

KAUNAS UNIVERSITY OF TECHNOLOGY MECHANICAL ENGINEERING AND DESIGN FACULTY

MARIUS ŠUMANAS

IMPROVEMENT OF INDUSTRIAL PRODUCT QUALITY

Master's Degree Final Project

Supervisor

Assoc. prof. dr. Kazimieras Juzėnas

KAUNAS, 2017

KAUNAS UNIVERSITY OF TECHNOLOGY MECHANICAL ENGINEERING AND DESIGN FACULTY

IMPROVEMENT OF INDUSTRIAL PRODUCT QUALITY

Master's Degree Final Project Industrial Engineering and Management (621H77003)

Supervisor

(signature) Assoc. prof. dr. Kazimieras Juzėnas (date)

Reviewer

(signature) Assoc. prof. dr. Paulius Griškevičius (date)

Project made by

(signature) Marius Šumanas (date)



KAUNAS UNIVERSITY OF TECHNOLOGY

Faculty of Mechanical Engineering and Design

(Faculty)

Marius Šumanas

(Student's name, surname)

Industrial Engineering and Management - 621H77003

(Title and code of study programme)

"Title of Final Project" DECLARATION OF ACADEMIC INTEGRITY

29 May 20 17 Kaunas

I confirm that the final project of mine, **Marius Šumanas**, on the subject "Improvement of industrial product quality" is written completely by myself; all the provided data and research results are correct and have been obtained honestly. None of the parts of this thesis have been plagiarized from any printed, Internet-based or otherwise recorded sources. All direct and indirect quotations from external resources are indicated in the list of references. No monetary funds (unless required by law) have been paid to anyone for any contribution to this thesis.

I fully and completely understand that any discovery of any manifestations/case/facts of dishonesty inevitably results in me incurring a penalty according to the procedure(s) effective at Kaunas University of Technology.

(name and surname filled in by hand)

(signature)

KAUNAS UN IVERSITY OF TECHNOLOGY FACULTY OF MECHANICAL ENGINEERING AND DESIGN

Approved:

Head of Production engineering Department (Signature, date)

Kazimieras Juzėnas (Name, Surname)

MASTER STUDIES FINAL PROJECT TASK ASSIGNMENT Study programme INDUSTRIAL ENGINEERING AND MANAGEMENT

The final project of Master studies to gain the master qualification degree, is research or applied type project, for completion and defence of which 30 credits are assigned. The final project of the student must demonstrate the deepened and enlarged knowledge acquired in the main studies, also gained skills to formulate and solve an actual problem having limited and (or) contradictory information, independently conduct scientific or applied analysis and properly interpret data. By completing and defending the final project Master studies student must demonstrate the creativity, ability to apply fundamental knowledge, understanding of social and commercial environment, Legal Acts and financial possibilities, show the information search skills, ability to carry out the qualified analysis, use numerical methods, applied software, common information technologies and correct language, ability to formulate proper conclusions.

1. Title of the Project

Improvement of industrial product quality

Approved by the Dean Order No.V25-11-8, 21 April 2017

2. Aim of the project

Analysis of quality improvement methods and formulations for product packaging improvement solution.

3. Structure of the project

Summary, Introduction, 1. Analysis of methods and tools for quality improvement in industry, 2. Application for quality improvement in production company 3. Design of specialized equipment, 4. Conclusions, References.

4. Requirements and conditions

To prepare final project according to KTU regulations and requirements

5. This task assignment is an integral part of the final project

6. Project submission deadline: 2017 June 1 st.

Student

Marius Šumanas (Name, Surname of the Student)

(Signature, date)

Supervisor

Assoc. Prof. Kazimieras Juzėnas (Position, Name, Surname)

(Signature, date)

Marius, Šumanas. Improvement of industrial product quality. *Master's degree* Final Project / supervisor assoc. prof. dr. Kazimieras Juzėnas; Faculty of Mechanical Engineering and Design, Kaunas University of Technology.

Research field and area: Technological sciences, Production engineering Keywords: *Quality, improvement, sterilization, Pareto analysis, bio-fertilizers*. Kaunas, 2017. 62 p.

SUMMARY

The main objective raised to this project – research existing methods for quality improvement in industry and adopt to existing manufacturing process of bio-fertilizers. The need occurred when simple calculations for product reliability were incorrect and some of the customer expectations were not met. Company had devoted budget for new machinery, facility's and subdivision creation to stand more competitive in new product market.

Product and process improved in creation of factory, but one factor left untouched – packaging. Final stage of manufacturing process is pouring fertilizers in to containers. Because of product sensitivity to medium around it, dirty environment reacts to bacteria in fertilizers and reduces its activity. For this reason sterilization of packaging canisters is required to maintain existing quality of product. Instant improvement in company is fatal for competitive market.

The creation of sterilization subdivision has three stages, but before that Pareto analysis was made to find problem for product reliability loss. Sterilization method analysis helped to choose best fitting substance to apply in sterilization. Next step is to design structure for mounting canisters. For sterilization process optimal time and amount of canisters execution, stainless pipe structure was made corresponding to the full height and width of chamber. For this Solid works software where used.

Solid works add in Flow motion helped to calculate air flow in metal structure and choose engine and confirm that designed pipe structure is correct and will work in existing conditions. Calculations for project price where made to count expenses for implementation. To reach higher level of company's quality improvement implementation of reiterative canisters usage was suggested. Marius, Šumanas. Pramoninio produkto kokybės gerinimas. *Magistro* baigiamasis projektas / vadovas doc. dr. Kazimieras Juzėnas; Kauno technologijos universitetas, Mechanikos inžinerijos ir dizaino fakultetas.

Mokslo kryptis ir sritis: Technologijos mokslai, Gamybos inžinerija Reikšminiai žodžiai: *Kokybė, gerinimas, sterilizacija, Pareto analizė, biotrąšos.* Kaunas, 2017. 62 p.

SANTRAUKA

Pagrindinis darbui iškeltas tikslas – išanalizuoti esamus kokybės gerinimo metodus pramonėje ir pritaikyti juos jau esamame bio trašų gamybos procese. Poreikis kilo kai paprastieji skaičiavimai planuojant produkto naudą buvo neteisingi ir nepatenkino keletos klientų poreikių. Siekiant būti konkurencingesniems gamintojas skyrė finansų naujai įrangai, patalpoms ir papildomiems skyriams kurti.

Produktas ir gamybos procesai buvo patobulinti statant naują gamyklą tačiau vienas iš faktoriu liko nepaliestas – pakavimo kanistrai. Galutinis gamybos veiksmas yra išpilstymas į kanistrus. Kadangi produktas yra biologiškai aktyvus, t.y. bakterijos, jos jautriai reaguoja į aplinką ir praranda savo savybes sumažindamos kokybę. Norint išlaikyti esamą produkto kokybę reikalinga pakuočiu sterilizacija. Gamybinių ir vadybos procesų gerinimas, klaidų atpažinimas ir šalinimas yra gyvybiškai svarbus konkurencingoje rinkoje.

Sterilizacijos padalinio sukūrimas turi tris etapus, tačiau prieš tai reikalingas konkrečios problemos identifikavimas. Tam atliekama Pareto analizė patvirtinti ir nustatyti gamybinius nesklandumus kurie įtakojo nuostolius kokybei. Pirmas etapas – sterilizacijos metodų analizė leido pasirinkti vandenilio peroksido būdą kaip tinkamiausią tokio tipo pakuotėms sterilizuoti. Sekantys punktai: technologiniai sprendimai. Metalinės konstrukcijos sukūrimas ir oro srauto tyrimas jos viduje siekiant tilpti į kamerą ir išpildyti reikalavimus pripildyti visus kanistrus sterilizacijos garų.

Šiuos veiksmus atlikti buvo naudojama 3D modeliavimo programa SolidWorks. Apskaičiuoti kaštai ir medžiagos reikalingos pasiekti norimą rezultatą. Taip pat SoliWorks papildinys Flowmotion leido sukurti užduotį ir simuliuoti oro srautą metalinės konkstrukcijos viduje parenkant tinkamo debeto variklį.

Table of contents

Introduction	
1. QUALITY IMPROVEMENT	2
1.1 Eight quality management principles	5
1.2 The revolution of techniques and tools for TQM	7
1.3 Demings PDSA	
1.4 Deming's Fourteen Points of Quality	10
1.5 Pareto analysis	11
1.6 Kaizen principle	
1.7 Kaizen events	
1.8 Implementing Quality	
1.9 Seven unneeded activities in manufacturing	19
2. APPLICATION OF PRODUCT QUALITY IMPROVEMENT	
2.1 Introduction to Bio-energy	
2.2 The need of bio fertilizers products	
2.3 The need for quality improvement	
2.4 Analysis of final product reliability (Pareto analysis)	
2.5 Possibilities to increase final product quality	
2.6 The basics of sterilization	30
2.7 Sterilization Methods	
2.9 Sterilization quality Assurance	40
2.10 Sterilization chamber implementation in to existing manufacturing process	41
3. STERILIZATION CHAMBER DESIGN	42
3.1 Pipe structure design	42
3.2 Calculations for material	45
3.3 Flow analysis	46
3.4 Installing sterilization process in to manufacturing of bio fertilizers	50
3.5 Additional value	52
Conclusions	53
References	54
Annexes	57

List of figures

Figure 1. Demings PDSA cycle [9]	9
Figure 2. Demings PDSA cycle diagram [9]	10
Figure 3. Pareto table of errors on order forms. [9]	
Figure 4. Pareto diagram of errors on order forms. [12]	13
Figure 5. Quality improvement roadmap. [12]	14
Figure 6. Six Sigma visualization	19
Figure 7. Bioenergy advertisement picture	23
Figure 8. Manufacture of bio fertilizers process chart	24
Figure 9. Canister for bio fertilizers packaging	25
Figure 10. Pareto analysis for final product realibility	
Figure 11. Canister technical drawing and measurements.	
Figure 12. Canister technical drawing and measurements	
Figure 13. Dry heat sterilization chamber [25].	
Figure 14. Liquid chemical sterilization [24].	
Figure 15. Ozone sterilization process explanation [25]	
Figure 16. Dry fog droplet action	39
Figure 17. Dry Fog 2 System [26]	40
Figure 18. Sketch with measurements for mainframe	43
Figure 19. Solid works drawing of pipe construction	44
Figure 20. Pipe structure visualization. Half assembled with canisters	45
Figure 21. Stainless steel pipe	45
Figure 22. Air flow simulation in structure	47
Figure 23. Air flow in A side oputlets (30 min)	
Figure 24. Air flow in B side oputlets (30 min)	
Figure 25. Air flow in each outlet 60 min side A	49
Figure 26. Air flow in each outlet 60 min side B	49
Figure 27. Canal ventilator DOSPEL WK100	50
Figure 28. Product packages movement in factory	51

List of tables

Table 1. Reasons of product quality loss	
Table 2. Canisters measurements	
Table 3. The measurements of stainless steel needed.	
Table 4. Air flow results in each outlet (30 min / 60 min)	57
Table 5. Test results of final product reliability	59
Table 6. Lodging number and sizes	61

Introduction

In the new rapidly growing market, the speed of your product improvement can be determined which part of the pie company will get in the beginning of the race. Velocity of market penetration with customer satisfaction can make a big gap between you and your competitors.

