Kaunas University of Technology

Faculty of Mechanical Engineering and Design

Analysis, Modernisation and Digitisation of Industrial Mixing

Master's Final Degree Project

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Project author

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Supervisor

Kaunas, 2019

Kaunas University of Technology

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Industrial Engineering and Management (6211EX018)

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Analysis, Modernisation and Digitisation of Industrial Mixing

Declaration of Academic Integrity

I confirm that the final project of mine, Valdas Stundys, on the topic „Analysis, Modernisation and Digitisation of Industrial Mixing " 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 has been plagiarised 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 project.

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 University of Technology

Faculty of Mechanical Engineering and Design

The task of the Master's final degree project

Given to the student – Valdas Stundys

1. **Title of the project –**

Analysis, Modernisation and Digitisation of Industrial Mixing

(In English)

Pramoninio medžiagų maišymo analizė, modernizavimas ir skaitmenizavimas

(In Lithuanian)

2. **Aim and tasks of the project –**

Aim: to analyse and develop mixing process environment, propose the modernisation solutions including (approach) of industrial digital transformation. The tasks are:

1. To Review and analyse digital transformation trends, needs and problems.
2. To develop mixing layout.
3. To prepare gap analysis.
4. To prepare project charter.
5. To propose solutions for modernization and digital transformation.

3. **Initial data of the project –**

The initial layout for the pre-booked area, the vision of mixing process needs and regulations.

4. **Main requirements and conditions –**

CE certified equipment, layout according to health and safety requirements ISO45001:2018. An automatically controlled system with minimum intervention of an operator.

Project author	Valdas Stundys		
	(Name, Surname)	*(Signature)*	*(Date)*
Supervisor	Jolanta Baskutienė		
	(Name, Surname)	*(Signature)*	*(Date)*
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Valdas Stundys. Analysis, Modernisation and Digitisation of Industrial Mixing. Master's Final Degree Project, supervisor Associated professor Jolanta Baskutienė; Faculty of Mechanical Engineering and Design, Kaunas University of Technology.

Study field and area (study field group): Production and Manufacturing Engineering (E10).

Keywords: process, analysis, layout, modernisation.

Kaunas, 2019. Number of pages 43.

Summary

The project explores the possibilities of a mixing process premise deployment in a new plant.
The analysis necessary for the implementation of the project has been carried out. Problems have been identified, and solutions for mixing room installation and equipment selection have been developed to ensure a relatively fast, cost-effective process assuring compliance in budget and requirements. The proposed solution includes the scope for extension. The equipment necessary for the implementation of the digital control selected. The analysis of the existing mixing premises within the company accomplished, and equipment layout was developed. The trends and needs of digitisation were analysed. The model of the mixing premise and equipment allocation was developed. The analysis included in the project showed, that solutions to equipment layout to be successful need management staff to be trained and guided.
It was found that the potential problem of digitisation is predefined by the limited number of software engineers, and lack of their creativity. The analysis of digitisation leads to the conclusion that data collection solutions should be deliberate, valuable, but not related to wastes in time and space.

Valdas Stundys. Pramoninio medžiagų maišymo analizė, modernizavimas ir skaitmenizavimas. Magistro baigiamasis projektas, vadovė doc. Jolanta Baskutienė; Kauno technologijos universitetas, Mechanikos inžinerijos ir dizaino fakultetas.
Studijų kryptis ir sritis (studijų krypčių grupė): Gamybos inžinerija (E10).

Reikšminiai žodžiai: procesas, analizė, išdėstymas, modernizavimas.

Kaunas, 2019. Puslapių sk. 43p.

Santrauka

Projekte nagrinėjamos patalpos maišymo proceso realizavimui naujoje gamykloje galimybės.
Atlikta projekto įvykdymui būtina analizė. Identifikuotos problemos ir parengti maišymo kambario įrengimo ir įrangos parinkimo sprendimai, užtikrinantys sąlyginai spartų, ekonomišką ir keliamus reikalavimus bei biudžetą atitinkantį procesą. Pasiūlytame sprendime įvertintos išplėtimo galimybes. Parinkta įranga, kuri reikalinga skaitmeniniam valdymui realizuoti.
Atlikta esančios patalpos ir įrangos analizė. Nagrinėtos skaitmenizavimo kryptys ir poreikiai. Sudarytas maišymo kambario ir įrangos išdėstymo modelis.
Projekte atlikta analizė parodė, kad įrenginių išdėstymo sprendimų sėkmingumui užtikrinti yra būtini mokymai vadovams.
Identifikuotos potencialios skaitmenizavimo problemos, kurias sąlygoja nepakankamas programavimo darbus vykdančio personalo skaičius ir riboti kūrybiškumo resursai. Skaitmenizavimo analizė leidžia daryti išvadą, kad duomenų kaupimo sprendimai turi būti apgalvoti, turėti vertę ir nebūti susiję su laiko ir vietos švaistymo nuostoliais.

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List of abbreviations and terms

Abbreviations:

Assoc. prof. – associate professor;
Prof. – professor.
A3 – problem-solving mythology which outcome is structured data presented on A3 format paper
NPI – new product implementation department
AR – Augmented reality
ME – manufacturing engineering
DX – digital transformation
AI – Artificial intelligence
IoT – Internet of Things
SE – Software engineers
OEE - overall equipment efficiency
WIP – work in progress material
KPI – key parameter indicator
PLC – programmable and logical controller
HMI – human-machine interface
URS – user requirement specification
SCADA - supervisory control and data acquisition system
GMP – good manufacturing practices
GAMP – good automated manufacturing practices
CGMP – current good manufacturing practice
CMMS – computerised maintenance management system

Introduction

After a customer audit, the considered company has received recommendations to improve the raw material environment:

- ✓ To improve the work environment in a raw material preparation room – safer, more ergonomic;
- ✓ To increase the repeatability by implementing the automated material delivery system;
- ✓ To migrate to an automated system platform;
- ✓ To Improve OEE;
- ✓ To Collect available data and assign to lots;
- ✓ To monitor the process.

Initially, the manufacturing process requires blending up to ten raw material components, in the picture below raw material named from P1 to P10, to get required WIP (work in progress) material for next manufacturing steps.

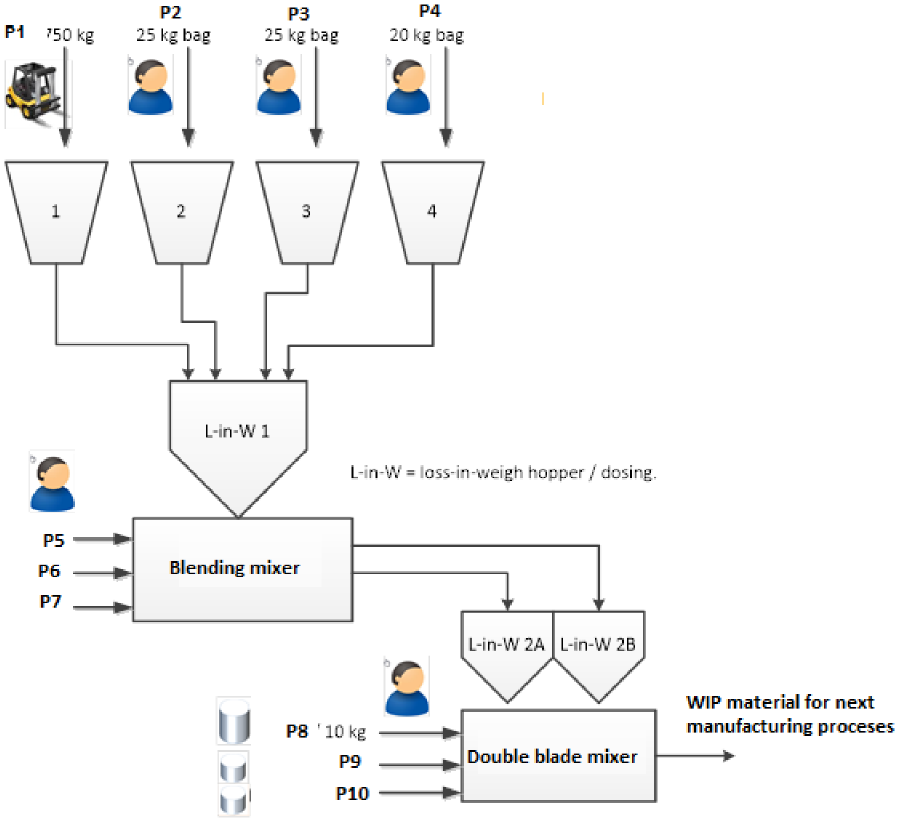


Fig 1. Old mixing room equipment layout

Picture 1 represents existing process flow where six operators, including forklift driver, are involved in performing the mixing operation. Currently, operators are responsible for dosing raw material manually by weights. The preparation process is a semi-automated process in small batches where each of them weight 35kg on average. Semi-automated means that process controlled by the operator and only mixer controlled by PLC.

The main issue here is the manual process takes too much time in preparation, because every dose of every component weighted separately manually. Also, mixing in small batches takes a longer time to produce the required volume demand to fulfil production needs. Even though preparation for different products, mixing takes a big part of available production time. Evaluation of old mixing layout are:

Table 1. Initial key parameters table

Property	**Current situation**
The system is capable of processing.	Materials from P1 to P10
Machine Availability (Uptime / available time)	On average 50%
Machine Performance	> 50%
Actual process speed upon production	> 50%
Yield (Good parts / total parts started)	> 80%
Operating Requirements	Six operators running process
Critical process	Weight of components
Repeatability	Repeatability of weighing process 0,5kg per 35kg WIP product amount

In the new build location, there is a need to build new mixing area for the production of mixed materials. There are available much of experience within the company. However, experience gained a while ago may not or do not comply with today's manufacturing trends and requirements for healthy and sustainable business.

