O2 Identification of relevant areas report

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1 Introduction

The situation in the chemical and pharmaceutical industries with stiff international competition requires a highly skilled workforce to secure quality and productivity. The sector represents a major part of the European process industry and where the industrial production employs 3,3 million Europeans in 94.000 enterprises with a multibillion turnover (2014: 1 078 billion €). This turnover is continually challenged by investments in the development of new products, the fact that patents are time limited, down to 10 years, with immediate releases of "copy products" from other parts of the world, intensifies the need for qualified staff rapidly taking on new tasks and challenges.

Laboratory functions and process operation are responding to new requirements as concerns complexity and a safe and sustainable production. This is partly due to new methods and technologies, new types of equipment and respective operational procedures, but over the last years also the emphasis on safety and security in the processes and strict environmental and sustainability criteria.

To be competitive in a fast developing market, the training quality, the relevance and flexibility of training provision between schools and work based learning is of utmost importance. Laboratory personnel and process operators with their skills and competences– tacit and tangible –represent a core part of the industry's intellectual capital.

This implies also that critical skills and crucial tacit knowledge acquired in workplace settings are central in the project. Video recordings of these performance based competences will be directly linked to the respective learning outcomes in the ECVET based multilingual qualification matrixes in Skillsbank.

To meet the requirements linked to the shared responsibility between schools and companies in the securing of compatible standards between the training providers and in the work based learning, the ECVET principles are basis. Using learning outcomes carefully defined and organised in logical units, the core qualification criteria will be operationally defined. For transparency purposes these qualification definitions will be developed transnationally and in multilingual versions. They will be supported by video clips as best practice examples as well as for the documentation of individual learners' performance towards certification and employability.

A standard ECVET implementation is relying on precise definitions of learning outcomes organised in structured units. When the differentiation between Competence / Responsibility and Autonomy), Skills and Knowledge is activated in the description of individual LOs, certain elements of skills and competence documentation may be lacking. These characteristics are technically labelled as tacit knowledge – "silent knowledge" which forms the parts of a learning outcome which can only be seen, experienced and documented through practical performance.

In the context of the priorities of the Erasmus+ programme, the horizontal one "Transparency and recognition of skills and qualifications", is directly mirroring the project ambitions. With the focus on work based learning the idea is to update and develop in-school training through close

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interaction with the industry itself. This should secure the relevance aspect, and with the video recording of individual learners' performance as well as best practice examples the quality aspect are covered as well. This is clearly asked for in the European VET priorities "Developing VET business partnerships aimed at promoting work-based learning in all its forms" and "increasing the quality of VET provision, the establishment of feedback loops to adapt VET provision based on outcomes, including by setting up or testing graduate tracking arrangements as part of quality assurance systems in line with the EQAVET recommendation".

This project pursues the following key objectives:

- Improvement of training quality and relevance implementing video technology linked to ECVET oriented learning outcomes in the chemical and pharmaceutical sector;
- Enhancing the ECVET defined learning outcomes with inclusion of tacit knowledge as documentation of performance of critical skills among process operators and laboratory technicians uploaded in the Skillsbank system;
- Develop VET institutions and enhancement of VET-industry cooperation through work based learning;
- Promoting recognition of work based learning, including prior learning independent of arena of experience, for permeability, flexible training pathways and alternative career options within the industry.

The partnership comprises 10 partners from 7 countries (AT, CZ, DE, FR, IT, NO, SK).

2 Identification of relevant areas in European VET, EQF level 4 - Tacit knowledge and critical skills

The intellectual output O2 is described, as an identification of relevant areas in European VET, EQF level 4 where performance of tacit knowledge and critical skills are essential in the laboratory and the process operation.
This IO will identify core activities requiring critical skills and tacit knowledge in chemical and pharmaceutical laboratories and process operation as they are observed by the partners, including the associate industry partners. The primary sources for this are the CREDCHEM, ChemPharmVET and PileUp qualification matrixes and the related assessment procedures.

2.1 The primary sources

2.1.1 CREDCHEM methodology to define units of learning outcomes

This document contains an explanation of the method to identify units based on working tasks and to identify the knowledge, skills and competence that the VET systems should enable learners to develop in order to be able to carry out these tasks. (CREDCHEM – Entwicklung und Erprobung eines Leistungspunktesystems zur Verbesserung der Mobilität im Chemiesektor, Final Report, 2012)

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2.1.2 PileUp Process Industry LEarning Unit Project

The aim of the Pile Up project was to develop common European units of learning outcomes that can be used to gain insight into and assess the skills and competences of workers in the chemical industry. This should enable them to PILE them UP to reach a higher level of qualification and consequently increase the chances of mobility of the workforce within Europe.

PILE UP aims at upgrading skilled workers by implementing units of learning outcomes in VET (Vocational Education and Training). This was achieved by innovating existing job profiles for Chemical Operator level 4 and Maintenance Technician level 4.

In the process first a common understanding of competence profiles in various European countries was generated, then leading to the construction of new units of learning outcomes and assessment tools. (PileUp Process Industry LEarning Unit Project, Final Report, 2013)

After that these outcomes were theoretically and practically tested in the VET sector and Process Industry.

2.1.3 ChemPharmVet

The ChemPharmVET project was based on previous achievements towards key competences for operators in the chemical industry with the overall objective to develop innovation in vocational education and training.

The project was based on the units of learning outcomes developed in the PILE UP project with the target of developing curricula for the training of operators in the chemical and pharmaceutical industry on EQF level 4.

With the further development of the PILE UP project with units of learning outcomes tested by stakeholders around Europe, a new European model curriculum and training programmes for VET providers for the training of operators in the chemical and pharmaceutical industry was created.

The main project outcomes of ChemPharmVET are the development of the Pile Up matrix extensions, including additional units of learning outcomes for operators in the chemical industry;

- a similar matrix of learning outcome units for operators in the pharmaceutical industry
- VET curricula, based on the matrixes, for the chemical and pharmaceutical industries;
- the pedagogical concept to implement VET model program in the different target countries;
- a new learning outcome based European model for VET that can be used for country specific curricula;
- tools for recognition of prior learning.

