## TRAINING PROGRAMME MANUAL OPERATOR IN CHEMICAL AND PHARMACEUTICAL INDUSTRY



Implementing new European model vocational education programme

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# **1. THE PROJECT**

Chemical and pharmaceutical industrial production employs millions of Europeans and offers all sorts of products, from plastics and metal alloys, to fertilizer, food and medical products for humans and animals.

The European chemical industry is a  $\in$ 673 billion industry and the world's top exporter and importer of chemicals, with a record  $\in$ 43.5 billion trade surplus in 2014.

As one of the largest and most diversified industries globally, the European chemical industry supplies virtually all sectors of the economy, providing innovative and sustainable solutions to today's economic and environmental challenges. It plays a vital role in providing all manufacturing sectors, as well as the construction, health and agricultural sectors, with essential products and services. It has created wealth and employment for millions of European citizens over the years. In the European Union (EU), it is the leading manufacturing sector in terms of value added per employee.

For improving competitiveness and to maintain high standards of health and safety and to promote the contribution of the European chemical industry to the economic, social and environmental life, it is critical to ensure a high competence level of all workers at all levels in the sector. Demographic change has become one of the most pressing challenges Europe is currently facing. Ensuring best possible accessibility and integration, especially of women and young workers, is therefore essential. One of the most dramatic, and indeed imminent, consequences of our ageing society concerns the shortage of skilled workforces in the chemical sector.

Giving employees the ability to acquire new skills and qualifications throughout their life in order to adapt to change and possible shifts in their career is a major challenge for businesses and employees. This will help to manage industrial, economic and technological changes in the chemical industry by offering high levels of mobility and development.

Access to process operators with relevant qualifications is now a growing problem. The shortage of labour is due to different factors, including demographic change (the ageing population) and a general lack of up-to-date training courses for those already working in the sector, and for young, potential recruits. To meet the challenges, the European Chemical Employers Group

(ECEG) and the EMCEF (European Federation of Chemical and General Workers Unions) signed a European Framework Agreement on competence profiles for operators. The Agreement has contributed to the formulation of specific requirements regarding what competencies - skills, knowledge and general aptitudes - operators must develop through vocational education and training.

## **PROJECT OBJECTIVES**

The "ChemPharmVET" project has been based on the results of the EU project "Pile Up", a Europe-wide description of the content of corresponding learning outcomes for process operators in the process industry. The "ChemPharmVET" project extended these results to the pharmaceutical industry and, furthermore, shows ways in which the knowledge, skills and competences described can be acquired. The project also reviewed the requirements for chemical sector in Europe and updated the related units of learning outcomes. They were the basis for developing a new European model for curricula for operators in European chemical and pharmaceutical industry to be implemented by VET providers in several European countries for the training of operators in the chemical and pharmaceutical industry. These curricula were developed and tested in cooperation with the respective industry associations, evaluated and fine-tuned in the course of the project.

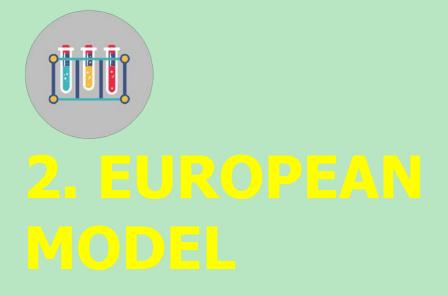
The overall aim of the European model curriculum is to contribute to secure employment and competitiveness of the chemical and pharmaceutical industries, strengthen initial and continuous VET for process operators, and thus improve the access to qualified labour for the two industries.

This manual was

developed to provide information to VET providers and other stakeholders how the new European curricula was used in developing specific programmes by the project partners and to provide contacts the experts to



involved to receive further explanations and guidance.



The curriculum has to build the basis for effective performance of the operators on the job in controlling, monitoring of the production and processing in the European chemical and pharmaceutical processing. Chemical processing and pharmaceutical industry are key in extracting, protecting and processing of the natural resources.

The proposed curriculum for operator in European chemical and pharmaceutical industry was developed at EQF level 4. The vocational training is spread over 250 to 300 hours.

The basis for developing curriculum has been units of learning outcomes that have the following structure:



The European model ULOs and ULOs adapted to the national requirements are attached in the annexes to this manual, and specifically:

- European model units of learning outcomes (ULOs);
- National model ULOs for Norway, Portugal, Slovakia and Slovenia.

## OBJECTIVES OF THE VET PROGRAMME

Chemical processing shall lay the foundation for practicing an occupation in controlling and monitoring production in the processing and pharmaceutical industry. The chemical process industry and the pharmaceutical industry is central in work with extracting, caring for and further processing natural resources. The subject shall contribute to sustainable extraction and utilization of nature's goods and contribute to reducing hazardous emissions.

Learning in the subject shall help develop the learners and the apprentice's competence in processing and production methods. Furthermore, learning in the subject shall contribute to the individual's development of an understanding of the relationship between production, environmental issues, economy and quality. Learning in the subject shall also promote communication skills and the ability to solve problems.

Learning in the subject shall arrange for varied training in the ability to assess and analyse processes, control settings and monitoring of process variables. Furthermore, the subject shall help the apprentice learn to work independently and cooperate across professional groups. Learning in the subject shall also promote respect, tolerance and equality. Working according to procedures, standards and requirements established for environment, health and safety are central themes in learning.

Training completed and passed in the subject will lead to a Trade Certificate at The European Qualifications Framework (EQF) level 4. The professional title is Process Operator in The European Chemical and Pharmaceutical Industry.

Job Title Process Operator in The European Chemical and Pharmaceutical Industry					
EQF Level	3 and 4. A study according to the European model curriculum leads to certification at level 4.				
Job description	Controlling and monitoring production in the processing and pharmaceutical industry				
Activities	Work in chemical processing and/or pharmaceutical industry				
Entry requirements	Lower secondary education – EQF level 2, or recognition or approval of prior learning at this level.				

