Харків  
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Методичні вказівки до практичних занять з курсу «Управління якістю» для студентів галузі знань 07 «Управління та адміністрування» (англійською мовою) / уклад. О.В. Прохоренко – Харків : НТУ «ХПІ». – 42 с.

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## INTRODUCTION

The course “Quality management” is aimed at mastering the approaches and methods of quality management as well as methods and tools used in the planning, design, implementation and development of quality management systems (QMS) in accordance with the requirements of international standards ISO 9001 series

The goal of the course is to provide students with theoretical knowledge and practical skills in the application of general principles, approaches and methods of projection, development, implementation, certification and continuous improvement of QMS in accordance with the provisions of ISO 9001 series.

The course conventionally consists of two parts. The first part is an overview of the evolution and modern approaches to quality management. The second part has a practical focus and introduces the ISO series of quality management standards, as well as aims to acquire practical skills in building a quality system at an enterprise in accordance with the requirements of the ISO 9001:2015 standard.

### **Competencies**

SC01. The ability to identify and describe the characteristics of organizations.

SC02. The ability to analyze the results of organization activity, to compare them with the factors of the external and internal environment.

SC04. The ability to determine the functional areas of the organization and the relationships between them.

SC10. The ability to work in a team and to establish interpersonal interaction in solving professional tasks.

### **Learning outcomes**

LO 04. To show skills of identification of problems and justification of management decisions.

LO 05. To describe the content of the functional areas of the organization

LO 06. To show skills of search, collecting, and analysis of information, calculation of indicators to substantiate management decisions.

LO 08. To apply management methods to ensure the effectiveness of the organization

## A MANUAL FOR PRACTICAL CLASSES

### Workshop 1. Quality Management Evolution

**Task 1.** Writing essay " How I understand quality management and what are its benefits for the organization?"

place on padlet

[https://padlet.com/a\\_prokhorenko/how-i-understand-quality-management-and-what-are-its-benefit-9uu9u28aypyeekon](https://padlet.com/a_prokhorenko/how-i-understand-quality-management-and-what-are-its-benefit-9uu9u28aypyeekon)

Discussion

**Task 2.** Choose any 2 of Deming's principles. Explain how you understand them. Suggest what needs to be done to implement them.

#### *References*

1. Quality Resources. The world's most comprehensive library of quality resources.  
<https://asq.org/quality-resources/>
2. The Toyota Way: 14 Management Principles from the World's Greatest Manufacturer by Jeffrey Liker McGraw Hill; 2nd edition (December 1, 2020)
3. Pyzdek, T., & Keller, P. (2013). Handbook for quality management: A complete guide to operational excellence. McGraw-Hill Education.

### Workshop 2. Root Cause Analysis (RCA)

#### Case NOVA POSHTA (2019)

NOVA POSHTA is the leader of express delivery in Ukraine. The company's mission is ease of delivery for life and business. Lean Institute Ukraine has been cooperating with the NOVA POSHTA company for 3.5 years and is very proud of the achievements of the lean team.

#### CHALLENGES:

- Shortening queues at the branch;
- Increasing the department's productivity;
- Speeding up the process of unloading parcels.

#### **Task 1.**

Suppose the root of problem “complain about queues” using “5 why” methodology.

#### **Task 2.**

Complete the “Fishbone” structure of problem

#### **Task 3** Identify Muda-Mura-Muri

Muda - It includes all the activities that consume resources without providing any additional value.

Mura – This type of waste includes the overuse of equipment or employees.

Muri -This type of waste includes operational unevenness that decreases productivity and efficiency in the long run.

### Solution

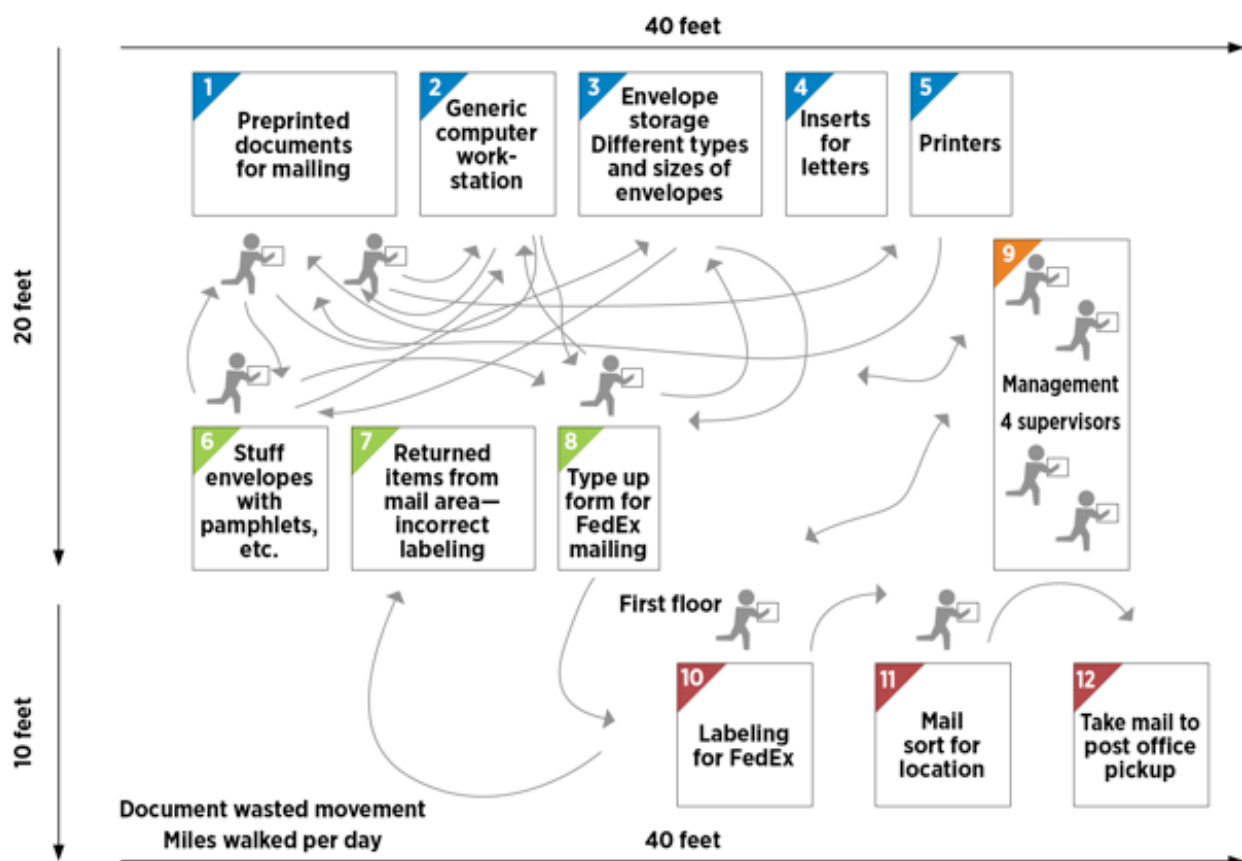
After taking measurements and using the value process map, we realized that the operator spends the most time searching for and moving to the parcel storage location. It turned out that the longest process, which makes the client the most nervous, is the search for the parcel.

With the help of the "Spaghetti" diagram and the map of standardized work, we understood to which places the most movements are made.

It was with the help of these data that we experimentally found the most optimal placement of cabinets with "addresses".

Having filmed the process, we analyzed it and realized that a high-quality and fast search depends on the high-quality placement of the parcel during unloading.

After observing the process and interviewing employees, we found that one of the reasons for the queue is that *customers cannot see half of the operators through the column in the middle of the hall*.



"Spaghetti" diagram

After observing the process of placing the package in the cell, we found that the operator spends time looking for a free shelf (instead of a cell). We conducted a quick "free cell" experiment.

The package reaches the cell 2 times faster! And it's ready for the client!

Customer satisfaction has increased significantly. They note how much faster the processes have become.

The number of customers increased by 40% due to improved service conditions.

NOVA POSHTA	RECEIVING	SHIPPING	LOADING
Value chain processes	1 entering data	1 entering data	1
	2 printing receipt	2 printing waybill	2
	3 bringing receipt	3 packing	3
	4 looking for parcel	4 labeling	4
	5 giving	5 placing	5
Identify MUDA	spending time searching for the parcel by the porter the client's time spent on moving to the porter		
Identify MURA	employees who are not visible behind the column are, in fact, wasteful resources		
Identify MURI	fewer or more workers are needed at different times of the day		

#### RESULT:

Space saving by 20%

43% faster parcel search

20% increase in department productivity

As a result of the aforementioned reduction of queues at the branch

COST OF CHANGES: UAH 0.

The most important achievement is people's interest and openness to change. Employees of the department gathered at 6 in the morning to change the places of cabinets, rearranged workplaces on the go, constantly generated new ideas.