Through this delivery the project has addressed the challenges recognised by the social partners at EU and national levels in VET and has contributed to:

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- make it easier for young people to get the right competences (skills, knowledge and general aptitudes) and to use them in appropriate jobs contribute to employment by equipping people with the right skills for the jobs of today and tomorrow in the chemical and pharmaceutical industry.
- give employees the ability to acquire required qualifications in order to adapt to change and possible shifts in their career. In doing so, the project has facilitated to meet industrial, economic and technological changes in the chemical and pharmaceutical industry and enabling future mobility and development of the workforce
- improve quality and relevance in VET for operators in the chemical and pharmaceutical industries, hereby improving their employability; improve attractiveness of the vocational education and training among young people by providing up-to-date VET programmes with perspectives of mobility
- enhance creativity and innovation of VET by promotion of partnerships between the world of VET and the labour market; support effectiveness of the labour market through the future supply of highly qualified and competitive specialists and decreasing the mismatch of qualifications.
- improve practical skills of VET learners by involving employers in the process of VET, facilitating work based learning. (ChemPharm VET Final Report, 2017)

2.2 Basis for the identification of relevant areas

Basis for the analysis are the units of learning outcomes (ULO), which were developed in the ChemPharm project. The ULOs reflect the work flow of the chemical and pharmaceutical operator, like it is conducted in the process industries and were developed by analysing real work tasks and national curriculae.

2.2.1 Units of learning outcomes

The work flow of the chemical and pharmaceutical operator was divided into four units, as followed:

ULO 1
Perform operational logistics

ULO 2
Conduct processes

ULO 3
Participate in quality control

ULO 4
Participating in maintenance and repairs

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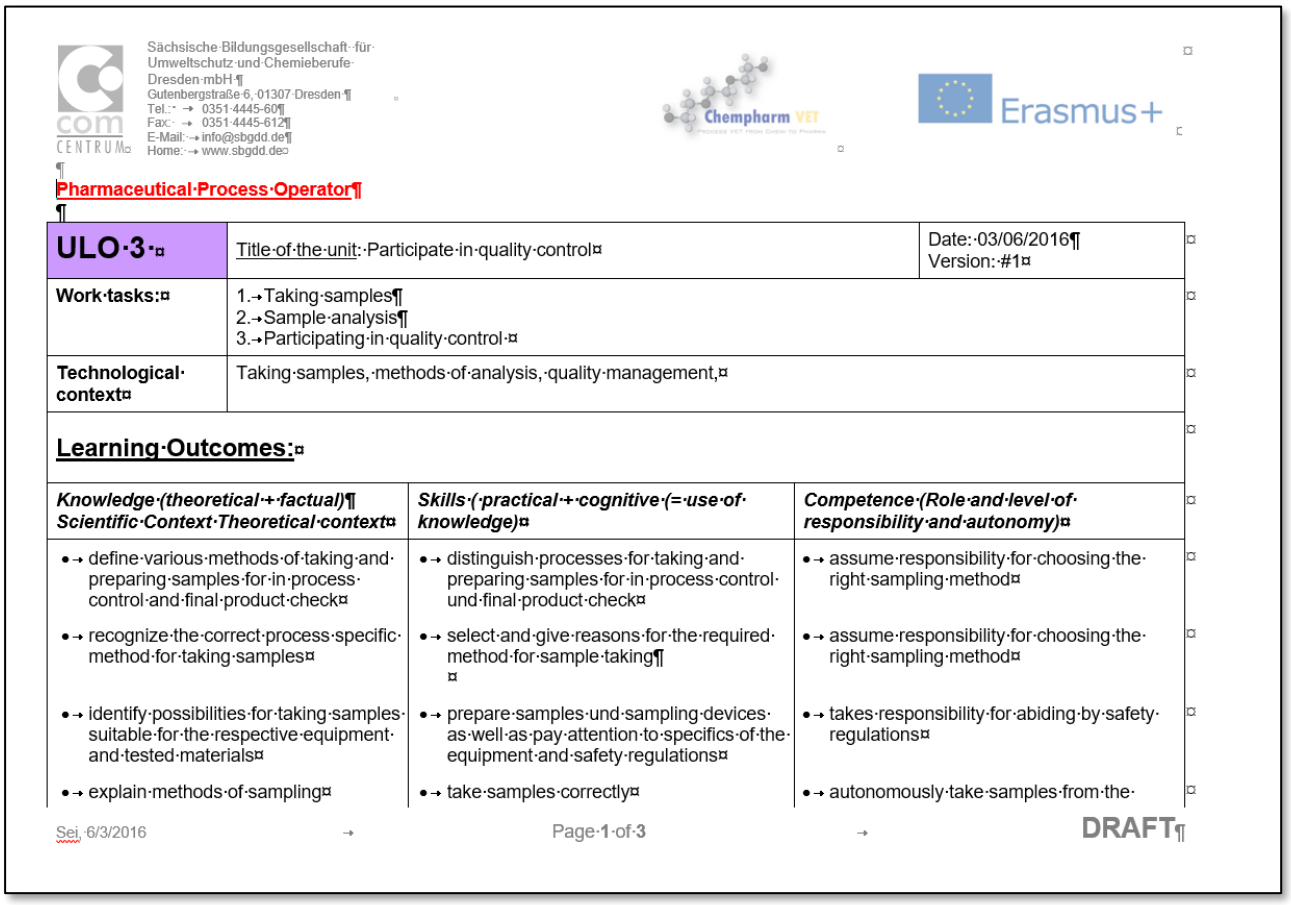
2.2.2 The designing of units of learning outcomes - the Matrix

On the basis of the analysed work tasks all learning outcomes of a unit will be generalized in a matrix. Thus the matrix describes the vocational competences which are to be acquired in this unit. The learning outcomes are described as follows: levels of competences, knowledge and skills.

As can be seen in the tablet of an ULO are bundled together and describing the knowledge, skills and competences that are necessary for this unit.



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Chempharm VET

Erasmus+

Pharmaceutical Process Operator

ULO 3	Title of the unit: Participate in quality control	Date: 03/06/2016 Version: #1
Work tasks:	1. Taking samples 2. Sample analysis 3. Participating in quality control	
Technological context	Taking samples, methods of analysis, quality management,	

Learning Outcomes:

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

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2.2.3 Common and specific competences

For the identifying of the relevant areas the competences are divided into two new sorts of competences.