My research is targeted to product quality improvement. When the new innovation or product is created and introduced to market competitors starts to grow exponential. Thus the leading company or creator of product (if innovation cannot be patented) has to improve quality of product, quality of service, marketing and so on to be in the lead. The companies who is starting new product is ahead by main uniqueness – know how. Manufacturing, supply chain line, first feedback from customer gives opportunity to improve product and stay in the lead.

Marketing principles can be used to take market share, to reach results, but to truly be grounded in the market place company has to build foundation for its success – product quality. This research is focused on products quality improvement by studying various techniques used in industry and business to reach next level, to keep up with the main principle of the market in capitalism society – constant development and growth.

Aims of the project is Analysis of quality improvement methods and formulations for product packaging improvement solution. Tasks to achieve this aim were formulated:

1. Analyse existing methods and techniques developed over the years regarding product or process improvement and quality management. The industrial revolution grew rapidly, with it – improvement of various different areas which makes influence for productivity of process making final product. There is many activities which expands process time or uses recourses ineffectively. Identifying those areas, noticing tendencies in processes and fixing or improving it rises quality.

2. Acknowledge company's process and find weak spots to create plan for product improvement generating bigger value in the market. Also making it bigger player in the market and harder to reach for competitors, especially when new type of product is entering market.

3. Analyse methods of sterilizations and choose best fitting technique according to price and implementation to existing conditions.

4. Design and calculate technical equipment needed for new subdivision implementation in manufacturing process according to conditions existing, without destruction or redesign of existing process. Manufacturing is not stopping.

5. Suggest improvements to existing manufacturing process to reach higher quality in long term.

1. QUALITY IMPROVEMENT

Quality Improvement is a simplified view point to the investigation of execution and step by step actions to improve it. This subject covers variety of models implemented, most famous is, FADE (focus, analyse, develop, execute), PDSA (plan, do study, act), Six Sigma or DMAIC, CQI - Continuous Quality Improvement or TQM – Total quality management. These models with various different actions is to get same goal - Improvement. They are forms of ongoing effort to make performance better. There is so many disciplines to improve quality. It depends on product, company's structure, time and resources, especially human resources. [1]

Quality improvement has various tools, approaches and techniques and is used worldwide. They are plain to understand and can used by any employee of the company, e.g. PDCA cycle or Deming's circle. Of course there is very complex problems or processes and more complicated (recourses and time consuming) methods is used - Six Sigma, Lean Sigma, Design for Six Sigma or EFQM excellence model. It is fatal that correct methods and approaches must selected for the eligible team and implemented correctly to the appropriate process. The successful execution of methods hinge on information, knowledge and implementation in manufacturing or service processes.[2]

Because of market grooving every day and becoming more and more competitive, companies have to give more space to satisfaction of a customer in more diverse ways. Customer satisfaction is a constant challenge for business, which if managed correctly determines is product brought and how many times . Understanding and fulfilling customer needs has to be viewed as one of the key principles for product or service design to take the lead sales. [3]

Quality in business

Creation of product or service, making something valuable means putting in input and getting output by differentiating input. Because there is big amount different acts upon input, every act has its influence to final outcome. Furthermore every act effects next step of differentiation and goes on to massive algorithm. Managing those acts, compering, analysing one's affect to other can lead to new insights for improvement ideas and ways to make things better.

There could be two ways to improve product quality – reengineer improve product feature/s (value that it is giving to the market) or generate new, cheaper, more productive ways of manufacturing of the product. Both approaches has their methodologies.

The real quality is the perceiving what customer feels, the envision of products or services quality comes from design manufacturer or service provider creates by developing his final outcome. The late American Management guru Peter F. Drucker said, "Quality in a product or service is not what the supplier puts in. It is what the customer gets out and is willing to pay for." [4]

To be attractive to your customer (your product to be attractive) manufacturer had to meet quality perception of your final customer. It isn't easy because customer not always car answer directly or specify numeric values that makes them happy about the product. In long years when capitalism was growing rapidly competitiveness grew too and business had to find more ways to measure and reach better quality to stay in the lead or at least survive in the market. Business with products which is introduced to the market for a long time had to find a methods to determine and measure out quality so that products and services would have standards that their customers will accept.

Measuring Quality

- Quality is specification driven does it meet the set requirements
- Quality is measured at start of life percent passing customer acceptance
- Quality is observable by number of rejects from customers

The quality distinctiveness of a product or service can be called as 'Determinants of Quality'. They are the characteristics that buyers search for to make a decision - if it is a quality product or service and buy it. People has many ways to name quality, each of them has core principal that is important for customer. Manufacturer or service provider has to perceive it to understand and make decisions to improve product quality. [5]

- A degree of excellence
- Conformance to requirements
- Totality of characteristics which act to satisfy a need
- Fitness for use
- Fitness for purpose
- Freedom from defects
- Delighting customers

Is quality standards are clear and defined or known correctly there is last question to answer – does product has those standards. If yes we can day that product or service is reliable .Reliability means - achieving those quality standards. This means the level of quality produces its equivalent reliability.

Definition of Reliability

Reliability is making product that correctly will generate value when needed, for the period required in environment which is expected to be valuable in. For a manufactured product the reliability comes from its construction, design, way it was manufactured correctly and accurately. For the service industry, reliability is complexity of processes that is made for customer to reach result in such a way that customer will be satisfied with time, although no side effects. Reliability for service is to count and execute process strategically developed in best way with optimal expenses to reach maximum quality.

Quality is valuable, because when you have it, it brings success to the customer, and consequentially, to the business the customer buys from.

Measuring Reliability

Reliability is customer satisfaction driven – the User was successful when they used the commodity. It is measured at the end of lifetime of product and it was functioning and producing value that it was created for as expected of user or stated by manufacturer or producer. Reliability can be measured by call outs from customer for maintenance or amount of product returned to warranty department to be fixed or changed to new one for keeping promise to customer that it has to produce expected value exchange to money paid by buyer.

Business and manufacturing processes without doubt has to be designed and analysed daily, weekly, monthly and so forth in order to achieve quality and reliability of product and service to meet intentions the customer has. Meeting expectations or in some marketing models giving more value than customer expects will satisfy buyer and will keep him coming and promote in strongest way – person to person.

Depended on the product or service high level of promotion is in social media. If quality and reliability overcomes expected results manufacturer could get surprise promotion "bomb" from customer – 5 stars video review. It could be strategic investment to reduce marketing expenses. Everything is interrelated.

1.1 Eight quality management principles

Customer focus – everything that company does is to depended of their customers and it is crucial to know the needs of customer. Also future changes and diversification of needs should be considered. In order to strive requirements and customer expectations should be exceed. Managing customer focus will increase revenue and market share. If the use of the organization's resources gets better and more clever customer satisfaction can increase by lowering price or delivering time of the product. If customer is satisfied he will come again, thus creating customer loyalty which leads to repeat business deals. [6]

There systematic steps that should be taken to implement quality improvement by customer focus:

- Analysing needs and expectations of a customer.
- Ensuring that the processes in business are connected to customer needs and expectations.
- Inside of company there should be communication of ensuring customer needs and meeting expectations.
- Measuring customer satisfaction and acting on the results.
- Managing relationships with customers in accurate, systematic way.
- There always have to be balance to ensure satisfaction of both interested parties, customer and employee, owners.

Second principle is *Leadership*. People who are leading team makes unity of purpose and path of for all people in organization. There should be created and kept functioning surroundings which allows every person to act and move freely in order to be fully involved for achieving common objectives of the business. Implementing this principle in company people will understand and be motivated towards the organization's goals and objectives. Leaders generate and unifies ideas and visions in different levels thus minimizing miscommunication between levels of company.[6]

Applying this principle, company starts to consider interests of all parties including suppliers, financiers, local communities and society as a whole by establishing a clear vision and setting challenging goals and targets for the organization's future.

By making and holding common values, fairness, exemplary people at all levels of the organization excludes worry and creates trust among teams. Also giving Employees the required resources, exercises, tasks and freedom to act with responsibility and accountability, leads to inspiration, encouragement and recognition people's contributions.

Involvement of people is third principle. People who is creating organization as a whole have to be fully involved, this enables their abilities to be used for the organization's benefit. It is a challenge to motivate people, using this principle company will have motivated and committed people within the team. Involvement increases in contribution for organization's purposes. People takes responsibility to own results and aspire to take part in contribution to continual improvement.

Principle four is *process approach*. A wanted result is reached more effectively when activities and related resources are managed as a process. Profit of process approach principle usually include lower costs and shorter cycle times through effective use of resources, improved, consistent and predictable results. By focusing and prioritizing opportunities of the company improves.

Results of integration principle four leads to systematically defining the activities necessary to obtain a desired result and establishing clear responsibility and accountability for managing key activities. By identifying and analysing the potency of key activities it becomes easy to spot the interfaces of main activities within and between the functions of the organization. Also dealing with the elements such as resources, methods, and materials can improve main activities of the company. Estimating risk factors, results and impacts of activities on customers, suppliers and other interested parties gives space to make more accurate planning and decisions with plan of risk control.[6]

System approach to management -5^{th} principle. Determining, understanding and managing common processes as a system leads to the business efficiency in achieving its goals. Benefits of this principle is integration and uniting of the processes. With ability to focus effort on the key functions wanted results are achieved faster. Also providing reliance to people who is interested as to the consistency, effectiveness and efficiency of the organization.

Understanding the interdependencies between the processes of the system leads to structuring system to achieve the organization's objectives in the most effective and efficient way. System approach helps structure that harmonize and integrate processes. Giving clear understanding of the roles and responsibilities which is necessary to achieve common objectives eliminates cross-functional barriers. By understanding organizational capabilities establishes resource constraints prior to action.

Continual improvement. By sixth principle the company's whole execution should be a main goal of the organization. This type of approach gives advantage through improved organizational processes. Company's flexibility to react quick rises with equalization of improvement activities occurs at all levels to an organization's strategic intent. Implementing this principle should

lead to giving people training in the methods and tools of continual improvement and. Creating objectives for guiding and conceding continual improvement

Principle 7 - *Factual approach to decision making*. Analyse information and data is essential to make effective. Decisions have to be informed and based on actual information and will lead to an increased ability to manifest the virtue of past decisions through reference to factual records. Ability to review, challenge and change opinions and decisions increases. Applying the principle of factual approach to decision making typically has to be relied on data and information sufficiently accurate. In company data becomes available to those who need it. Information has to be studied using tested and working methods, determining decisions and taking action based on that analysis, of course intuition and experience is mixed in whole formula to reach maximum potential.