#### *References*

1. Quality Resources. The world's most comprehensive library of quality resources.  
<https://asq.org/quality-resources/>
2. The Toyota Way: 14 Management Principles from the World's Greatest Manufacturer by Jeffrey Liker McGraw Hill; 2nd edition (December 1, 2020)
3. Pyzdek, T., & Keller, P. (2013). Handbook for quality management: A complete guide to operational excellence. McGraw-Hill Education.
4. Unlocking Lean Six Sigma: A Competency-Based Approach to Applying Continuous Process Improvement Principles and Best Practices by Dr. Wesley E. Donahue, Kindle Edition
5. Rathi, R., Garza-Reyes, J., Kaswan, M. S., & Singh, M. (Eds.). (2023). Lean Six Sigma 4.0 for Operational Excellence Under the Industry 4.0 Transformation. CRC Press.
6. Pažek, K. (Ed.). (2021). Lean Manufacturing. BoD–Books on Demand

#### **Workshop 3. "A3 Problem solving "**

A3 thinking is based on the plan-do-check-act cycle. This powerful way of thinking developed by Toyota is written on ledger-sized paper (11 x 17 inches) – the A3 report – that a team can use to define or clarify problems, suggest solutions, and record the results of improvement activities. The report is broken into different sections, each clearly labeled and arranged in a logical flow. The A3 report is an effective tool because it contains not only text, but also pictures, diagrams, and charts, all of which enrich and clarify the data and improve communication.

The report typically has left and right sections, with many blocks in each section.

On the left section, there are four headings:

**Theme:** Succinctly states the problem(s) being addressed in one or two sentences.

**Background:** A description of all pertinent information needed to understand the scope of the problem at hand.

**Current Condition:** Helps develop an understanding of what is currently happening using a value-stream map. The map should be enhanced by inserting quantitative information (e.g., setup times, takt time), notes, and illustrations to enhance readability and help develop a good understanding of all existing conditions.

**Cause Analysis:** Helps determine the cause of the current problem, using various root cause analysis tools, ideally the 5 Why's technique.

On the right section, there are three headings:

**Target Condition:** Considerations of possible improvement ideas that could rectify the problem. Toyota calls these improvement ideas "countermeasures," implying that a solution is currently being reached for a specific problem only until a better solution is found. These countermeasures are the objective the team uses to draw the target condition or future state map, which shows how the improved process will work with these countermeasures in place.

**Implementation Plan:** Identifies the steps that need to be completed to realize the improvements outlined under the future state map. The participants clearly write the changes necessary to improve the process, prioritize the changes, establish a timeline to complete the changes, and identify the expected results.

**Follow-Up:** The activities that are not completed in the time outlined, which help document problems encountered during the implementation so the future implementation can be improved. In addition, results of the implementation are also written down to outline what specific improvements have been realized.

Below is a completed problem-solving A3 report for NOVA POSHTA case.

**Task 1.** Review, discuss, and make adjustments as needed.

**Task 2.** Complete the quiz 1 <https://forms.office.com/e/BNWYqhPTzY>

### *References*

1. Quality Resources. The world's most comprehensive library of quality resources. <https://asq.org/quality-resources/>
2. Learn Toyota's 8 Step Practical Problem Solving Methodology. <https://youtu.be/gd3uUI2fFPA?si=nV0qMmdUzHab1fA9>
3. The Toyota Way: 14 Management Principles from the World's Greatest Manufacturer by Jeffrey Liker McGraw Hill; 2nd edition (December 1, 2020)
4. Pyzdek, T., & Keller, P. (2013). Handbook for quality management: A complete guide to operational excellence. McGraw-Hill Education.
5. Pažek, K. (Ed.). (2021). Lean Manufacturing. BoD—Books on Demand

<b>Background</b>	PLAN
customers complain about queues. branches are overloaded with parcels for customer service, more and more employees are needed in the branch, that is, the efficiency of the branch decreases	
<b>Current condition</b>	PLAN
Receiving (15 min) : 1. The client contacts the operator. The operator enters data into the database, identifies the parcel, receives payment and prints a check (5 min) 2. The client turns to the porter, who finds the parcel on the receipt and hands it over to the client (10 min). Shipping (12 min): 1. The client provides information about the sender and the recipient, the operator enters the data into the database and issues a waybill to the client (copy) (5 min). 2. Operator packs the parcel and labels it (5 min), load it on pallet (7 min) Queue is 2 – 5 people Number of employees in department - 10	
<b>Goal / Target Condition</b>	PLAN
Shortening queues at the branch to..... Increasing the department's productivity..... Speeding up the process of unloading parcels to.....	
<b>Root Cause Analysis</b>	PLAN
complain about queues → they wait too long → 1) operators and porters served for too long , → the porter is looking for the parcel for a long time → <b>the marking on the receipt does not indicate the location of the parcel, the location is far from the carrier</b> 2) customer spends time going to the porter → girls work as operators, they do not carry heavy parcels → <b>the marking on the receipt does not indicate the weight or volume of the parcel, the parcels are far from the operator</b> 3) customers do not see part of the operators due to the pillar in the middle of the room, and therefore do not go to them.	

### A3: <problem statement>

Owner:	
Mentor:	
Date:	

<b>Countermeasures (experiments)</b>	DO
enter the marking of parcels taking into account their weight enter the marking of parcels in accordance with their location rearrange equipment and furniture	
<b>Confirmation (results)</b>	CHECK
Shortening queues at the branch to..... Increasing the department's productivity..... Speeding up the process of unloading parcels to..... the complaints stopped The number of customers increased by 40% due to improved service conditions	
<b>Follow up (actions)</b>	ACT
Sharing experience on another branches	



## **Workshop 4. Initiation of the QMS project.**

### **Case OILBI**

The OILBI company is a small enterprise with a unique technology: extraction of concentrate from vegetable (sunflower) oil. Concentrate of vegetable origin, without preservatives and additives. Contains a complex of Omega-fatty acids (3,6,9), 100% fatty acids.

Equipment: thin-film distiller, pumps for supplying raw materials and finished products, cooling compressor, pumping system.

To confirm the quality of the final product, the company uses the services of an independent laboratory. An independent laboratory provides a conclusion on the compliance of the final product with the requirements of TU U 20.1-32576132-003:2018 (industry standard).

The company's clients are pharmaceutical factories; manufacturers of perfumes and cosmetics; beauty salons.

The company's suppliers are trading firms, farmers - suppliers of vegetable oils.

The company also uses the services of the Independent Laboratory Research Center (a laboratory that provides a conclusion on the final product) and equipment maintenance and repair companies.

The company's own property is a premises with an area of 200 square meters, which is a warehouse for raw materials, a dressing room and a toilet, a laboratory, premises for a pumping station, a hardware shop, a warehouse for finished products and office premises.

The company's staff consists of the (1) Director, who also performs the functions of the Manager of the purchase of raw materials and the sale of finished products, the (2) Head of Production and the (3) Equipment Operator, the (4) Storekeeper (managing the supply of raw materials and the acceptance of finished products) and who also performs the functions the Laboratory Technician (the person responsible for laboratory measurements and conformity of the quality of raw materials and finished products), and (5) Senior Accountant who performs the role of HR manager. Production is serially produced depending on the volume of orders.

The global task is to prepare the company for certification for compliance with the requirements of ISO 9001:2015.

**Task 1.** Create the plan of actions need to be done.

### **Solution.**

1. Diagnostic audit (PEST, SWOT, Client research, etc)
2. Determination Company's context and relevant issues (Vision)
3. Establishing a Quality Policy
4. Register of objectives and risks

**Task 2.** Suggest and formulate your clients needs. Create a questionnaire for survey.

### **Types of customer needs (example)**

– Price - The item is affordable and appropriately priced for the quality;

- Convenience - Saves time and effort;
- Image and status (as in an item of clothing or technology) - Looks good, impresses others, makes the customer feel good about themselves;
- Durability and lifespan - Built to last, dependable, and won't break;
- Packaging type - Resealable, refillable, recyclable, or all of the above;
- Support and aftercare - Customer knows they can get questions answered and problems solved;
- Effectiveness - Gets the job done;
- Formulation - Free from unwanted ingredients or materials, containing desirable elements (for example gluten-free, or containing active friendly bacteria).

### Solution

Stakeholders	Needs / expectations
Clients	<ol style="list-style-type: none"> <li>1. Adequate product quality (compliance with the requirements established by the customer, as well as the requirements of regulatory acts).</li> <li>2. Adherence to the production and delivery terms agreed with the customer.</li> <li>3. Quality service (in particular, customer consultations)</li> </ol>
Supervisory bodies, public organizations, individual citizens interested in preserving the environment	<ol style="list-style-type: none"> <li>1. Ensuring safety when using products manufactured by the enterprise.</li> <li>2. Compliance with requirements for emissions of harmful substances into the atmosphere, soil and water.</li> <li>3. Compliance with noise level requirements around the enterprise.</li> </ol>
Company employees	<ol style="list-style-type: none"> <li>1. Adequate salary level.</li> <li>2. Compliance with labor and social guarantees.</li> <li>3. Absence of any form of discrimination.</li> <li>4. Maintenance of proper, comfortable working conditions.</li> <li>5. Additional work motivation.</li> </ol>
Contractors	<ol style="list-style-type: none"> <li>1. Timely fulfillment of orders.</li> <li>2. Favorable, acceptable price.</li> <li>3. Timely payment.</li> <li>4. Timely fulfillment of all other contractual obligations.</li> </ol>
Bodies of state power and local self-government	<ol style="list-style-type: none"> <li>1. Timely and full payment of taxes, fees and other mandatory payments;</li> <li>2. Compliance with legislation: labor, environmental, labor protection, land, construction regulations, etc</li> </ol>
Society as a whole	<ol style="list-style-type: none"> <li>1. Creation of jobs.</li> <li>2. Payment of taxes and fees to meet social needs.</li> <li>3. Creating a positive image of the Ukrainian manufacturer.</li> </ol>
Company owner	<ol style="list-style-type: none"> <li>1. Steady profit growth.</li> <li>2. Equity growth</li> </ol>

### References

- 1 Lebedynets, V., Prokhorenko, O., Brin, P., & Nehme, M. (2022). On the way to QMS implementation: the main milestones and issues in emerging economy. *Torun International Studies*, 1(15), 113–131.
- 2 ISO 9001:2015 Quality management systems — Requirements. INTERNATIONAL STANDARD ISO 9001
- 3 ISO 9000:2015 Quality management systems — Fundamentals and vocabulary

- 4 B2B Market Research Questions <https://www.driveresearch.com/market-research-company-blog/b2b-market-research-questions/>
- 5 Questionnaire Templates & Examples <https://eu.jotform.com/form-templates/customer-questionnaire>
- 6 Customer needs analysis: Definition & research methods <https://www.qualtrics.com/experience-management/research/customer-needs-analysis/>
- 7 What is Customer Satisfaction? <https://asq.org/quality-resources/customer-satisfaction>

**Workshop 5. SIPOC diagram. Registers of risks and opportunities.**

The quality management principles are: customer focus; leadership; engagement of people; process approach; improvement; evidence-based decision making; relationship management.