2.2.3.1 Common competences

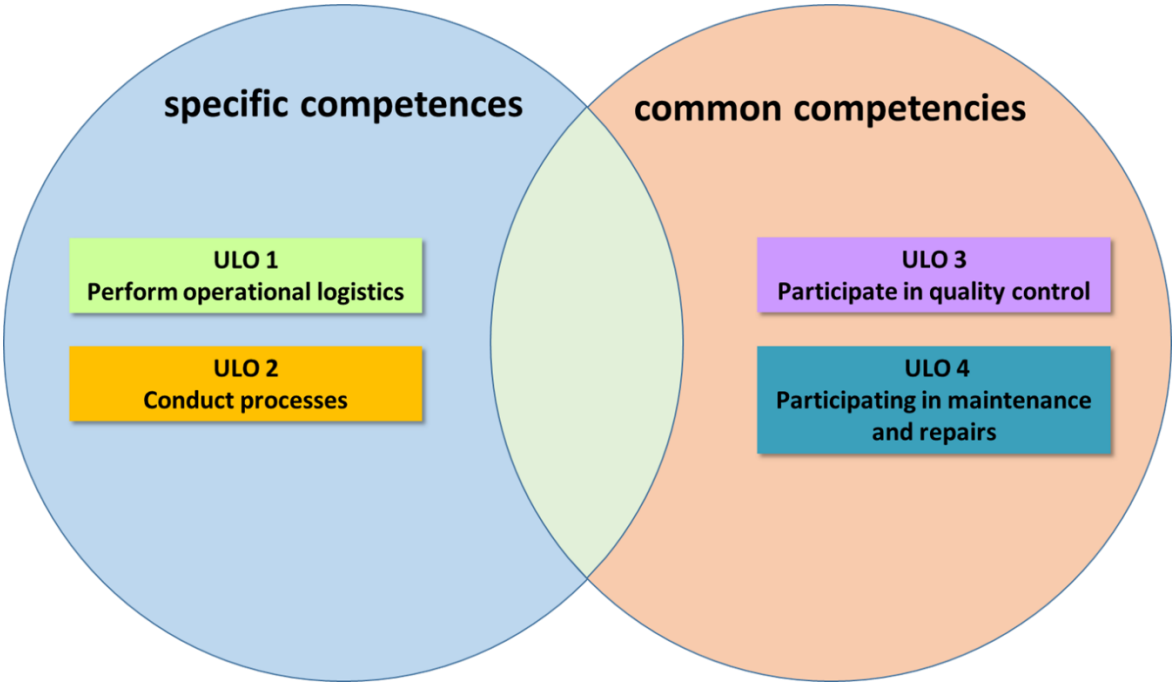
Some of the competences that are described in the ULOs are common to all chemical and pharmaceutical operators. For example, most of the quality control analyses are defined by standards and are therefore the same for all operators.

2.2.3.2 Specific competences

Competences needed for specific equipment, technical plant or company organisation and regulations that are not common to all operators.

2.2.3.3 Classification of the ULOs

For the following identification of relevant areas the ULOs were classified to specific or common competences. In both competence areas, contents of the four ULOs can be found. More contents for specific competences are in ULO 1 “perform operational logistic” and ULO 2 “conduct processes” on the other hand in ULO 3 “participate in quality control” and ULO 4 “participate in maintenance and repairs” more common competences could be found. The picture below symbolizes the classification.



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3 Tacit Knowledge

3.1 Definition of tacit knowledge

"We can know more that we can tell". - Michael Polanyi (1966)[1]

The term "tacit knowing" or "tacit knowledge" is attributed to Michael Polanyi in 1958 in Personal Knowledge. In his later work The Tacit Dimension he made the assertion that "we can know more than we can tell." (Polanyi, 1966) He states not only that there is knowledge that cannot be adequately articulated by verbal means, but also that all knowledge is rooted in tacit knowledge.
Tacit knowledge can be defined as skills, ideas and experiences that people have but are not codified and may not necessarily be easily expressed (Chugh, 2015). 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. This kind of knowledge can only be revealed through practice in a particular context and transmitted through social networks. To some extent it is "captured" when the knowledge holder joins a network or a community of practice.
Some examples of daily activities and tacit knowledge are: riding a bike, playing the piano, driving a car, hitting a nail with a hammer and putting together pieces of a complex jigsaw puzzle, interpreting a complex statistical equation (Chugh, 2015).
In the field of knowledge management, the concept of tacit knowledge refers to a knowledge which cannot be fully codified. Therefore, an individual can acquire tacit knowledge without language. Apprentices, for example, work with their mentors and learn craftsmanship not through language but by observation, imitation, and practice.
The key to acquiring tacit knowledge is experience. Without some form of shared experience, it is extremely difficult for people to share each other's thinking processes.
Tacit knowledge has been described as "know-how" – as opposed to "know-that" (facts). This distinction is usually taken to date back to a paper by Gilbert Ryle, given to the Aristotelian society in London in 1945. In this paper Ryle argues against the (intellectualist) position that all knowledge is knowledge of propositions ("know-that"), and the view that some knowledge can only be defined as "know-how" has therefore, in some contexts, come to be called "anti-intellectualist". There are further distinctions: "know-why" (science), or "know-who" (networking). Tacit knowledge involves learning and skill but not in a way that can be written down. On this account knowing-how or embodied knowledge is characteristic of the expert, who acts, makes judgments, and so forth without explicitly reflecting on the principles or rules involved. The expert works without having a theory of his or her work; he or she just performs skilfully without deliberation or focused attention. Embodied knowledge represents a learned capability of a human body's nervous and endocrine systems (Sensky, 2002).

[1] Michael Polanyi (11 March 1891 – 22 February 1976) was a Hungarian-British polymath, who made important theoretical contributions to physical chemistry, economics, and philosophy. He argued that positivism supplies a false account of knowing, which if taken seriously undermines humanity's highest achievements.