Mutually beneficial supplier relationships. Business consists of large amount of interested parties as a whole, they are interdependent and a cooperation strengthens relationship, enhances the ability of both to create value. They all should react and be flexible to changing of customer needs. Using last principle contribute for optimization of costs and used resources:

- Creating relationships balance with short-term gains and long-term considerations.
- Connection with same or common goal having partners.
- Determining and choosing key suppliers.
- Clear and honest interaction.
- Giving information also about future plans.
- Establishing joint development activities.
- Giving recognition about improvements and achievements by suppliers. [6]

1.2 The revolution of techniques and tools for TQM

The history of assurance conformity to desired reliability can be traced to the middle ages. Craft Guilds has established standards for differentiation for their goods to get good reputation of their trades. Tradesmen and craftsmen made inspections and analysis of products right on the workbench. When manufacturing sizes was quite low-volume informal inspection of products, checking and review of worker was enough. But when industrial revolution made its jump the need of quality control with more effective operations became necessity. By early 1911 concept of quality started to grow exponential. Frederick W. Taylor published 'The Principles of Scientific Management'. His first step was create framework for improving workers productivity in manufacturing using statistical theory. Taylor created few concepts which became basic foundation for future theory evolution:

• Functional specialization – find and define tasks to be performed under standard conditions

- Process analysis of time and motion to increase productivity
- Quality control final product inspection, as distinct function conducted by person not directly involved in production process.

Taylor's complicity can be traced until now, some of this techniques are still used today like

beacon to several engineering tools and cycle time reduction methods. Frederic main goal was productivity gain while in the 1920s, Dr. Walter Shewhart approached quality control as proactive function embedded in the process, rather that act and make decisions only on inspection and measurements of final product. Applying statistical theory to the management of quality, he developed the first modern control chart and demonstrated that eliminating variation in the process leads to a good standard of end products [8]. He blaze the trail Shewharts Learning and Improvement cycle, which is greatly known as continuous steps leading to total quality improvement. These steps is known as *Plan, Do, study, act* and in later time adapted by Deming as *PDSA* cycle.

1.3 Demings PDSA

Dr. W. Edwards Deming took importance for management in both individual and company level when talking about quality. He stated that 80 % - 90 % of quality misfortune came from poor management control. It made quite diverse approach for improving quality drawing out organization-wide cultural change. Deming invited employees and management departments cooperation approach as the way to achieve high quality. Plan, Do, Study, Act cycle has been improved taking Shewart's learning and improvement cycle as foundation of quality improvement methodology. Its goal is to make it continual improvement by reducing difference between the customer requirements and process performance.

To adopt PDCA cycle occurred highly more effective than using 'right the first time' technique. Plan, Do, Study, Act is method to continuously look for better ways to improve. It has valuable feature that it can be used for manufacturing a product and managing a program. The PDCA gives space to two kinds of corrective action – temporary and permanent. The temporary is focused at results by practically tackling and fixing the problem and permanent corrective action, on the other hand, consists of analysis and reducing the root causes and thus targets the sustainability of the improved process.[2]



Figure 1. Demings PDSA cycle [9]

Deming developed a number of methodologies, most famous is System of Profound Knowledge (theories of optimization, variation, knowledge and psychology). This is whole theory is foundation to contribute for quality crises and also known as Deming's 14 points of quality - plan that he believed applied to any size or type organization.



Figure 2. Demings PDSA cycle diagram [9].

1.4 Deming's Fourteen Points of Quality

1) Create constancy of purpose towards improvement of product and service, with the aim to become competitive and to stay in business, and to provide jobs.

2) Adopt the new philosophy. We can no longer live with commonly accepted levels We are in a new economic age. Western management must awaken to the challenge, must learn their responsibilities, and take on leadership for change.

3) Cease dependence on inspection to achieve quality. Eliminate the need for inspection on a mass basis by building quality into the product in the first place.

4) End the practice of awarding business on the basis of price tag. Instead, minimize total cost. Move toward a single supplier for any one item, on a long-term relationship of loyalty and trust.

5) Improve constantly and forever the system of production and service, to improve quality and productivity, and thus constantly decrease costs.

6) Create modern methods of training on the job.

7) Institute modern methods of supervision of production workers. The responsibility of foremen must be changed from numbers to quality.

8) Eliminate fear, so that anyone can work effectively for the business.

9) Eliminate walls between departments. Employees in design, research, sales and marketing, production, manufacturing, all must work as a team, to anticipate errors of production a product or service.

10) Eliminate slogans, exhortations, and targets for the work force asking for zero defects and new levels of productivity. Such exhortations only create adversarial relationships, as the bulk of the causes of low quality and low productivity belong to the system and thus lie beyond the power of the work force.

- Eliminate work standards (quotas) on the factory floor. Substitute leadership.
- Eliminate management by objective. Eliminate management by numbers, numerical goals. Substitute leadership.

11) Destroy barriers that takes out the hourly worker of his right to pride of workmanship. The responsibility of higher level worker has to be modified from absolute numbers to quality.

12) Remove barriers that rob people in management and in engineering of their right to pride of workmanship.

13) Institute a vigorous program of education and self-improvement.

14) All employees of the company has to work to accomplish the transformation. The change is everybody's job. [9]

Deming was working with Dr. Joseph Juran and he was quite big influencer to the Japanese quality industry and big figure for evolution of quality management in the U.S. he is creator of *PARETO PRINCIPLE*. It states that if you identify vital processes, which is most important you will get bigger return – 80 % return comes from 20 % effort. Juran wrote famous book about quality – "Quality control handbook" and it serves as the basis for Lean, Six Sigma and other important techniques and methodologies.

1.5 Pareto analysis

This is a tool used to establish priorities, dividing contributing effects into the "vital few" and "useful many." A Pareto diagram includes three basic elements:

The contributors to the total effect, ranked by the magnitude of contribution

The magnitude of the contribution of each expressed numerically

The cumulative-percent-of-total effect of the ranked contributors. Figure 4 shows a Pareto table. Figure 5 shows the same data in a Pareto diagram. Note the three basic elements as reflected in each figure. [10]

Pareto analysis can determine that a incommensurate improvement is reached by ranking different causes of a problem and by giving most focus on those solutions or items with the biggest impact. The main idea is that not all inputs have the same or even proportional impact on a given output. This type of decision-making can be used in many fields of endeavor, from government policy to individual business decisions.

1	2		3
Order-Form Item	Number of Errors	Percent of Total	Cumulative- Percent of Total
G	44	29	
J	38	25	29
М	31	21	54
Q	16	11	75
В	8	5	86
D	5	3	91
С	3	2	95
A	1	0.67	97
0	1	0.67	98
R	1	0.67	98
N	1	0.67	99
L	1	0.66	99
I	0	0	100
E	0	0	100
н	0	0	100
к	0	0	100
F	0	0	100
Р	0	0	100
TOTAL	150	100	100

Figure 3. Pareto table of errors on order forms. [9]



Figure 4. Pareto diagram of errors on order forms. [12]

Pareto principle is used in various different areas, it is quite universal. From manufacturing till human recourse and logistics. Also it has been used in a variety of coaching and customer relationship management software programs. The business is dependent on the advisor's ability to provide excellent customer service, as its fees rely on its customer's satisfaction.

People that have used the Pareto principle felt enrichment in time management, productivity and whole client satisfaction.

The Pareto principle can be applied to many businesses, especially those that are clientservice based. It also can be used on a personal level. This method is commonly used to time management, most of their time is wasted on second rate actions instead of focusing on the most important tasks.[11]

Dr. Joseph Juran approaches quality from customer point of view. He states that quality satisfaction is in high level when number of features and values brought from product or service meet customer expectations, mostly in design, availability, safety and comfort of use. Rather focusing on just end customer we have to look to whole process more widely. Each person through whole chain, from inside customers to the final user is and supplier and customer. Numerous theories was developed but two concepts in particular serve as the basis for creation a traditional quality system and supports strategic management of quality. Quality trilogy means quality planning, quality control and quality improvement and his quality planning roadmap.

On planning stage, it is crucial to identify who your customers are and analyse out their expectations. After this management company is able to define the exact needs and functions for product / process / service / system, etc., and develop them.

On control step there has to be known what has to be measured and set a goals stated for execution. The data by measuring actual results let us act on the gap between performance and created goal. In Statistical Process Control (SPC), there are few methods that could be used in the "control" phase of the Juran Trilogy: Pareto Analysis, flow diagrams, fishbone diagram, and control charts.

In quality improvement stage there are four different "strategies" for improvement that can be used to achieve result:

- 1. Repair: Reactive; fix what's broken.
- 2. Refinement: Proactive; continually improve a process that isn't broken (like the continual pursuit of perfection in Lean)
- 3. Renovation: Improvement through innovation or technological advancement
- 4. Reinvention: Most demanding approach; start over with a clean slate.[12]



Figure 5. Quality improvement roadmap. [12]

Juran identified 8 milestones as integral to a quality planning roadmap:

- Determine who are the customers.
- Determine the needs of those customers.

- Develop a product that responds to those needs.
- Optimize the product features to meet your needs as well as customer needs.
- Develop a process that is able to produce the product.
- Optimize the process.
- Prove that the process can produce the product under operating conditions.
- Transfer the process to operations. [8]

When in 1950s and 60s, quality gurus brought their concepts to Japan where industry emerged not only had great velocity to adopt and improve but also expounded on what became enduring concepts. There was born and applied new principle – *Kaizen*.

1.6 Kaizen principle

It is core principle of quality management in general and is embedded within methods of total quality management and lean manufacturing. It is like a philosophy, not only greater than any method but it becomes a way of life, mostly seen in even in business vision an mission statements, embedded to organizations core values.

Kaizen or continuous improvement is a method where labour at all levels of a business work hand by hand to achieve every day improvements to the manufacturing process. It combines the collective talents inside a departments to create a high synergy for improvement.[13]

Kaizen principle is philosophy and action plan in one. Talking from action plan perspective Kaizen is about engineering events focused on improving tactical places within the business. These events involve teams of employees at all levels, with an especially strong accentuation on involving plant floor employees.

As a way of life, Kaizen is about creating environment where all people working with each other are working with one idea, looking out, discussing and making improvements to the organization. In business who truly adopts lean philosophy, it becomes a core type of thinking for all levels of the company employees – from managers to plant floor workers.

Kaizen employing these key principles:

• Every is a key word in Kaizen: improving everything that everyone does in every aspect of the organization in every department, every minute of every day.

- Evolution rather than revolution: making 1% improvements to 100 things is more effective, less disruptive and more sustainable than improving 1 thing by 100% when need becomes critical.
- Everyone involved in a process or activity, however apparently insignificant, has valuable knowledge and participates in a working team or Kaizen group.
- Everyone is expected to participate, analysing, providing feedback and suggesting improvements to their area of work. Management facilitates this empowerment.
- Every employee is involved in the running of the company and is trained and informed about the company, fostering commitment, interest and job satisfaction. [8]

1.7 Kaizen events

- 1. Set goals and provide any necessary background.
- 2. Review the current state and develop a plan for improvements.
- 3. Implement improvements.
- 4. Review and fix what doesn't work.
- 5. Report results and determine any follow-up items.