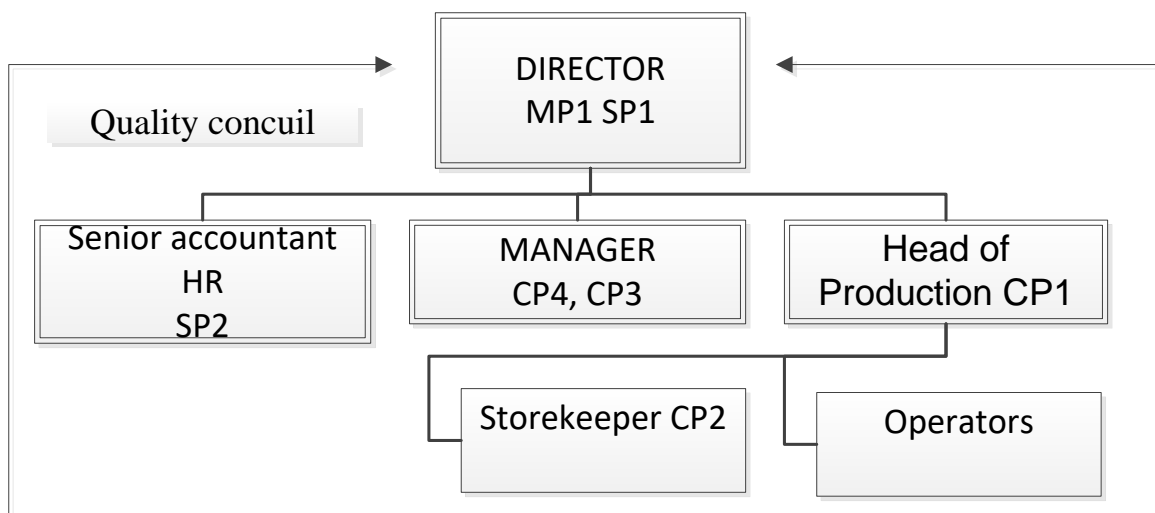
The **process approach** involves the systematic definition and management of processes, and their interactions. A SIPOC diagram documents business's suppliers, inputs, process, outputs, and customers. It isn't meant to provide too much detail, but rather give decision-makers key information about each process. Most often, SIPOC diagrams are used to improve or understand processes associated with customer experience.

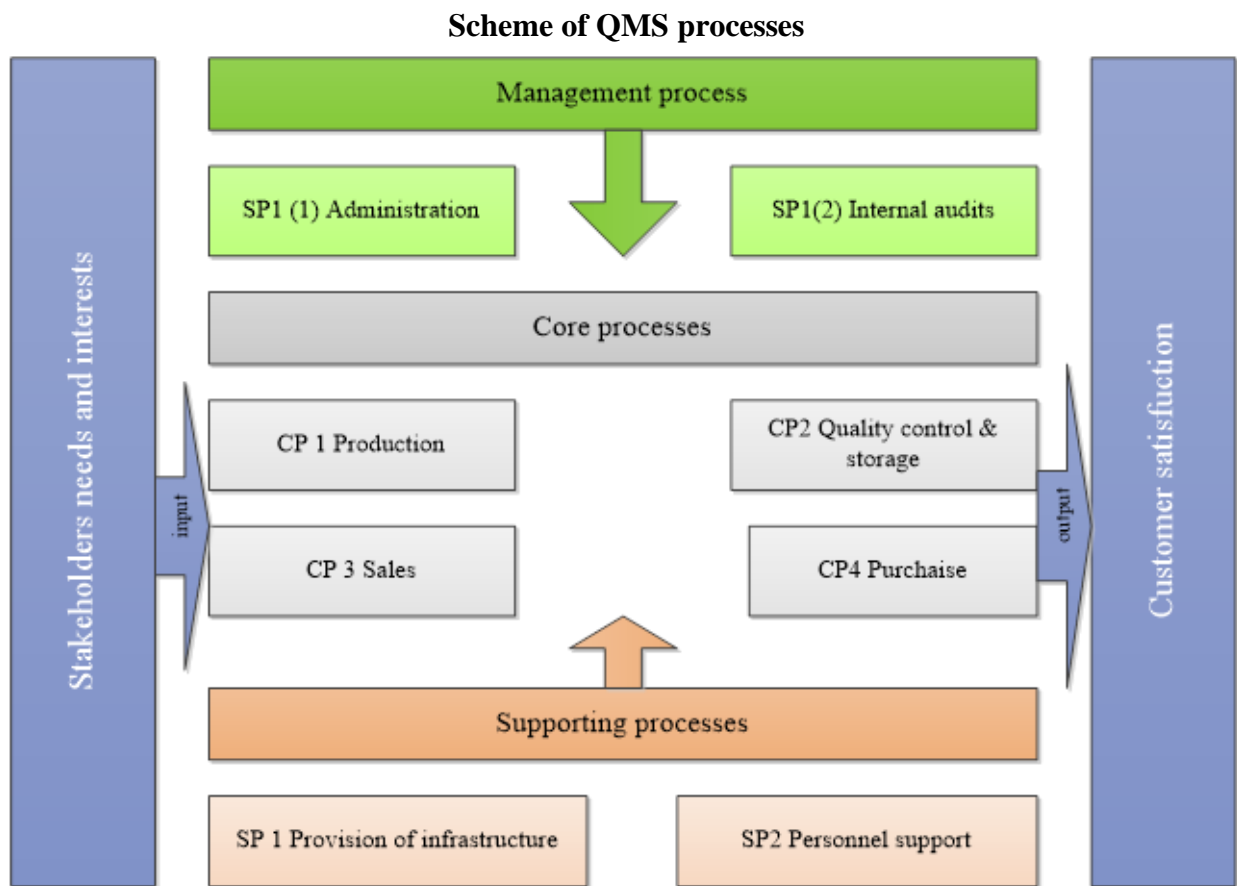
Supplier	Input	Business-process	Output	Client

**Task 1.** Using the case OILBI complete organizational chart and select business-processes.

**Solution.**

**Organization structure**





The concept of **risk-based thinking** has been implicit in previous editions of International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analysing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities.

**Task 2.** Using the case OILBI and the template below complete register of risks and opportunities

### *References*

1 Lebedynets, V., Prokhorenko, O., Brin, P., & Nehme, M. (2022). On the way to QMS implementation: the main milestones and issues in emerging economy. *Torun International Studies*, 1(15), 113–131.

2 ISO 9001:2015 Quality management systems — Requirements. INTERNATIONAL STANDARD ISO 9001

3 ISO 9000:2015 Quality management systems — Fundamentals and vocabulary

4 What is a SIPOC diagram? 7 steps to map and understand business processes.

<https://asana.com/resources/sipoc-diagram>

## REGISTER OF RISKS AND OPPORTUNITIES

№	Process code	Risk	Potential impact (threat / opportunity)	Cause of occurrence	Degree of im-	Probability	Risk rate	Measures to minimize risk / promote opportunity	Responsible executor /
<b>MP 1 Administration</b>									
1	<b>MP 1</b>	Lack of ideas regarding the development of the company's activities	Cessation of development, indirect losses, loss of customers, reduction of orders, direct losses / Rest and revival of a "fresh look", Diversification of activity	Ignoring or misrepresenting trends and prospects for the development of the industry, market conditions.  Lack of results or incorrectly conducted marketing research. Insufficient qualification of the manager	3	2	<b>6</b>	To improve technical and marketing research activities, Participate in professional exhibitions and conferences.  To invite leading specialists from various areas of the company's activities for work or for the purpose of practical consultations, trainings, seminars. Participate in benchmarking projects.	Director / During the year / The risk is acceptable, precautions are not required
2	<b>MP 1</b>	Incorrect or incomplete audit results	Obtaining unreliable or incomplete audit data can negatively affect management decision-making and planning  / Possibility of obtaining unexpected results	<ul style="list-style-type: none"> <li>- Lack of support from management</li> <li>- Incompetence of auditors</li> <li>- Bias or personal interest of the auditor in the audit results</li> </ul>	3	3	<b>9</b>	Involvement of at least one external auditor and appointment of him/her as the Chief Auditor  Appointment of a specific person as the chief auditor and training him/her to obtain an auditor certificate at an independent training center	Director
<b>Production (CP1)</b>									
3	<b>CP1</b>	Violation of order production deadlines	Loss of income, penalties, loss of client  / Possibility to achieve shorter than agreed order execution time if delays are effectively eliminated	<ul style="list-style-type: none"> <li>- Untimely supply of raw materials</li> <li>- Schedule overload (technical impossibility)</li> <li>- Equipment failure</li> </ul>	3	4	<b>12</b>	<ul style="list-style-type: none"> <li>- Creation of an insurance reserve for finished products</li> <li>- Creation of an insurance reserve for raw materials and materials</li> </ul> Timely warning of equipment failure	Head of production
4	<b>CP1</b>	Release of products that do not meet established requirements	Penalties, increased costs, impact on company reputation.  / Possibility of selling at a reduced price	<ul style="list-style-type: none"> <li>- Operator error.</li> <li>- Non-compliance with the requirements of the technological process</li> </ul> Equipment and / or measuring equipment failure	5	4	<b>20</b>	<ul style="list-style-type: none"> <li>- Testing operators' knowledge of the control stages of the technological cycle of product production.</li> <li>- Timely briefing for operators.</li> <li>- Timely update technical documentation, taking into account corrective actions in the technological process.</li> <li>- Timely warning of equipment failure</li> </ul>	Head of production