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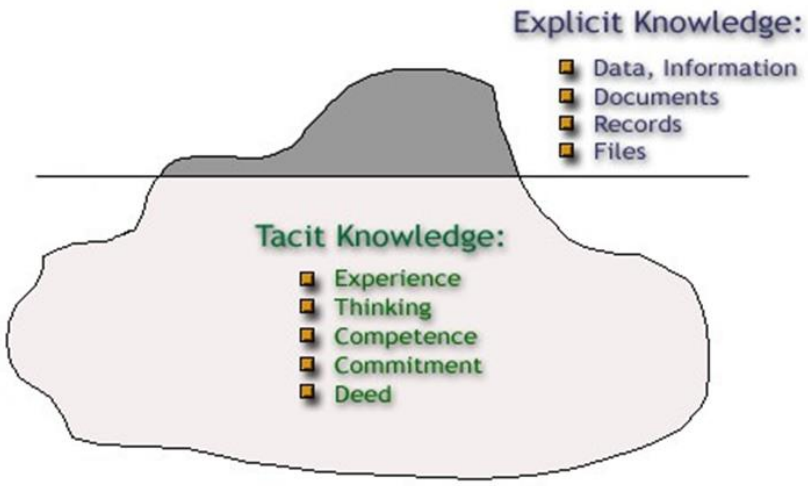
Tacit knowledge vs. explicit knowledge: although it is possible to distinguish conceptually between explicit and tacit knowledge, they are not separate and discrete in practice. The interaction between these two modes of knowing is vital for the creation of new knowledge. (Wikipedia, 2019)

In summary, tacit learning can be described as deeply personal experience, aptitudes, perceptions, insights, and know-how that are implied or indicated but not actually expressed — it resides in individuals and teams.



The "Iceberg" metaphor describes the relationship between Explicit & Tacit Knowledge

(http://steveo1967.blogspot.com/2013/06/tacit-and-explicit-knowledge-and.html, 1967)

The picture of the “iceberg” shows that the sum of tacit knowledge a person have is much bigger than the explicit knowledge. Tacit learning therefore represents a high potential for training in terms of vocational training. The ChemTube project is founded to make tacit learning tangible with the help of visualization.

3.2 Identification of relevant areas for tacit knowledge

To show how the relevant areas for tacit knowledge could be identified the ULO 3 “participate in quality control” was chosen as an example. The content of ULO 3 has more common competences than specific ones.

3.2.1 Example for tacit knowledge as common competence in ULO 3

For this analysis the matrix of ULO 3 was taken to find a common competence. Next step is to find work tasks for this competence. At last, in the work task examples for tacit knowledge could be found.

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Chempharm VET

Erasmus+

Pharmaceutical Process Operator

ULO 3	Title of the unit: Participate in quality control	Date: 03/06/2016 Version: #1
Work tasks:	1. Taking samples 2. Sample analysis 3. Participating in quality control	
Technological context	Taking samples, methods of analysis, quality management,	

Learning Outcomes:

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

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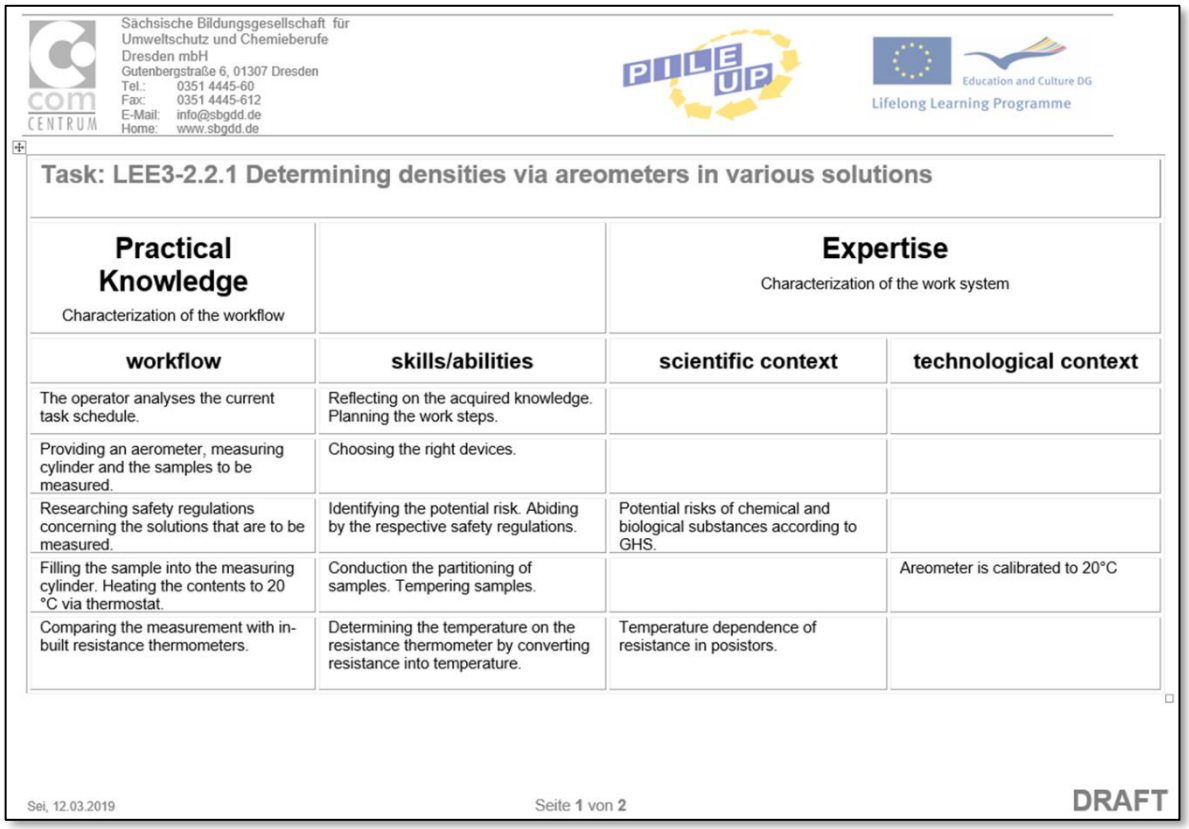
O2 Identification of relevant areas

Autonomously execute analyses is one of the common competences that are described in ULO 3.

Survey of available work tasks made for the PileUp project:

ULO3-2.1.1 Determination of the temperature in the absorber liquids	
ULO3-2.2.1 Determining densities via areometers in various solutions	
ULO3-2.2.2 Determining densities of solids via pycnometer	
ULO3-2.3.1 Checking conductivity of fluids	
ULO3-2.4.1 Measuring pH-values in waste water samples	
ULO3-2.6.1 Analysing smell, color tint and turbidity of process water	
ULO3-2.9.1 Analysing sediment volume according to DIN 38409 H9	
ULO3-2.10.1 Bacteriological examination of water in the technical center	

Out of survey of available work tasks for this common competence was investigated according to contents of tacit knowledge. In “ULO3-2.2.1 Determining densities via areometers in various solutions” a typical example for tacit knowledge could be found.