## JOB PROFILE OF THE OPERATORS

## VET PROGRAMME STRUCTURE

The study consists of four units:

- 1. **Operational logistics**: The work tasks in this unit are to prepare, execute and monitor a logistic plan.
- 2. **Processes**: The work tasks in this unit are to conduct physical processes (thermal, mechanical, EI&C), chemical processes, biological processes and pharmaceutical processes.

The technological context consists of:

- Preparation of the process;
- Handling of machinery;
- Control of working processes.
- 3. **Quality control**: The work tasks in this unit are:
  - Taking samples;
  - Sample analysis;
  - Participating in quality control.

The technological context consists of taking samples, methods of analysis and quality management.

- 4. **Maintenance and repairs**: The work tasks in this unit are:
  - Working permits;
  - Lock out and tag out of installation;
  - Maintenance or repair.

The technological context consists of maintenance of equipment and machinery used in chemical and pharmaceutical processing industry.

In addition, there will be teaching in the basic skills required for the EQF level 3 and 4.

## LEARNING METHODS

The study consists of lectures providing the students and apprentices with the necessary knowhow on the subjects identified as essential for obtaining the learning outcomes defined in the curriculum. This theoretical training will be complemented with laboratory training and practical training with qualified instructors for obtaining both the formal knowledge and the informal

tacit knowledge for being a certificated craftsman on level 4 of the European Qualifications Framework (EQF).

Apprentices and students within chemical and pharmaceutical processing need to work with their instructors and learn the craftsmanship not only through language, but also by observation, imitation and practical training. The tacit knowledge has to be learned in a community of practice.

Working is interconnected with learning and consequently, workplace learning is the way in which skills are upgraded and knowledge is acquired at the place of work.



The European model ULOs are in Annex 1.

## OUTCOME OF VALIDATION

European model has been validated by relevant VET providers and representatives from chemical and pharmaceutical companies in Slovenia, Slovakia, Portugal, Norway and Germany. The validation was carried out using guidelines developed by ISQ of Portugal.

In the validation process, the VET and industry experts rated each learning outcome in terms of relevance to the qualification for operator in chemical and pharmaceutical industry. The global rating for each unit, calculated on the basis of validating individual learning outcomes, was over 74%, as indicated in the chart below.



The validation concluded that the 4 ULOs for "operator in European chemical and pharmaceutical industry" are adequately covering the qualification requirements for the professions covered by this qualification.

The overwhelming majority of experts consider that thee defined learning outcomes are adequate to enable the learner's assessment. In some national contexts, the European model can correspond to a national qualification level (NQF) linked to EQF level 5, since some experts considered it too complex and detailed in comparing them with their national qualification standards and related curricula. In this respect, some learning outcomes could be revised in applying the European model in specific country context. For example: choosing the methods of analysis, interpreting the results of analysis (depending in what extend it is meant), choosing the way of packaging the products, more complex calculations and statistical analysis of data without prior algorithms, knowledge of using software system, describing the options for sterile manufacturing and packaging medical products, and describing possible ways for packing the products.

Most of the respondents have agreed that the ULOs in the European model, can be used in their national curriculums. The details of using the European model ULOs in the partner countries are provided in the next chapter.



# **3. VET PROGRAMMES**

## **SLOVENIA**

Gospodarska zbrojnica Slovenie - Združenje kemijske industrije (Chamber of Industry of Slovenia - Association of Chemical Industry) developed in cooperation with Šolski center Ljubljana (Education centre Ljubljana) reviewed their programme for technologist in chemical industry (EQF 5) using the outcomes of the ChemPharmVET project. Taking into account this review, a new VDET programme was developed for operator in chemical and pharmaceutical industry at EQF level 4.

The VET programme will be piloted from April 2018. The programme includes 208 hours of vocational training: 100 hours of theoretical training and 108 hours of practical training, and additionally 14 hours are allocated for consultations and meeting with a tutor. The programme also includes one-month practical training in pharmaceutical industry.

In the pilot, admission requirement is: completed technical vocational training programme at SQF level 4 (SQF - Slovenian Qualification Framework). Priority will be given to unemployed persons with completed technical vocational training programme (SQF level 4) and current employees from the pharmaceutical industry that need increasing their qualification.

#### **OBJECTIVES OF THE VET PROGRAMME**

Operational Technologist in the Chemical/Pharmaceutical Industries (POT-KE 1)

The aim of the programme is to help young unemployed individuals possessing general/generic competencies obtain professional/vocational competencies so as to find employment in the chemical and pharmaceutical industries, which suffer from a shortage of suitably qualified staff.

Operator in the Chemical and Pharmaceutical Industries (POT-KE 2)

After reviewing the outcomes of the ChemPharmVET project further activities in 2017/ 2018 dedicated to the training of staff for the chemical and pharmaceutical industries ware prepared. Following the initiative of the pharmaceutical industry and its needs in manufacturing, ACIS undertook partial correction of the programme POT-KE in 2017. The profile was named Operator in the Chemical and Pharmaceutical Industries. Access criteria for students are as follows: completed technical vocational training programme (SQF, level 4). Priority will be given to currently unemployed individuals with completed technical vocational programmes (level 4) and the already employed staff in the pharmaceutical industry so as to complement their competencies.

#### **KEY TARGET SKILLS/KNOWLEDGE/GENERAL COMPETENCES**

Operational Technologist in the Chemical/Pharmaceutical Industries (POT-KE 1)

- Theoretical and practical knowledge from the contents of the chemistry syllabus for general upper secondary schools linked to the knowledge of technology and chemistry from the chemical technician syllabus (level 5 of complexity).
- Learning about chemical safety, response to accidents by taking key first aid measures, environmental chemistry and sustainable development principles as essential for health and environmental protection and for the implementation of European sustainable development principles.
- Some basic communication skills needed for good interpersonal relations and successful teamwork in the production, insight into ethics and values.
- Practical insight into the course of technological processes in several chemical companies, with emphasis on meeting quality standards and health and environment protection standards on the job and learning about different areas and working methods of operational technologist in the chemical industry.