## **Workshop 6. . Establishing a Quality Policy. Register of objectives (OKR).**

**Task 1.** Using the case OILBI and results of previous tasks complete the vision and quality policy)

**Solution** (see Annexes A and B).

Objectives and Key Results (OKR) methodology can be used by any sized organization in any sector and helps create an analytical basis for decision making and helps focus attention on what matters most.

Examples of OKRs

Objective: Increase Customer Retention

Key Result 1: Reduce customer churn rate by 15% by the end of the quarter

Key Result 2: Increase the number of customer referrals by 20% by the end of the quarter

Action: revamp and market our customer referral program

Objective: Improve Product Quality

Key Result 1: Increase our product quality customer satisfaction survey score to 8 or higher within the next month

Key Result 2: Reduce the number of product defects by 20% by the end of the quarter

Action: Implement a new quality control process and train all employees on how to use it within the next month

Objective: Increase Customer Satisfaction

Key Result 1: Improve our customer satisfaction survey score to 90% or higher within the next month

Key Result 2: Launch a customer appreciation program and register 500 sign-ups by the end of the quarter

Action: Launch a customer feedback campaign and implement suggested changes

KPIs and OKRs are similar in definition and purpose. Key Performance Indicators (KPIs) are the critical (key) indicators of progress toward an intended result. They help you understand if you are achieving your goals. The primary difference is the way they are implemented. KPIs tend to be tracked continuously on a dashboard, while OKRs tend to be scored quarterly in a yes/no fashion depending on whether not a particular OKR was achieved. For example, an organization might track a product quality measure on a dashboard for years and years. A short-term OKR might be to improve that quality measure by 10% by the end of a particular quarter.

Balanced Scorecard is the system that make OKRs so effective, such as a regular cadence of iterative strategy adjustment and a focus on individual accountability, target setting and action planning. To take advantage of the strengths of both tools, Balanced Scorecard should be used to frame and operationalize high-level strategy. Mission, Vision, Values, Goals, Objectives, Measure, Targets, and Initiatives should all be organized and aligned so that individuals and teams creating their OKRs understand what the organization is trying to accomplish. Alignment is created by connecting Objectives at each level and is managed in an iterative, bidirectional manner.

**Task 1.** Using the case OILBI and the template below complete register of objectives

REGISTER OF OBJECTIVES

Process code and name / Process owner	Goals	deadlines
<p>Administration (MP1) Director</p>	<p>Develop and implement the procedure for evaluating suppliers (outsourcers) of the main groups of services (transportation, legal support, information and technical support, hosting/maintenance of the company's website). Form a portfolio of service providers: ensure the availability of signed contracts for each group of the nomenclature with at least 2 potential suppliers.. To prepare a competent auditor from among the company's employees to organize and systematically conduct internal audits of the QMS 4. Develop, document and put into practice the procedure for conducting internal audits to diagnose and develop the company's QMS</p>	<p>01.11.2025 01.12.2025 01.08.2025 01.08.2025</p>
<p>Production (CP1) Head of Production</p>	<p>To ensure the initial quality of products in accordance with TU.U 20.1-32576132-003:2018 at the level of at least 95% of production volumes. Confirmation of quality is the Protocol of an independent test of a certified laboratory. Establish the regulation of the production process and its main parameters (time, productivity, labor costs, energy consumption, share of waste, share of repair defects, etc.) and ensure compliance with the regulation by at least 95% (or in more detail for each item of the regulation): by 3. Ensure the level of claims (the number of produced orders with quality claims relative to the total number of produced orders for the same period of time) is no more than 5% per year. The analysis should be carried out every six months.</p>	<p>01.12. 2025.</p>
<p>Quality control &amp; Storage (CP2) Storekeeper</p>	<p>1. Introduce electronic logs of registration of the results of incoming, current and outgoing control 2. Ensure 100% incoming quality control of all batches of raw materials and materials.</p>	<p>01.06.2025.</p>
<p>Sales (CP3) Manager</p>		
<p>Purchase (CP4) Manager</p>		
<p>Personnel support (SP2) Senior Accountant / HR manager</p>		
<p>Provision of infrastructure (SP1) Head of Production</p>		

### *References*

- 1 Lebedynets, V., Prokhorenko, O., Brin, P., & Nehme, M. (2022). On the way to QMS implementation: the main milestones and issues in emerging economy. *Torun International Studies*, 1(15), 113–131.
- 2 ISO 9001:2015 Quality management systems — Requirements. INTERNATIONAL STANDARD ISO 9001
- 3 ISO 9000:2015 Quality management systems — Fundamentals and vocabulary
- 4 40 Best Manufacturing KPIs and Metric Examples for 2024 Reporting <https://insightsoftware.com/blog/30-manufacturing-kpis-and-metric-examples/>
- 5 Supplier management KPIs <https://taulia.com/resources/blog/supplier-management-kpis/>

### **Workshop 7. Documented procedure**

The terms 'documented procedure' and 'record' used in ISO 9001:2015 have both been replaced by the term 'documented information', which is defined as information required to be controlled and maintained by an organization, as well as the medium on which it is contained.

An efficient and sustainable organization of the technical work requires of the definition and establishment of documented technical procedures. Such procedures allow to ensure the harmonization in work practice and fulfilment of minimal requirements for ensuring a commensurable quality of the results. The technical procedures shall include:

- a clear definition of the scope of the procedure;
- a technical description of the theoretical (or implicit) principles on which the procedure is based on;
- the main steps to be followed and the sequence of tasks to be performed;
- the format to report the achieved results;
- a clear statement of the criteria of quality performance achieved.

**Task 1.** Using the case OILBI complete documented procedure of any of process/

**Solution** (see Annexes C and D).

### *References*

- 1 Lebedynets, V., Prokhorenko, O., Brin, P., & Nehme, M. (2022). On the way to QMS implementation: the main milestones and issues in emerging economy. *Torun International Studies*, 1(15), 113–131.
- 2 ISO 9001:2015 Quality management systems — Requirements. INTERNATIONAL STANDARD ISO 9001
- 3 ISO 9000:2015 Quality management systems — Fundamentals and vocabulary
- 4 Process documentation: The ultimate how-to with examples. <https://asana.com/resources/process-documentation>
- 5 ISO 9001 Procedures. <https://www.iso-9001-checklist.co.uk/iso-9001/iso-9001-templates.htm>

## **Workshops 8-9. Internal audit (Business game)**

ISO 19011:2018 defines an audit as a "systematic, independent and documented process for obtaining audit evidence [records, statements of fact or other information which are relevant and verifiable] and evaluating it objectively to determine the extent to which the audit criteria [a set of policies, procedures or requirements] are fulfilled."

**Process audit** verifies that processes are working within established limits. It evaluates an operation or method against predetermined instructions or standards to measure conformance to these standards and the effectiveness of the instructions. A process audit may:

- Check conformance to defined requirements such as time, accuracy, temperature, pressure, composition, responsiveness, amperage, and component mixture.
- Examine the resources (equipment, materials, people) applied to transform the inputs into outputs, the environment, the methods (procedures, instructions) followed, and the measures collected to determine process performance.
- Check the adequacy and effectiveness of the process controls established by procedures, work instructions, flowcharts, and training and process specifications.

### **Four Phases of an Audit cycle (PDCA)**

**P - Audit planning and preparation** consists of planning everything that is done in advance by interested parties, such as the auditor, the lead auditor, the client, and the audit program manager, to ensure that the audit complies with the client's objective. This stage of an audit begins with the decision to conduct the audit and ends when the audit itself begins.

**D - Audit execution** is often called the fieldwork. It is the data-gathering portion of the audit and covers the time period from arrival at the audit location up to the exit meeting. It consists of multiple activities including on-site audit management, meeting with the auditee, understanding the process and system controls and verifying that these controls work, communicating among team members, and communicating with the auditee.

**C - Audit reporting:** The purpose of the audit report is to communicate the results of the investigation. The report should provide correct and clear data that will be effective as a management aid in addressing important organizational issues. The audit process may end when the report is issued by the lead auditor or after follow-up actions are completed.