After 1970's success of Japanese industry of implementing quality management American industry was forced to take example and implement know how and the knowledge to their industry as well. Mostly in in the automobile and electronic sector because it industry and product demand skyrocketed ant Japanese product started to grab bigger and bigger amounts of market shares offering higher quality, production time and of course price of product. In U.S. it became economic crisis and organizations and whole industry had to adopt and join quality movement. This led to bigger and faster methodology improvement and development. The book Total Quality Control by Armand V. Feigenbaum contributed to conceptual foundation and practical application of QM. He is considered the originator of total quality management. Feigenbaum stressed a systems approach to quality and focused on the costs of quality as separable into costs for prevention, appraisal and failures. Through the late 70s and 1980s, Philip B. Crosby emerged as a quality leader, with seminal concepts such as "Quality is Free" and "Zero Defects". Crosby based his quality improvement process on "four absolutes of quality":

- Quality is conformance to requirements
- The system of quality is prevention
- The performance standard is zero defect
- The measurement of quality is the price of non-conformance

1.8 Implementing Quality

As many commonalities as there are in the philosophies of the "quality gurus", it's important to realize there are also contradictions. As a result, there are MANY methods for quality improvement in use today that cover product-, process- and/or people-based improvement, including:

ISO - Guidance on use for process improvement and process capability determination.

QFD – quality function deployment, also known as the House of Quality approach, that focuses on customer wants or needs in the (re)design of a product or service.

Kaizen – Japanese for change for the better; the common English term is continuous improvement.

Zero Defect Program – created by NEC Corporation of Japan, based upon statistical process control and one of the inputs for the inventors of Six Sigma.

Six Sigma – combines established methods such as statistical process control, design of experiments and failure mode and effects analysis (FMEA) in an overall framework.

PDCA – Shewhart / Deming's plan, do, check, act cycle for quality control purposes. Six Sigma's DMAIC method (define, measure, analyze, improve, control) may be viewed as derivation of this.

Taguchi methods — statistical oriented methods including quality robustness, quality loss function, and target specifications.

The Toyota Production System - reworked in the west into "Lean manufacturing".

TQM – total quality management is a strategy aimed at embedding awareness of quality in all organizational processes. First promoted in Japan with the Deming prize, it has been adapted in the U.S. as the Malcolm Baldrige National Quality Award and in Europe as the European Foundation for Quality Management award (each with their own variations).

BPR – business process reengineering, a management approach aiming at 'clean slate' improvements (abandon existing practices). [8]

It has to be accurate strategic planning and analysing which methodology is best in one or different way of business, also we have to keep in mind recourses to needed to reach results implementing theory in to practice, does it align to goals and budget of the company.

For example Six sigma is a methodology which was created mobile company Motorola in 1986 with the purpose to improve their business by eliminating defects.

It has since evolved into a broadly used organizational approach that focuses on reducing variations and achieving output improvements through problem solving. Six Sigma practitioners utilize the DMAIC method (define [the problem], measure, analyze, improve, control). Features that distinguish Six Sigma from earlier quality initiatives include:

• Achieving measurable financial returns from the project.

• Increased emphasis on passionate management leadership and support.

• A hierarchy of "Champions," "Black Belts," 'Green Belts', etc. to implement the Six Sigma process.

• Making decisions on the basis of verifiable data, rather than assumptions.

Six Sigma is named after a statistical concept where a process only produces 3.4 defects per million opportunities (DPMO). Six Sigma can therefore be also thought of as a goal, where processes not only encounter less defects, but do so consistently (low variability). Basically, Six Sigma reduces variation, so products or services can be delivered as expected reliably. [14]

The Six Sigma is based on statistical concept: defective items be minimized by maintaining 6 standard deviations (6 sigma's) between the process mean (average) and its upper and lower specification limits. Six sigma also accounts for the tendency of processes to degrade over the long term. A six sigma process can tolerate a "shift" of 1.5 standard deviation and still maintain a safety cushion between the process mean and its specification limits.



Six Sigma: Statistically Visualized

Figure 6. Six Sigma visualization

Six Sigma employs many widely used quality management tools, such as Design of Experiments, Pareto charts, Chi-square test, Cost-benefit analysis, root cause and regression analyses, and more. While the approach has achieved significant bottom-line results for many organizations, it has also been criticized for potential negative effects such as ignoring the customer, stifling creativity (especially in research) and being oversold or inappropriately applied by consultants. Still Motorola managed to reach high performance and dominate market for the start of mobile business.

Some of methodologies cover each other and makes synergy to get better results. One of the options is Lean Six Sigma.

1.9 Seven unneeded activities in manufacturing

All companies has one or more problems, but most painful is effectiveness, being more accurate – absence of effectiveness. Word effectiveness in Lean system can be translated to - unneeded activities, which is not bringing value to the company and customer isn't willing to pay for it elimination. Japanese call it "muda" [15]

Muda (無駄)

Eliminating waste is away to increase company efficiency. Add value to the product or decrease waste. Word "muda" is waste in Japanese. Toyota company engineer Taiichi Ohno –If you want to eliminate muda's you have to know where and what they are. For every muda there is strategy to eliminate it and make process more effective and sustainable. [15]

Overproduction - Making product which is not needed or cannot be sold in normal time period. Overproduction is expensive to manufacturer because investment done and revenue not coming back. Toyota system is called Just in time (JIT), every piece and part is made only then is needed. To stop overproduction the production has to be stopped to locate problem. Main principal is to plan and manufacture only what is needed and what can be sent or sold on sight.

Waiting - When part is not moving or to continue manufacturing process we need to wait. Usually more than 99% products waits in front of other part to be tooled. This occurs from bad process management, long distance from shops. Goldratt in his book "Theory of Constraints" said that one hour downtime of main shop means wasted the whole hour for company and cant be brought back. Connecting all processes in mind that each feeds the other can drastically reduce waiting.

Logistics - Moving product is also process, thus its not generating value to the product. Vice versa usually transportation can make it worse. Reducing transportation isn't possible, but making a map of transportation can help to find most optimal way to reduce it.

Inappropriate treatment - Most of organizations is using expensive, high accuracy tools and machinery even if they can get same results with simple tools with good management of the placing for the shops. Toyota is well known for cheap tool automatization, perfect maintenance, mostly for of old ones. Less investment means less loss.

Unneeded inventory - Unneeded inventory – result of overproduction and waiting. It shows problems in manufacturing shops which has to be identified and taken care of. It expands the time for product completion, uses much space, reduces communication.

Unneeded movement - The word for this would be – ergonomics. There has to be counted every movement, eliminated unneeded motion, not contributing or harder than possible movements. (Labour actions).

Defects - Direct effect to manufacture success or failure has defected parts or products. All uncalculated and not expected time to rebuild or correct mistakes brings additional warehouse space, repeated check for quality, additional planning, loss of productivity. Common expenses in industry is defect riddance.

Unrealized labour - It is additional eight factor. In company there is working not just active hands and legs of worker, but also productive, creative and seeking fulfilment people. Managing creativeness of labour there can be eliminated other seven Muda's [16].

2. APPLICATION OF PRODUCT QUALITY IMPROVEMENT

2.1 Introduction to Bio-energy

Bioenergy Group was founded in year 2003. It consists of companies that consult farmers, produce and import bio fertilizers for soil ant plants.

It manufactures biological products that increase soil fertility, restore its natural balance and increase plant productivity. Its main manufactured products consist of bacteria that fix nitrogen, release phosphorus, increase potassium absorption and fight with plat diseases that are caused by fungies.

The season of 2014 was a breaking point of Bio-energy, they started to increased producing rates and invest in new technologies for even better quality of their products. In 2014 exported more that 1000 tons of bio fertilizers to 11 different countries.

Products are tested and used in many geographic and climatic conditions: from short vegetation periods in Siberia up to hot and log summers in Bulgaria. Bio fertilizers are used in wheat, rape, sugar beat, barley, corn crops. Trials also show great results in vegetables and fruits. For creating products Bio-energy cooperate with 4 universities, more than 5 different laboratories and a huge group of scientists. They are always looking for new solutions for the biggest problems that appear in crop growing. 3 of our products are awarded as the best innovative fertilizers in the biggest agro exhibition in Baltic region "Ka pasesi...".

Company's main goal is to restore natural balance in the soil and increase its fertility. The product offers unique high quality bio fertilizers that can be used in all sorts of crops regardless of the climate conditions, a business opportunity where the client is happier because it helps him to grow a more economically efficient harvest, training of staff of farmers and helps in trials and marketing.



Figure 7. Bioenergy advertisement picture.

2.2 The need of bio fertilizers products

The creation of a new product is responsibility of research and development division, where microbiologists working together with team of agronomists.

For some farmers the biggest problem it is phosphorus deficiency, form some the biggest problem is to low economical efficiency because of big inputs, for some moisture problems. It is impossible to solve all problems at once, or even to solve one problem with a single use of a biological fertilizer. It is a step by step process. For example: A Farmer has a filed with a high pH level which is more than 7,5. Every year he is giving high amounts on NPK fertilizer but the plants are always showing phosphorus deficiency. When the pH level is higher than 7 phosphorus in the soil is being fixed by calcium. Calcium phosphate is a form of phosphorus that is not available for the plants therefore plants show phosphorus deficiency. [17]

The solution came - FOSFIX is a bacterial fertilizer than consists of bacteria bacillus megaterium var. phosphaticum, which after applied in the soil starts to release the plant unavailable phosphorus and transform it to plant available form. After using FOSFIX within 2 months you can increase up to 30% of plant available phosphorus in the soil. It is a very high percentage that can be achieved not only in the trial stations, but more than 4 years of experience of reaching this number in the farmers fields as well.

FOSFIX does not regulate the pH level of soil, this means if farmer wants to get the same effect of a bigger amount of plant available phosphorus he should use it every year. Of course to monitor those processes and make decisions regarding nutrition inputs Bio-energy always recommend to have soil analysis done.

Today farmers with biological fertilizers can optimize their plat nutrition system, decrease NPK inputs, reduce the amount of pathogens in the soil, improve plant residue mineralization, improve soil quality, increase their yields and economical efficiency. [17]

As the agricultural technologies always improve, the BIOENERGY LT try to achieve new thing as well. There was question created how to increase quality of these products and make it better and of course more competitive in the market.

Because product is manufactured in biological basis this means that company sells a living organism – bacteria. Manufacturing of bio-fertilizers starts in laboratory where clean and sterile environment is main objective to produce product.

Process is quite simple first steps is to manage to grow small amount of bacteria family in tubes. Later, when bacteria reaches stage of maturity it is introduced to various medium for reproduce and sleep stage. This process is very sensitive to environment changes and reacts to smallest temperature changes or introduction to outside substances.

After bacteria is in sleep stage it waits to be used. When is applied to the soil it reacts to O2 and starts doing its nature process – to fixate nitrogen or release potassium (depends on which bacteria is used).



