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Background

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. [1]

The European chemical industry is a €673 billion industry and the world's top exporter and importer of chemicals, with a record €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. [2]

The chemical and pharmaceutical industries are facing increasing competition from low-cost areas. In order to maintain the position as a profitable and attractive sector of the economy, they must be in the forefront when it comes to efficient production, and development of new production methods and products. This requires access to highly qualified personnel at all levels. Highly qualified staff is furthermore a prerequisite for securing health, safety and environmental protection for staff and the surroundings. [3]

Development of a curriculum for European chemical and pharmaceutical industry has been a task within a strategic partnership "Chempharm VET" with partners from Slovakia, Slovenia, Portugal, Germany and Norway. The partners represent schools, training centers and associations of chemical and pharmaceutical industry. [4]

Aims

Access to process operators with relevant qualifications is now a growing problem. The shortage of labor 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. [5]

Based on these specifications, the Leonardo da Vinci project PILE UP (Project 2011-1-NL1-LEO05-05209) involved social partners and developed a set of common European units of learning outcomes (knowledge, skills and competencies) for operators in the chemical industry. [6]

Whereas the PILE UP project specified WHAT should be the learning outcomes of VET for operators in the chemical industry, there is still a need to describe HOW these should be developed. Due to the differences between the two branches, there is also a request for learning outcome descriptions and a curriculum for the pharmaceutical industry VET.

This requires an even more structured approach towards qualification definitions and descriptions with a full implementation of the ECVET principles and EQF/NQF/SQF comparisons, partly to identify the overlaps and partly as a clear specification of the differences. Learning outcome units and curricula should be widely accessible throughout Europe.

On this background:

The overall aims with this curriculum will be 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.

Objectives for the education of the subject

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. [7]

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.

The job profile for operators in chemical processing and pharmaceutical industries

Job Title	Process Operator in The European Chemical and Pharmaceutical Industry
EQF Level	3 and 4. A study according to this 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.
Note	Approval of previously acquired skills can shorten the study (Recognition of prior learning/competences).

Entry requirements

The entry requirement for this study is finished and completed primary school and lower secondary education at EQF level 2, or recognition or approval of prior learning at this level.

Recognition of prior learning (RPL)

Recognition of prior learning can help learners and employers recognise learning that has come from experience and/or previous formal, non-formal and informal learning.

Competences acquired outside formal education and training can be assessed and recognised as parts of the formal educational system. The main purpose is to avoid

unnecessary repeat learning sequences. The situation regarding RPL in Europe 1990 - 2000 is discussed by Jens Bjørnåvold at Cedefop in the report "Making learning visible".[8]

The Scottish Credit and Qualifications Framework (SCQF) has made information and guidance of RPL:

"The Recognition of Prior Learning (RPL) is the process for recognising learning that has come from experience and/or previous formal, non-formal and informal learning. This could include knowledge and skills gained within school, college and university and outside formal learning situations such as through life and work experiences or even through a hobby.

RPL can be used by a wide range of people either to help them re-enter learning or to contribute towards a programme of learning or simply to identify their skills in order to progress in their career. Through RPL it may be possible to make a claim for SCQF Credit Points which can reduce the amount of time needed to achieve the required learning programme or qualification." [9]

Toolkits for recognition of prior learning have been made. One example is the toolkit made of The Scottish Credit and Qualifications Framework. [10]

Structure of the study

The study consists of four units:

1. Perform operational logistics
   The work tasks in this unit are to prepare, execute and monitor a logistic plan.

2. Conduct processes
   The work tasks in this unit are to conduct psysical processes (thermal, mechanical, EI&C), chemical processes, biological processes and pharmaceutical processes.
   The technological context consists of:
   1. Preparation of the process
   2. Handling of machinery
   3. Control of working processes.

3. Participate in quality control
   The work tasks in this unit are
   1. Taking samples
   2. Sample analysis
   3. Participating in quality control

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

4. Participate in maintenance and repairs
   The work tasks in this unit are
   1. Working permits
   2. Lock out and tag out of installation
   3. Maintenance or repair

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

Learning outcomes for all units are enclosed as appendices.