**A - Audit follow-up and closure:** According to ISO 19011, clause 6.6, "The audit is completed when all the planned audit activities have been carried out, or otherwise agreed with the audit client." Clause 6.7 of ISO 19011 continues by stating that verification of follow-up actions may be part of a subsequent audit.

### **Game plan.**

Students are divided into 2 groups. Group 1 plays the role of auditors who must audit the process(es) owned by students in Group 2. Process owners (group 2) provide auditors (group 1) with a documented procedure of their process in advance. Auditors (group 1):

- prepare a checklist (see Annex E);
- conduct an audit survey of process owners and eliminate conformities and non-conformities;

- prepare an audit report (see Annex F) and announce it to the process owners.

Then the groups change roles.

When preparing the checklist, the auditor should review the documented procedure and prepare questions to ensure that the process meets the requirements of:

a) the ISO 9001:2015 standard;

b) the documented procedure;

as well as allows for the appropriate result.

Based on the audit results, each group should discuss the audit report and develop corrective and preventive actions. Each group of owners should also report whether they consider it appropriate to make changes to the documented procedure of their process.

**Participation in the game is assessed by lecturer (mentor) according to the following criteria:**

- correctness of the auditor's checklist (audit content);
- auditors' behavior during the audit (result-oriented, tactful, complete use of data collection opportunities)
- completeness of the audit report.

#### *References*

- 1 Lebedynets, V., Prokhorenko, O., Brin, P., & Nehme, M. (2022). On the way to QMS implementation: the main milestones and issues in emerging economy. *To-run International Studies*, 1(15), 113–131.
- 2 ISO 9001:2015 Quality management systems — Requirements. INTERNATIONAL STANDARD ISO 9001
- 3 ISO 19011:2018 – Auditing Management Systems
- 4 What Is Auditing? <https://asq.org/quality-resources/auditing>

#### **Workshop 10. Final test and discussion**

**Task 1.** Go to the 1-st task (workshop 1). Writing essay " How I understand quality management and what are its benefits for the organization?" placed on padlet [https://padlet.com/a\\_prokhorenko/how-i-understand-quality-management-and-what-are-its-benefit-9uu9u28aypyeekon](https://padlet.com/a_prokhorenko/how-i-understand-quality-management-and-what-are-its-benefit-9uu9u28aypyeekon)

And add a comment if your opinion has changed after taking this course.

Discussion

**Task 2.** Complete the quiz 2. <https://forms.office.com/e/NrM1cbVPj8>

## REFERENCES

- 1 ISO 9001:2015 Quality management systems — Requirements. INTERNATIONAL STANDARD ISO 9001
- 2 ISO 9000:2015 Quality management systems — Fundamentals and vocabulary
- 3 ISO: Global standards for trusted goods and services. <http://www.iso.org/iso/home.html>;
- 4 The International Quality Awards 2025 are open for entries. <http://www.irca.org/>;
- 5 Pyzdek, T., & Keller, P. (2013). Handbook for quality management: A complete guide to operational excellence. McGraw-Hill Education.
- 6 Total Quality Management: Key Concepts and Case Studies (D.R Kiran, 2016).
- 7 Conformity assessment. Requirements for bodies providing audit and certification of management systems : ISO/IEC 17021:2011 – [Valid from 2011-02-01]. – Second edition, 2011. – 44 p
- 8 The Toyota Way: 14 Management Principles from the World's Greatest Manufacturer by [Jeffrey Liker](#) McGraw Hill; 2nd edition (December 1, 2020)
9. Quality Resources. The world's most comprehensive library of quality resources. <https://asq.org/quality-resources/>
- 10 Unlocking Lean Six Sigma: A Competency-Based Approach to Applying Continuous Process Improvement Principles and Best Practices by Dr. Wesley E. Donahue, Kindle Edition
11. Rathi, R., Garza-Reyes, J., Kaswan, M. S., & Singh, M. (Eds.). (2023). Lean Six Sigma 4.0 for Operational Excellence Under the Industry 4.0 Transformation. CRC Press.
12. Pažek, K. (Ed.). (2021). Lean Manufacturing. BoD–Books on Demand.
13. Bedgood, C. J. (2024). A Leader's Guide to Designing High Performing Quality Management Systems: The 7 Keys that Solve, Achieve, Sustain, and Transform Organizational Outcomes in High-Risk Environments. CRC Press.
14. Adam, P. A. (2023). Agile in ISO 9001: How to Integrate Agile Processes Into Your Quality Management System. Springer Nature.
15. Lebedynets, V., Prokhorenko, O., Brin, P., & Nehme, M. (2022). On the way to QMS implementation: the main milestones and issues in emerging economy. *Torun International Studies*, 1(15), 113–131.

## ANNEX A

### VISION "OILBI" LLC

for the period until 2027

LLC "OILBI" positions itself on the market as a manufacturer of a unique product made of high-molecular compounds, in particular, concentrates of omega-fatty acids and related products.

Our products are ingredients for pharmaceutical and cosmetic products, used both in industry and at home. Such use is possible thanks to the quality and safety of the product, the functionality of its assortment, the convenience of packaging and detailed accompanying documentation.

The **mission** of our company is to create ingredients for the beauty and health industry. This is our contribution to ensuring the development of Ukrainian industry and small business.

We strive to develop in such directions.

1. Improving product quality and bringing it into line with global standards
2. Active promotion of products and acquisition of new knowledge through participation in specialized exhibitions and competitions, laboratory testing.
3. Ensuring incoming quality due to stable and balanced relations with suppliers.
4. Consolidation in the B2B sector through the conclusion of contracts with leading manufacturers of the pharmaceutical and cosmetic industry of Ukraine, as well as with representatives of small businesses. We expect an increase in the volume of sales in absolute terms by at least 5% annually.
5. Development of the product range due to new ingredients and packaging doses,
6. Entering the B2C sector thanks to the development of the range of products, in particular, packaging doses, through the creation of an online store and accompanying demonstration materials.
7. Entering the international market and concluding a contract with foreign companies in the amount of 10% of the B2B sector.

The company's **sales channels** are direct interaction with key customers in the B2B sector, in the future - an online store.

The company's **key partners** are suppliers of external resources (enterprises for the production of vegetable oil, glass containers, packaging and labeling), certified research laboratories, suppliers of transport services, IT service based on contractual relations. The company has created a database of suppliers, which is subject to constant monitoring, evaluation and updating.

Production, warehouse and office premises are our own property and allow us to effectively use the company's capacities and realize its potential.

The company's **key resources** are production facilities, technologies, personnel.

The **production capacities** and technologies of the company are able to ensure the indicated increase in sales volumes and the required level of output quality.

The **company's staff** is highly qualified and open to new knowledge, aware of the goals and directions of the company's development, and interested in achieving the specified goals.

The company's **core values** are creativity and responsibility, and the company encourages staff to implement these values through two-way communication, transparency, and material and moral motivational means.

Director

Igor IVCHENKO

## ANNEX B

### QUALITY POLICY LLC "OILBI"

Our company is a Ukrainian producer of organic polyunsaturated fatty acids. Our product is used in the cosmetic and pharmaceutical industry, in Ukraine and abroad. In the near future, the "OILBI" product will be available for home use as well.

The main goal of the Company is to ensure the stable quality and safety of products in accordance with national and international standards for the maximum satisfaction of the needs and expectations of consumers.

Achieving this goal is realized due to the following principles:

- involvement of competent specialists in all main processes and constant improvement of their skills;
- purchase of all types of resources only from verified suppliers;
- timely, high-quality maintenance and responsible operation of production equipment, measuring equipment, communications and other elements of the company's infrastructure;
- constant provision of proper sanitary conditions at the workplace, compliance with all requirements for personnel hygiene;
- laboratory control of all batches of finished products;
- constant motivation of employees to ensure a responsible attitude to their work, constant search for improvement opportunities;
- support for systematic feedback from customers, as well as proper response to complaints, claims, wishes and other appeals of interested parties;
- improvement of the quality management system based on the assessment of its effectiveness, diagnosis of processes by conducting internal audits, development of corrective actions and actions to optimize activities;
- systematic analysis of the company's activities by management, identification of risks and taking timely actions to minimize them.

The Company's management is responsible for implementing the Policy in the field of quality and communicating it to all employees of the enterprise, as well as providing processes with financial and material resources.