Figure 8. Manufacture of bio fertilizers process chart.

2.3 The need for quality improvement

After 2015 market increase company had got solid amount of revenue. Ass market increased as so and amount of competitors. In order to keep up in first place in Baltic states and reach other markets product quality had to be improved as well.

Actions taken to improve quality started in every level of product manufacturing, also to sales, marketing, logistics and human resources. But mainly the focus on quality improvement was gathered to product quality improvement by reengineering of product manufacture plant. Studies was done in more detailed way in different soils, different countries to study and make mixture more active when process is used. After laboratory researches and analysis of results everything was improved but one thing – packaging.

Because product is biological (living organisms) carried to final customer, the environment in which it is held has quite big influence to final product quality. For company Bioenergy, they choose plastic containers. There is two types for packaging (colour is not important) 10 litres and bigger one -20 litres.



Figure 9. Canister for bio fertilizers packaging

2.4 Analysis of final product reliability (Pareto analysis)

Some of customers did not get expected result after using the products and was disappointed. When the steps was taken to start analyse to improve quality, final product activity/reliability had to be checked.

Plan for product quality check and increase

1. Analysis of a product quality with sterilization of packaging containers. Request a competent facility (probably university with faculty of chemical science, KTU, ASU, ect.)

Make a research on bacteria efficiency placed in canisters with normal medium and sterilized one.

2. If sterilization makes a difference of final product quality - make presentation on need of sterilization subdivision. Get approval.

3. Preparing for integration. Appoint person to be trustworthy and accountable for creation, integration and management of sterilization subdivision.

4. Analysis of sterilization methods. Cooperating with scientists of chemistry and biology analyze sterilization methods. Find devices needed. Request best price.

4.1 Choose best option.

4.2 Counting price of specific method integration.

4.3 Investment and value created ratio evaluation.

4.4 Ordering devices needed.

5. Creating subdivision. Building or managing manufacture process to integrate in premises for subdivision.

5.1 Lean calculations for manufacturing process flow

5.2 Manufacture engineering parts. Create unique devices to make sterilization process fast and efficient.

6. Adopting packaging division with sterilization chamber.

(4 and 5 closely interacts with each other, should be started in the same time)

As it was suspected the packaging canisters had affect to final product quality. There where taken 100 final packages tested bacteria activity level of substance.

Research in agronomical laboratory shown bacteria activity dropped in 15 canisters (table 4.) by 18 % after filling it to packaging containers. This means not all of, but significant amount of product goes to customer not in full reliability and do not create value as it was calculated in sales stage when customer is discussing with agronomist of sales department.



Figure 10. Pareto analysis for final product realibility.

These non-compliances occurred in 15 canisters because of main 4 reasons:

Final product reliability	Reason
77 %	Muddy inside of packaging container
80 %	Refuse in canister
68 %	Muddy inside of packaging container
77 %	Muddy inside of packaging container
69 %	Not fully closed cap
71 %	Muddy inside of packaging container
77 %	Muddy inside of packaging container
80 %	Holey canister
80 %	Muddy inside of packaging container
84 %	Muddy inside of packaging container
75 %	Muddy inside of packaging container
77 %	Refuse in canister
72 %	Muddy inside of packaging container
70 %	Muddy inside of packaging container
67 %	Muddy inside of packaging container

Table 1. Reasons of product quality loss

1. Not fully closed cap allows air to get inside and react to product. Also when canisters are carried to final customer it can spill around and make it dirty and reduces visual value of the product. Just one was found dooring test.

2. Large refuse were found inside container mixed with product. With first perspective it seems that refuse has organic origin – fragments of wood. The Action was taken and manufacturer of packaging containers was informed with photos and notice of unwanted substances in canisters.

3. Also holey canister was noticed in examination of containers. Holes was small, but still allows air to get in container thus activating product before it reaches and is used by customer loosing vast amount of reliability. Some of product spilled through holes and reduced visible value of the product.

4. 73,3 % of canisters that was noticed with product quality loss had greasy medium inside which reacted with product and activated bacteria before it reaches the soil. Main problem found – inside of canisters had to be cleaned before pouring product and sealing it.

Bio-energy is not manufacturing containers, it buys them from Poland plastic manufacturer company. It seems that the engineering process of those containers includes high levels of heat and aggressive medium. In micro level some of chemical waste is left on inside walls of containers after casting it.

The bacteria reacts to it and some of it dies, some become active (take in mind that it has to be in sleep stage to have full strength when introduced to the soil). That means when product is filled in containers it loses its quality. Customer gets product not in full value. He can not feel it because there is no practice to compare it. Furthermore quality can be increased from manufacturers decision and make product produce bigger value, making customer more satisfied and tear of competitors.

2.5 Possibilities to increase final product quality

The aim of project is to find solution for bio product sterile packaging. Many of bio product are small or very small, micro level product like bacteria, spores micro level organism which is used in various situations, as an end product or middle stage input to get final product or desired outcome.

All microorganisms has to be placed in some kind matrix (environment) to live, develop and be prepared for function it was created. There has to be perfect food, temperature conditions, no interaction with other aggressive substances that could harm product properties.

This type of bacteria is kept in 10 or 20 litter containers as final product and is distributed to 11 countries so far. In 2014 there was 1000 tons sold of this type of bacteria.

If by this projects implementation side by side would go management of customer waste collecting, double value can be achieved. Canisters are made of plastic and could be reused.

The solution preventing impact is to change or clean containers. Choosing different container is considered too expensive. Option for packaging would be glass bottles, which is very vulnerable and price of these many packaging products would increase final price of the product. Cleaning was chosen to be practical to reach desired outcome. Because it is in very small, micro level, washing with simple water isn't an option ether. Best method to clean inside of containers is – sterilization.



Figure 11. Canister technical drawing and measurements.

2.6 The basics of sterilization

Sterilization is the process of destroying all kinds of microbial flora, including their spore forms, and viruses through physical or chemical influences. It is considered to be sterile if the probability of its bioburden is equal to or less than 10 to the power of -6. Sterilization should be performed on medical products that come into contact with the patient's blood, contacting the wound surface and contacting the mucosa and may cause damage to its integrity. Sterilization is a complex

process, for the successful implementation analysis of sterilization product method has to be considered.

Sterilization is a complex process. It is imperative that healthcare workers and technicians involved in the reprocessing and sterilization of medical devices have a thorough knowledge and understanding of the scientific principles and methods of sterilization utilized in today's health care settings.

To make sterilization process efficient main conditions and considerations has to made:

- The sterilants and sterilizing equipment must be validated and appropriate in design and operation to achieve the correct combination of temperature and sterilants combination to be lethal to microorganisms.
- Product or devices has to be properly cleaned from bioburden to make sterilization effective in maximum level
- To reach maximum sterilization there has to be conditions created to contact surface with sterilant.

All methods of sterilization are made to reduce or eliminate microorganisms, that's why people using this method to clean surface have to have in mind that it could be harmful to person. To reduce risk associated with different sterilants and equipment can be forsing staff education, using suggested precaution, established policies and procedures and following the producer instructions for use. [19]

2.7 Sterilization Methods

Sterilization is carried out by physical methods: steam, air, radiation, using infrared radiation, and chemical methods: solutions of chemical agents and gases (In recent years, ozone (sterilizer C0-01-SPB) and plasma sterilization ("Sterrad" installation) have been used, installations based on ethylene oxide, formaldehyde vapors have been used. The choice of method of sterilization of products depends on their resistance to sterilization methods.

Steam sterilization

Sterilization is carried out by physical methods: steam, air, radiation, using infrared radiation, and chemical methods: solutions of chemical agents and gases (In recent years, ozone (sterilizer C0-01-SPB) and plasma sterilization ("Sterrad" installation) have been used, installations based on ethylene oxide, formaldehyde vapors have been used. The choice of method of sterilization of products depends on their resistance to sterilization methods.

Steam sterilization

By a steam method, medical products, parts of instruments and apparatuses made of corrosionresistant metals, glass, surgical linen, dressing and suture material, rubber products (catheters, probes, tubes), from latex, plastics are sterilized.

In the steam method, the sterilizing agent is water saturated steam at an excess pressure of 0.05 MPa - 0.21 MPa (1.1-2.0 bar) at a temperature of 110- 134 °C. The sterilization process takes place in sterilizers (autoclaves). The complete cycle is from 5 to 180 minutes.

Despite the fact that steam treatment is quite effective, it can not always provide sterilization of the tool. The reason for this is that the air cavities in the objects to be sterilized can serve as a thermal insulator, such as dental turbine tips. To solve this problem in autoclaves, the function of creating a preliminary vacuum in the pulsed mode is used. Advantages of the method - short cycle, the possibility of sterilization of non-resistant products, the use of various types of packaging. The disadvantage is the high cost of equipment.

This type of sterilization is useful for small products and is active for outside of product. Unfortunately unsuitable for canisters inside sterilization. One of the key conditions is amount that can be sterilised in one time. Processing one by one is not an option.



Figure 12. Canister technical drawing and measurements

Dry air sterilization

Sterilization with the air method is carried out by dry hot air at a temperature of 160 $^{\circ}$, 180 $^{\circ}$ and 200 $^{\circ}$ C (table). The dry air method sterilizes medical products, parts of instruments and apparatuses of corrosion-resistant metals, glasses marked 200 $^{\circ}$ C, products made of silicone rubber.

Before sterilization by air, the products are pre-sterilized and must be dried in a drying oven at a temperature of 85 ° C until the visible moisture disappears. The full cycle is up to 150 minutes. The advantage of hot air sterilization compared to the steam method is the low cost of equipment. Disadvantages are: a long complete sterilization cycle (at least 30 minutes), the danger of damage to instruments by high temperatures, the inability to sterilize tissues and plastics, only one control parameter is temperature, high energy costs.



Figure 13. Dry heat sterilization chamber [25].

Gas sterilization method

For the gas method of sterilization, a mixture of ethylene oxide and methyl bromide is used in a weight ratio of 1: 2.5 (OB), ethylene oxide, formaldehyde vapor in ethyl alcohol, ozone.

Sterilization with a mixture of OB and ethylene oxide is carried out at a temperature of not less than 18 ° C, 35 ° C and 55 ° C, in pairs of formaldehyde solution in ethyl alcohol at a temperature of 80 ° C. Before gas sterilization, the products are dried after pre-sterilization treatment until the visible moisture disappears. Removal of moisture from the cavities of products is carried out using a centralized vacuum, and in its absence by means of a water jet pump connected to a water tap. When sterilizing OB and ethylene oxide, air is removed to a pressure of 0.9 kg/cm². When using a portable device after the end of sterilization it is kept in a fume hood for 5 hours.

Ozone produced in the ozone sterilizer C0-01-PBS sterilizes products of simple configuration from corrosion-resistant steels and alloys, unpackaged at a temperature of no more than 40 $^{\circ}$ C. The sterilization cycle (access to the regime, sterilization, decontamination) is 90 minutes. After sterilization, the instruments are used for their intended purpose immediately without additional ventilation. The shelf life of the products is 6 hours, subject to the rules of asepsis. When packaging in sterile two-layer cotton fabric, the sterility period is 3 days, and when kept in a cell with bactericidal irradiators - 7 days.