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

A possible schedule for the study

The schedule of the teaching differs in the different European countries. Here are some examples:

In Germany there are four years of training as an apprentice in a company combined with theoretical and practical study in a training centre.

In Norway there are two years of theoretical and practical study in an upper secondary school and two years of training in a company as an apprentice.

In Slovenia there are three years of theoretical and practical study in an upper secondary school.

In Portugal, there are any level 4 EQF qualification specific for the chemical and pharmaceutical industry operator, however, there are one qualification of level 4, which is delivered in vocational, educational and training centres, which can be considered most appropriated and/or similar, when compared with the pharmaceutical operator, which is:

Industrial Chemical Technician;
This training course is divided in three parts:

- General and Scientific (around 1500 hours)
- Technological and Expertise (1225 hours)
- Internship in workplace (600 hours/840 hours in a company, industry or other)

This means that learners have, more or less, two years of theoretical and practical study in the training centre (**General and Scientific** + **Technological and Expertise**), combined with an **internship in the workplace**- 600 to 840 hours in a company.

A vocational education and training programme is recognized as three years of study after finishing the lower secondary school for level 4 of the European Qualifications Framework (EQF).

Methods of teaching and practical training as part of the study

The study consists of lectures teaching the students and apprentices the necessary know-how based on the subjects necessary for obtaining the learning outcomes defined in this curriculum. In addition, there are necessary 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).

Tacit knowledge can be defined as skills, ideas and experiences that people have in their minds and are, therefore, difficult to access because it is often not codified and may not necessarily be easily expressed. [11]

With tacit knowledge, people are not often aware of the knowledge they possess or how it can be valuable to others. Effective transfer of tacit knowledge generally requires extensive personal contact, regular interaction and trust. [12]

Apprentices and students within chemical 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. This is what is called “workplace learning” and has to be an important part of this study programme.

Cambridge Business English Dictionary defines “workplace learning” as:

- Lessons or training that people receive while they are at work and that are paid for by their employer
- A period of time during which a student works for an organization in order to gain knowledge and experience [13]

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. Broadly speaking however, it can be defined as the acquisition of knowledge or skills by formal or informal means that occurs in the workplace. Workplace learning mostly occurs through work-related interactions, and is generally described as contributing to the learning of both the individual employee and the organization as a whole. Research shows that 80% of the work-related learning occurs informally and this includes self-directed learning, networking, coaching and mentoring. Therefore, workplace learning can include formal elements but is predominantly informal in nature, and is often incorporated into workplace social interactions and everyday practices. According to

some authors, workplace learning is also 'culturally bound', meaning that the skills that an employee learns represent the requirements of his or her tasks within the organization. [14]

Disclaimer

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Appendices:

1. Description of Unit 1: Perform operational logistics

The work tasks in this unit are to prepare, execute and monitor a logistic plan.

The learning outcomes are to be:

Knowledge (theoretical + factual) ***Scientific Context*** ***Theoretical context***	***Skills (practical + cognitive = use of knowledge)***	***Competence (Role and level of responsibility and autonomy)***
• knowledge of 2nd language	• understand /compare the required specification for supplies and products	
• knowledge of used software systems	• consults others where necessary (colleagues, supervisor)	• instruct a team on all necessary work steps needed to provide raw material of the right quality autonomously
• explain about different logistic systems (Just in time, Make to order, make to stock, push and pull, fifo, lifo)	• maintain accurate records and documentation • report deviations correctly and inform the involved departments/colleagues/customers	• monitor that the (safety) instructions concerning the transportation and preparation of raw material are followed by all members of a team
• understand the planning of introduction of new products	• liaise with suppliers to ensure supplier has adequate back up stock levels	• assume responsibility of his/her own safety and of a team
• describe the function of Material Safety Data Sheets	• manage hazards including handling and safe disposal according to environmental rules and procedures	• coordinate his/her own work schedule and of a schedule of a team
• recognise different kind of quality systems (ISO)	• carry out /ensure quality checks prior to supplies being used or products being dispatched	• assume responsibility of the cost efficiency of the works executed by a team and optimises hand on tool times
• explain environmental rules and regulations • explain safety rules • define the pharmaceutical specifics of materials	• respond to safety and environmental requirements within the task	• monitor that the team provides the right raw material of the right quality for the production process
• explain working instructions • explain process diagrams (P&ID)	• read and understand the plan of production schedules in relation to customer demand	• report on team work progress