Aim: to analyse and develop the mixing process area, propose the modernisation solutions, including the approach of industrial digital transformation.

To reach the aim of the project, the following tasks must be solved:

1. To review and analyse the current state and define digital transformation trends, needs and problems.
2. To develop a mixing process area layout.
3. To prepare gap analysis.
4. To prepare project charter.
5. To develop solutions for modernisation and digital transformation.

1. Digital transformation trends, needs and problems analysis

The company has business locations worldwide. It produces health care products to make life more rewarding and dignified for people who use “Hollister” products and services. It employed about 4000 people. “Hollister” decided to increase production capacity and choose Lithuania as the country for expansion.

Within my responsibilities is NPI – new product implementation. In other words that are more scientific, my activities related to manufacturing engineering — our department is implementing new projects or capacity increase projects. On a day-to-day basis, we are performing project equipment and workplaces implementation, as well as calculating process equipment and router costs for new possible opportunities, or savings. Here, starts the development of manufacturing engineering and technical processes. Selecting equipment, we care about tact time or cycle time of operation. Using “MOCK-UP” or paper dolls, we simulate how everything is provisionally going to look like, what maintenance might be in need, ergonomics of operators, and production performance of operators. Paperwork instruction represents the requirements for assembly.

The considered department is the ones who implements new and not tested technologies in Kaunas location. Last year seven worldwide known but not tested in Kaunas location technologies such as plastic heat staking, plastic welding by laser, fully automated assembly lines, selective soldering, double crimp press, solar sensor 3D calibration, and testing stands, high-pressure plastic moulding process were implemented. All the mentioned technologies known in the world for years. However, dependant on the complexity of our applications we have found them completely new and some of them requires training to get familiar with them even for professionals with 10 or more years’ of experience to keep processes within six sigma.

All the mentioned technologies require data, information, knowledge, and experience for decision-making. Also, from a hardware standpoint, all equipment requires drawing analysis, user experience with software and operation manuals, work instructions.

Raw material preparation room implementation is a real ongoing project in a real company. The project had to/have to pass stages like, preparation for the project – project charter, AFE approval, in-depth research in preparation, equipment performance study and research in overall system performance. Digital part of this equipment is the area where improvements still possible. From here, the digital transformation from a manual process to an automated system controlled by compute should be considered. Data collection, information generation, and knowledge for decision making development, communication between other departments and with other systems are part of digital transformation. The analysis of the process provides the possibility to describe the process and propose the solution for the transition from the manual and locally controlled to automated process. Also, by using digital transformation, the process parameters, process control, and data collection will be available for anyone remotely.

1.1. Changes and innovations

“Analysis, Modernisation and Digitisation of Industrial Mixing” from its meaning it is a process of changes - it is an alteration to either in people, either in structure, either in technology. (Čiutiene, 2014/2015) Change itself, as a process, is a modification of the structure or process of a system. Change from its nature may be **reactive** or **proactive**. When changes brought due to the pressure of external forces, it called reactive change.

The management on its own, to increase organisational effectiveness, initiates proactive change. Only proactive modifications discussed in this document.

The outcomes of proactive change also lead to innovation - Process of taking a creative idea and making into a useful product, service, or method of operation**. –The innovation must be new to the organisation, although other organisations or companies could have originally developed it.**

- Scientific research and experimental development create ideas – where possible to make changes or innovations. In this way, many trials with production, equipment need to execute.
- Production – creates ideas in the production area, following the principles established by experimental trials and developments, where outputs transformed into production.

Change = innovation =novelty – it is the introduction of a new or significantly improved process, to an organisation. This also means technologically improved commodity equipment that incorporates software that improves user-friendliness or convenience by:

- Technological features;
- Opportunities to use;
- Functional features;
- Construction;
- Design;
- New equipment's;
- New methods of organisation production processes.

Key guidelines of the process of changes are:

- The need for changes must be recognised, and weak spots identified.
- There is no need to know exactly what to do, but it must be clear if something does not work.
- How changes the work and what exactly should be changed?
- The decision must be suitable for those who will implement.
- The requirements must be acceptable and realisable.

By using key guidelines, it is necessary to look through raw material preparation room modernisation and implementation. Description of what the target is and what the steps are on how to get there.

1.2. ME – manufacturing engineering

Manufacturing engineering (ME) is a subject matter of engineering, which is dealing with different manufacturing practices. It is the research and development of systems, processes, machines, tools, and equipment for manufacturing. Manufacturing engineering (ME) as an activity takes place between product design and the manufacturing process. (Marius Rimašauskas, 20170215)

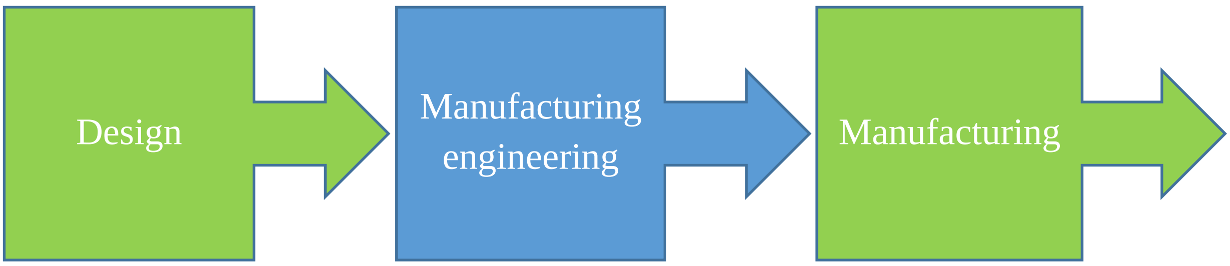


Fig 2. Manufacturing engineering spot in a manufacturing company

ME it is a service function to the manufacturing department where all new products and all updates on the products coming into production. Manufacturing engineering is the whole of technical support, organisational and economic means, making it possible to develop qualitative manufacturing technology. Manufacturing engineering consist of technological processes:

- Technological operations sequence,
- Machine-tools,
- Technological equipment,
- Materials and blanks, their outlay,
- Dimensions and tolerances,
- Operation time,
- Measurement methods and equipment,
- Part design,
- Criterions of part inspection.

Technological processes (TP) developed for manufacturing products, their components, and parts. They determine the machining methods used for a product or component to make raw materials. It describes in a very detailed manner how the actual manufacturing must perform.

ME decision making. On average, manufacturing engineering job activities spat into three tasks:

40% - data collection and calculations,
15% - technical decision making,
45% - text and document preparation.

From given figures visible than 40% (data collection) plus 45% (documentation) of manufacturing engineering activity time might be reduced by giving these tasks to computer integrated systems or artificial intelligence (AI).

The technical decision in production is data-driven. Data vs Knowledge description:

- Data is not information – data is raw facts and events.
- Information is data with context and perspective.
- Knowledge is information with guidance for action based on insight and experience.

Computer Integrated Manufacturing CIM – the control philosophy when functions of production are rational, they coordinated by using computers, links and information technologies.

Overall, manufacturing engineering in the mean of the field is most flexible and most open for innovations and changes where R&D mistakes must be solved, and only innovative processes and best practices passed to the manufacturing shop floor.

1.3. Digital transformation

The term “Industry 4.0” created to describe the changes caused by the digitisation. In industry, it is currently propelling the manufacturing sector into the digital platform. A concept like industry 4.0 and the Internet of things represents a shift in business and society, resulting in a growing number of connected and automated devices, machines and products. Industry 4.0 (Tobias Wagner, Christoph Hermann, Sebastian Thiede, 2018) is about to complete digital connectivity between the means of production and employees involved in that process. Facilitates revolutionary developments in production operations by allowing highly qualified flexible workers to collaborate with intelligent cyber-physical systems in smart processes.

By digital modernisation, companies willing to save 30%-40% of the budget on maintenance, including stock buffers and time-consuming operations. The target also to boost productivity by up to 30% by teaching operators how to handle issues that takes the time of other engineers.

Also, Digital transformation is a technology pushed continuous improvement/change process which affects manufacturing companies and socially. The main factors are here connectivity, flexible data value streaming and embedded computing. It is clear that digital transformation not possible without software. (IEEE, 2018).

Digital Transformation (DX) is all about technologies getting together for increased productivity, social welfare, and value creation. DX mend to grow high during upcoming years and mend to be adopted by most companies as a cost-saving activity, process or technology. However, targets are not readily achievable. There are many stoppers like those that companies are not ready for DX structure wise. IT policies do not correlate to DX strategies, return on investment lower than expected, culture-wise people not prepared for its implementation. Also, digital transformation not easy to implement on existing systems due to software engineers lacks skills, lack of recognition, lack of quickly achievable benefits, and so forth. (Pascal Paillé, Norrin Halilem, 2018)

DX perspectives and strategies guided by lots of software technologies (Park, 2015). Units with embedded electronics like sensors, controllers, actuators other microdevices more and more connected through the IoT to one network. From here, cloud storages, data analysis, and other services are easily achievable in the manner of usage for different purposes. Database creation of any kind even for AI learning. AI uses both sources of embedded systems and IT knowledge.

Software engineers and software are closely and mutually related to each other in creating real value in digital transformation. It is clear that software engineers must follow all latest tendencies regarding digitisation and even more- manage, create and sustain it**.** In this case, the creativity of SE might be exhausted, and such capacity it is tough to control and predict. There is no need for any new software programs while the requirement is that existing software application must full fill digital transformation needs.