Key skills and competences:

- Read and interprets technical and technological documentation;
- Read, understand and follow instructions and standard procedures;
- Work with the materials, chemicals, tools, devices and machines safely;
- Follow the instructions and operate machines, devices and technological equipment;
- Carry out routine operations in the workplace;
- Understands the process, visually and electronically;
- Take and prepare samples of materials;
- Performs relevant analyses and evaluates obtained results;
- Carry out measurement of the control using manual and instrumentation methods;
- Carry out the evaluation of qualitative parameters of raw materials and products;

- Describe the function of the most important types of machinery and equipment in chemical production;
- Use personal protective equipment;
- Identify product errors, weak points for miss-haps and potential accidents and suggests improvement;
- Communicate with other person from the team;
- Recognize failures of devices and provide assistance to a dedicated maintenance team;
- Identify the safety parameters of the required range of chemicals in terms of their importance for use in chemical production;
- Define the principles of technological discipline, safe and hygienic work in the conditions of the chemical production process;
- Define the principles of health and work environment protection, and environmental protection;
- Obey the principles of occupational health and safety, work environment, environmental protection.

#### Operator in the Chemical and Pharmaceutical Industries (POT-KE 2)

After the pilot, the evaluation of the programme will be made, underlining the key target skills, knowledge and general competences gained throughout the programme. At ACIS an effort will be made to introduce the programme to the level of SQF level 4. ACIS is also in constant contact with the Institute of the Republic of Slovenia for Vocational Education and Training (CPI), which develops guidelines for the field of vocational education and training (VET) which are being prepared at the state level of the Republic of Slovenia and is in constant cooperation with EU institutions.

Slovenian model ULOs in Slovenian language are attached to the Slovenian version of the manual.

## SLOVAKIA

Zväz chemického a farmaceutického priemyslu SR (Association of Chemical and Pharmaceutical Industry of the Slovak Republic), Stredná odborná škola Hlohovec (High school in Hlohovec) and Stredná odborná škola Nováky (High School in Nováky) with support of ViaEuropa Competence Centre reviewed the existing VET programmes and developed new programmes for operator in chemical and pharmaceutical industry to be implemented in 2018 - 2019.

#### **OBJECTIVES**

The programme will be targeting graduates who can work in chemical production as well as in food and pharmaceutical production. Graduate will know the principles of technological operations, how to manage them and can influence them during the production process.

The graduate will be able to handle operations under operational and laboratory conditions, will be able to measure and control the parameters of chemical and biotechnological processes and perform other activities that form the basis of his professionalism. The graduate will be able to control the setting of the technological parameters in the relevant parts of the production process and can control the automation elements of the machines and production lines. Additionally, he/she will be capable of identifying equipment failures and providing synergy in maintenance processes. He/she will be able to identify variations in the quality of raw materials and products and to provide synergy in the quality management process as well.

Operator will work in a team, actively communicate and participate in the organization and management of the workplace.

The admission criteria require completed lower secondary general education and successful completion of the admission procedure.

This programme will innovate the existing 4-year VET programme Chemist-Operator (identification number 2860 K).

#### **KEY TARGET SKILLS/KNOWLEDGE/GENERAL COMPETENCES**

#### Skills and general competences:

- Recognize the function of the technological devices used in the particular process;
- Reads and interprets technical and technological documentation;
- Work with the materials, chemicals, tools, devices and machines safely. Use personal protective equipment;
- Follow the instructions and set up and operate machines, devices and some technological equipment in the particular industry;
- Carry out routine operations with the control elements of the manufacturing plant;
- Read and check the key parameters of the process, insert necessary records into the operating software Set and check the measuring instruments;
- Takes samples of materials, prepares them for analysis, performs relevant analyses and evaluates obtained results;
- Carry out measurement of physicochemical parameters in basic technological operations using manual and instrumentation methods;

- Carry out the evaluation of qualitative parameters of raw materials and products using basic physicochemical methods;
- Express the measured values in SI units, make calculations for other frequently used technical units;
- Identify the importance and inclusion of the most important technological operations in chemical production;
- Describe the function of the most important types of machinery and equipment in chemical production and its parts;
- Identify the physical parameters used to regulate chemical production processes, express them using physical quantities and make the necessary calculations;
- Identify the safety parameters of the required range of chemicals in terms of their importance for use in chemical production;
- Identify technologically significant qualitative indicators of raw materials, intermediates and chemical products and the principles of their measurement;
- Define the principles of technological discipline, safe and hygienic work in the conditions of the chemical production process;
- Define the principles of health and work environment protection, and environmental protection;
- Recognize uncomplicated failures of devices and their resources. Provide assistance to a dedicated maintenance team;
- Identify product errors, analyse causes and suggest improvements;
- Document the work of chemical plant (or parts thereof). Read and interpret records properly;
- Obey the principles of occupational health, work environment, environmental protection.

#### Knowledge:

- Define basic concepts and laws of general, inorganic and organic chemistry, use of chemical names and symbols;
- Describe the composition of homogenous and heterogeneous mixtures, perform related calculations;
- Identify the importance and inclusion of the most important technological operations in chemical and pharmaceutical production;
- Describe the function of the most important types of machinery and equipment in chemical and pharmaceutical production;

- Identify the physical parameters used to regulate chemical and pharmaceutical production processes, describe them using physical quantities and make the necessary calculations;
- Identify the safety parameters of the required range of chemicals in terms of their importance for use in chemical and pharmaceutical production;
- Identify technologically significant qualitative indicators of raw materials, intermediates and products and the principles of their measurement;
- Define the principles of technological discipline, safety and hygienic requirements at work in the condition of the chemical and pharmaceutical production processes;
- Define principles of health at work and protection of working environment, protection of human health and the environment.