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Task: LEE3-2.2.1 Determining densities via areometers in various solutions

Practical Knowledge Characterization of the workflow		**Expertise** Characterization of the work system	
workflow	**skills/abilities**	**scientific context**	**technological context**
The operator analyses the current task schedule.	Reflecting on the acquired knowledge. Planning the work steps.		
Providing an aerometer, measuring cylinder and the samples to be measured.	Choosing the right devices.		
Researching safety regulations concerning the solutions that are to be measured.	Identifying the potential risk. Abiding by the respective safety regulations.	Potential risks of chemical and biological substances according to GHS.	
Filling the sample into the measuring cylinder. Heating the contents to 20 °C via thermostat.	Conduction the partitioning of samples. Tempering samples.		Areometer is calibrated to 20°C
Comparing the measurement with in-built resistance thermometers.	Determining the temperature on the resistance thermometer by converting resistance into temperature.	Temperature dependence of resistance in posistors.	

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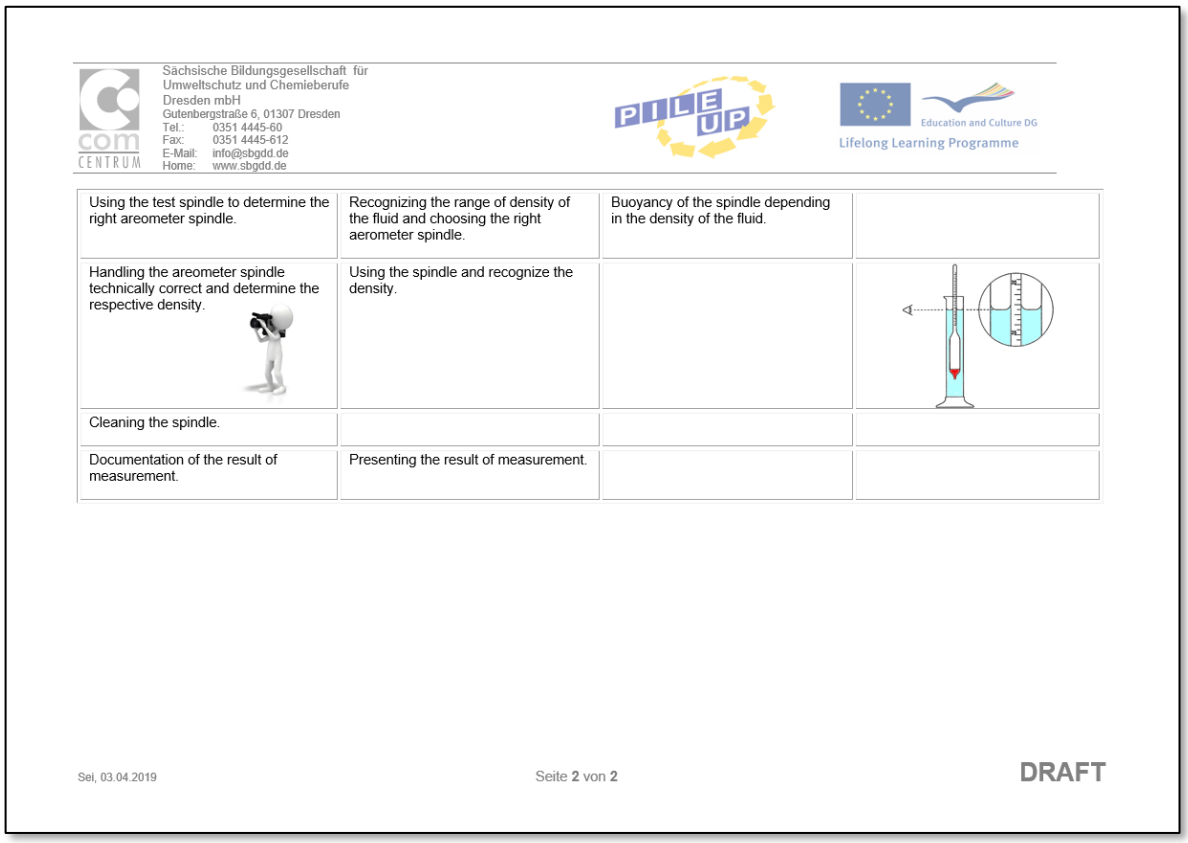

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Using the test spindle to determine the right areometer spindle.	Recognizing the range of density of the fluid and choosing the right aerometer spindle.	Buoyancy of the spindle depending in the density of the fluid.	
Handling the areometer spindle technically correct and determine the respective density.	Using the spindle and recognize the density.		
Cleaning the spindle.			
Documentation of the result of measurement.	Presenting the result of measurement.		

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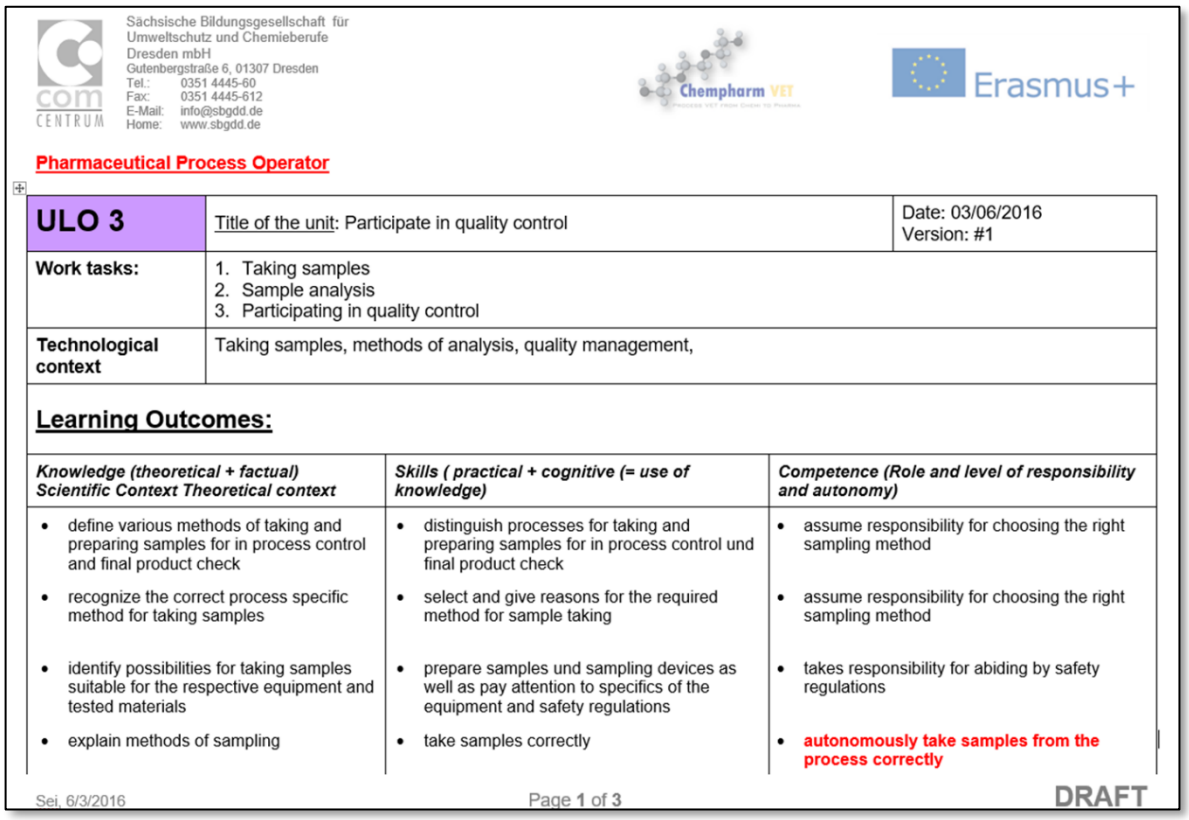
"Handling the aerometer spindle technically correct and determine the respective density" was identified as an example for tacit knowledge. The way to put the spindle into the liquid and to spin it, cannot adequately articulated by verbal means. The required skills for measuring the density with the areometer can only be conveyed practically and must be shown accordingly. At this point, the project idea of the ChemTube project takes effect and presents the required competence in a film.