Because of strict conditions and very big aeration time this sterilization method doesn't fit existing conditions to sterilize fertilizers packages.

Infrared sterilization

New methods of sterilization are reflected in the sterilizer of infrared sterilization, intended for sterilization treatment of metal medical instruments in dentistry, microsurgery, ophthalmology and other fields of medicine.

The high efficiency of the IR sterilizing effect ensures complete destruction of all microorganisms investigated, including such as: epidermidis, aureus, sarina flava, Citrobacter diversus, Str. Pneumonia, Bacillus cereus.

Fast, within 30 seconds, the output to the mode of $200 \pm 3 \degree C$, a short cycle of sterilization treatment - from 1 to 10 minutes, depending on the chosen regime, along with low energy intensity.

Sterilizer IR sterilization is easy to operate, does not require specially trained operators, and the method itself refers to environmentally friendly technologies. Unlike steam, air or glasperlene sterilization, IR sterilization does not have an aggressive effect of the sterilizing agent.

Sterilization with chemical agents

This method is used for the sterilization of products whose materials are not thermally stable, and the application of other officially recommended methods is impossible. The disadvantage of this method is that the products can not be sterilized in the package and after the end of sterilization they must be washed with a sterile liquid (water or 0.9% sodium chloride), which, if the rules of asepsis are violated, can lead to secondary seeding with microorganisms of sterilized products.

For chemical agents, sterile containers of glass, heat-resistant plastics that can withstand steam sterilization, metals coated with enamel are used. The temperature of the solutions, with the exception of special regimes for the use of hydrogen peroxide and the lysoformin 3000, should be at least 20 $^{\circ}$ C for aldehyde-containing agents and at least 18 $^{\circ}$ C for the remaining agents.

The chemical method of sterilization is widely used to process "problematic equipment", for example, for equipment with fiber optics, anesthesia equipment, pacemakers, dental instruments. Such modern sterilizing agents as glutaraldehyde, orthophthalic and succinic acid derivatives, oxygen-containing compounds and peracetic acid derivatives in the mode of express sterilization and "Classical sterilization" are used.

Plug the product is sterilized in an exploded view. To avoid violation of the concentration of sterilization solutions, the products immersed in them must be dry. processing cycle is 240-300 minutes, which is a significant shortcoming of the method. A further disadvantage is the high cost of disinfectants. Advantage - there is no special equipment. Washed sterile products after removing liquid from canals and cavities are used immediately for the purpose or after packaging in a two-layer sterile cotton coarse calico, placed in a sterile box laid out with a sterile sheet for a period of not more than 3 days.

All work on the sterilization of products is carried out in aseptic conditions in special rooms, prepared as an operating unit. Staff use sterile protective clothing, gloves, goggles. Rinsing of the products is carried out in 2-3 shifts of sterile water, 5 minutes each.

If surface (inside of canisters) needed to be sterilized would be counted and multiplied with anticipatory sales for the year, amounts of chemicals and the time to process all of them would be massive and irrational to implement in to manufacturing process of bio fertilizers.



Figure 14. Liquid chemical sterilization [24].

Ozone sterilization

The development of modern medical technology requires the development of new effective methods of cold sterilization. Surgical instruments with micron sharpening, endoscopic and laparoscopic equipment, catheters do not withstand temperature treatment with air or steam under

pressure. Limited use of temperature treatment is associated with the widespread use in modern medicine of polymers, optics, glue compounds. Plastics are also used for internal and external prosthetics in dentistry, facial surgery, traumatology, etc.

At present, liquid and gas methods of cold sterilization based on highly toxic chlorinecontaining compounds, ethylene oxide, formaldehyde, hydrogen peroxide are used in the practice of medical and prophylactic institutions, the use of which is associated with the following problems:

- A long sterilization time (4-6 hours).
- Difficulties in recycling of reagents, their adverse impact on the environment.
- The need to remove traces of sterilizing agent from tools and equipment by washing in sterile water or by prolonged aeration with sterile air.
- Adverse effect of a number of sterilizing substances and their derivatives on the health of personnel performing sterilization.
- The use of liquid sterilization of medical instruments is also limited by the inability to use packages and, therefore, simple methods of maintaining the sterility of products until they are used.

Ozone sterilization has a low gas temperature during the sterilization cycle (up to 40 ° C), has a low energy consumption (120 W with a sterilization chamber volume of 10 liters), a relatively short duration of the sterilization cycle, is easy to operate, can be installed directly in the doctor's office, does not require consumables. Materials and chemically resistant disinfectants to be recycled, does not require the washing of products or aeration after the sterilization cycle. Sterilization occurs in ozone, which has a high oxidizing ability. Ozone is obtained from atmospheric oxygen and at the end of the sterilization cycle is converted to oxygen.

Ozone sterilizer is successfully used in departments and offices of dentistry, laparoscopy, endoscopy, microsurgery, urology, plastic surgery, reflexology, etc. For the sterilization of medical instruments. Ozone sterilization cycle time is approximately 4.5 hours, at a temperature of 30 °C – 35 °C, unfortunately takes too long to implement to this project.



Figure 15. Ozone sterilization process explanation [25]

Hydrogen Peroxide Sterilization

This method using hydrogen peroxide creates a plasma cloud. This agent sterilizes by oxidizing key cellular components, which inactivates the microorganisms.

Plasma cloud exists only when engine to generate it is turned on. When it is switched off it creates water vapor and oxygen, arises in no toxic residues, harmful emissions, or the need for environmental monitoring. Temperature for hydrogen peroxide sterilization has to be maintained in the 40-50°C range, which makes it quite suitable for use with sensitive to heat and moisture environment. [21]

Examined basic principles and methods of sterilization I have come to conclusion of best method in my situation - Hydrogen Peroxide Sterilization. This method is safe and environment friendly too. Consumables are not explosive, inflammable or toxic. Hydrogen peroxide sterilize method has some minuses too. It is a strong oxidant, some materials can not be reacting with it, such as paper products. Paper can not be sterilized because of cellulostics in which the hydrogen peroxide would be completely absorbed by the paper.

This method does not require any additional material or lodging preparation, it is completely nontoxic to engines, computers or other equipment. This allows to engineer easy chamber design for sterilization process implementation. [17.]

After researching the available alternatives, the plant decided to investigate a dry fogging approach. The technology selected — the Minncare Dry Fog (DF) System — produces very fine droplets of disinfectant that are dispersed throughout a room. The disinfectant used by this system is a proprietary cold sterilant solution consisting of a stable mixture of peracetic acid and H2O2 that is bactericidal, fungicidal, virucidal, and sporicidal. During the DF process, the humidity level of the room to be treated is first raised to 80%. Then the dry fog solution is evenly and completely dispersed in the room.

The Minncare Dry Fog 2 system provides an easy to use, high technology solution for clean room and critical area fogging. The combination of our highly effective Minncare Cold

Sterilant chemical and our state of the art Dry Fog delivery system enables users to rapidly and safely deliver Minncare vapor to even the most complex areas. Its sanitary and autoclavable design will permit its use in the most critical areas within pharmaceutical and other industries concerned with maintaining the utmost levels of sterility.

The Minncare Dry Fog 2 System produces and ultrafine droplet size that tends to bounce off of hard surfaces and thus avoid excessive condensation, corrosion and surface wetting issues associated with a fine mist bio-decontamination procedure.





Figure 16. Dry fog droplet action

A single DF unit can disinfect rooms up to 1,000 cubic meters in size. Figure 26 shows a sample DF system setup. The disinfectant droplets are only 7.5 microns in diameter, so they bounce off solid surfaces and resist the excessive condensation, possible corrosion, and surface wetting commonly associated with other fogging or manual cleaning procedures. The droplets eventually evaporate and the vapor penetrates normally in accessible areas resulting in a more thorough disinfection process. The chemical is fully biodegradable, requires a extremely short process time, and is much less corrosive than aldehyde-based materials.

Dry fog system will be used not also to disinfect product packages, but make laboratory sterile. It is hard to calculate what part of price goes to sterilization chamber. The clean working environment for biological product is crucial and can not be ignored. Companies using methods and ways to improve their product event without direct revenue count, in long run will reach higher quality and trust of customers leading to bigger market share and stronger competitiveness.



Figure 17. Dry Fog 2 System [26].

2.9 Sterilization quality Assurance

Control of sterilization efficiency is carried out by physical, chemical and bacteriological methods. The physical methods of control include: measurement of temperature, pressure and time of application of sterilization.

For chemical control over decades, chemical substances having a melting point close to the sterilization temperature were used. Such substances were: benzoic acid - for steam sterilization; Sucrose, hydroquinone and some others for controlling air sterilization. If there was a melting and a discoloration of these substances, the result of sterilization was considered satisfactory.

For this project there after sterilization chamber manufacturing simple ICPVS-Medtest will be used to check level of moisture inside of canisters. [17]

2.10 Sterilization chamber implementation in to existing manufacturing process

The conditions are quite simple, in to existing manufacturing process, before purring in to containers and moved to logistics sector, there has to be designed one more step for sterilization of containers before final product is packaged. The manufacturing plant is quite big and not all space is used, it allows easy implementation of additional division without moving or redesign existing process and stopping manufacture.

The manufacturing process of bio fertilizers in Bio-energy already has lean system in order. To add additional division to the plant and process makes sterilization chambers design bit difficult, but hopefully sterilization of packages effects just last stages of manufacturing process, not touching any existing algorithms. I am adding just one more chamber before pouring final product to canisters. The sterilization gas is poured in to the chamber and effects everything around it. The problem occurs from design of canister. The surface to be sterilized is inside and the only place to get in is small 52 mm diameter pouring cap. The idea is to design structure of pipes that on one side will be hocked up with intake of sterilization gas and releasing through outlets where canisters will be hanged by pouring caps. This way all the gas will go through structure and fill canisters inside with sterilization gas and will make its purpose.

The research to for design has two stages:

1. Create structure design to fill chamber with many canisters ass possible to make process maximum efficient in amount which can be sterilized on one circle.

2. Check flow of sterilization gas in outlets of pipe structure to be sure that all canisters will get enough gas and will be sterilized fully in one process circle.

3. STERILIZATION CHAMBER DESIGN

3.1 Pipe structure design

The sterilization chamber has erea of 10,22 sq. meters. Measurements of inside of new lodging is 220 cm height, 190 cm width. The goal is to create optimal way to sterilize maximum amount of canisters in one process. The measurements is clear to use maximum height and width.

The constant is size of canisters:

Canisters size					
Lenght	300 mm				
Widht	258 mm				
Height	377 mm				

Table 2. Canisters measurements

To optimize the process there is maximum 6x6 canisters fitting on one side of structure, which makes 36x2 (two sides) – 72 in total on one structure. By these measurements full structure fits in the chamber almost perfectly, which means task one is complete – make optimal design to fit maximum canisters using all the space.