Slovak model ULOs in Slovak language are attached to the Slovak version of the manual.

## PORTUGAL

#### **OBJECTIVES OF THE VET PROGRAMME**

By the end of the course, learners should be able to detect and solve problems associated with performing and conducting productive process operations in an industrial unit, taking into account qualitative and quantitative analysis techniques, the chemical processes and technology, instruments of measurement and control, respecting the safety, hygiene and health at work and environmental protection.

#### **KEY TARGET SKILLS/KNOWLEDGE/GENERAL COMPETENCES**

- Identify and characterize the various processes and industrial technologies and regulation methods for chemical industry.
- Identify and characterize the different starting operations and control of a manufacturing circuit or section and the respective equipment.
- Use the planning and organization work techniques.
- Interpret drawings, schemes and other technical specifications on the production technologies, raw materials and products.
- Use the tools and metrology techniques.
- Using sampling techniques.
- Identify and use different laboratory materials and equipment.

- Using the execution techniques of the laboratory work basic operations.
- Using the techniques of quantitative and qualitative analysis of samples.
- Interpret the results of analyses.
- Diagnosing defects in the manufacturing process, deficiencies in equipment and deviations in production.
- Using the techniques of driving and regulating equipment.
- Equipment monetization techniques.
- Set parameters for regulating equipment according to their characteristics and product manufacturing.
- Apply quality control techniques.
- Apply the technical procedures for prevention of occupational hazards in the workplace.
- Apply the safety, hygiene and health and environmental protection relating to professional activity.
- Use the technical documentation regarding the registration of the activity.

The European training curricula for the "Process Operator in the European Chemical and Pharmaceutical Industry" was presented to some education representatives from VET centres in the chemical sector. The feedback to the Curricula was very positive, since there is no national standard in the National Qualification Catalogue in Portugal, for the Operator in Chemical and Pharmaceutical Industry, and despite some elements can be found in some existing national qualifications, as is the case of the Industrial Chemical Technician, the Chempharm Curricula covers more learning outcomes and tasks, specifically in the pharmaceutical industry part.

Portuguese model ULOs in Portuguese language are attached to the Portuguese version of the manual.

## NORWAY

#### **OBJECTIVES OF THE VET PROGRAMME**

The European "ChemPharmVET" curriculum described in Chapter 2 is a very good and accurate tool for operators in the chemical process industry.

Norway already has a very well-functioning curriculum at this level (Level 4) and at the lower level. Therefore, the European model was used to carry out comparative analysis of the model with Norwegian programme. The Norwegian curriculum covers the areas required by the national industry and the country's Education Directorate (UDIR). Nationally, Norway is not ready to use the European model yet.

The European curriculum is built up by ULO1, ULO2, ULO3 and ULO4. These ULO's are a very good tool for the operator who is undergoing training. These provide an accurate, systematic

and logical connection between training and the use of a curriculum. For those of the companies and apprentices in Norway who want to use the ULOs for help in the training, this are recommended.

#### **KEY TARGET SKILLS/KNOWLEDGE/GENERAL COMPETENCES**

Chemical processing shall lay the foundation for practicing an occupation in controlling and monitoring production in the processing industry and for purifying drinking water, sewage water and industrial water. The chemical process industry is central in work with extracting, caring for and further processing natural resources. The subject shall contribute to sustainable extraction and utilisation of nature's goods and contribute to reducing hazardous emissions.

Learning in the subject shall help develop the apprentice's competence in processing and production methods. Furthermore, learning in the subject shall contribute to the individual's development of an understanding of the relationship between production, environmental issues, economy and quality. Learning in the subject shall also promote communication skills and the ability to solve problems.

Learning in the subject shall arrange for varied training in the ability to assess and analyse processes, control settings and monitoring of process variables. Furthermore, the subject shall help the apprentice learn to work independently and cooperate across professional groups. Learning in the subject shall also promote respect, tolerance and equality. Working according to procedures, standards and requirements established for environment, health and safety are central themes in learning.

#### Production and maintenance:

- plan, execute and assess work in line with instructions, procedures and existing regulations
- use technical flow charts
- give an account of operational aspects of the unit and appurtenant processing equipment
- start, operate and stop production units and processes
- optimise production with help from measurements and analyses
- monitor, analyse and troubleshoot with help from tools, equipment and own judgement
- solve operational and maintenance tasks with an interdisciplinary team

- prepare the processing equipment for maintenance
- carry out systematic preventive maintenance on the equipment
- prepare the processing equipment for start-up
- follow run-down and emergency stop procedures
- use measuring, controlling and regulating equipment, and give an account of how these work
- use control and monitoring systems
- implement measures according to warnings and emergency procedures

#### Product and product flow:

- use data sheets and documentation based on routines for environment, health and safety and quality control
- give an account of the company's value chain from raw material to product
- discuss and elaborate on factors that influence profitability of production
- give an account of what happens chemically, biologically and physically during unit operation and processes
- give an account of the company's organisation, distinctive characteristics and role in a local, national and international context
- perform operational analyses and evaluate the analyses against the specifications

#### Documentation and quality:

- use drawings, schedules, images, instructions, procedures and standards at work
- report using oral and written skills in Norwegian and English using digital tools
- register and report on deviations
- document work according to instructions, procedures and existing regulations

- give an account of the company's affect on the environment and the consequences this has for operations and deviations
- perform work according to ethical guidelines for the trade
- discuss and elaborate on problem-solving and optimising production in Norwegian and English with colleagues and other professional groups

Norwegian model ULOs are in Annex 5.