3.2.2 Example for tacit knowledge as specific competence in ULO 3

The example of a specific competence was also found in ULO3. Although the numbers of common competences are higher, several specific competences can be found in this ULO. Analogous to the procedure for the example of the common competences, the matrix of ULO3 is analysed. After the analysis, the corresponding work tasks are examined according to content with tacit knowledge.



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Pharmaceutical Process Operator

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Technological context	Taking samples, methods of analysis, quality management,	

Learning Outcomes:

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• 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**

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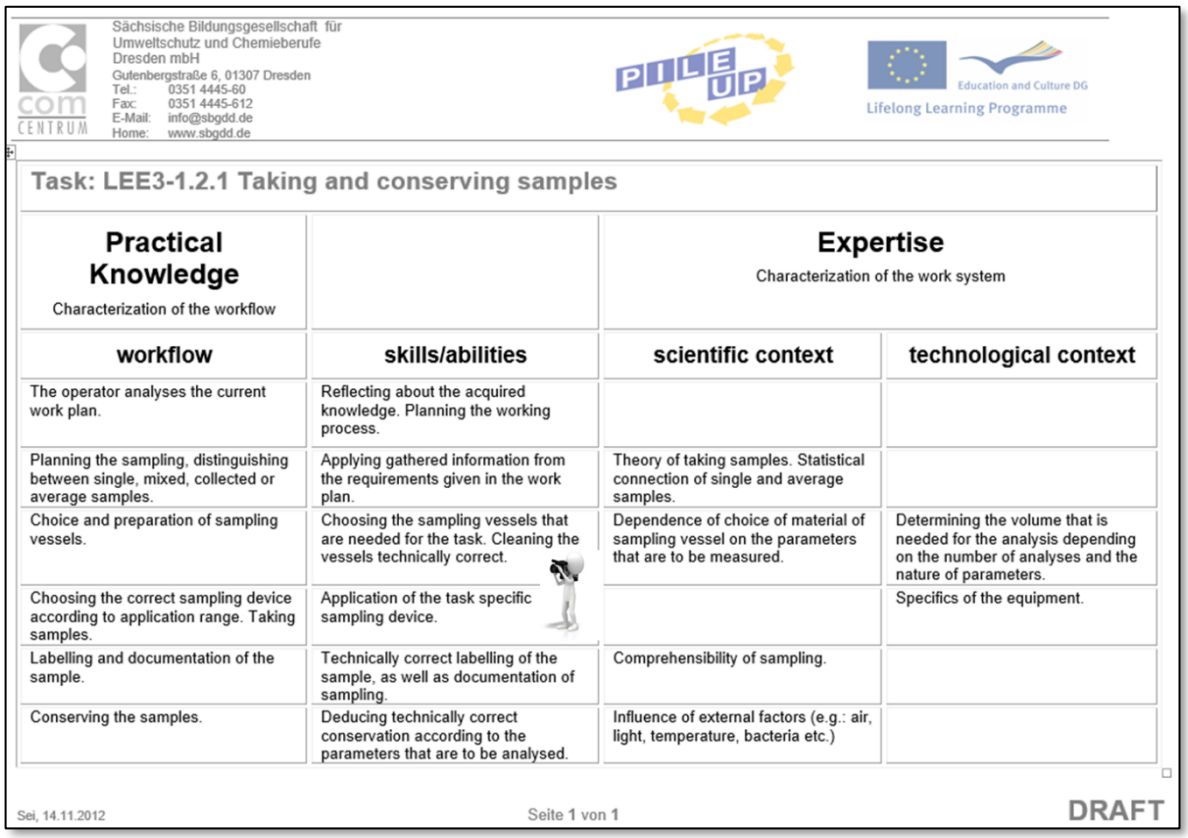
"Autonomously take samples from the process correctly" is found as an example for specific competences that are described in ULO 3.

Survey of available work tasks made for the PileUp project:

ULO3-1.2.1 Taking and conserving samples	
ULO3-1.2.2 Work task from production: Taking samples from tanks	
ULO3-1.2.3 Work task from production: Taking samples from a tub	
ULO3-3.1 Investigation of prepared food samples for residues of pesticides by LC-MS/MS, maintenance of the analyzers; implementation and documentation of quality assurance measures	

Out of survey of available work tasks for this specific competence was investigated according to contents of tacit knowledge. In "ULO3-1.2.1 Taking and conserving samples" a typical example for tacit knowledge could be found.