Systems engineering for DX includes:

- Cloud services, location-based services, online apps, remote diagnosis, Continuous software updates, and emergency functions;
- Cybersecurity performance for modern software systems;
- Service-oriented advanced operating systems with secure communication platforms;
- Machine learning, in multisensory fusion, picture recognition, data analytics for automated processes, and predictive maintenance for industry;
- System-level modelling, testing, and simulation with models in the loop.

System engineering requires practice and experience in using tools to make it robust, functionally safe, and usable (Ana Cachada ; Jose Barbosa ; Paulo Leitño, 2018).

Planning of Digitalization. – (Johannes Stoldt, 2018)

Planning of digital transformation integration, for instance in manufacturing companies, is difficult because it was not foreseen in product range and at manufacturing equipment. Margins are also small to keep up with other competitors. However, the Digital Factory idea attracts decision-makers to move digitalisation way at the planning process to meet full advantage of newly available technologies. Decision-makers must evaluate or get knowledge about their company situation within its current environment from an internal as well as an external perspective. Only after that, the following step like analysis, definition, and desired target state and feasibility studies performed.

The next step has to be modelling. It is all about the realisation of prototypes and business models and strategies. The final but most challenging step is to roll out and change management processes and adjusts the whole organisation to new digitised one. Planning consist of:

- Data flow and collection.
- Machinery and logistics communication.
- Material information flows.
- Floor space and layout.
- Auxiliary operations integration.
- Organisation: planning of structures, sequences, and required qualifications
- Building, design, and infrastructure

Focus on technology and cost.

Companies must be innovative in technology and cost at the same time. The ability to successfully implement innovations in a short time is challenging and key competitive factor. Innovations determine not only new products and optimised processes but also wholly new necessary technologies, such as what we are observing in the digital transformation.

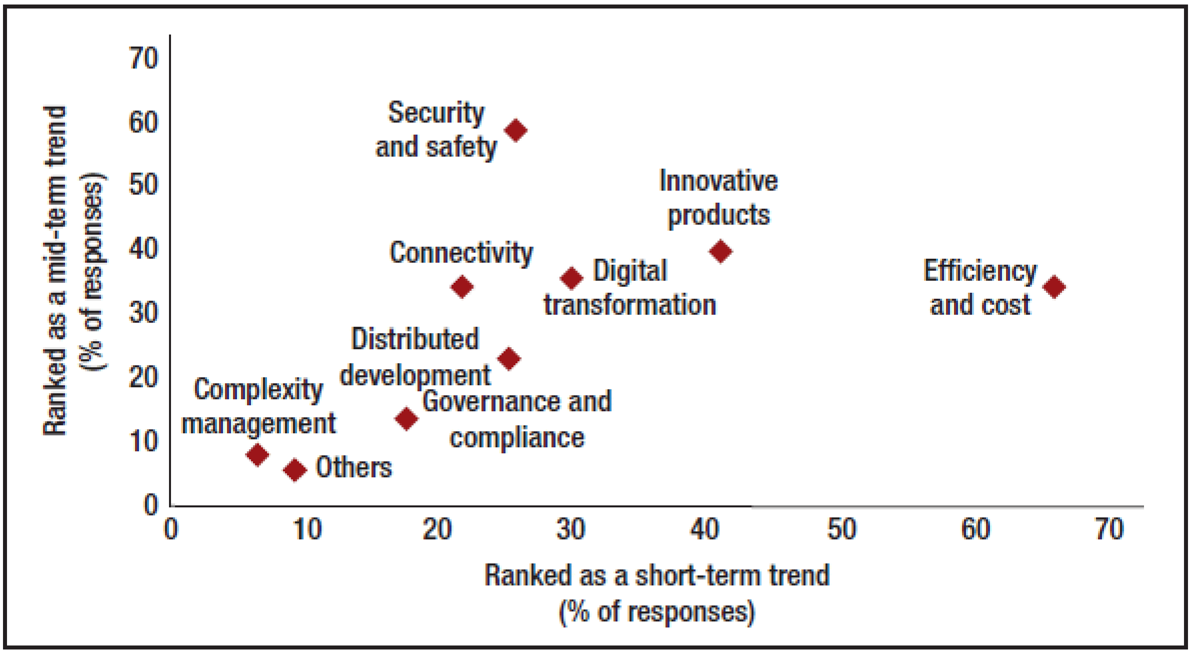


Fig 3. Industry trends overview (Christof Ebert ; Kris Shankar, 2017).

Based on the graph, there are five most ranked trends in the industries:

A) Connectivity to networks and the internet of things.

B) Digital transformation – respondents named this as cost-saving an innovative trend.

Then follows the most valuable and essential the company's trends like:

C) Security – every company, no matter it is using cloud storage or own servers, they want to be sure that their data are safe from destruction and stealing.

D) Innovative products – with this trend target is to get higher innovative than other competitors can.

E) Efficiency and cost- this trend leads to existing production costs reduction to be compatible on the market.

The Digital Transformation: Find New Solutions

Everybody can learn from the past. Today, it is important to learn from the future (Accenture, 2016)

In the digital transformation, we see five major recurring patterns:

- Collaboration (in other words means the relationship between consumer Internet, social network, single-customer segmentation, configurators for products and services, digital money, computer-assisted collaboration, and crowdsourcing);
- Comprehension (augmented reality, semantic search, big data handling, smart data, data analytics, the data economy, online data validation, and data quality);
- Connectivity (mobile computing, mobile services, cyber-physical systems, the Industrial Internet, machine-to-machine communication, sensor networks, and multisensory fusion);
- Cloud (cloud storage, location-based networks, sustainability, and energy efficiency);
- Convergence (mobile enterprises, bioinformatics, the Internet of Things [IoT], pervasive sensing, and autonomous systems).

Focus not on tools but also integrated processes and methodology. Use such methodologies to consistently model the different abstraction levels, from business processes to functions logic, and from architecture to implementation.

Augmented reality

In figure 4, the maintenance engineer is standing next to equipment with googles or mobile app and see equipment-related information. The system shows machine status, working hours, may also show OK parts produced and other related data, which any database could provide. From PLC itself, there is a possibility to take counters for special reasons data.

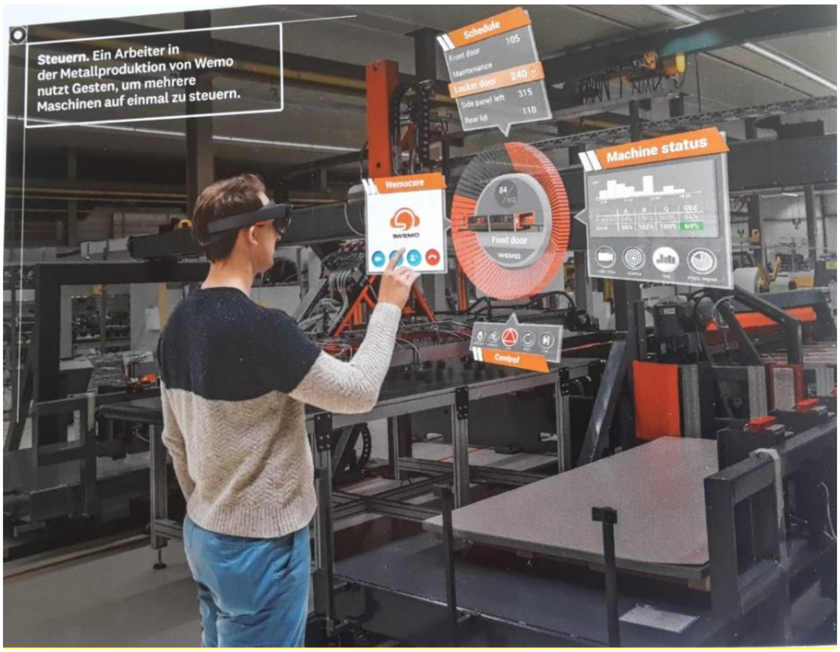
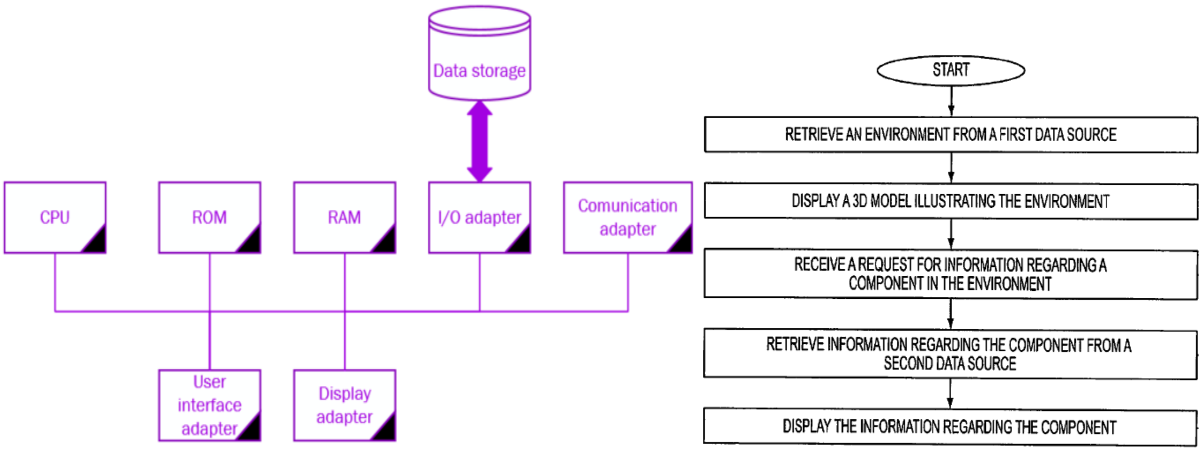


Fig 4. Page from "Sonderdruck" journal February 2018 edition taken in Hannover Messe

For the end, target state more likely expressed through application to help operators and maintenance engineers perform their tasks much quicker and in completely another way as if it is today. AR, together with AI, manages to support maintenance engineers in problem finding cases. Operator manufacturing instructions and action data collection may help to reduce the cost of exploitation.