## **SLOVENIA**

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## PORTUGAL

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# Annex 1

ULO 1	Date:30/11/2017 Version: final			
Work tasks:	Prepare, execute and monitor a logistic plan			
Technological context				
Learning Outc	omes:			
Knowledge (theor Scientific Context T context		Skills (practical + cognitive (= use of knowledge)	Competence (Role and level of responsibility and autonomy)	
Prepare, execute an a logistic plar				
<ul> <li>(Just in time, Make stock, push and pull understand the plar of new products</li> <li>describe the function Safety Data Sheets</li> <li>recognise different systems (ISO)</li> <li>explain environment regulations</li> <li>explain safety rules</li> <li>explain working insi- explain process dial recognise and explain</li> </ul>	software systems ent logistic systems to order, make to II, fifo, lifo ) nning of introduction on of Material kind of quality ntal rules and tructions grams (P&ID)	<ul> <li>understand /compare the required specification for supplies and products</li> <li>consults others where necessary (colleagues, supervisor)</li> <li>maintain accurate records and documentation</li> <li>report deviations correctly and inform the involved departments/colleagues/customers</li> <li>liaise with suppliers to ensure supplier has adequate back up stock levels</li> <li>manage hazards including handling and safe disposal according to environmental rules and procedures</li> <li>carry out /ensure quality checks prior to supplies being used or products being dispatched</li> <li>respond to safety and environmental requirements within the task</li> <li>read and understand the plan of production schedules in relation to customer demand</li> <li>arrange and manage deliveries</li> </ul>	<ul> <li>instruct a team on all necessary work steps needed to provide raw material of the right quality autonomously</li> <li>monitor that the (safety) instructions concerning the transportation and preparation of raw material are followed by all members of a team</li> <li>assume responsibility of his/her own safety and of a team</li> <li>coordinate his/her own work schedule and of a schedule of a team</li> <li>assume responsibility of the cost efficiency of the works executed by a team and optimises hand on tool times</li> <li>monitor that the team provides the right raw material of the right quality for the production process</li> <li>report on team work progress</li> <li>optimise work processes through open communication with operators, maintenance team members, contractor</li> </ul>	

•	transport, bunker, silo. explain calculations and mass balance	•	arrange and manage dispatches respond to changes in the planned logistic schedule	•	team members, management, suppliers and (internal) customers propose and assume responsibility of
•	understand and explain statistical concepts (like average, standard deviation) in relation to data from suppliers and customer needs.	•	deals cost- consciously with materials and products		improvement the initiatives and projects

ULO 2 Title of the unit: Conduct processes				Final Version	
Work tasks:	Work tasks: Conduct physical processes (thermal, mechanical, EI&C) Conduct chemical processes Conduct biological processes				
Technological context	Preparation of the proc	ess, handling of machinery, control of the workin	g process		
Learning Outcome	<u>95:</u>				
Knowledge (theore Context Theoretica	etical + factual) Scientific al context	Skills ( practical + cognitive (= use of knowledge)	Competence (Role a responsibility and a		
1) <b>Preparation of</b>	the process:				
<ul> <li>outline fundamental basics of production planning (including process optimization, work safety and quality management)</li> </ul>		<ul> <li>evaluate the task schedule/work plan according to the current situation of the plant</li> </ul>	<ul> <li>autonomously execute all steps of the adapted work plan/ task schedule</li> </ul>		
		<ul> <li>adapt the work plan to task specific needs (taking into account the optimization of processes, work safety regulations and product quality)</li> </ul>	<ul> <li>autonomously instruct their team on adapted work plan and monitor that steps are being carried out</li> </ul>		
<ul> <li>express fundamentals of the respective production process.</li> </ul>		<ul> <li>select respective instrumentation according to the process being conducted</li> </ul>		ruct their team on the use after consulting the entation diagram	
<ul> <li>name equipment the process</li> </ul>	that is needed to conduct	<ul> <li>clarify equipment parts and describe their function correctly</li> </ul>	<ul> <li>take responsibility installation of the e team</li> </ul>	for the correct quipment used by the	
<ul> <li>explain the operative equipsion</li> </ul>	ation mode of the ment				

describe the equipment set up correctly	install the respective equipment correctly	<ul> <li>take responsibility for the correct installation of the equipment used by his team</li> </ul>
<ul> <li>have knowledge of the operation mode and set up of the equipment</li> </ul>		
<ul> <li>relate specific operational needs that have to be kept in mind when preparing the equipment</li> </ul>	<ul> <li>execute specific operational needs according to the process that is to be conducted</li> <li>handle equipment correctly</li> </ul>	<ul> <li>instructs team on the correct preparation of the equipment</li> </ul>
<ul> <li>describe processes and explain operating software systems</li> </ul>	<ul> <li>describe and explain processes and their visualization on the screen</li> </ul>	<ul> <li>take responsibility for the processes and the operating software systems</li> </ul>
<ul> <li>relate standard operating procedures (sop)</li> </ul>	<ul> <li>work accurately and precisely</li> </ul>	<ul> <li>executes and controls respective process preparation autonomously and verifies quality and safety of the process</li> </ul>
describe fundamentals of process control and instrumentation technologies	<ul> <li>recognize the hazard potential of the process</li> </ul>	assume responsibility for fellow workers
• explain the operation mode of a scale		
<ul> <li>describe possible ways to fill the equipment vessels with raw material.</li> </ul>	• fill the vessels technically correct with raw materials and takes equipment specifics into account	<ul> <li>autonomously fill of raw material into the vessels according to the equipment specifics.</li> </ul>
<ul> <li>explain fundamentals of transferring materials taking into account safety regulations</li> </ul>	<ul> <li>fills vessels technically correct, abiding by safety regulations</li> </ul>	<ul> <li>considered autonomously, the correct filling and compliance with safety regulations.</li> </ul>
<ul> <li>research features and safety regulations (such as h/p phrases) of deployed chemicals and biologically hazardous substances</li> <li>name properties of raw material</li> </ul>	choose and uses the respective preventive measures and ppe	<ul> <li>self-observance of the safety and use of the correct ppe.</li> </ul>
<ul> <li>name important preparation measure for raw material</li> </ul>	<ul> <li>prepare the raw material according to process needs</li> <li>weigh in the required amount of raw</li> </ul>	<ul> <li>autonomously initiate weighing in of raw material and take responsibility for the correct weighing</li> </ul>
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	material	according to the specific situation		
describe fundamentals of proce	ess control			
<ul> <li>define values and relate their in the context</li> </ul>		required values by applying al rules to the operation specifics	•	take responsibility for the calculation of the required values.
<ul> <li>name theoretical rules for calcuration required values/ determination</li> </ul>		ecessary parameters	•	take responsibility for the proper execution
<ul> <li>identify symbols and their mean piping and instrumentation diag</li> </ul>	0	piping and instrumentation	•	take responsibility for the proper execution
<ul> <li>name rules concerning the compiping and instrumentation diagonal</li> </ul>		an instrumentation and piping abiding by the used standards into natrix	•	take responsibility for the proper execution
<ul> <li>identify points of measurement piping and instrumentation diag</li> </ul>		umentation diagram abiding the	•	take responsibility for the proper execution
<ul> <li>relate ways of obtaining informative the operation mode</li> </ul>	mode of	es information about the operation the points of measurement in the nt he is currently using	•	take responsibility for the proper execution
<ul> <li>name regulations on marking E technology in a piping and instr diagram.</li> </ul>		ndardized points of measurement ing and instrumentation diagram	•	takes responsibility for the proper execution
explain principles of scaling con relate their mode of operation		controller abiding by the tioned principles correctly	•	take responsibility for the proper execution
<ul> <li>relate important values and why measured</li> </ul>	into resp • evaluate	spective values and export results ective software (such as Excel) recorded data by help of the on of trend graphs	•	take responsibility for the proper execution