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Task: LEE3-1.2.1 Taking and conserving samples

Practical Knowledge Characterization of the workflow		**Expertise** Characterization of the work system	
workflow	**skills/abilities**	**scientific context**	**technological context**
The operator analyses the current work plan.	Reflecting about the acquired knowledge. Planning the working process.		
Planning the sampling, distinguishing between single, mixed, collected or average samples.	Applying gathered information from the requirements given in the work plan.	Theory of taking samples. Statistical connection of single and average samples.	
Choice and preparation of sampling vessels.	Choosing the sampling vessels that are needed for the task. Cleaning the vessels technically correct.	Dependence of choice of material of sampling vessel on the parameters that are to be measured.	Determining the volume that is needed for the analysis depending on the number of analyses and the nature of parameters.
Choosing the correct sampling device according to application range. Taking samples.	Application of the task specific sampling device.		Specifics of the equipment.
Labelling and documentation of the sample.	Technically correct labelling of the sample, as well as documentation of sampling.	Comprehensibility of sampling.	
Conserving the samples.	Deducing technically correct conservation according to the parameters that are to be analysed.	Influence of external factors (e.g.: air, light, temperature, bacteria etc.)	

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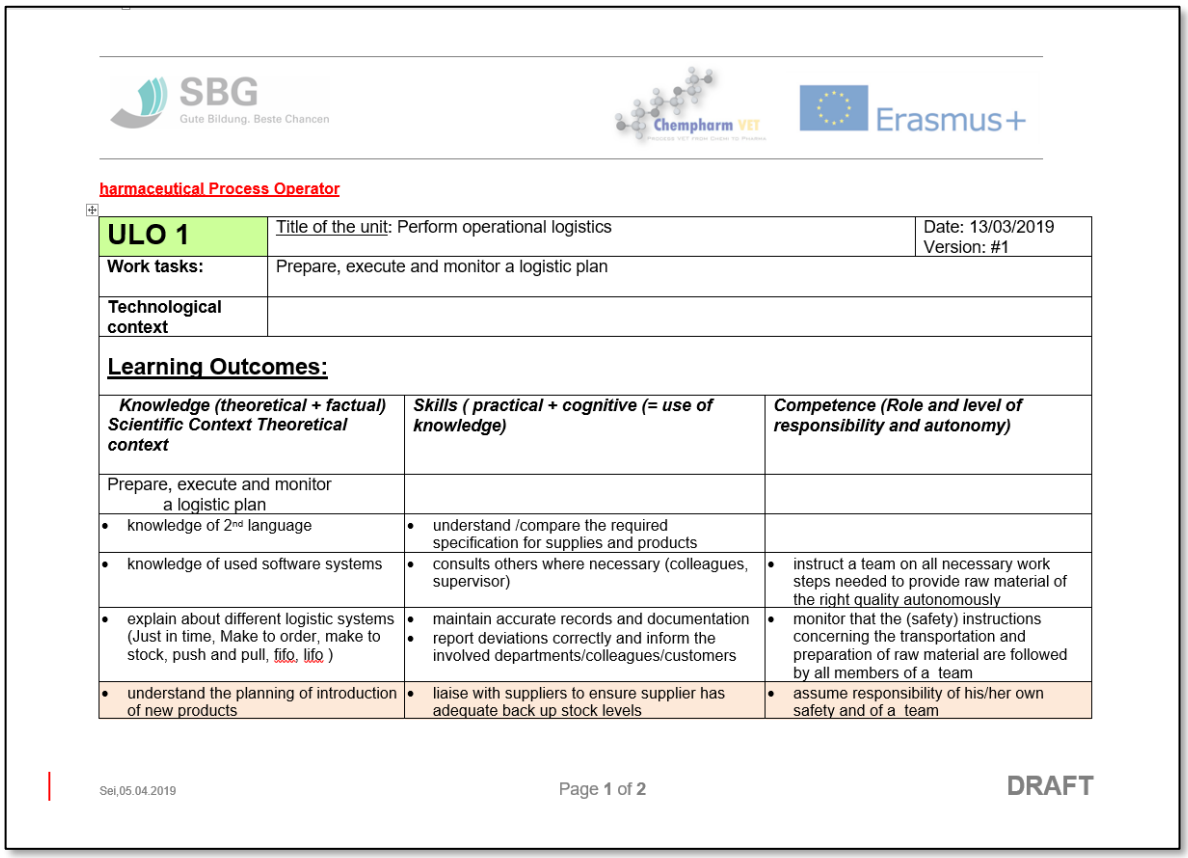
"Application of the task specific sampling device" was identified as an example for tacit knowledge, which is specific for the sampling tools and the technical equipment that been used. Therefor a film of the handling of the sampling device could only be used for an example of this competence. This film is only suitable for vocational training if the same tools and technical equipment are used.

3.3 Summary and identification of relevant areas for tacit knowledge

- For the identification of relevant areas for tacit knowledge the competences, as described in the units of learning outcome, are divided into common and specific competences.
- The competences of the ULOs were analysed for contents containing parts of tacit knowledge.
- The competences found are assigned corresponding work tasks.
- The work tasks were analysed to identify tacit knowledge.

On the following pages the results of identification of relevant areas are shown. The **common competences** in orange, the **specific competences** in blue.

O2 Identification of relevant areas



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harmaceutical Process Operator

ULO 1	Title of the unit: Perform operational logistics	Date: 13/03/2019 Version: #1
Work tasks:	Prepare, execute and monitor a logistic plan	
Technological context		

Learning Outcomes:

Knowledge (theoretical + factual) Scientific Context Theoretical context	*Skills (practical + cognitive (= use of knowledge)*	*Competence (Role and level of responsibility and autonomy)*
Prepare, execute and monitor a logistic plan		
• 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