Remote maintenance system (Houston, Texas, United States Patent No. 20120310602, 12/06/2012) are efficient then data comes from multiple sources, and combines into one an easy navigable display. Also, other forms like virtual reality via mobile devices like mobile phone, virtual reality glasses can be displayed. Figure 5



a) b)

Fig 5. Principal visualisation equipment layout (a) and communication stream (Houston, Texas, United States Patento Nr. 20120310602, 12/06/2012) (b).

Information stored in data storage and requested by user via communication device. After communication session finished data saved to the same database storage.

1.4. Patents review

Factory layout. A patent search showed that factory layout, shop layout patents registered while ago like (Singapore, SG Patento Nr. 8621786, 2007) and there are not many of them. The issue here is that layout itself may follow some requirements, but overall it is factory, production and product specific. This is precisely the internal factory business and described by “LEAN” thinking methods and tools. The systemic layout approach might be ergonomics for operator access, machine or equipment maintenance access. It is also a point of internal process engineer’s creativity where budget is limited, and factory management needs running production in a tested, trusted way. The management opinion is willing to change by implementing “LEAN” or continues improvement thinking and tools where savings achievable. However, these achievements not documented, and there are no applications for patents.

Event monitoring – automatic performance monitoring system for event detection and description (United Kingdom, Hampshire Patent No. 20050154688, 07/14/2005). The system with event detection, log creation and performance assessor. After event detected the system generates alert. The performance assessor monitors rate at which alerts generated and registered. Actions needs to take place if alert rate exceeds the limits. Such a system valuable in production especially with automated lines during start up. The most bug hunting happens at a very beginning of production or validation period. Where alerts may not be so important if it is just for a few seconds. However, after production start every delay counts and make significant influence to OEE.

1.5. Industrial mixing

Mixing equipment knowledge. Viewing registered patents mixing process seems one of the oldest or at least patents registered first. Material mixing overall are old and know process even nowadays, mixing itself not different like it was a hundred years ago. The new approach is where to place the mixer unit inside the production layout, how to feed material, how to take produced WIP material and transfer to next operation if required.

Computer controlled systems become popular. The systems managed to feed the right weight of one component or a couple of components and pass to next mixing and process steps (United States Patento Nr. 5674005, 1997) (United States Patento Nr. 5240324, 1993). The inventions patented more than twenty years ago already the computer controlled. Manual human intersection reduced to a minimum.

However, moving to industry 4.0, there is required some more features even though the process is capable of doing the required activities.

Mixing is a subject known from 1950. Mixing definition is reduction of inhomogeneity in order to achieve required process results. (Paul, 2004).

Main problems: how much mixing is enough, and how to define good and bag mixes?

Mixing equipment have same functional parts, but it vary from process to process and dependant on size. Difference may be not only mixing direction but also in blades design and size dependant on needs.

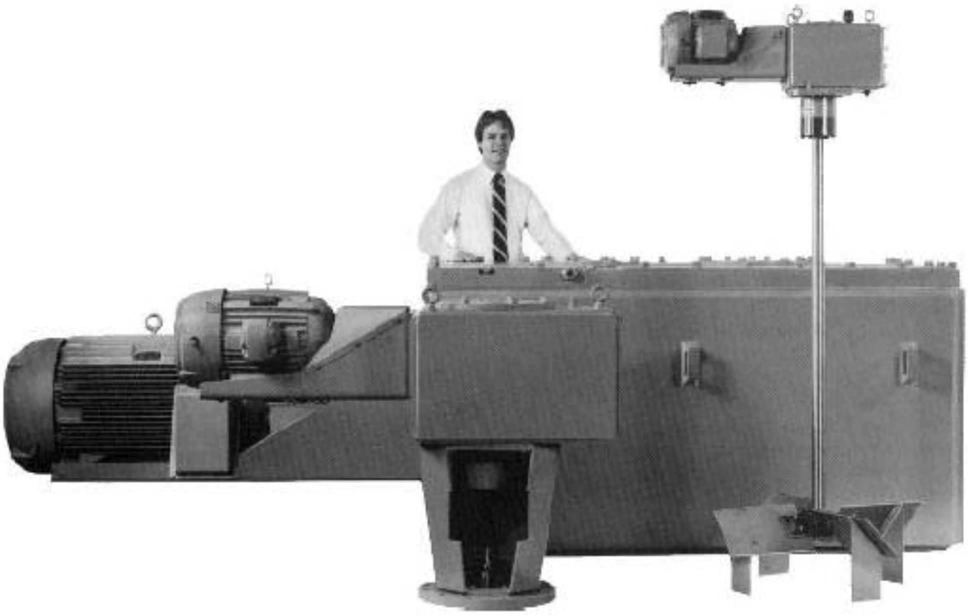


Fig 6. Different sizes and configurations of mixers (Paul, 2004)

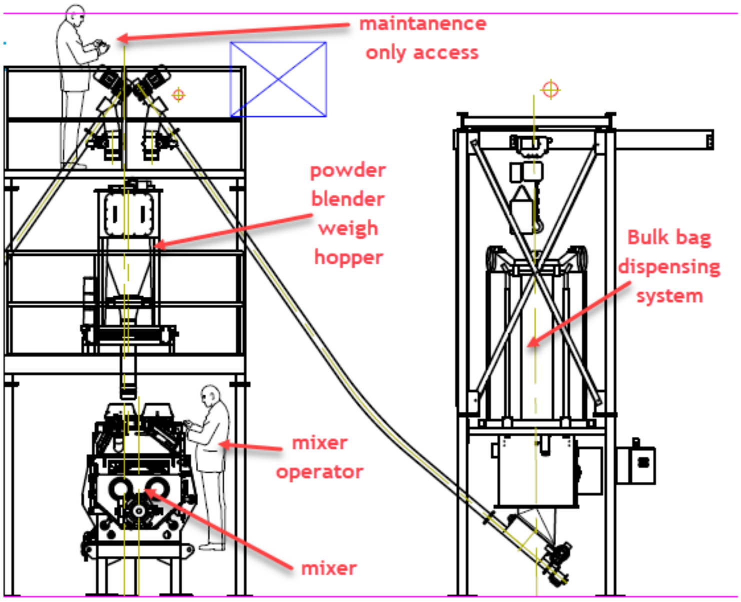


Fig 7. Different sizes and configurations of mixers

Principal picture 7 describes main equipment components of mixing process.

Bulk bag dispensing system requires for feeding raw materials to next process step. The configuration may vary from process to process and depending on material consistency.

Powder blender, weight hopper – this is important part for of mixing process. It helps to control dosing process by weighting materials for required weights. Blender at the same time helps to distribute materials just before main mixing process.

Mixer – mixer from its purpose and materials intended to mix may be special mechanical shape.

Allocation of such equipment it is important area wise and maintenance wise.

The weak spot of mixing process is evaluation of mixing result. Research are ongoing how to evaluate mixing quality. In the given figure, there are mentioned number of ways how to make evaluation. (Maryam Asachi, Ehsan Nourafkan ⇑, Ali Hassanpour, 2017) (Humair Nadeem ⁎, Theodore J. Heindel, 2017)

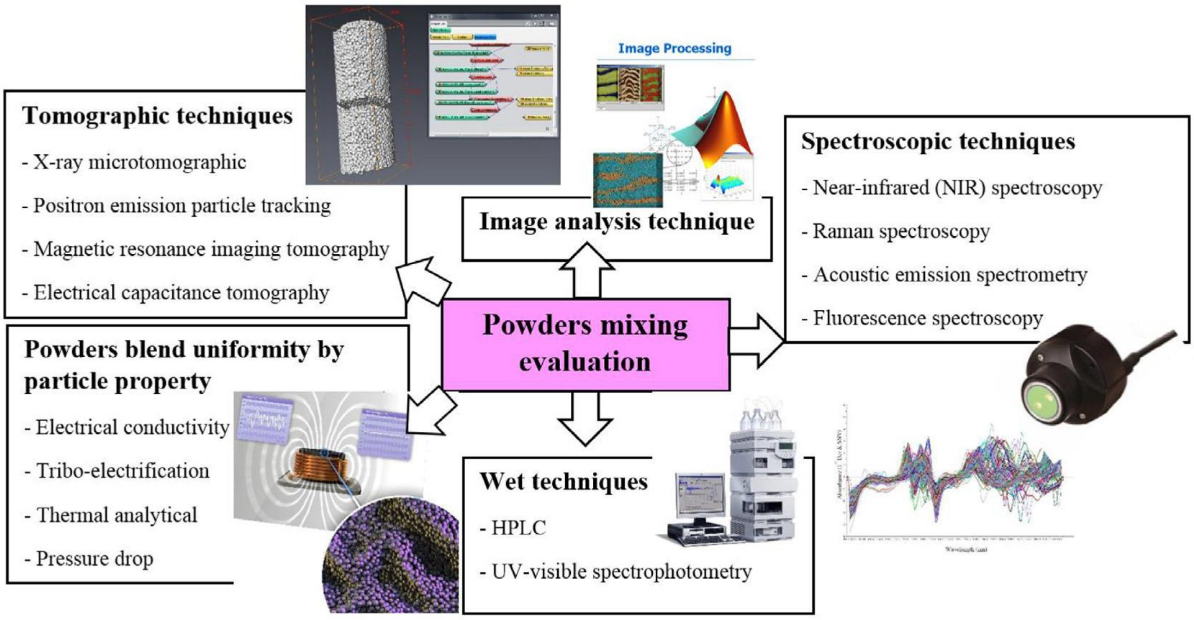


Fig 8. Technologies of mixing quality evaluation

Water absorption test, tag testing also needs to be mentioned as a quick evaluation testing.