2)	Handling of machinery:				
,	<b>,</b>				
•	fundamentally understand the basics of production planning (including process optimization, work safety, quality management etc.) outline the process and names task steps explain basics of process balancing	•	carry out the task schedule as it is intended.	•	instruct team on the correct handling of chemicals and equipment/laboratory techniques according to safety regulations take responsibility for the task schedule being carried out by the team according to his specifications
•	express fundamentals of the production	•		•	supervise
	process and its ideal conduct		suppliers stock levels to ensure production targets	•	autonomously adjust equipment settings to situational needs of the process and instructs co-workers in the process
•	identify basic operations and basic functions of the software	•	use correct materials and hardware according to situation	•	autonomously decide on ramifications to start and stop the process safely instruct fellow workers on these ramifications assume responsibility for his and his colleagues' safety
•	identify specific requirements of the starting process according current process and situation	•	handle machinery manually (and via screen) according to process specifications operate it-equipment like pcs, touch screens, joy sticks, printers	•	autonomously decide on ramifications to start and stop the process safely instruct fellow workers on these ramifications assume responsibility for safety.
•	identify possible ways of filling and emptying the vessels technically correct				
•	relate how a research for application ranges is conducted	•	research the application range of equipment on the internet and in reference books	•	instruct team on the application range of the respective equipment supervise that the equipment is used in the prescribed way
•	relate the operation mode of the equipment and know how to shut it down appropriately	•	write an appropriate protocol containing all results	•	take responsibility for the documentation
•	names production standards and relates the importance of clean equipment to reach these standards	•	correctly dismantles and reinstalls the equipment clean the equipment correctly and	•	autonomously instruct his team on the in plant standards regarding the cleanliness of the equipment
•	describe the setup of the equipment		accurately abiding by safety regulations and plant intern standards	•	supervise that these standards are maintained by his team
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<ul> <li>explain how to safely transfer and add raw material into the equipment</li> </ul>	<ul> <li>handle chemicals and equipment according to safety regulations</li> <li>transfer/ add the raw material into the equipment correctly, taking specific safety regulations into account</li> <li>estimate requirements for material against</li> </ul>	<ul> <li>take responsibility for the keeping of respective in plant standards</li> <li>instruct his team on the correct handling of chemicals</li> </ul>
<ul> <li>relate how and why to clean/ finish the</li> </ul>	<ul> <li>supplier's stock levels to ensure production targets</li> <li>clean/ finish the product correctly</li> </ul>	<ul> <li>autonomously instruct team on how to</li> </ul>
<ul> <li>product</li> <li>name possible by-products and contaminants for specific reactions</li> </ul>		<ul> <li>clean the products correctly</li> <li>take responsibility for the correct and accurate cleaning of products and the resulting quality</li> </ul>
<ul> <li>relate requirements on the container according to respective stored product</li> </ul>		<ul> <li>autonomously instruct team on the right containers for respective products</li> <li>assume responsibility for the correct storing of products</li> </ul>
contrast normal operation and emergency     situations	malfunctions in the production process (also by help of automatically generated details) and deal with them adequately	<ul> <li>supervise a team in adjusting processes according to respective specification</li> </ul>
<ul> <li>identify important measuring values that describe how well the process runs</li> <li>plan how to record data in a useful way</li> </ul>	and/or environmental problem	<ul> <li>assume responsibility for the quality of the product.</li> </ul>
<ul> <li>plan how to record data in a useful way</li> <li>Calculate required values using given equations (chemical and mathematical equations)</li> </ul>		<ul> <li>Autonomously evaluate required values taking theoretical foundations into account and thereby control the process</li> </ul>
Explain how to compile characteristic     curves	Compile a characteristic curve	Autonomously evaluate required values taking theoretical foundations into account and thereby control the process
<ul> <li>Describe experimental set up that are to be tested</li> </ul>		<ul> <li>Autonomously determine the ideal parameters for the experiment</li> <li>Take safety regulations into account</li> </ul>
Explain the influence of experiment	<ul> <li>Evaluate the respective data and compile a</li> </ul>	<ul> <li>Autonomously instruct team on the</li> </ul>

	specific factors on the experimental process	characteristic curve in form of a graph using calculation software	respective parameters
•	Describe fundamentals of evaluating characteristic values		