• describe the primary and secondary packaging	• test, evaluate, document and make mandatory labeling	• autonomously selecting the right packaging materials
• recognise and explain the storage and transportation systems, like vessels, air transport, bunker, silo, tube systems and pipelines	• arrange and manage deliveries • arrange and manage dispatches • respond to changes in the planned logistic schedule	• optimise work processes through open communication with operators, maintenance team members, contractor team members, management, suppliers and (internal) customers
• explain calculations and mass balance	• deals cost- consciously with materials and products	• propose and assume responsibility of improvement the initiatives and projects
• understand and explain statistical concepts (like average, standard deviation) in relation to data from suppliers and customer needs.	•	•

2. Description of Unit 2: Conduct processes

The work tasks in this unit are to conduct psysical processes (thermal, mechanical, EI&C), chemical processes, biological processes and pharmaceutical processes.

The technological context consists of:

1. Preparation of the process
2. Handling of machinery
3. Control of working processes.

The learning outcomes are to be:

1) **Preparation of the process:**		
• outline fundamental basics of production planning (including process optimization, work safety, quality management and GMP)	• evaluate the task schedule/work plan according to the current situation of the plant	• autonomously execute all steps of the adapted work plan/ task schedule

	• adapt the work plan to task specific needs (taking into account the optimization of processes, work safety regulations and product quality)	• autonomously instruct their team on the adapted work plan and monitor that all steps are being carried out
• express fundamentals of the respective production process.	• select respective instrumentation according to the process being conducted	• autonomously instruct their team on the instrumentation to use after consulting the piping and instrumentation diagram
• name equipment that is needed to conduct the process • explain the operation mode of the respective equipment	• clarify equipment parts and describe their function correctly	• take responsibility for the correct installation of the equipment used by the team
• describe the equipment set up correctly • have knowledge of the operation mode and set up of the equipment	• install the respective equipment correctly	• take responsibility for the correct installation of the equipment used by his team
• relate specific operational needs that have to be kept in mind when preparing the equipment	• execute specific operational needs according to the process that is to be conducted • handle equipment correctly	• instructs team on the correct preparation of the equipment
• describe processes and explain operating software systems	• describe and explain processes and their visualization on the screen	• take responsibility for the processes and the operating software systems
• relate standard operating procedures (sop)	• work accurately and precisely	• executes and controls respective process preparation autonomously and verifies quality and safety of the process
• define the options for microbiological contamination and eliminate it	• perform and check of decontamination according to predetermined standards	• autonomously implementation and testing of decontamination measures
• describe the options for sterile manufacturing and packaging of medicines	• perform and check of the sterile preparation according to prescribed standards	• autonomously implementation and testing of sterile manufacturing and packaging
• describe fundamentals of process control and instrumentation technologies	• recognize the hazard potential of the process	• assume responsibility for fellow workers

• explain the operation mode of scales		
• describe possible ways to fill the equipment vessels with raw material.	• fill the vessels technically correct with raw materials and takes equipment specifics into account	• autonomously fill of raw material into the vessels according to the equipment specifics.
• explain fundamentals of transferring materials taking into account safety regulations	• fills vessels technically correct, abiding by safety regulations	• considered autonomously, the correct filling and compliance with safety regulations.
• research features and safety regulations (such as h/p phrases) of deployed chemicals and biologically hazardous substances	• choose and uses the respective preventive measures and personal protective equipment	• self-observance of the safety and use of the correct personal protective equipment
• describe characteristics and regulations of medical products		
• name properties of raw material and their pharmaceutical properties		
• name important preparation measure for raw material	• prepare the raw material according to process needs • weigh in the required amount of raw material according to the specific situation	• autonomously initiate weighing in of raw material and take responsibility for the correct weighing
• describe fundamentals of process control		
• define values and relate their importance in the context	• calculate required values by applying theoretical rules to the operation specifics	• take responsibility for the calculation of the required values.
• name theoretical rules for calculations of required values/ determination of setting	• choose necessary parameters	• take responsibility for the proper execution
• identify symbols and their meaning in a piping and instrumentation diagram	• read the piping and instrumentation diagram	• take responsibility for the proper execution
• name rules concerning the compilation of a piping and instrumentation diagram	• compile an instrumentation and piping diagram abiding by the used standards into a given matrix	• take responsibility for the proper execution