2. Layout preparation

The layout development related to internal considered company needs. However, it must comply with the “Full account of CGMP, safety, health, environmental, ergonomic, operational, maintenance, recognised industry guidance, and statutory requirements”. The absence of a consistent and widely accepted interpretation of some of the regulatory requirements has led to increased cost in engineering new facility. This has also led to longer lead times and, in some cases, delays in bringing products to market. (Singapore, SG Patent No. 8621786, 2007). Even if the layout complies with requirements, it still may lead to net cost-effective production. Layout development considered in this project too.

2.1. Initial layout

The initial layout design created to book the space in a production area for the mixing process environment while constructions activities were ongoing. Room size planned for the area for two mixing units (1, 2) and one for the future expansion. „Raw material racks were intended to be outside of the mixing process area. Dust extraction systems located inside the room (4).

Fig 9. The initial layout of the mixing process area (Walters, 2018)

Considering such a room as a working area, result would be positive. Room separated into two areas - one for raw material supply and „INPUT“(green arrow), the other area for the production and „OUTPUT“(blue arrow).

The minus of such layout is the ratio between used spaces versus total space. Visually the value should be as close as possible to one – full usage. In this case, room usage would be approximately 0,5. For better room allocation, the list of requirements created.

2.2. Layout requirements

To implement the mixing room needs to describe an area where all equipment allocated and installed. To any of these statements, separate risks assessment may apply.

- The ratio value between the used areas versus used area must be close to one.
- The area is accessible for forklift truck – wide enough.
- Area to accommodate necessary equipment for required processes and future expansion.
- The area contains Engineering supplies for daily activities as well as emergency.
- The pressure in the room must have a possibility for adjustment to prevent dust contamination in the whole factory.
- Automated door opening system for the entrance to the area – entrance-exit control
- Areas for forklift access – restricted area for humans ISO 45000
- Designated places for material placement, individual material have its place – Lean thinking.
- Storage location for materials. Lean "Kanban" process – fill the empty area by missing stuff.
- The platform for operators required to prevent them from accidents with forklifts.
- Sliding doors on the platform for the incoming material and accident prevention
- Lifting unit to feed material bags into hoppers – ergonomics and safety of the operator
- Dust prevention system on hoppers to prevent operators and area from dust contamination
- Platforms for maintenance to prevent accidence ISO 45000
- Required equipment implemented with the service areas EC Council Directive 2006/42/EC known as the Machinery Directive
- Equipment allocated the way to suit the process needs – Lean manufacturing

2.3. Layout, second edition

The second layout presents what company willing to place into the mixing process environment. It appears that four mixing units planned. To save space, aisles used for forklift access. As a result, the increased number of doors, 12 in total, specified. The second layout shown in figure 6.

Pluses of such a room are that this room has already required equipment and all related details to do the job – all five critical units have predefined allocation spaces.
Minuses of such layout are:
Increased number of doors – which means there will be issues in keeping the area clean, and it will be hard to keep all doors shut. Powder contamination on the floor next to every entrance.
Even though feeding systems seems located reasonably, the mixing process lack of order, the flow is not fluent the material "INPUT"(green arrow) and "OUTPUT" (blue arrow) are not clear — all equipment guided to the middle of the room.

Fig 10. Second, layout (Walters, 2018)

The area usage still requires improvement and optimisation because there is an empty area available.

2.4. Final edition layout

The evolution of layouts influenced by lean manufacturing understanding, equipment allocation and cost of it. At a very beginning, there was a need only to have a placeholder for upcoming, not finally agreed and designed production environment. During the time, more information gained and related production requirements confirmed, and the needs of exact equipment clarified. At the very beginning, there were two mixing units on the drawing with the provisional allocation of supporting equipment.

The layout three are real “Ice breaker”; however, it has minus - the issue with it that it increased area and building columns become part of mixing area (S. Anil Kumar;N. Suresh, 2009).

The number of updates where made:

Forklift aisles included in room area; it helped to reduce the number of doors. The mixing units divided into four sections; as an advantage, no matter which mixing unit comes first, it will occupy one of four spots prepared. Facility wise layout becomes flexible – like foldable paper. There comes a possibility to build an area for one mixer unit. By mirror effect possible to add the second mixer and via using the same mirror effect build room for another two mixers.

Fig 11. Final base layout

There still foreseen maintenance access, fire-extinguishing systems allocated next to each door up on regulations. There is marked the area where forklift trucks can access and pedestrians restricted area. All area needed equipment allocated according to production flow and “LEAN” manufacturing principals. Operators can move only in the middle of the room, which allows them to concentrate only in that area. The flow starts from material feeding with the forklifts and flows out via pedestrian aisle in the middle of the room. An equipment malfunction reduced to a minimum as long as the next mixing unit can support production.

3. Automated equipment

Equipment process wise does not differ from the one described in the introduction. The difference is the automation level. The new equipment has to have possibilities to be controlled as less as a possible manual way. Basic single module program layout presented in table 3.

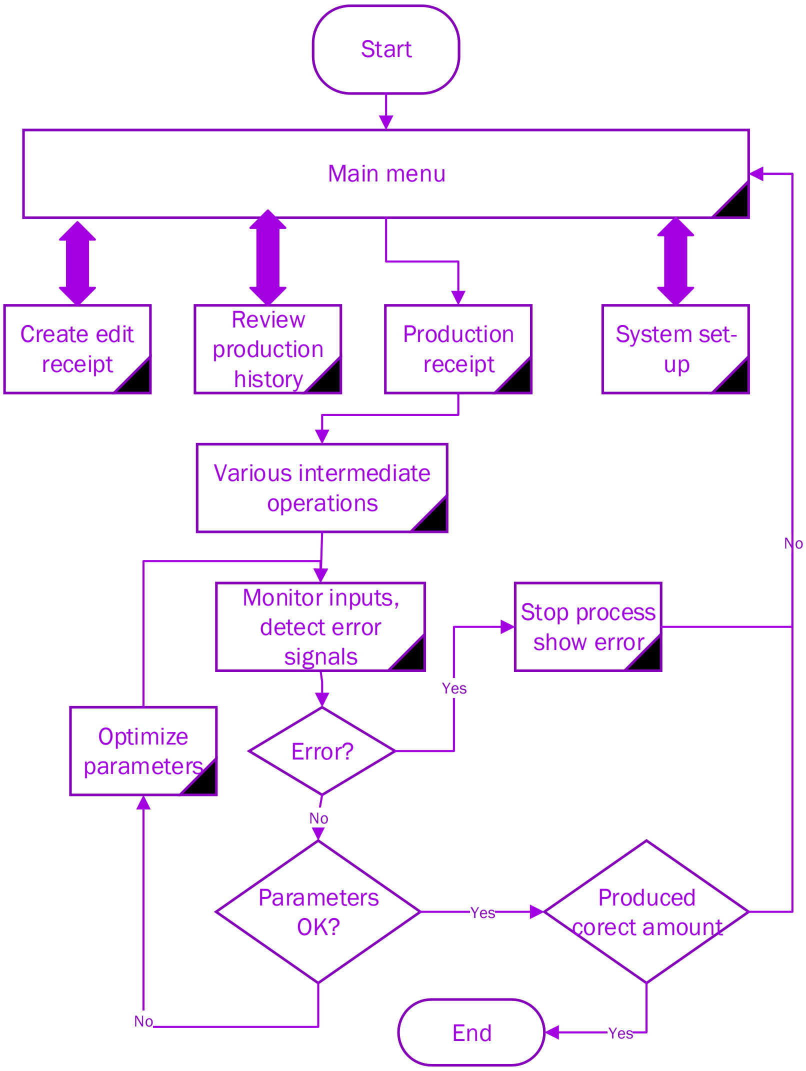


Fig 12. Single module basic program layout (United States Patent No. 5240324, 1993).

The main menu is accessible to the operator or an advanced user. In most cases, it is accessible via dedicated passwords.

Create/edit receipt, Review production history, Production receipts, System set-up – these are a separate window on HMI screen. Main functions described by naming the windows – for easy navigation on the HMI.

Rest windows are dedicated for process steps tracking and may be adjusted upon user and process needs.

Given table helps to adjust and control only one process. This level of automation was at the industry 3.0 were computer controlled systems were high-end systems. Today such system would be functional. However, it does not comply with the latest requirements of industry 4.0.

To get closer to industry 4.0, it needs to update such a scheme to a more advanced one. Target is to connect all sub-systems to one, not only process and mechanical wise connected system, integrate them into one virtual system — integration vision provided in figure 9.