Director

Igor IVCHENKO

**ANNEX C**  
**PROCESSES REGLAMENT**

Core processes: CP1 – Production, CP2 – Quality control & Storage, CP – Sales, CP4 – Purchase,  
 Supporting processes: SP1 – Provision of infrastructure, SP2 – Personnel support  
 Management processes: MP1 – Administration

Processes Suppliers	Input	Process Code and Name / Process Owner	Output	Processes Clients
<i>Administration</i>	Vision, Production plan, Budget	<b>Production (CP1)</b> Head of Production	Applications for repair/maintenance/replacement of infrastructure elements	<i>Provision of infrastructure</i>
<i>Sales</i>	Order (contract)		Journal of production accounting. Samples of finished products for control	<i>Sales / Quality control &amp; Storage</i>
<i>Purchase</i>	Information on the receipt of raw materials, materials, and other purchased goods		<b>Finished product, waste</b>	<b>External client</b>
<b>External supplier</b>	Raw materials		Report	<i>Administration</i>
<i>Provision of infrastructure</i>	Information on the condition of production and auxiliary equipment; hardware as a resource (not an input)			
<i>Purchase</i>	Samples of raw materials for control. Certificate of quality	<b>Quality control &amp; Storage (CP2)</b> Storekeeper External counterparty (accredited laboratory)	Test results (test reports / reports of non-conformities / quality certificates)	<i>Purchase</i> <i>Sales</i> <i>External</i>
<i>Production</i>	Samples of finished products for control			

<i>Administration</i>	Vision, Sales plan, Budget	<b>Sales (CP3)</b> <i>Manager</i>	Concluded contract order	<b><i>Production</i></b> <b>External client</b>
<b>External client</b>	Order		A set of documents for shipment (expenditure invoices, reports of completed works, goods and transport invoices, quality certificates, etc.)	<b>External client</b>
<b><i>Production</i></b>	Journal of production accounting. Samples of finished products for control			
<b><i>Quality control &amp; Storage</i></b>	Test results (test reports / reports of non-conformities / quality certificates)		Report	<i>Administration</i>
<i>Administration</i>	Vision, Purchase plan, Budget	<b>Purchase (CP4)</b> <i>Manager</i>	Contract with supplier	<i>Administration /</i> <b>External supplier</b>
<b>External supplier</b>	Information from the supplier (catalogue, price, draft contract); a set of accompanying documentation (waybill, quality certificates, etc.)		Information on the receipt of raw materials, materials, goods. Accompanying documents (waybills, quality certificates, etc.). Application for entry control	<b><i>Quality control &amp; Storage / Production</i></b>
<b><i>Quality control &amp; Storage</i></b>	Test results (test reports / reports of non-conformities / quality certificates)		Return documents or claim	<b>External supplier</b>
			Report	<i>Administration</i>
<b>External contractor</b>	Information from contractors (offers, catalogs, prices or draft contracts)	<b>Provision of infrastructure (SP1)</b> Head of Production	Contract for maintenance, repair, construction work, etc. (for approval and transfer to contractors)	<i>Administration /</i> <b>External contractor</b>
<b><i>All processes</i></b>	Order for repair/maintenance of equipment, facilities, premises, buildings and other infrastructure elements		Information on performed maintenance / repair / replacement / modernization of equipment and other infrastructure elements. Acts of completed works	<b><i>All processes</i></b>
<i>Administration</i>	Resource base development plan (separately or as an element of the annual, quarterly, etc. plan)		Report	<i>Administration</i>

<b>External informational resources</b>	Database of potential employees	<b>Personnel support (SP2)</b> Senior Accountant / HR manager	Information about vacancies. Requirements for the competence of employees	<i>All processes</i>
	Information from organizations engaged in recruitment, training, certification, etc		Training plans and other measures for the development of the competence of employees	
<i>All processes</i>	Information on the current / required competence of personnel		Information about the status of open vacancies	
	Order for closing vacancies		The company's knowledge database	
<i>Administration</i>	Personnel development plan (budget) (separately or as a fragment of the annual, quarterly plan, etc.)		Personnel documentation	<i>Administration</i>
			Report	
<i>All processes</i>	Reports on the performance of processes (quarterly, annual, etc.). Requests/needs for development, approval, updating, replacement, archiving, storage and disposal of documented information, resource needs, etc.	<i>Administration (MP1)</i> Director	Strategy, Vision, Policy, goals of different levels, plans for different periods of time, etc. Budgets. Developed, considered, controlled documentation. Marketing reports. Risk and opportunity action plans. Corrective and preventive action plans. Orders on conducting audits, etc. Program of internal audits Reports on the results of internal audits	<i>All processes</i>
<i>Sales, Purchase</i>	Contracts, customer orders for the purchase of products			
<b>External</b>	Information about market needs, actions of competitors, other interested parties; changes in legislative and regulatory requirements, etc			

Matrix of responsibilities

	CP1 Production	CP2 Quality control	CP3 Sales	CP4 Purchase	SP1 Provision of in- frastructure	SP2 Personnel sup- port	MP1 Administration
Director / Manager			+	+			+
Senior Accountant / HR manager						+	
Head of Production	+				+		
Storekeeper / Laboratory Technician		+					

**ANNEX D**

Limited liability company

"OILBI"

APPROVED

Director

\_\_\_\_\_ Igor IVCHENKO

April 26, 2024

**DOCUMENTED PROCEDURE**

**"ADMINISTRATION"**

**DP MP1**

**Dnipro, 2024**

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### 1 TERMS, DEFINITIONS AND ABBREVIATIONS

**Audit** - systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

**Audit criteria** - set of requirements used as a reference against which objective evidence is compared

**Audit plan** - description of the activities and arrangements for an audit

**Budget** - financial plan adopted for a certain period of time (year, quarter), which shows the projected value of the target income for this period, as well as the costs associated with obtaining such income and the capital that must be attracted to achieve the target indicators.

**Conformity** - fulfilment of a requirement

**Correction** - is an action taken to eliminate a nonconformity.

**Corrective action** - is an action taken to eliminate the cause of the nonconformity.

**Non-compliance** – non-fulfillment of the established requirement.

**Organization's environment** - is a set of internal and external factors that can influence the organization's approach to developing and achieving its goals.

**Preventive action** - an action taken to eliminate the cause of a potential nonconformity or other potentially undesirable situation.

**Process** - set of interrelated or interacting activities that use inputs to deliver an intended result

**Quality policy** – the officially formulated intentions of the company's management; a guideline for setting goals and making decisions in the field of quality.

**Record (protocol)** - a document that contains data on the results obtained or provides evidence of the work performed.

**Risk** - effect of uncertainty: An effect is a deviation from the expected – positive or negative.

**Vision** - a description of the ideal state of the company in the future. Guideline for progress to success.

## **2 REFERENCES**

1. [ISO 9001:2015](#) Quality management systems— Requirements.
2. ISO 9000:2015 Quality management systems — Fundamentals and vocabulary.
3. [ISO 19011:2018](#) Guidelines for auditing management systems.
4. ISO 9004:2018 Managing for the sustained success of an organization—A quality management approach

## **3 PURPOSE AND SCOPE**

The process MP1 "Administration" determines the directions of development and general principles of activity, goals that are set before the Company in general and before each of its processes in particular, carries out a systematic assessment and analysis of the effectiveness of the QMS and the Company's activities as a whole on the basis of internal audits and research of the organization's environment. The results of internal audits are also the basis for further planning of activities.

The process manages activities with:

- organizing and conducting internal audits, analyzing information on the functioning of the QMS in order to determine whether it is suitable, relevant and effective; you-meaning of risks and opportunities;
- planning of the main activity, necessary changes and corrective actions, regulation and documentation of information. Proper functioning of the MP1 ensures continuous improvement of the Company's activities

## **4 RESPONSIBILITY AND AUTHORITY**

The owner of the process is the director of the Company, who is responsible for:

- development and approval of the Vision, Policy in the field of quality, organization of development and approval of the Strategy; plans and budgets;
- organization and conduct of internal audits,
- receipt of information necessary for analysis from all sources specified by this DP;
- ensuring completeness and objectivity of information analysis;
- making a decision to take corrective actions, the need for which arose in the process of analyzing the company's activities.

The responsibility for fulfilling the requirements and monitoring the relevance of this DP is assigned to the director of the Company. Responsibility for the implementation of plans, budgets, adjustments, corrective and preventive actions rests with the heads of processes and structural divisions of the Company.

## 5 PROCESS MODEL

Processes Suppliers	Input	Output	Processes Clients
<i>All processes</i>	Reports on the performance of processes (quarterly, annual, etc.). Requests/needs for development, approval, approval, updating, replacement, archiving, storage and disposal of documented information, resource needs, etc.	Strategy, Vision, Policy, goals of different levels, plans for different periods of time, etc. Budgets. Developed, considered, controlled documentation. Marketing reports. Risk and opportunity action plans. Corrective and preventive action plans.	<i>All processes</i>
<i>Sales, Purchase</i>	Contracts, customer orders for the purchase of products	Orders on conducting audits, etc. Program of internal audits	
<b>External</b>	Information about market needs, actions of competitors, other interested parties; changes in legislative and regulatory requirements, etc	Reports on the results of internal audits	

## 6 PROCESS DESCRIPTION

### 6.1 Process Planning

Process planning involves:

- creation of a collegial body (Quality Council), which participates in the analysis of the Company's activities, as well as determining the powers of such a body;
- determination of the sources of information necessary for analyzing the QMS, as well as the forms of providing such information and its periodicity.
- preparation of the annual audit program, identification of auditors and their proper training;
- drawing up Plans and budgets based on information analysis.

Sources and providers of process planning information are listed in Table 1.

Table 1 Sources of information for documents

Element	Necessary information
Vision	Owner's expectation Information from the outside, in particular about trends in market development. Marketing research
Policy	<ul style="list-style-type: none"> <li>– Vision.</li> <li>– Information about the external environment, in particular about the expectations of customers, market participants and society as a whole.</li> <li>– Results of internal audits and performance analysis reports of all QMS processes.</li> </ul>
Register of risks	– Reports on the results of risk identification and assessment from managers of all QMS processes.
Strategic plan	<ul style="list-style-type: none"> <li>– Vision (Vision).</li> <li>– Quality policy.</li> </ul>

	<ul style="list-style-type: none"> <li>– Information from the outside, in particular about trends in market development. Marketing research Marketing research Marketing research</li> <li>– Proposals of managers of QMS processes.</li> </ul>
Budget	<ul style="list-style-type: none"> <li>– Strategic plan</li> <li>– Results of financial activities for previous years.</li> </ul>

## **6.2 Process execution (Do phase).**

### **6.2.1.High level documentation.**

The Vision is developed by the owner (director) of the Company and can be submitted for consideration by the managers of QMS processes with the opportunity to make suggestions or comments. The Vision is drawn up in an arbitrary form, approved by the Director's order and must be brought to the attention of all employees of the Company.