• identify points of measurement in a given piping and instrumentation diagram	• marks points of measurement in a piping and instrumentation diagram abiding the used standards	• take responsibility for the proper execution
• relate ways of obtaining information about the operation mode	• researches information about the operation mode of the points of measurement in the equipment he is currently using	• take responsibility for the proper execution
• name regulations on marking E/I & C technology in a piping and instrumentation diagram.	• enter standardized points of measurement into a piping and instrumentation diagram correctly	• takes responsibility for the proper execution
• explain principles of adjusting controllers and relate their mode of operation	• adjust the controller abiding by the aforementioned principles correctly	• take responsibility for the proper execution
• relate important values and why they are measured	• record respective values and export results into respective software • evaluate recorded data by help of the compilation of trend graphs	• take responsibility for the proper execution

2) **Handling of machinery:**		
• fundamentally understand the basics of production planning (including process optimization, work safety, quality management etc.) • outline the process and name the 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 process and its ideal conduct	• estimate requirements for material against suppliers stock levels to ensure production targets	• supervise • 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 conditions of the start process according to current 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		
• explain how to search for information about the prescribed way of operating equipment	• derive from available documentation and information sources the prescribed way of operating the equipment for particular applications	• instruct team on the prescribed way of operation of the equipment • supervise that the equipment is used in the prescribed way
• explain 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
• name production standards and relate the importance of clean equipment to reach these standards • define Clean-in-place (CIP), Wash-in-place (WIP) and Sterilisation-in-place (SIP) technology • describe the setup of the equipment	• correctly dismantle and reinstall the equipment • clean the equipment correctly and accurately abiding by safety regulations and plant intern standards	• autonomously instruct his team on the in plant standards regarding the cleanliness of the equipment • supervise that these standards are maintained by his team • take responsibility for the keeping of respective in plant standards
• explain how to safely transfer and add raw material into the equipment • describe solid, semisolid and liquid medicines regarding the pharmaceutical peculiarities	• handle chemicals and equipment according to safety regulations • transfer/ add the raw material into the equipment correctly, taking specific safety regulations into account • estimate requirements for material against supplier's stock levels to ensure production targets	• instruct his team on the correct handling of chemicals
• explain how and why to purify/ finish the product	• purify/ finish the product correctly	• autonomously instruct team on how to purify the products correctly

• name possible by-products and contaminants for specific reactions		• take responsibility for the correct and accurate purification of products and the resulting quality
• describe possible ways for packaging the products	• package the product technically correct according to product specifications and required regulations	• autonomously package the product according to the type of product and equipment specifics
• explain requirements on the container according to respective stored product	• choose the right container for the respective product, abiding by work place safety regulations	• autonomously instruct team on the right containers for respective products • assume responsibility for the correct storing of products
• describe the proper disposal of chemical and biological waste	• classify the waste according to the specified rules	• dispose waste correctly and autonomously
• distinguish between normal operation and emergency situations	• point out unsafe situations and malfunctions in the production process (also by help of automatically generated details) and deal with them adequately	• supervise a team in adjusting processes according to respective specification
• identify important measuring values that describe how well the process runs	• respond to faults which can cause safety and/or environmental problem	• assume responsibility for the quality of the product.
• plan how to record data in a useful way	• record data according to specified plan	
• Calculate required values using given equations (chemical and mathematical equations)	• Calculate required values taking equipment specifics into account • Conduct the experiment carefully and accurately • Record the required data	• Autonomously evaluate required values taking theoretical foundations into account and thereby control the process
• Explain how to compile characteristic curves	• Compile a characteristic curve	Autonomously evaluate required values taking theoretical foundations into account and thereby control the process
• Describe experimental setups that are to be tested	• Adjust experiment specific parameters • Take safety measures into account	• Autonomously determine the ideal parameters for the experiment • Take safety regulations into account
• Explain the influence of experiment specific factors on the experimental process	• Evaluate the respective data and compile a characteristic curve in form of a graph using calculation software	• Autonomously instruct team on the respective parameters
• Describe fundamentals of evaluating characteristic values		