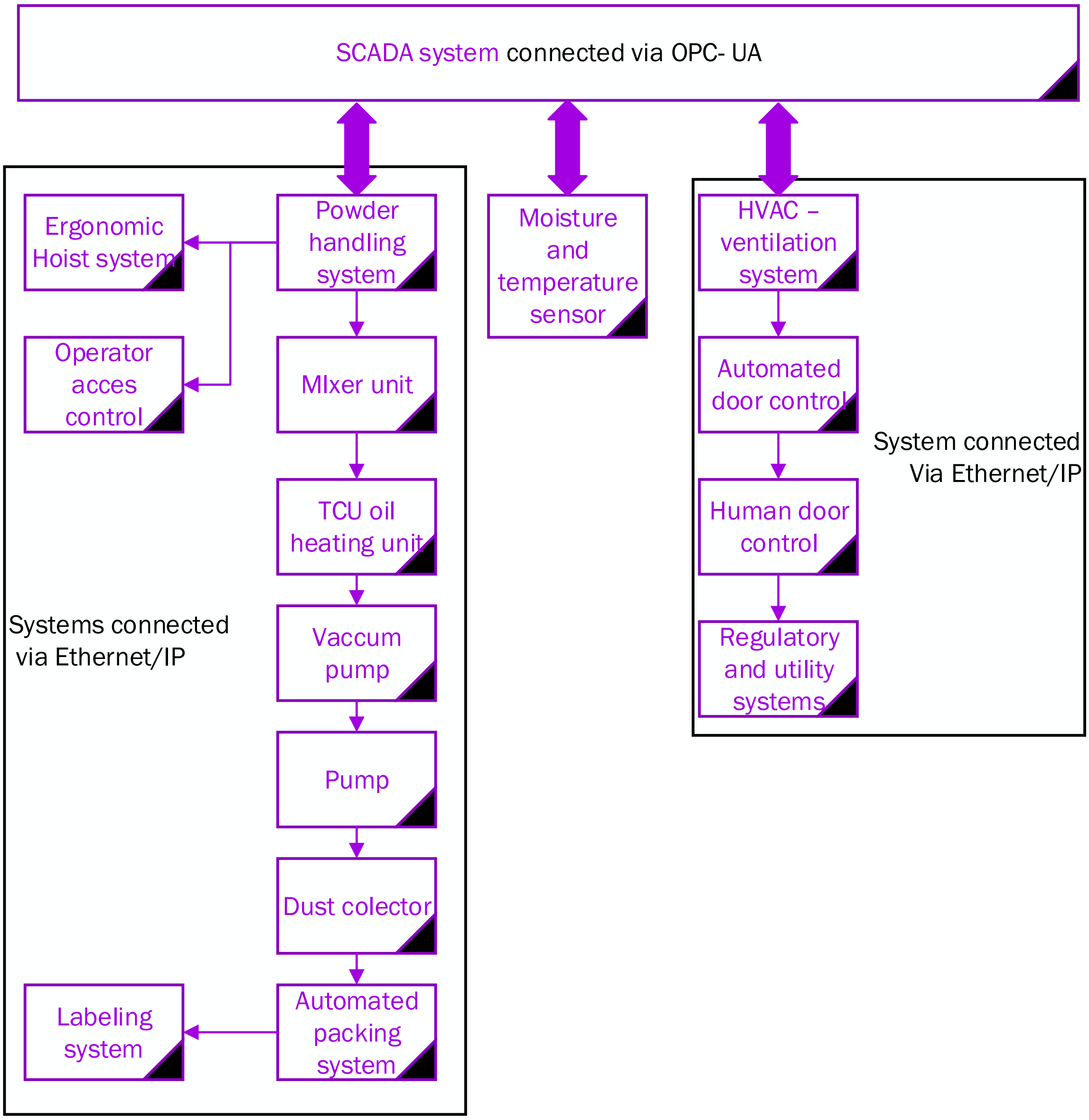


Fig 13. The figure shows the vision of an integrated system

The figure shows that all sub-systems connected to one SCADA system for communication and data collection purposes. Even though, like powder handling system manage to connect and control slave systems in its sub-network. To connect to SCADA system required OPC-UA protocol. To connect PLC's from master devise to slave preferable Ethernet/IP. To fulfil such vision dedicated equipment and budget needed.

3.1. Equipment GAP analysis

Gap- analysis identifies gaps between optimised allocation and integration of the inputs and current level. In this case, there is a need to break down equipment related and evaluate what the future state is and what are the recommendations to reach it.

Table 2. Equipment gap analysis

Equipment	Current state	Future state	Recommendations to reduce the gap
Mixer unit	Semi-automated equipment controlled by PLC	Semi-automated equipment integrated with master PLC	Machine with all possible self-control functions with the integration with the master control unit option.
TCU of oil heat system	Manually controlled heater	TCU unit fully integrated into a Master automated system	Heater with integrated PLC for self-monitoring and data collection.
Vacuum pump	Manually controlled vacuum pump	Vacuum pump unit fully integrated into a Master automated system	Vacuum pump with integrated PLC for self-monitoring and data collection.
Dust collector	N/A	Dust collector unit fully integrated into a Master automated system	Dust collector with integrated PLC for self-monitoring and data collection.
Powder handling system	Semi-automated equipment controlled by PLC	Powder handling system unit fully integrated into a Master automated system	Powder handling system with integrated PLC for self-monitoring and data collection work as a master unit.
Pump	Manually controlled unit	Pump unit fully integrated into a Master automated system	Pump with integrated PLC for self-monitoring and data collection.
Ergonomic Hoist system	N/A	Hoist system integrated into the SCADA system	Unit with integrated PLC for self-control, data collection.
Labelling system	Manually controlled unit	Fully integrated unit for traceability system.	Unit with the possibility of external communication
Automated packing	Manually controlled unit	Integrated self-sufficient unit	A system with autonomous ability, with integration communication
Operator access control.	Manually controlled	A preferable system with minimum operators	All processes and master system designed operator freeway.
Moisture and temperature sensors	N/A	Reports moisture and temperature data for collection and problem-solving.	Implement moisture and temperature sensors with the possibility to get data automatically.

HVAC-ventilation system	Semi-automated equipment.	Automated equipment with controlling algorithm with the ability to control other devices	Implement the controller with more possibilities to control.
Automatic doors control	Manually controlled	Doors with open closing logic, also log file	Implement doors with PLC module and capability to communicate.
Human doors control	Manually controlled	Doors with open closing logic, also log file	Implement doors with PLC module and capability to communicate.
Fire extinguisher system	Dependant on regulations	N/A	N/A
Lighting	Manually controlled	Intelligent lighting system applies light only areas where it's needed	Install an intelligent lighting system with the ability to save, and logging data
Pressed air system	Utility systems	Consumption measured at all time	Install intelligent meter with communication ability
Chilled water access	Utility systems	Consumption measured at all time	Install intelligent meter with communication ability
Electricity	Utility systems	Consumption measured at all time	Install intelligent meter with communication ability
SCADA system	N/A	SCADA system gets all data from the system, prepares analysis for the required view, and controls systems remotely if needed.	Implement a SCADA system with the ability of data collection, reporting, controlling, with the possibilities to be updated for future needs.

Equipment description in chapter 3.2.

3.2. Equipment description

Mixer unit – main function to perform the mixing process. Equipment from its functionality capable of monitoring power, control valves, manage the process by implemented sensors. Have PLC, have the possibility to store receipts and may be integrated as “Slave” or “Master” device. Main risks – mixer blades do not turn according to required parameters, mechanical issues.

TCU – temperature control unit for oil heating. Equipment dedicated to worm up or cool down equipment during the mixing process. The unit supports mixer. Main communications are status and temperature value monitoring, log files. The equipment acts only as a Slave device. Main risks – equipment not switched on, or not performing its task.

Vacuum pump - assists in the process. The unit supports a mixing unit. Primary communication is status, vacuuming program, log file if needed. Main risks - equipment not switched on, or not performing its task.

Dust collector – following Directive 2014/34/EU – every area must be ATEX rated. Mixing area can have a dusty environment at least for a short period. Equipment protects operator and room from dust. Primary communication is status, waste barrel level value. The machine serves as a Slave device.

Hoist system – helps the operator to lift weights during loading. Equipment does not have straight interaction with the mixing process, because upload itself goes to hoppers. However, it would help to record the loading process data.

Powder handling system – Is the main component in this process. First, it controls the loading and dosing of all ingredients into the mixing process. ATEX rated System consist of sensors, drives, measurement equipment, PLC and HMI. The system may work as a Master or Slave device. Main risks are – not fed of components, not correct amount of ingredients, mechanical stuck, receipt control issues. Lost data after a power interruption, slave devices control problems.

Pumps – device feeds liquid material into process. Process specific equipment. There are sensors, servo drives, valves under control of PLC and HMI. Equipment can serve as Master or Slave device. Main risks are – not fed or incorrect amount of material, the air in the system. The system generates data and can send them out.

Labelling and weighting system serves as a control for the amount supplied by the powder dosing system against volume taken away from the mixing process. Equipment may work as part of the system or separately. Data collection is necessary. Main risks are incorrect measured weights, not printed labels.

Moisture sensors – dedicated to monitoring room air conditions. Collected data used for monitoring purposes. Data goes only to the SCADA database.

SCADA system – collects the data from every process. It implemented and assigned to every monitored process. Risk – incorrect data collection may lead to wrong decisions. Data without usage may become a waste of server space.

Facility control unit – Are Recording data from the resources used for production. It logs door activity, how often and for how long doors are open and sends data to HVAC to keep required negative air pressure in the room. Monitors the debit of chilled water, monitors, pressed air consumption. These functions may transfer to another device, which capable of acting as required.

HVAC- ventilation system – ventilation system controls in and out air supply, temperature and pressure in the room, which for cleaning reason have to be negative. Risks – Air supply system cannot keep the required temperature — Air system contaminated by dust. Air system cannot keep required air pressure.

Automatic doors control – keeps separated two areas – mixing area and main production area. There should be a trigger for door opening with reason while forklift truck entrance, however, door-opening time controlled to support HVAC system function. Risks – doors opening trigger works incorrectly, doors opening timing incorrect.