Control of the working process:		
	make a production plan	<ul> <li>take responsibility for the delivered products to maintain plant intern standards</li> </ul>
describes the standards to be met by the product	<ul> <li>deliver products that full fills plant intern standards</li> </ul>	<ul> <li>take responsibility for the delivered products to maintain plant intern standards</li> <li>instruct team on these standards</li> </ul>
explain the security systems	<ul> <li>monitor and assess the process and recognize faults and problems during the process</li> </ul>	<ul> <li>autonomously check the assessment of the working process by his colleagues on the basis of his experience</li> </ul>
	<ul> <li>complete log sheets, sample results, product quality certificates, maintenance request forms, reports and any other written form required by the day to day running of the plant</li> </ul>	<ul> <li>instruct team on emergency procedures and supervise these procedures</li> </ul>
have knowledge of how to neutralize or minimize the effect of a developing	•	<ul> <li>decide on improvement action autonomously after consulting with his</li> </ul>
emergency situation	<ul> <li>identify a basic approach for a solution to react to a hazardous problem</li> </ul>	<ul> <li>team</li> <li>evaluate the deviations from the desired</li> </ul>
	<ul> <li>change and adjust the production depending on faults detected</li> </ul>	specifications, possible causes and the solutions for improving the faults
	• establish the deviations from the desired	autonomously and instruct a team on
	specifications, possible causes and the solutions for improving the faults	<ul> <li>improvement actions</li> <li>instruct team on emergency actions</li> </ul>
	• use operating and emergency procedures as a guide to take the correct actions until	autonomously and take responsibility for their success
	authoritative assistance arrives	• monitor and direct all operations in
	<ul> <li>report on the process upset clearly and accurately</li> </ul>	hazardous situations concerning the safe of the plant, personnel and environment,
	monitor and directs all operations in	taking responsibility for the success of these operations
	hazardous situations concerning the safety of the plant, personnel and environment	<ul> <li>supervise the correct logging and writing</li> </ul>
	<ul> <li>until authoritative assistance arrives</li> <li>fill in and update necessary documentation about the process, products and safety</li> </ul>	necessary documentation about the process, products and safety instructions
	instructions correct	
describe and reasons the importance of		<ul> <li>autonomously instruct team to regularly</li> </ul>
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	taking samples and how to take them		sampling devices		take samples and thereby controls the production process, relating the
•	identify fundamental parameters that define process quality	•	measure the required values.	•	importance of this practice to his team supervise the process of sample taking and evaluate the respective results autonomously
•	have knowledge of influencing factors in the process	•	adjust parameters according to the requirements	•	supervise the process of sample taking and evaluate the respective results autonomously
•	relate when and why to measure respective values	•	end the process if a certain value is reached	•	supervise the process of sample taking and evaluate the respective results autonomously
•	define required values	•	interpret the measured values and determine the need for optimization	•	supervise the process of sample taking and evaluate the respective results autonomously
•	describe ways how to (mathematically) determine these values as well as the importance and principles of optimal parameter settings	•	adjust respective parameters as to maintain/reach optimal parameter settings	•	autonomously determine the need for optimization and enact all necessary measures
•	define the respective values and means of their determination correctly	•	determine the respective value correctly.	•	be competent in using methods for process control
•	relate the use of the values in quality control	•	operate the laboratory techniques correctly	•	be competent in using methods for process control
•	relate mode of operation of e/i & c technology	•	check the e/i & c technology correctly and evaluate their functioning	•	be competent in using methods for process control
•	specify the importance of a test series at set value and explain how to conduct it	•	conduct a test series at set value as to determine the state of parameter settings	•	be competent in using methods for process control
•	explain how to evaluate data by help of reference data	•	compile trend graphs of respective values and evaluate them keeping in mind the optimal parameter setting	•	be competent in using methods for process control
•	report mathematical grounding of determining corrective factors	•	calculate the respective corrective factors compare the recorded data with a reference (graphs or classification standards etc.) and evaluate the data	•	evaluate the results recorded in the protocol autonomously
•	reproduce the general form of a protocol in which he can document all relevant steps of action	•	write an appropriate protocol documenting all steps of action compare the results to set required values correctly update the documentation and	•	evaluate the results recorded in the protocol autonomously

<ul> <li>communic maintenan equipment</li> <li>deduce the information</li> </ul>	ng to the procedure ate correctly with manufacturing, ce companies etc. for production essential matters from and gives well-founded or improvement
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ULO 3	Title of the unit: Participate in quality controlFinal version			
Work tasks:	<ol> <li>Taking samples</li> <li>Sample analysis</li> <li>Participating in quality control</li> </ol>			
Technological context	Taking samples, met	hods of analysis, quality management,		
Learning Outo	comes:			
Knowledge (theoretical + factual) Scientific Context Theoretical contextSkills ( practical + cognitive (= use of knowledge)Competence (Role al responsibility and all				
	methods of taking and les for in process l product check	<ul> <li>distinguish processes for taking and preparing samples for in process control und final product check</li> </ul>	<ul> <li>assume responsibility for choosing the right sampling method</li> </ul>	
<ul> <li>recognize the commethod for taking</li> </ul>	orrect process specific ng samples	<ul> <li>pick and reasons the required method for sample taking</li> </ul>	<ul> <li>assume responsibility for choosing the right sampling method</li> </ul>	
	ities for taking samples respective equipment erials	<ul> <li>prepare samples und sampling devices as well as pay attention to specifics of the equipment and safety regulations</li> </ul>	<ul> <li>takes responsibility for abiding by safety regulations</li> </ul>	
<ul> <li>have knowledge taking</li> </ul>	e of the kind of sample	<ul> <li>take samples correctly</li> </ul>	autonomously takes samples from the equipment correctly	
<ul> <li>have knowledge and storage of s</li> </ul>	e about the packaging samples	<ul> <li>pack and store samples correctly</li> </ul>	autonomously store samples correctly	
explain methods	s for sample	<ul> <li>compile a documentation for the</li> </ul>	assume responsibility for the correct	