3) **Control of the working process:**

	• make a production plan	• take responsibility for the delivered products to maintain plant intern standards
• describes the standards to be met by the product	• deliver products that full fills plant intern standards	• take responsibility for the delivered products to maintain plant intern standards • instruct team on these standards
• explain the safety systems	• monitor and assess the process and recognize faults and problems during the process • 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	• autonomously check the assessment of the working process by his colleagues on the basis of his experience • instruct team on emergency procedures and supervise these procedures
• have knowledge of how to neutralize or minimize the effect of a developing emergency situation	• start emergency procedures and call authoritative / supervisory staff • identify a basic approach for a solution to react to a hazardous problem • change and adjust the production depending on faults detected • establish the deviations from the desired specifications, possible causes and the solutions for improving the faults • use operating and emergency procedures as a guide to take the correct actions until authoritative assistance arrives • report clearly and accurately on the process fault • monitor and direct all operations in hazardous situations concerning the safety of the plant, personnel and environment until authoritative assistance arrives • fill in and update necessary documentation about the process, products and safety instructions correctly	• decide on improvement action autonomously after consulting with his team • evaluate the deviations from the desired specifications, possible causes and the solutions for improving the faults autonomously and instruct a team on improvement actions • instruct team on emergency actions autonomously and take responsibility for their success • monitor and direct all operations in hazardous situations concerning the safety of the plant, personnel and environment, taking responsibility for the success of these operations • supervise the correct logging and writing of necessary documentation about the process, products and safety instructions
• describe and explain the importance of taking samples and how to take them	• take samples operating the respective sampling devices	• autonomously instruct team to regularly take samples and thereby control the production process, relating the importance of this practice to his team

• identify fundamental parameters that define process quality	• measure the required values.	• supervise the process of sample taking and evaluate the respective results autonomously
• have knowledge of factors influencing the process	• adjust parameters according to the requirements	• supervise the process of sample taking and evaluate the respective results autonomously
• explain 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 required 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 implement all necessary measures
• define the respective values and means of their determination correctly	• determine the respective value correctly	• autonomously use methods for process control
• explain the use of the values in quality control	• operate the laboratory techniques correctly	• autonomously use methods for process control
• explain mode of operation of e/i & c technology	• check the e/i & c technology correctly and evaluate their functioning	• autonomously use methods for process control
• specify the importance of test series at the set value and explain how to conduct it	• conduct test series at the set value as to determine the state of parameter settings	• autonomously use 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	• autonomously use methods for process control
• explain mathematical basics 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 format of a protocol in which all relevant steps of action are documented	• write an appropriate protocol documenting all steps of action • compare the results to the required values • correctly update documentation and log according to the procedure • communicate correctly with maintenance and manufacturers of the tools and equipment • derive essential issues from information and make proper suggestions for improvement	• evaluate the results recorded in the protocol autonomously

3. Description of Unit 3: Participate in quality control

The work tasks in this unit are

1) **Taking samples**
2) **Sample analysis**
3) **Participating in quality control**

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

The learning outcomes are to be:

Knowledge (theoretical + factual) ***Scientific Context Theoretical context***	***Skills (practical + cognitive (= use of knowledge)***	***Competence (Role and level of responsibility and autonomy)***
• define various methods of taking and preparing samples for in process control and final product check	• distinguish processes for taking and preparing samples for in process control und final product check	• assume responsibility for choosing the right sampling method
• recognize the correct process specific method for taking samples	• select and give reasons for the required method for sample taking	• assume responsibility for choosing the right sampling method
• identify possibilities for taking samples suitable for the respective equipment and tested materials	• prepare samples und sampling devices as well as pay attention to specifics of the equipment and safety regulations	• takes responsibility for abiding by safety regulations
• explain methods of sampling	• take samples correctly	• autonomously take samples from the process correctly