Human doors control - keeps separated two areas – mixing area and main production area. There should be an alarm for information that doors are open, timing, as a trigger, have to be used. There might be a solution to have an automatic. Risks – doors opened too long, which leads to misbalance HVAC system activity.

Pressed air system – this system is a supply for other functions, which requires pressed air to do their actions. Air meter has to be used to get data about real consumption. Risks – pressed air pressure too low to support functions. Consumption too high, because of leakages.

Chilled water access - this system supports other systems, which requires cooling. Water measurement must be in place to log used water amount. The temperature monitoring system must be for recording incoming and outgoing water temperatures. Risks - water comes at an incorrect temperature — insufficient amount.

3.3. Risks

Every modernisation or new equipment evaluated according to **ISO 14972:2012** risk assessment of developing production units that are effective in the industry. All mentioned and other upcoming risks assessed via evaluation of severity, occurrence and chance, where proper detection method must take place. In table 2, there is risk assessment analysed from the equipment as a module functionality.

Table 3. Equipment failure analysis

Equipment	Failure mode	Failure effect	SEV	Potential cause	OCC	Preventative actions	DET	RPN
Mixer unit	Not running	Material not mixed correctly	4	Miscommunication with Master unit	1	Operator training	4	16
	Brake down	Material not mixed correctly	4	Parts not according specification	1	Certificate from supplier	3	12
TCU of oil heat system	Unit malfunction	material not mixed	4	Sensor malfunction	1	Temperature value, in Master PLC	1	4
Vacuum pump	Unit malfunction	material not mixed	4	Unit malfunction	1	Vacuum value, in Master PLC	1	4
Dust collector	Unit malfunction	effects safety of operators	4	Unit malfunction	1	Status value, in Master PLC	1	4
Powder handling system	Not running	Material not mixed correctly	4	Miscommunication with Master unit	1	Operator training	4	16
	Incorrect dosing	Material not mixed correctly	4	Parts not according specification	1	Certificate from supplier	3	12
	Brake down	Material not mixed correctly	4	Parts not according specification	1	Certificate from supplier	3	12
Pump	Unit malfunction	Material not mixed correctly	4	Unit malfunction	1	Status value, in Master PLC	4	16
Hoist system	No data from the unit.	No effect	1	Communication issues	1	Status value, in Master PLC	1	1
Labelling system	Missing label	Mixed parts	4	Printer issues	2	Operator training,	4	32
Automated packing	Incorrect packing volume	Customer not happy	4	Dosing system malfunction	2	Weights value in Master PLC, periodical calibration	1	8
Operator access control.	Not trained operator access	Material not mixed correctly	4	Access system malfunction	1	Status value, in Master PLC	5	20
HVAC-ventilation system	Went off	Material not mixed correctly	4	Missing communication	1	Status value, in Master PLC	1	4
Automatic doors control	Doors closing malfunction	Area contaminated	2	Sensors went off	1	Status value, in Master PLC, alarm	1	2

Human doors control	Doors closing malfunction	Area contaminated	2	Sensors went off	1	Status value, in Master PLC, alarm	1	2
SCADA system	Missing data	No traceability	2	Communication issues	1	Status value, in Master PLC,	5	10

Risk analysis is a complicated process, and it takes more than one iteration. Also, risk evaluation might be done from different points of view like analysing from design, operation, equipment side and other.
After naming all the risks and countermeasures user requirement specification created.

3.4. URS – user requirement specification

Equipment shall be built according to standards, regulations and requirements. To get quotations for any systems mentioned above, "URS" – user requirement specifications shall be created. The document consists of chapters. Chapter 1 presents why URS created. Section 2 describes which products related to the requested equipment. Section 3 describes quality requirements, process requirements, production requirement and Key parameter indicators – KPI's:

Table 4. Table of target key parameter indicators

Property	Requirement
The system will be capable of processing:	Material named in URS.
Machine Availability (Up time / available time)	> 80% excluding external circumstances plus Continues improvement activities
Machine Performance	> 97% excluding external circumstances
Yield (Good parts / total parts started)	> 96%
Overall equipment efficiency OEE	> 75%
Operating Requirements	One operator has to have the possibility of two-run two mixers.
Critical Measurement	Weigh-out readings outside of tolerance on +/- 0.5% per batch over ten runs.
Repeatability	Defined for Weighting only. Generally, as errors seen at test +/-0.5kg.
CE requirements	Must comply with all applicable machine safety directives. Must have CE certificate.
ATEX requirements	ATEX rated equipment, ATEX report shall be provided by the vendor.

Chapter 4 describes technical requirements like specifications, drawings requirements according to standards and regulations:

- EC Council Directive **2006//EC is known as the Machinery Directive** – mechanical machine design directive. Safety-related point - Fixed guard fixings cannot be loose; the machinery Directive states that they must remain attached to either the guards or machinery when the guards removed, as per Directive 2006/42/EC section 1.4.2.1.
- EN 60204-1:2006+A1:2009 Safety of machinery - Electrical equipment of machines - Part 1: General requirements.

- Machine electrical wiring to conform to BS EN 62061:2005+A2:2015 Safety of Machinery – Functional safety of safety-related electrical, electronic and programmable control systems. Machine electrical wiring to conform to:
- 1: BS EN 60445: 2010 Basic and safety principles for man-machine interface, marking and identification –Identification of equipment terminals, conductor terminations and conductors
- BS EN 60261: 2005 Safety of Machinery – Functional safety of safety-related electrical, electronic and programmable control systems.
- EN60204-1:2006 Safety of Machinery – Electrical, equipment of Machines. General Requirements
- The control panel shall use pushbuttons with colour coding to BS EN 60073:2002 - Basic and safety principles for man-machine interface, marking and identification - Coding principles for indicators and actuators.
- Conform to directive 86/188/CE - Protection of Workers from the Risks Related to Exposure to Noise.
- ISO 9001:2008 – machines must be calibrated before final testing on site performed.
- ISO 13485:2003 - Medical devices -- Quality management systems - Requirements for regulatory purposes, equipment validation stages description.

Other requirements from various standards and directives or experience, which related to companies strategies and equipment validation, training, maintenance, documentation, PLC branding others may apply.

4. Project Charter

Project Leader	**Valdas Stundys**
Business Need	To support global expenditure and to support operation in Kaunas, there is a need to install new, modern, automated mixing process area.
Project Objective	Plan and execute activities to successfully implement production to Kaunas on fully validated equipment according to approved Process Validation Plan
Project Justification	Ensure footprint in other locations for future expansion etc. and to get significant and increasing production volume to Kaunas on focus products with limited technical and logistic complexity.

Project Scope & Constraints	• Specify infrastructure and environment requirements including space, material loading equipment, installation & operational requirements including digitalisation of processes.
	• Develop area for global mixing strategy. The strategy will cover mixer volume, mixer styles, and the need for automated powder handling/delivery systems.
	• The mixing system will include an automated and semi-automated material dispensing systems for the powders and resins
	• Mixer "EC200-3"; planning, building, qualification and operation in Kaunas.
	  o Mix production in Kaunas will be determined based on quantity and growth rate, coupled with current capacity in other locations on an ongoing basis.
	  o CE mark
	  o Integrated into the Kaunas SCADA system
	  o Documentation related.
	• The following items are not in the scope of this charter:
	  o Other up or downstream processes and or equipment
	  o Inspection and or inspection equipment needed for testing mix characteristics.

Deliverables from other projects	Dedicated Mixing room with required infrastructure including power, Compressed Air, Chilled and treated water, Material loading equipment, dedicated doors, and regulations related infrastructure. Other down or upstream machines transferred to, and qualified, in Kaunas. GMP production system to define the flow, change over tactics, maintenance policy and spare management IT infrastructure for remote access to the machine from machine vendor company as well as for SCADA system.

	Manufacturing Intelligence (SCADA) infrastructure A quality system including product drawings and specification, test methods and test equipment HR Systems to provide adequately trained operating personnel BOM's and routes and material requirements for production startup Purchase of Raw material and WIP storage and handling material

Deliverables	This charter defines the project deliverables for in house mixing.
	
	• Mixer and powder handling system fully operational including ancillary equipment validated and released for the first shift by Q4 2020 – full operation possible no later than six months after the first release for production.
	    o Including designing ATEX equipment and procedures
	    o Including all powder dispensing systems as required
	    o Including all ancillary equipment; conveyors, cutting, work stations etc
	• Mixer and powder handling system will be software validated per the PVP of the project.
	• I have measured mixed Kg's per hour, Yield and Uptime at SAT to facilitate a targeted annual Capacity of Xk Kg's based on optimised Operation, 48 weeks. Target volume first year is Xk Kgs.
	    o Real Kg/hr will be determined after testing with the new integrated mixing system.
	    o Planned batch size will be approximately Xkg for each mix.
	    o Real batch run times for each mix will be determined during OQ testing.
	    o Estimated batch times will be defined from semi-automated and manual mixing processes.
	