preparation taking and storing samples

- have knowledge about plant intern guidelines for sample analysis
- identify chemical, physical and/or microbiological parameters that are needed for quality assessment according to guidelines
- describe methods of analysis for determining parameters
- register results of the analysis
- define required specifications and/or standards of the product
- identify possible deviations
- describe the results of quality assessment
- name results
- define possibilities to mend deviations
- recognize and check further quality criteria
- describe deviations in a complex situation

samples

- organize and document the passing on of samples to the lab
- interpret decisive characteristics for quality
- executing analyses at production process
- present and evaluating results of an analysis
- deduce characteristics for quality of the product
- evaluate deviations depending on the qualitative goal
- present measured results in technically correct for
- report on the results and the respective conclusions
- execute adjustments of equipment parameters
- evaluate interventions on the equipment by taking and analysing samples again
- report deviations and started ramifications to supervisors

#### documentation

- assume responsibility for passing on samples
- assume responsibility for passing on samples
- autonomous execution of analyses
- evaluate results of the analyses
- take responsibility for the evaluation of the results.
- supervise the working process
- take responsibility for the documentation of results
- proactively inform the involved team
- autonomous execution
- supervise the working process
- take responsibility for passing on information

<ul> <li>recognize and define possibilities to augment quality</li> </ul>	<ul> <li>deduce possibilities to augment quality specifically for the process together with colleagues</li> </ul>	<ul> <li>autonomously supervise the working process and recognize potential for optimization</li> </ul>
<ul> <li>have knowledge about important models ad methods of process development and optimization (e.g.: GMP, GLP)</li> </ul>	<ul> <li>apply models and methods of process development and optimization (GMP, GLP)</li> </ul>	<ul> <li>apply models and methods of process development and optimization autonomously</li> </ul>
<ul> <li>name quality specifications, working conditions and regulations regarding safety and environmental protection</li> </ul>	<ul> <li>integrate regulations into the process</li> </ul>	<ul> <li>autonomous integrates regulations into the process</li> </ul>

ULO 4	Title of the unit: F	Participating in maintenance and repairs		Final Version	
Work tasks:	<ol> <li>Working perm</li> <li>Lock out and</li> <li>Maintenance</li> </ol>				
Technological context	Chemical Proces				
Learning Outco	<u>mes:</u>				
Knowledge (theo Scientific Context context	pretical + factual) Theoretical	Skills (practical + cognitive (= use of knowledge)	Competence (Role and level of responsibility and autonomy)		
1. Working permits					
<ul><li>is complete</li><li>judge and explain</li></ul>	e of used software office) agrams (P&ID) ntal rules and s if the working permit if the optimal e equipment is used es during in relation to in relation to	<ul> <li>understand /compare the required documentation of machinery and working permits</li> <li>consults others when necessary (colleagues, maintenance)</li> <li>consults others when necessary (colleagues, maintenance)</li> <li>proactive behaviour in maintenance of the installation parts</li> <li>use the correct personal protective equipment</li> <li>use operating procedures, administrative checks, emergency response and other management approaches to prevent incidents or to minimize the effect of an incident by hot-work procedures and confined space entry permits</li> <li>identify and use of proper personnel safety material and equipment</li> </ul>	<ul> <li>instruct and monitor that of a work permit are folk a team</li> <li>assume responsibility of of a team</li> <li>monitor the quality of the team</li> <li>optimise work processes communication with ope team members, contract management and suppli</li> <li>propose and assume re- improvement initiatives a</li> </ul>	f his/her own safety and e work executed by a s through open erators, maintenance tor team members, iers sponsibility of	

2.	Lock out and tag out of installation				
•	express knowledge of technical condition of machinery explain maintenance instructions express knowledge of 2 <sup>nd</sup> language, English/German express knowledge of used software systems (windows office) explain process diagrams (P&ID)	•	shut down, isolate and prepare process units or production equipment for maintenance maintain accurate records and documentation report deviations correctly and inform the involved departments/colleagues monitor own or contractor maintenance work and identify unsafe and improper working procedures and conditions read and understand the plan of maintenance schedules	• • • •	instruct a team on all necessary work steps for shutting down, isolating and preparing process units for maintenance autonomously supervise documentation of maintenance preparation assume responsibility of his/her own safety and of a team report deviations proactively and correctly and inform the involved departments/colleagues report on team work progress optimise work processes through open communication with operators, maintenance team members, contractor team members, management and suppliers propose and assume responsibility of improvement initiatives and projects
3.	Maintenance or repair				
•	explain about different maintenance systems (preventive / corrective maintenance) explain equipment manuals know the working regulations understand and explain the working principles of equipment (like pumps, valves, measure & control equipment, seals, piping). understand the principles of electricity in relation to safety recognise, explain unsafe or critical situations and mention possible measures	•	perform and monitor minor repair and maintenance work according audited procedures on mechanical, electrical and instrument field assist and cooperate with maintenance personnel during refurbishing, de- bottlenecking and turnaround activities organise and use tools, machinery, equipment, chemicals and energy for doing proper and safe maintenance work monitor the use of reliable equipment and working methods during maintenance work	•	instruct a team on all necessary work steps autonomously if the need for maintenance work occurs assume responsibility of his/her own safety and of a team coordinate his/her own work schedule and the schedule of a team concerning minor repairs and maintenance work assume responsibility of the cost efficiency of the works and repairs executed executed by a team and optimises hand on tool times report on the state of maintenance in the plant autonomously and proactively optimise work processes and detect maintenance needs through open communications with operators, maintenance team members, contractor team members, management and suppliers

•	<ul> <li>propose and assume responsibility of improvement and maintaining of the equipment state initiatives and projects</li> </ul>