• have knowledge how the samples are packed and stored	• pack and store samples correctly	• autonomously store samples correctly
• explain methods for sample preparation, taking and storage	• compile a documentation for the samples	• assume responsibility for the correct documentation
• have knowledge about plant internal guidelines for analysis of samples	• organize and document the transfer of samples to the lab	• assume responsibility for transfer of samples
• identify chemical, physical and/or microbiological parameters that are needed for quality assessment according to guidelines	• interpret decisive characteristics for quality	• assume responsibility for transfer of samples
• describe methods of analysis for determining parameters	• execute analyses at production process level	• autonomously execute analyses
• determine the results of the analysis	• present and evaluate results of an analysis	• evaluate results of the analyses
• define required specifications and/or standards of the product	• deduce characteristics for quality of the product	• take responsibility for the evaluation of the results
• identify possible deviations	• evaluate deviations depending on the qualitative goal	• supervise the working process
• describe the results of quality assessment	• present measured results in technically correct for	• take responsibility for the documentation of results
• describe results of analyses	• report on the results and the respective conclusions	• proactively inform the involved team
• define possibilities to minimize deviations	• execute adjustments of equipment parameters	• autonomously execute task
• recognize and check further quality criteria	• evaluate interventions on the equipment by taking and analysing samples again	• supervise the working process
• describe deviations in a complex situation	• report deviations and started actions to supervisors	• take responsibility for passing on information
• recognize and define possibilities to improve quality	• deduce possibilities to improve quality specifically for the process together with colleagues	• autonomously supervise the working process and recognize potential for optimization

• describe the possibilities for the development and optimization of drugs	• select the necessary equipment and the required auxiliaries • expertly use the required measuring devices	• autonomous carry out the tests, detect and evaluate the results
• explain important models and methods of process development and optimization (e.g.: GMP, GLP)	• apply models and methods of process development and optimization (GMP, GLP)	• apply models and methods of process development and optimization autonomously
• name quality specifications, working conditions and regulations regarding safety and environmental protection	• integrate regulations into the process	• autonomously integrate regulations into the process

4. Description of Unit 4: Participating in maintenance and repairs

The work tasks in this unit are:

1. Working permits
2. Lock out and tag out of installation
3. Maintenance or repair

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

The learning outcomes are to be:

Knowledge (theoretical + factual) ***Scientific Context*** ***Theoretical context***	***Skills (practical + cognitive (= use of knowledge)***	***Competence (Role and level of responsibility and autonomy)***
1. Working permits		
• express knowledge of 2nd language • express knowledge of used software systems • explain process diagrams (P&ID) • explain environmental rules and regulations	• understand /compare the required documentation of machinery and working permits • consult others when necessary (colleagues, maintenance) • consult others when necessary (colleagues, maintenance)	• instruct and monitor that the (safety) instructions of a work permit are followed by all members of a team • assume responsibility of his/her own safety and of a team • monitor the quality of the work executed by a team

• explain safety rules • describe how the equipment is prepared for maintenance • check and explain whether the optimal personal protective equipment is used • describe safety rules during maintenance work • explain used tools in relation to methods • explain used tools in relation to personnel safety material and equipment.	• act proactively in maintenance of the installation • use the correct personal protective equipment • Apply operating, control and emergency procedures and other management measures for preventing dangerous situations, especially in working with hot equipment parts and in narrow spaces • identify and use proper personnel safety material and equipment	• optimise work processes through open communication with operators, maintenance team members, contractor team members, management and suppliers • propose and assume responsibility for improvement initiatives and projects
2. Lock out and tag out of installation		
• demonstrate knowledge of technical condition of machinery • explain maintenance instructions • 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 autonomously a team on all necessary work steps for shutting down, isolating and preparing process units for maintenance • 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 different maintenance systems (preventive / corrective maintenance) • explain equipment manuals	• perform and monitor minor repair and maintenance work according audited procedures on mechanical, electrical and instrument field	• instruct a team on all necessary work steps autonomously if the need for maintenance work occurs
• 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	• support and cooperate with maintenance personnel • organise and use tools, machinery, equipment, chemicals and energy for doing proper and safe maintenance work	• 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 by a team and optimises hand on tool times
• recognise unsafe or critical situations and explain appropriate measures	• monitor the use of reliable equipment and working methods during maintenance work	• 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 • propose and assume responsibility for improvement and maintenance of the equipment