	• MI/SOP training documentation in English due time to be translated
	• HMI software in the required language, and switchable to English on the HMI and in the program
	• Machine documentation for technical reference in the requested language and English.
	• Initial supply of critical spare parts and consumable items

Project Risk	This charter defines the significant project risks of the transfer project as follows:
	
	• Mixer design is not confirmed. If an easy clean mixer is not achievable, the mixer capacity will be affected due to increased cleaning time between mixes. Risk mitigation steps are:
	    ◦ One easy clean mixer is in production and will be ordered before Kaunas 1.
	    ◦ Mixing knowledge team is reviewing the cleaning procedure and requirements for each mix change over.
	    ◦ A non-opening mixer will be taken into consideration if the current mixer design becomes non-functional.
	    ◦ Run times, batch sizes and KG's per year will be justified to a non-opening easy clean mixer
	• Machine vendor, subsequently delaying the project, slows the building of Mixer. The main risk mitigation measures are:
	    ◦ Review vendors' project schedule
	    ◦ Schedule site visits to review progress to plan
	    ◦ Schedule regular project review meetings with the vendor project manager.
	• Planned mixer performance, KG's per hour, is not meeting the planned ramp-up schedule. The main risk mitigation measures are:
	    ◦ Troubleshooting guide and support from other locations.
	    ◦ Process review and additional training as required for the mixer operators.
	    ◦ GMP system should deliver a clear operational strategy including maintenance and production support
	    ◦ Agreement of Equipment output & Waste level requirements from sponsors and stakeholders to include realistic ramp-up phase.
	    ◦ Revise equipment output and waste levels.
	• An increase in required Production Volumes for all or some product families could exceed the planned production capacity of the Kaunas plant. The main risk mitigation measures are:
	    ◦ A Production Model will identify the maximum possible production volumes.
	    ◦ The top-up of the mix will be shipped from the appropriate plants to meet the increased demand.

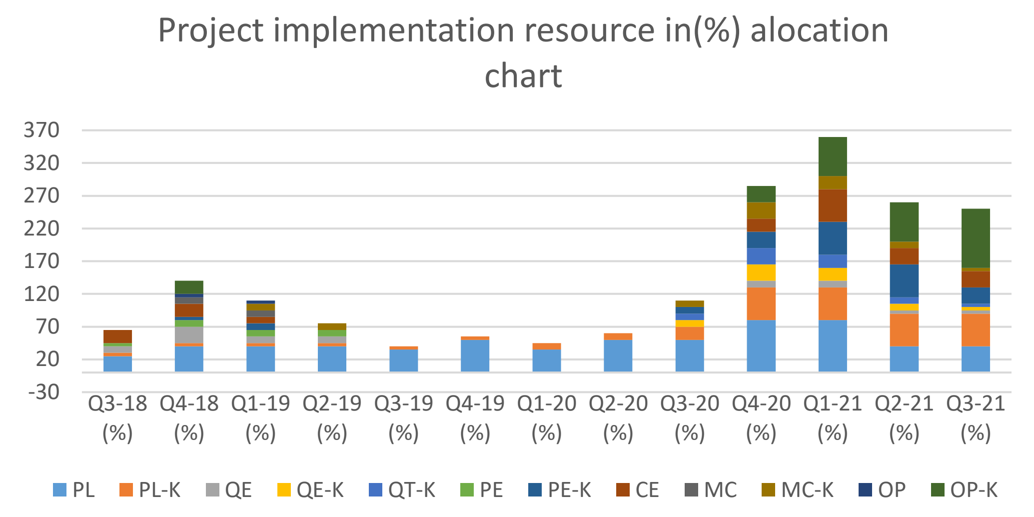
Project Structure &	• The Project will operate based on GAMP 5 model

Communication	• The project team will consist of a core group drawn from the key functional areas of Ostomy Engineering, Operations, Facility Engineering and Quality Assurance who have in-depth knowledge of their functional responsibility area. • The project demands a significant resource and time commitment, which in specific phases requires 100% dedication to the Kaunas Plant project of key Core Team members over the project life cycle. • Support teams will be required, and the core team members will be responsible for engaging with the broader team and managers in their functional area. • The sponsors, team leader and facilitator will ensure the process followed, the work supported, and the deliverables met. The project team will consist of a core team that will drive team activity to meet milestones and to ensure the proper targets met to ensure project success. • Four square reports will be used for a status update • Issues and significant concerns must be escalated to the Sponsors and Steering Committee
Project Governance	The project sponsors before the commencement of the preparation phase will approve this charter and commitment will be given by functional managers to ensure that the team resources are available for the period defined. The Project Team will clarify roles and responsibilities during the preparation phase. The Team Leader will ensure that sponsors are regularly updated on progress and address any issues that may arise, which could affect the project deliverables. Appropriate procedures applied to ensure confidentiality of the data generated and the maintenance of the information for future reference. No change to the project scope permitted without the approval of the Sponsors.

Resource Estimate: Project leader

Role	**Q3-18 (%)**	**Q4-18 (%)**	**Q1-19 (%)**	**Q2-19 (%)**	**Q3-19 (%)**	**Q4-19 (%)**	**Q1-20 (%)**	**Q2-20 (%)**	**Q3-20 (%)**	**Q4-20 (%)**	**Q1-21 (%)**	**Q2 21 (%)**	**Q3 21 (%)**
PL	**25**	**40**	**40**	**40**	**35**	**50**	**35**	**50**	**50**	**80**	**80**	**40**	**40**
PL-K	**5**	**5**	**5**	**5**	**5**	**5**	**10**	**10**	**20**	**50**	**50**	**50**	**50**
QE	**10**	**25**	**10**	**10**	**0**	**0**	**0**	**0**	**0**	**10**	**10**	**5**	**5**
QE-K	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**10**	**25**	**20**	**10**	**5**
QT-K	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**10**	**25**	**20**	**10**	**5**
PE	**5**	**10**	**10**	**10**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
PE-K	**0**	**5**	**10**	**0**	**0**	**0**	**0**	**0**	**10**	**25**	**50**	**50**	**25**
CE	**20**	**20**	**10**	**0**	**0**	**0**	**0**	**0**	**0**	**20**	**50**	**25**	**25**
MC	**0**	**10**	**10**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

MC-K	**0**	**0**	**10**	**10**	**0**	**0**	**0**	**0**	**10**	**25**	**20**	**10**	**5**
OP	**0**	**5**	**5**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
OP-K	**0**	**20**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**25**	**60**	**60**	**90**



NEEDS resources identified then review and update -
Project Leader (PL); Quality Engineer (QE); Process Engineer (PE); Control Engineer (CE); Mechanic (MC); Mechanic Kaunas (MC-K); Operator (OP); Process Engineer Kaunas (PE-K); Quality Engineer Kaunas (QE-K); Operator Kaunas (OP-K); Quality tech Kaunas (QT-K)

Project Estimated Cost:

Estimated budget 325k EUR. The budget limited to the equipment needed for dedicated mixes production only.

- Mixer unit – 90k EUR
- Material handling system – 130k EUR
- Other support equipment – 20k EUR
- Dust collection/suppression system – 20k EUR
- Installation, qualification labour & materials & travel – 20k EUR
- Test equipment for Quality requirements – 15k EUR
- Contingency for mixer, powder system, dust collection – 20kEUR

Cash spending plan

Mixing room implementation with one unit	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020	Q4 2020	Q1 2021
AFE Approval									
Equipment Order									
Design & Build									
Factory Acceptance Test									
Installation & Site Acceptance									
Qualification									
Production Start									

5. Suggestions for modernisation

During this project, the mixing process environment creation process was reviewed. The risk assessment and gap analysis are needed to improve production. Improvement is always a conflict between the business case and value of it.

1. It is suggested to analyse the possibilities and improve the functionality of all units as much as possible at the time of building or implementing it the first time.
2. During the project, at the Gap analysis stage, the equipment containing various communication possibilities was chosen. In such a way, an opportunity to collect the data after the mixing process starts and to define which data is required and which is waste will be ensured.
3. It is suggested to implement SCADA system with the maximum number of possible options available. During the literature analysis, there was noted that Software engineer's knowledge and abilities are limiting the digital transformation. The more understanding it is possible to acquire, the better the decisions process engineer can make. Consequently, more requests for updates it is possible to create.
4. As long as the equipment is dedicated to automation, there should be a possibility for fully automated production and reduced to a minimum manual intervention of employees. However, it might be limited by the nature of the manufacturing process.
5. In the final layout, the area for forklift trucks access is clearly defined. There should be a possibility to implement automated raw material delivery system following by "Kanban" lean thinking. To identify triggers for which material needed is not a hard job at the end. Autonomous delivery process specific and risk assessment must be performed before implementation.
6. SCADA system has to be integrated with room functionality for two reasons. The first reason for logging data, second – for remote communication and control.
7. The need for traceability module integration and configuration have to be evaluated.
8. MRP system integration into the SCADA system would help the manufacturing department to control production processes and orders.
9. Integration of AI might reduce the need to log in remotely for data analysis and decision-making. However, AI decisions and help need to be approved as operatable.

Conclusions

1. A current state analysis of the considered process environment within the company was accomplished, and trends, needs and problems related to the digital transformation were identified. The modernisation should start from the change initiation within the company, taking into account that digitisation is limited by software engineer resources. The proposed steps towards the digitisation are related to the constantly changing process of improvement, which starts with the necessary current changes within the company aiming to get advantages in the future.
2. The mixing process environment layouts were developed. It was defined that it is not enough to make the proposed changes in process layout. The education of the process staff and managers is also of great importance, aiming to reach the successful implementation of the developed solutions.

   Three layouts options were developed, and their advantages and disadvantages were identified. While creating the layout, it is essential to analyse the process before placing the requirements, and there should be more than one iteration while selecting the most suitable one.

   The third layout option was chosen for the building and implementation.
3. The gap analysis was developed, aiming to ensure the process, which is most effective and working efficiently. The gap analysis provided the possibility to create a vision of the developed solution and identify the most important aspects to be changed.

   Equipment GAP analysis showed the solution result with existing flexibility related to the improvement of the process.

   URS creation helped to get quotation level and provisional timing of the project.
4. The project charter was developed and approved for implementation. The advantage of the developed project charter is related to the defined resource allocation over time.
5. The possible solutions for modernisation and digital transformation of the considered facility were proposed. Some proposals need to be implemented straight away; some of them are the start of the digitisation process within the company.

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