The quality policy is formulated in accordance with the purpose and environment of the Company, is the basis for setting goals in the field of quality and establishes the obligation to satisfy the applicable requirements and constantly improve the quality management system.

The quality policy is drawn up, communicated and made public in the same order as the Vision.

The register of risks and opportunities is compiled by the director upon submission of information by the managers of all QMS processes by December 25 of the current year, after which it is analyzed (if necessary, adjusted) and approved by the director by January 10 of the following year.

The register of risks and opportunities is used together with other information in the development of the Strategic Plan and Budget.

The strategic plan is a list of the Company's goals, which are formulated no later than December 10 of the year preceding the planned one. The director is responsible for organizing the strategic session. All members of the working group must be notified of the date and place of the strategic session no later than 10 days in advance.

The strategic plan must be brought to the attention of the managers of all processes of the Company and made public as provided for the Policy in the field of quality.

The objectives contained in the Plan should be:

- agreed with the Policy in the field of quality;
- measurable;
- appropriate from the point of view of product compliance and increase of customer satisfaction;
- covered by monitoring;
- brought to the attention of persons involved in their achievement;
- updated

When planning how to achieve your quality goals, you need to determine

- what should be done;
- what resources will be needed;
- who will be responsible;

- when it will be completed;
- how the results will be evaluated.

After discussion and approval by all process managers, the Plan is approved by the Director's Order. On the basis of the Strategic Plan, lower-level plans for individual processes and for short periods are formed.

Budgeting is a technology of financial planning, accounting and control of income and expenses received from the Company's activities at all levels of management, which allows analyzing and determining projected and real financial indicators for each aspect of financial accounting within the approved financial structure.

The purpose of budget planning is to describe the future state of the Company in economic indicators in order to ensure the achievement of financial and economic goals defined by the Strategic Plan. The Company's budget is drawn up by the Chief Accountant and approved by the Director.

### **6.2.2. Internal audits**

Conducting internal audits involves: preparation for conducting an audit of a certain process (analysis of documents for compliance with the requirements of which the audit must be conducted, drawing up an auditor's checklist), conducting an internal audit "on site", drawing up a report based on the results, developing a plan for corrective or preventive actions; checking the effectiveness of their implementation.

In the course of the on-site audit, the auditor must obtain the necessary certificates that allow to draw reasonable conclusions about compliance with the requirements and compliance with the audit criteria. Data collection is carried out by: staff interviews, document analysis and observations of the activities of employees in the field.

Any information important for audit purposes is recorded in checklists.

According to the results of the audit, the head of the audit group no later than a week after the day of the audit draws up a Report on the results of the internal audit, which should contain: number and date, scope of the audit (process); list of auditors, audit criteria (links to regulatory documents); audit results (conclusions) (recorded non-conformities, increased risks, important observations, positive aspects, as well as provided recommendations for improving activities).

The head of the process (department) together with the head of the audit group analyzes the detected inconsistencies and risks, develops a plan of corrective actions to correct the inconsistencies and eliminate (or minimize) the reasons that caused them. The term of implementation of the planned measures must be agreed with the director and the head of the verified process. The manager of the process (department) is responsible for the implementation of the planned measures.

The Director once a year (or as needed) summarizes the results of internal audits and uses them for further planning and identifying opportunities for improving the QMS.

### **6.3 Process evaluation (Check phase)**

The effectiveness of the process is achieved through the thorough and timely implementation of all the provisions of this DP and is evaluated according to the following indicators:

Characteristic of indikator	measurement frequency	Result registration	Responsible persona
The degree of achievement of goals	Once a year	Protocol for evaluating the effectiveness of quality management system processes	Director Quality Council
Quality of auditors' recommendations and proposals	According to the results of internal audits		Director

The methodology for assessing the quality of planning involves surveying the Company's process managers on a 5-point scale, where 1 symbolizes the corresponding plan as "poor" and 5 as "high-quality".

### **6.5 Improvement (Act phase)**

Process improvement should be carried out through:

- the most responsible implementation of all components of the cascade planning system described in this DP;
- optimization of the number of indicators to be planned, so as not to increase the complexity of planning, on the one hand, and not to miss any indicator that is really important;
- increasing the interest of each participant in the planning of the Company's activities in a responsible attitude to this work;
- minimization of the use of subjective factors that can negatively affect the development of plans and their adequate evaluation;
- use of modern planning methods.



ANNEX F

INTERNAL AUDIT REPORT

№ \_\_\_ date \_\_\_\_.\_\_\_\_.202\_\_ .

**1 Purpose:** ascertainment the compliance of the QMS process with the requirements of the ISO 9001 standard, legislative, regulatory and internal requirements, as well as determining the potential for development and improvement of activities.

**2 Audit objects:** Process:  
\_\_\_\_\_  
\_\_\_\_\_

**3 Audit criteria:** ISO 9001:2015, legislative and regulatory framework, regulatory documentation of QMS

**4 Audit team: \***

Auditor 1 (Leader): \_\_\_\_\_  
Auditor 2: \_\_\_\_\_ Auditor 3: \_\_\_\_\_  
Auditor candidate (trainee): \_\_\_\_\_  
Expert (s): \_\_\_\_\_

**AUDIT CONCLUSION:**

*Activities within the checked object:*

- Conforms   
Conforms partially   
Not conforms

<b>NC – non-conformity / CNC – critical non-conformity</b>			
<i>№</i>	<i>Description</i>	<i>Category</i>	<i>Standard point</i>

<b>INCREASED RISKS</b>

**RECOMMENDATIONS FOR IMPROVEMENT**

--

**STRENGTHS**

--

**Head of audit team**

**Process owner**

\_\_\_\_\_.\_\_\_\_\_.202\_\_\_\_

\_\_\_\_\_.\_\_\_\_\_.202\_\_\_\_

ANNEX G

**Limited liability company**

**"OILBI"**

APPROVED

Director

\_\_\_\_\_ Igor IVCHENKO

April 26, 2024

**QUALITY GUIDLINE**

**Dnipro, 2024**

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### 1 GENERAL INFORMATION ABOUT THE COMPANY

The OILBI LLC company is a small business company with a unique technology: extraction of concentrate from vegetable (sunflower) oil. Concentrate of vegetable origin, without preservatives and additives. Contains a complex of Omega-fatty acids (3,6,9), 100% fatty acids.

Equipment: thin-film distiller, pumps for supplying raw materials and finished products, cooling compressor, pumping system.

To confirm the quality of the final product, the company uses the services of an independent laboratory. An independent laboratory provides a conclusion on the compliance of the final product with the requirements of TU U 20.1-32576132-003:2018 (industry standard).

The company's clients are pharmaceutical factories; manufacturers of perfumes and cosmetics; beauty salons

The company's suppliers are trading firms, farmers - suppliers of vegetable oils

The company also uses the services of the Independent Laboratory Research Center (a laboratory that provides a conclusion on the final product) and equipment maintenance and repair companies.

The company's own property is a premises with an area of 200 square meters, which is a warehouse for raw materials, a dressing room and a toilet, a laboratory, premises for a pumping station, a hardware shop, a warehouse for finished products and office premises.

The company's staff consists of the (1) Director, who also performs the functions of the Manager of the purchase of raw materials and the sale of finished products, the (2) Head of Production and the (3) Equipment Operator, the (4) Storekeeper (managing the supply of raw materials and the acceptance of finished products) and who also performs the functions the Laboratory Technician (the person responsible for laboratory measurements and conformity of the quality of raw materials and finished products), and (5) Senior Accountant who performs the role of HR manager. Production is serially produced depending on the volume of orders.

The company works with more than 12 customers from Ukraine, as well as from 3 countries of Europe, the former USSR and North America.

The company's products are provided with detailed instructions for storage, transportation and intended use.

The company cooperates with certified laboratories to conduct research on product quality and improvement.

## 2 ORGANIZATIONAL ENVIRONMENT. EXTERNAL AND INTERNAL FACTORS

In accordance with the requirements of the ISO 9001:2015 standard, the Company determines, monitors and analyzes information on external and internal factors that are appropriate for its purpose and that affect the Company's ability to achieve planned results. The Company's PEST analysis presents the factors of the macro environment and their impact on the results of operations. The analysis of suppliers, strategic partners, competitors and customers (SSCC-analysis) allows to reveal the direct impact on the Company's activities.