The design is chosen to have main pipe in bigger diameter to spread sterilization gas faster trough smaller ones. Air debit has to be around 400 m³ per hour so small pipe would overcharge engine and not all or just small amount of few would get enough gas.



Figure 18. Sketch with measurements for mainframe.



Figure 19. Solid works drawing of pipe construction



Figure 20. Pipe structure visualization. Half assembled with canisters

3.2 Calculations for material

Main construction part is oval pipes. Three different diameters -60 Ø mm holding vertical pipes, 100 Ø mm main pipe and 40 Ø mm outlet pipes. The material will be used chromium nickel stainless steel (04X18H10, 08X18H10T). Usually it is used for in chemical, food industry, build reservoirs. It can handle more than 600 degrees temperature. Thin, will not allow structure to rust because of hydrogen pumped through inside and quite light to easily move the construction around.



Figure 21. Stainless steel pipe

No.	Туре	Diameter inside (mm)	Туре	Length (mm)	Amount of pieces	Total (mm)
1.	Round	60	316	1890	2	3780
2.	Round	60	316	1640	4	6560
3.	Round	100	316	1690	1	1690
4.	Round	40	316	150	72	10800
5.	Square	20x40	316	1360	1	1360
6.	square	20x40	316	876	2	1752
7.	Sheet	1	316	120x120	4	

Table 3. The measurements of stainless steel needed.

The pipes for outlet and hanging of the canisters has to be 40 mm diameter to have empty space for air overload inside canisters to come out. Different distance from air engine will create different airflow and can not be made equal. The principle is to fill all canisters with at least 20 litres of air mixed with sterilization gas.

The price in Lithuanian market for these type of pipe is around 10,90 euros/m for 60 Ø mm, 7,30 euro/m for 40 Ø mm and 13,90 euro/m for 100 Ø mm. Full length for pipes needed will make a price for material – 77,80 euro total for pipe construction. Other material, like holding legs and wheels for moving isn't calculated because factory has spare parts left fully functioning and doable for the project. Welding is best option to connect all the pipes in to one structure. There is space and machinery to cut, bend and weld in one division.

3.3 Flow analysis

Other objective of research project goal execution is to calculate what kind of engine should be mounted on pipe construction and how much air has to be inflated in to structure to fill all 72 canisters with at least 20 litters of air with sterilization gas.

For this goal I used SolidWorks flow simulation ad in. There was made three different calculations for three types of engines. The results had shown that to reach desired outcome in all outlets it is enough to create 170 m³/h air flow in to the system.



Figure 22. Air flow simulation in structure

The sterilization process is complete after 45 minutes. The whole process takes one hour, from the start of mounting canisters on construction to filling it and tacking out of chamber. Goal is to fill all canisters at least **20 litters**.

The structure is symmetrical and has sides A and B. The simulation of air flow in it was made in two conditions of time – 30 minutes and one hour. The results has shown that both side outlets without exception had more than 20 cubic meters of air flowed through it. This come to conclusion that this pipe structure is fulfilling the conditions and design is eligible for the project.

Results vary in different outlets, but still in acceptable range. This happens because of pipe structure sharp corners and air flow is going inside bends and comes around or creates vortexes, thus weakening flow in places there flow had to many obstacles to overcome.

Flow of 1 m³ equals to 1000 L, this means at least 0,2 m³ has to go out from each outlet. For Inlet I chose 400 m³/h (0.111 m³/s) ventilator as an engine to create flow. Results exceeds the needs. Every canister will get sterilization fog from outside and will fulfil the aim of the project. Result table is shown in Table 5 (page 60).



Figure 23. Air flow in A side oputlets (30 min)



Figure 24. Air flow in B side oputlets (30 min)



Figure 25. Air flow in each outlet 60 min side A



Figure 26. Air flow in each outlet 60 min side B

Engine to fit requirements is Canal ventilator DOSPEL WK100.

Output 400m3/h

Pressure - 340Pa

Noise 60dB/1

Power - 70 W

Price - 70,10 EUR



Figure 27. Canal ventilator DOSPEL WK100

The price for all project material is:

Sum = 209,80 + 71,10 + 11,200 (Price of fog machine) = 11348,90 EUR

3.4 Installing sterilization process in to manufacturing of bio fertilizers

The sterilization division is one of the final processes towards product manufacturing. After it only comes pouring and logistics by the marketing, which is not directly connected to product development. The difference from before will be just simple process for packages to go thru sterilization chamber. Other processes will not be effected or redesigned.

- Sterilization of 72 canisters will take around 60 minutes from start of the process:
- Preparations (mounting canisters on pipe structure) 10 min

- In the same time sterilization chamber is filled with hydrogen peroxide gas 10 min.
- 30 min takes to fully reach all canisters and sterilize inside of each and one of them.
- 20 minutes left for evaporate chamber, pushout structure, and unmount canisters ready to fill with product



Figure 28. Product packages movement in factory

Number 26 is warehouse for containers. From Poland it is delivered every month according to order plan given by sales department. Before filling with product containers is mounted on pipe structure and sterilization chamber (27) is filled with hydrogen peroxide. The process takes 45 minutes from the start of filling room till taking canisters out to corridor to pouring room (28) – the final stage for product manufacturing.

3.5 Additional value

To reach maximum quality using Kaizen principle in this project there is one more step to be taken to increase value in bio-fertilizers manufacturing – reusable packaging.

If sterilization chamber will be successful integrated the sales and marketing department will create new approach to customer with more environment friendly ideas and sales pitch. Marketing will have one more argument to dictate our mission statement – "everything for Her – everything for the earth".

To calculate project return ratio, reused packages should be counted. Problem occurs to communicate with final customer to bring him in to cooperation with manufacturer and manage his time to agree on the time when exact time product will be used, or bring the product to farmer just in time so packages can be brought back not injured and able to reuse it again. With sterilisation chamber in manufacturing process, prices for packaging could become absolute or reduced significantly.

The final customer has to get lower prices or other attractive deal to join the reusable containers project, but still for the company it will be profitable reuse packages as much as the marketing sides increased arguments and "value for nature" generating profile.

Other idea for quality improvement of company was created doing this project – automatic calculation for anticipation for next year yield. Aleksandras Stulginskis university programmes usually consists of agronomist studies which using biological factors can calculate future yield depending on conditions of existing soil (bacteria, humus, previous fertilizer norms), adding existing features to the formula of seed breed and variate in fertilizers norms anticipation for next year yield is accurate in around 70 %.

This is easy way to add algorithm to application and distribute it though customers like innovation with commercial of existing products in Bio-energy product line.

Conclusions

- After analysis of existing quality improvement methods I suggest to use Pareto analysis to find and identify existing errors in manufacturing process. Quality improvement will lead to increased competiveness of company and keep one step ahead in new market when new competitors occurs rapidly.
- Because of high technological and financial advantage comparing to other new players in the market Bio-energy invested to research and develop product quality improvement project. To improve product Pareto analysis was made and was found a packaging problem which reduces biological product activity thus - reliability of a product.
- 3. To improve quality the decision to sterilize packages (containers) was initiated. Most reliable method to achieve goal is hydrogen peroxide. Filling chamber with H₂O₂ eliminates microorganism on every surface fog settles on. This is very cheap and easy to use method. The need of technological solution occurred because surface to sterilize is inside of packaging container. Only through small cap fog can reach inside wall of canister. The structure was designed according to sterilisation chamber measurements, to fit maximum canisters in one process.
- 4. I have designed system, hollow pipe structure for optimal mounting of the packaging containers, made air flow simulation inside it. This let me to choose right engine for air flow to mount on the system. The structure allows to sterilize 72 canisters in one process and engine ensures minimal requirements for project 20 liters flow inside canisters. SolidWorks software where used in both steps of research project mechanical part design creation. It makes more accurate calculations to achieve goals right first time.
- 5. Integrating sterilisation chamber in to manufacturing does not interact with existing manufacturing process and will increase customer satisfaction about the product generated value. If reusable packaging project will be success company will detach from competitors with high jump and will make profits to grow by exponential curve.
- 6. Possibility to integrate packages reuse project occurred. Involvement of sales department employs who have direct communication could offer to carefully use product without damaging canisters thus reuse it again in further sales. This could reduce price of the project and bring more value and close connection to the customer. Also it could lead to contribution of plastic waste reduction and will make company more environment

References

- HRSA. Q QU UA AL LI IT TY Y I IM MP PR RO OV VE EM ME EN NT T. [online].
 2011. [Accessed 22 May 2017]. Available from: https://www.hrsa.gov/quality/toolbox/508pdfs/qualityimprovement.pdf
- PIPAN, Karmen Kern. Quality improvement methodologies PDCA cycle, RADAR matrix , DMAIC and DFSS Quality Improvement Methodologies - PDCA Cycle, RADAR Matrix, DMAIC and DFSS. 2010. No. November.
- XU, Qianli, JIAO, Roger J, YANG, Xi, HELANDER, Martin, KHALID, Halimahtun M and OPPERUD, Anders. An analytical Kano model for customer need analysis. *Design Studies* [online]. 2009. Vol. 30, no. 1, p. 87–110. DOI 10.1016/j.destud.2008.07.001. Available from: http://dx.doi.org/10.1016/j.destud.2008.07.001
- DRUCKER:, Peter F. and CUSTOMERS, Delivering Value to. Peter F. Drucker: delivering value to customers. *Measuring Business Excellence* [online]. 2002. Vol. 6, no. 4,
 p. mbe.2002.26706dae.007. DOI 10.1108/mbe.2002.26706dae.007. Available from: http://www.emeraldinsight.com/doi/10.1108/mbe.2002.26706dae.007
- 5. The Relationship between Customer Satisfaction and Service Quality: a study of three Service sectors in Umeå. [online]. [Accessed 22 May 2017]. Available from: http://www.diva-portal.org/smash/get/diva2:448657/FULLTEXT02.co
- ISO. Quality management principles. 2015 [online]. 2015. P. 20. DOI ISBN 978-92-67-10650-2. Available from: http://www.iso.org/iso/pub100080.pdf
- MORPHOLOGY, Ling. Principle 1 : Principle 2 : Principle 3 : Principle 4 : [online]. 2010.
 P. 1–2. Available from: http://www.iso.org/iso/qmp.htm
- 8. AGES, Middle. Quality Management : Then , Now and Toward the Future. . 1990.
- W. E. DEMING INSTITUTE. Dr. Deming's 14 Points for Management [online]. 2016. [Accessed 1 May 2017]. Available from: https://deming.org/managementsystem/fourteenpoints
- 10. *QUALITY*. [no date]. ISBN 007034003X.
- 11. Pareto Principle. [online]. [Accessed 1 May 2017]. Available from:

http://www.investopedia.com/terms/p/paretoprinciple.asp

- The Juran Trilogy | Continuous Improvement Blog. [online]. [Accessed 1 May 2017]. Available from: https://blogs.mtu.edu/improvement/2014/02/27/the-juran-trilogy/
- Kaizen Creates a Culture of Continuous Improvement. [online]. [Accessed 1 May 2017]. Available from: http://www.leanproduction.com/kaizen.html
- The Basics of Lean Six Sigma. [online]. [Accessed 1 May 2017]. Available from: https://goleansixsigma.com/wp-content/uploads/2012/02/The-Basics-of-Lean-Six-Sigmawww.GoLeanSixSigma.com_.pdf
- 15. MELTON, T. THE BENEFITS OF LEAN MANUFACTURING What Lean Thinking has to Offer the Process Industries. [online]. [Accessed 8 May 2017]. DOI 10.1205/cherd.04351. Available from: http://www.mimesolutions.com/PDFs/WEB Trish Melton Lean Manufacturing July 2005.pdf
- MABIN, Victoria. Goldratt's " Theory of Constraints" Thinking Processes: A Systems Methodology linking Soft with Hard. [online]. [Accessed 8 May 2017]. Available from: https://www.systemdynamics.org/conferences/1999/PAPERS/PARA104.PDF
- Microbes Will Feed the World, or Why Real Farmers Grow Soil, Not Crops Modern Farmer. [online]. [Accessed 10 May 2017]. Available from: http://modernfarmer.com/2014/04/microbes-will-feed-world-real-farmers-grow-soil-crops/
- THE BASICS OF STERILIZATION. [online]. [Accessed 9 May 2017]. Available from: http://www.casemed.com/caseacademy/downloads/CASDF003.pdf
- 19. 2. ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION, GUIDELINES FOR THE SELECTION AND USE OF REUSABLE RIGID STERILIZATION CONTAINER SYSTEMS FOR ETHYLENE OXIDE STERILIZATION IN HEALTH CARE FACILITIES, ANSI/AAMI ST33:1996. ANSI/AAMI ST77:2013 -Containment devices for reusable medical device sterilization. 2013.
- Training Manual for Health Care Central Service Technicians. [online].
 [Accessed 9 May 2017]. Available from: https://leseprobe.buch.de/imagesadb/2d/68/2d68b595-878d-43f4-88a4-615e887afa68.pdf
- 21. ADAM, Everett E, CORBETT, Lawrence M, FLORES, Benito E, HARRISON, Norma J, LEE, T S, RHO, Boo-ho, RIBERA, Jaime, SAMSON, Danny and WESTBROOK, Roy.

International Journal of Operations & amp; Production Management. *International Journal of Operations & Production Management International Journal of Operations & amp; Production Management Iss International Journal of Quality & amp; Reliability Management* [online]. 1997. Vol. 17, no. 3, p. 842–873. [Accessed 22 April 2017]. DOI 10.1108/01443579710171190. Available from: http://dx.doi.org/10.1108/01443579710171190

Annexes

Surfa	Volume Fl	ow Rate	m ³ /	30min	m³/h s	side A	Litter	s/30 min	Litter	s/h side
ce No.	[m ³ /s] side A	A II B	side A	II B	II B		side A	II B	A II B	
1	0,0013	0,0014	2,34	2,52	4,68	5,04	2340	2520	4680	5040
2	0,0013	0,0003	2,34	2,16	4,77	4,45	2001	2530	4580	4550
3	0,0014	0,0012	2,52	2,16	5,04	4,32	2520	2160	5040	4320
4	0,0015	0,0014	2,7	2,52	5,4	5,04	2700	2502	5400	5040
5	0,0004	0,0003	0,72	0,54	1,44	1,08	720	540	1440	1080
6	0,0013	0,0013	2,34	2,34	4,68	4,68	2340	2340	4680	4680
7	0,0015	0,0016	2,7	2,88	5,4	5,76	2700	2880	5400	5760
8	0,0014	0,0014	2,52	2,52	5,04	5,04	2520	2520	5040	5040
9	0,0011	0,0011	1,98	1,98	3,96	3,96	1980	1980	3960	3960
10	0,0011	0,0011	1,98	1,98	3,96	3,96	1980	1980	3960	3960
11	0,0015	0,0015	2,7	2,7	5,4	5,4	2700	2700	5400	5400
12	0,0015	0,0016	2,7	2,88	5,4	5,76	2700	2880	5400	5760
13	0,0014	0,0014	2,52	2,52	5,04	5,04	2520	2502	5040	5040
14	0,0014	0,0013	2,52	2,34	5,04	4,68	2520	2304	5040	4680
15	0,001	0,0009	1,8	1,62	3,6	3,24	1800	1602	3600	3240
16	0,001	0,0009	1,8	1,62	3,6	3,24	1800	1620	3600	3240
17	0,0014	0,0014	2,52	2,52	5,04	5,04	2520	2502	5040	5040
18	0,0013	0,0014	2,34	2,52	4,68	5,04	2340	2050	4680	5040
19	0,0015	0,0015	2,7	2,7	5,4	5,4	2700	2700	5400	5400
20	0,0014	0,0014	2,52	2,52	5,04	5,04	2520	2502	5040	5040
21	0,0011	0,0011	1,98	1,98	3,96	3,96	1980	1908	3960	3960
22	0,0011	0,001	1,98	1,8	3,96	3,6	1980	1800	3960	3600
23	0,0014	0,0014	2,52	2,52	5,04	5,04	2520	2520	5040	5040
24	0,0015	0,0015	2,7	2,7	5,4	5,4	2700	2700	5400	5400
25	0,0025	0,0025	4,5	4,5	9	9	4500	4500	9000	9000
26	0,0022	0,0021	3,96	3,78	7,92	7,56	3960	3780	7920	7560
27	0,0017	0,0017	3,06	3,06	6,12	6,12	3060	3060	6120	6120

Table 4. Air flow results in each outlet (30 min / 60 min)

28	0,0017	0,0016	3,06	2,88	6,12	5,76	3060	2808	6120	5760
29	0,002	0,002	3,6	3,6	7,2	7,2	3600	3600	7200	7200
30	0,0025	0,0025	4,5	4,5	9	9	4500	4500	9000	9000
31	0,0036	0,0036	6,48	6,48	12,9	12,9	6480	6408	1296	12960
32	0,0036	0,0036	6,48	6,48	12,9	12,9	6480	6048	1296	12960
33	0,0025	0,0025	4,5	4,5	9	9	4500	4500	9000	9000
34	0,0024	0,0024	4,32	4,32	8,64	8,64	4320	4302	8640	8640
35	0,0033	0,0033	5,94	5,94	11,8	11,8	5940	5940	1188	11880
36	0,0036	0,0036	6,48	6,48	12,9	12,9	6480	6480	1296	12960

Bacteria activity after packaging (%) Azofix / Fosfix							
Test No.	Norm	Azofix	Fosfix	Test No.	Norm	Azofix	Fosfix
1	90	95	99	51	90	98	97
2	90	67	97	52	90	93	96
3	90	97	97	53	90	77	92
4	90	95	99	54	90	95	96
5	90	96	99	55	90	99	94
6	90	99	94	56	90	96	96
7	90	95	97	57	90	97	69
8	90	99	97	58	90	93	99
9	90	96	97	59	90	93	99
10	90	98	98	60	90	98	98
11	90	97	96	61	90	92	77
12	90	99	99	62	90	95	94
13	90	93	98	63	90	97	94
14	90	95	94	64	90	95	96
15	90	93	95	65	90	95	93
16	90	92	93	66	90	98	93
17	90	93	77	67	90	99	98
18	90	98	97	68	90	75	95
19	90	94	99	69	90	99	96
20	90	96	96	70	90	95	97
21	90	93	68	71	90	99	95
22	90	96	94	72	90	94	98
23	90	92	95	73	90	94	98
24	90	97	97	74	90	99	95
25	90	94	93	75	90	96	99
26	90	96	97	76	90	95	97
27	90	68	95	77	90	95	96
28	90	95	98	78	90	71	98
29	90	92	96	79	90	92	96
30	90	95	92	80	90	97	94
31	90	80	92	81	90	94	77
32	90	93	95	82	90	93	96
33	90	95	80	83	90	94	99
34	90	99	97	84	90	98	92
35	90	96	99	85	90	93	92

Table 5. Test results of final product reliability

36	90	94	92	86	90	92	98
37	90	97	93	87	90	96	94
38	90	93	98	88	90	92	75
39	90	69	93	89	90	96	94
40	90	99	99	90	90	94	93
41	90	97	97	91	90	97	93
42	90	99	98	92	90	77	94
43	90	97	97	93	90	94	95
44	90	93	93	94	90	99	97
45	90	97	92	95	90	94	94
46	90	97	93	96	90	97	96
47	90	94	96	97	90	96	72
48	90	96	99	98	90	95	70
49	90	95	94	99	90	94	98
50	90	94	92	100	90	92	96

Table 6. Lodging number and sizes

No.	Lodging	Size m ²
1.	Cabinet	36,44 m ²
2.	Corridor	34,20 m ²
3.	Cabinet	16,96 m ²
4.	Cloakrooms	16,55 m ²
5.	WC	1,55 m ²
6.	WC	1,44 m ²
7.	Shower	2,09 m ²
8.	Shower	2,09 m ²
9.	Cloakrooms	8.26 m ²
10.	Kitchen	18,47 m ²
11.	Shower	2,06 m ²
12.	Shower	1,95 m ²
13.	Cloakrooms	9,48 m ²
14.	Cloakrooms	4,74 m ²
15.	Cloakrooms	3,98 m ²
16.	Cloakrooms	4,78 m ²
17.	Tambour	2,25 m ²
18.	Corridor	7,15 m ²
19.	Corridor	8,49 m ²
20.	Stock	15,27 m ²
21.	Tambour	3,63 m ²
22.	Spreads preparation room	17,91 m ²
23.	СР	27,56 m ²
24.	Finished goods warehouse	390,12 m ²
25.	Shower	3,23 m ²
26.	Warehouse for packaging containers	149,71 m ²
27.	STERILIZATION CHAMBER	$10,22 \text{ m}^2$
28.	Packaging room	20.12 m ²
29.	Corridor	31.16 m ²
30.	Gas generator room	36,15 m ²

31.	Air compressor	35,40 m ²
32.	Warehouse	16,87 m ²
33.	Changing room	7,62 m ²
34.	Corridor	6,0 m ²
35.	WC	1,58 m ²
36.	Shower	2,06 m ²
37.	Laboratory	23,16 m ²
38.	Laboratory	11,2 m ²
39.	Autoclave	2,66 m ²
40.	Autoclave	2,66 m ²
41.	Washing room	12,86 m ²
42.	Corridor	5,17 m ²
43.	Laboratory	8,98 m ²
44.	Warehouse	1,66 m ²
45.	Changing room	6,04 m ²
46.	Operators room	16,22 m ²
47.	Manufacturing room	141,11 m ²
48.	Warehouse	3,12 m ²
49.	Packaging room	34,04 m ²
50.	Tambour	2,09 m ²
51.	Electricity room	$2,0 \text{ m}^2$
TOTAL:		1231,74 m ²