### External factors of the macro environment (PEST analysis)

<i>Factor</i>	<i>Impact</i>	<i>Rate</i>
<b><i>Political and legal</i></b>		
<i>Legislation of Ukraine</i>	Establishing requirements for products or the quality management system as a whole. Establishing requirements for labor relations. Establishing requirements for business relations with counterparties	
<b><i>Economical</i></b>		
<i>Rates of taxes, fees and other mandatory payments</i>	The size of these rates significantly affects the formation of the cost of products and, accordingly, the competitive position of the Company in the market, and also determines the amount of profit that remains at the disposal of the Company	
<i>Foreign currency exchange rates</i>	Foreign currency exchange rates have an indirect effect on the cost of raw materials, contractor services, the level of wages, etc.	
<i>Bank rates</i>	Changes in lending rates affect the ability to attract additional financial resources to ensure sustainable growth	
<i>Markets served by the Company</i>	Since the market of the pharmaceutical and cosmetic industry is developing at a fairly fast pace, both in large and small business, the Company must foresee appropriate directions of growth not only in B2B (Business-To-Business), but also in B2C (Business-To-Consumer) sectors	
<i>Minimum wage</i>	The size of the minimum wage indirectly affects the cost of raw materials and services, contractor services, the amount of taxes, fees and other mandatory payments, labor costs, etc. On the other hand, this factor affects the purchasing power of end consumers	
<b><i>Technological</i></b>		
<i>New technologies on the market</i>	The market on which the Company operates has significant rates of technological development. A necessary condition for maintaining competitive advantages and increasing market share is constant monitoring of changes and the Company's response to them.	
<b><i>Social and cultural</i></b>		
<i>People's attitude towards health and look</i>	Since the Company's products are oriented towards the cosmetic industry, the Company is significantly influenced by the public's attitude towards appearance and health care. Today, this factor has a beneficial effect in Ukraine, because the desire to look good turns into a constant need	

### External factors of the microenvironment (SSCC)

Factor	Impact	Rate
<b>Suppliers</b>		
Availability on the market, range and cost of raw materials	Availability of a sufficiently large number of producers of raw materials makes it possible to ensure proper selection and guarantee its compliance with requirements. The cost of raw materials, materials and other goods and material values, as well as energy carriers, directly affects the cost price of the Company's products.	
The quality and cost of contractors' services	The quality and cost of contractors' services affects the final result and the cost of the Company's products, and is also one of the key factors for making a decision on making changes to the Company's management system	
<b>Strategic partners</b>		
The quality and cost of transport services	It is essential for compliance with the conditions of storage of quality characteristics of products, and also affects the price of the contract. This factor affects the way products are delivered to the consumer (directly) and the Company's profitability (indirectly)	
Distributors	The presence of distributors increases the Company's sales volume and contributes to the growth of profits. On the other hand, working with distributors reduces the profitability of a product unit and increases the risks associated with reputation, quality of service to end consumers	
<b>Competitors</b>		
Products manufactured by competitors	The Company's products are unique, there are no analogues in Ukraine. However, competition among producers of raw materials / components of finished cosmetic products, containers and packaging in this industry in Ukraine is quite high	
Prices and terms of delivery of competitors.	The company uses the transport services of contractors, therefore the terms of transportation do not have significant differences from competitors	
Working conditions in competing companies	Taking into account the small-scale nature of the construction of production "to order", the payment of labor has a rather high dependence on the frequency and volume of orders. At the same time, the Company creates favorable working conditions for both office and technical workers, taking into account compliance with occupational health and safety requirements. Therefore, working conditions in the Company are not worse, and in some respects are better than competitors	
<b>Clients</b>		
Awareness, loyalty and solvency of customers (B2B sector)	Given that the product is relatively new on the market, the Company should direct significant efforts to promote the product and spread information about it among medical and cosmetology institutions, pharmacies. Loyalty of customers - manufacturers of cosmetic products, beauty salons, etc. - is decisive for ensuring sales and determines the growth or reduction of production, as well as setting requirements for product quality. The solvency of customers depends both on the competent conduct of business and on the solvency of end consumers, and thus also determines the Company's sales volume	
Solvency of end consumers (B2C sector)	The solvency of end consumers of products who consume pharmaceutical or cosmetic products and are clients of beauty salons indirectly affects the demand for the Company's products and is determined by macro-environmental factors	

The company also determines the factors of the internal environment that determine the functioning of the quality management system.

### **Characteristics of internal factors of the company**

<b>Factor</b>	<b>Impact</b>	<b>Rate</b>
Competence and qualifications of personnel	The quality of decisions made by the Company, the ability to implement projects, and constantly improve directly depend on the level of competence of the management team. Competence and qualifications of personnel directly affect the quality of manufactured products, the Company's ability to develop and implement new products, attract customers and promote products.	
Knowledge base	A properly functioning knowledge base ensures compliance with the QMS and the stability of the Company's functioning.	
Corporate culture	Corporate culture affects both the loyalty of employees and the formation of the Company's competitive advantages through the creation of a good image due to high-quality service and product quality	
Working conditions	Working conditions are one of the main factors affecting the level of employee satisfaction with work and their loyalty	
Wage level	Wage level determines the competitiveness of the Company as an employer, and, as it affects the cost of production, indirectly also determines the competitiveness of the Company's products	
Personnel development	Creates an opportunity for employees to effectively obtain the required level of qualifications required for the proper functioning of the Company	
Technologies	Technologies are one of the carriers of the Company's competitive advantages, as they determine product quality at all stages of its creation and, accordingly, consumer satisfaction	
Technical equipment	The availability of appropriate technical equipment is a necessary condition for the proper functioning of the production process, technical control, storage, delivery, etc.	
Company Structure	The Company's structure determines the hierarchical distribution of authority and responsibility, as well as the effectiveness of internal and external relations.	
Quality management system	The integration of the QMS into the company structure determines the possibility of timely and complete diagnostics of its activities, the level of regulation of the performed works that affect the quality of products and the quality of service, registration and analysis of important information, making timely and adequate decisions regarding improvement and minimizing risks, etc.	

The company has identified stakeholders and their requirements that are relevant to the QMS.

### Understanding the needs and expectations of stakeholders

Stakeholders	Needs / expectations
Clients	Adequate product quality (compliance with the requirements established by the customer, as well as the requirements of regulatory acts). Adherence to the production and delivery terms agreed with the customer. Quality service (in particular, customer consultations)
Supervisory bodies, public organizations, individual citizens interested in preserving the environment	Ensuring safety when using products manufactured by the enterprise. Compliance with requirements for emissions of harmful substances into the atmosphere, soil and water. Compliance with noise level requirements around the enterprise.
Company employees	Adequate salary level. Compliance with labor and social guarantees. Absence of any form of discrimination. Maintenance of proper, comfortable working conditions. Additional work motivation.
Contractors	Timely fulfillment of orders. Favorable, acceptable price. Timely payment. Timely fulfillment of all other contractual obligations.
Bodies of state power and local self-government	Timely and full payment of taxes, fees and other mandatory payments; Compliance with legislation: labor, environmental, labor protection, land, construction regulations, etc
Society as a whole	Creation of jobs. Payment of taxes and fees to meet social needs. Creating a positive image of the Ukrainian manufacturer.
Company owner	Steady profit growth. Equity growth

Every year, at team meetings, the Company's management reviews the list of interested parties, as well as their needs and expectations, as well as makes decisions, appoints responsible persons and takes actions to maximize the satisfaction of the relevant needs.

## 3 STRUCTURE AND SCOPE OF THE QUALITY MANAGEMENT SYSTEM

### 3.1 The scope of the quality management system

The Company's quality management system covers processes related to the production of one type of product - the bidistilled "OILBI" fatty acid concentrate; it does not apply to any other activities of the Company.

### 3.2 Exclusion from the requirements of the ISO 9001:2015 standard

The company recognized that the requirements of the ISO 9001:2015 standard relating to the design and development of products and services (Chapter 8.3) **are not relevant** to the scope of the quality management system due to the fact that it is not engaged in the development of new types of

products. The technological process, equipment and premises are exclusively focused on the production and production of bidistilled "Oilbi" fatty acid concentrate.

Also, the requirements of clause 8.5.1 "Control of production of products and provision of services (f)" were recognized **as inappropriate**, because the final output of the technological process is always checked by further measurement of the controlled parameters, respectively, approval and periodic re-approval of the ability to achieve the planned results of the production processes unnecessary

Clause 8.5.3 "Property of customers or external suppliers" of the ISO 9001:2015 standard was also recognized as **inappropriate** requirements, because neither the property of customers nor the property of external suppliers is used in the production of products. The raw materials required for the production of the product are purchased by the Company from external suppliers before they enter the territory of the enterprise. The requirements of clause 8.5.5 "Activities after delivery" were deemed **inappropriate**, because after the delivery of the product to the customer, the Company does not perform any actions, except for feedback to customers. Failure to meet the requirements defined as **inapplicable** (Chapter 8.3 and clauses 8.5.1, 8.5.3, 8.5.5 of the ISO 9001:2015 standard) does not affect the Company's ability or responsibility to ensure compliance of its products and increase customer satisfaction.

### **3.3 Use of externally provided processes, products and services**

The Company outsourced part of the processes necessary for the functioning of the quality management system to third-party contractors. All external suppliers perform a process or part of a process based on the organization's decision. Such processes include:

- quality control (performed by an independent authorized laboratory);
- selection of a raw material supplier (performed by a competent organization);
- repair, construction work, work on maintenance of energy supply systems, production and auxiliary equipment, measuring equipment (performed by third-party specialized organizations);
- marketing and promotional projects, development and production of advertising materials, selection of counterparties for sales, etc. (performed by third-party specialized organizations).

The Company applies criteria to select and evaluate the effectiveness of external suppliers, as well as their re-evaluation, taking into account their ability to perform processes or deliver products and services in accordance with requirements (if such suppliers are not monopolies). Documented information about these works and any necessary actions performed based on the results of the assessment is kept (contracts, acts of completed works, etc.).

## **4 DESCRIPTION OF QUALITY MANAGEMENT SYSTEM PROCESSES**

### *Contents of DPs*

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