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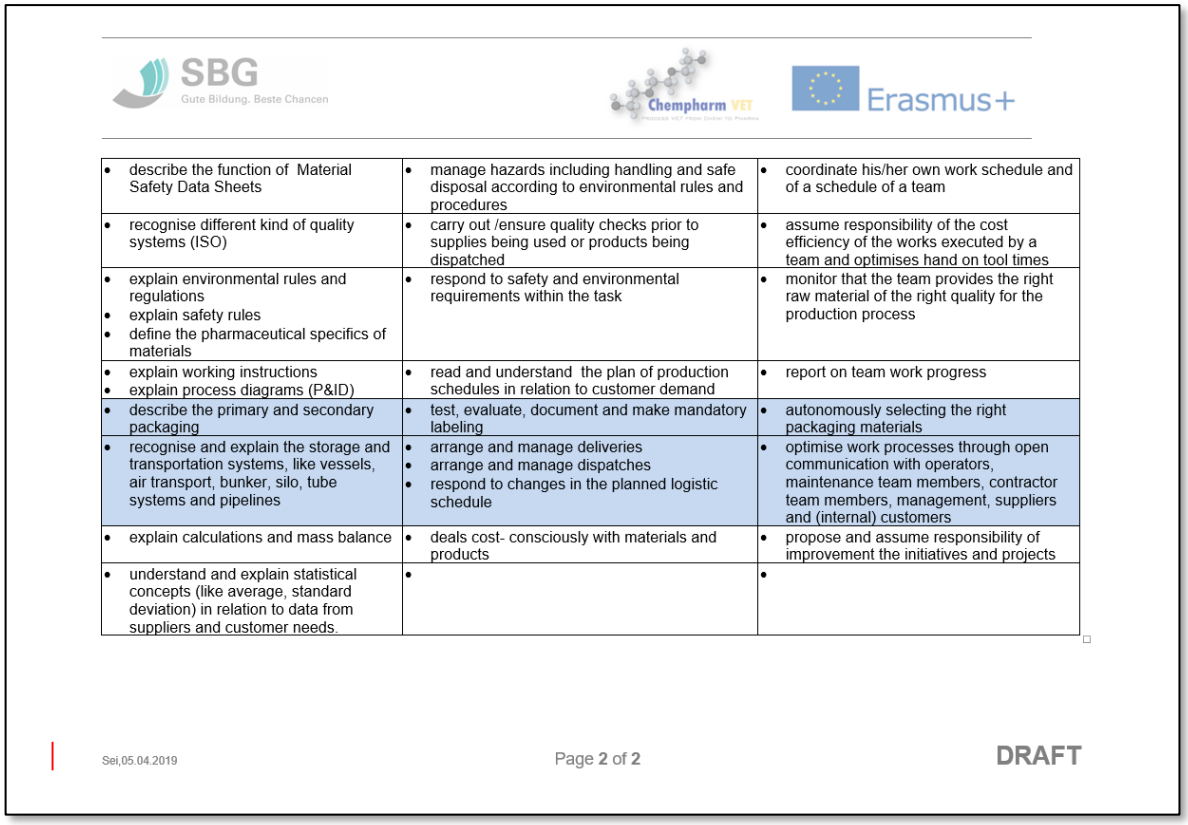

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• describe the function of Material Safety Data Sheets	• manage hazards including handling and safe disposal according to environmental rules and procedures	• coordinate his/her own work schedule and of a schedule of a team
• recognise different kind 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.	•	•

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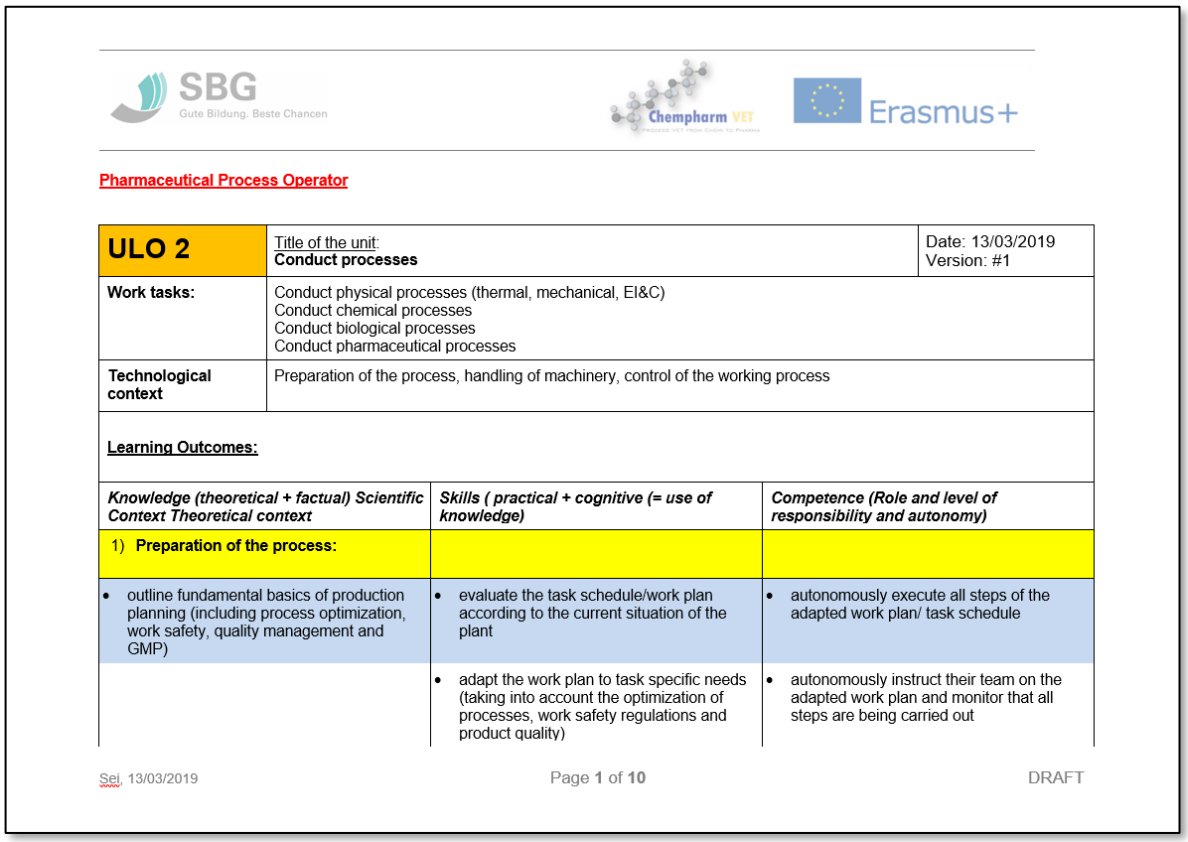
O2 Identification of relevant areas



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Pharmaceutical Process Operator

ULO 2	Title of the unit: **Conduct processes**	Date: 13/03/2019 Version: #1
Work tasks:	Conduct physical processes (thermal, mechanical, EI&C) Conduct chemical processes Conduct biological processes Conduct pharmaceutical processes	
Technological context	Preparation of the process, handling of machinery, control of the working process	

Learning Outcomes:

Knowledge (theoretical + factual) Scientific Context Theoretical context	***Skills (practical + cognitive (= use of knowledge)***	***Competence (Role and level of responsibility and autonomy)***
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

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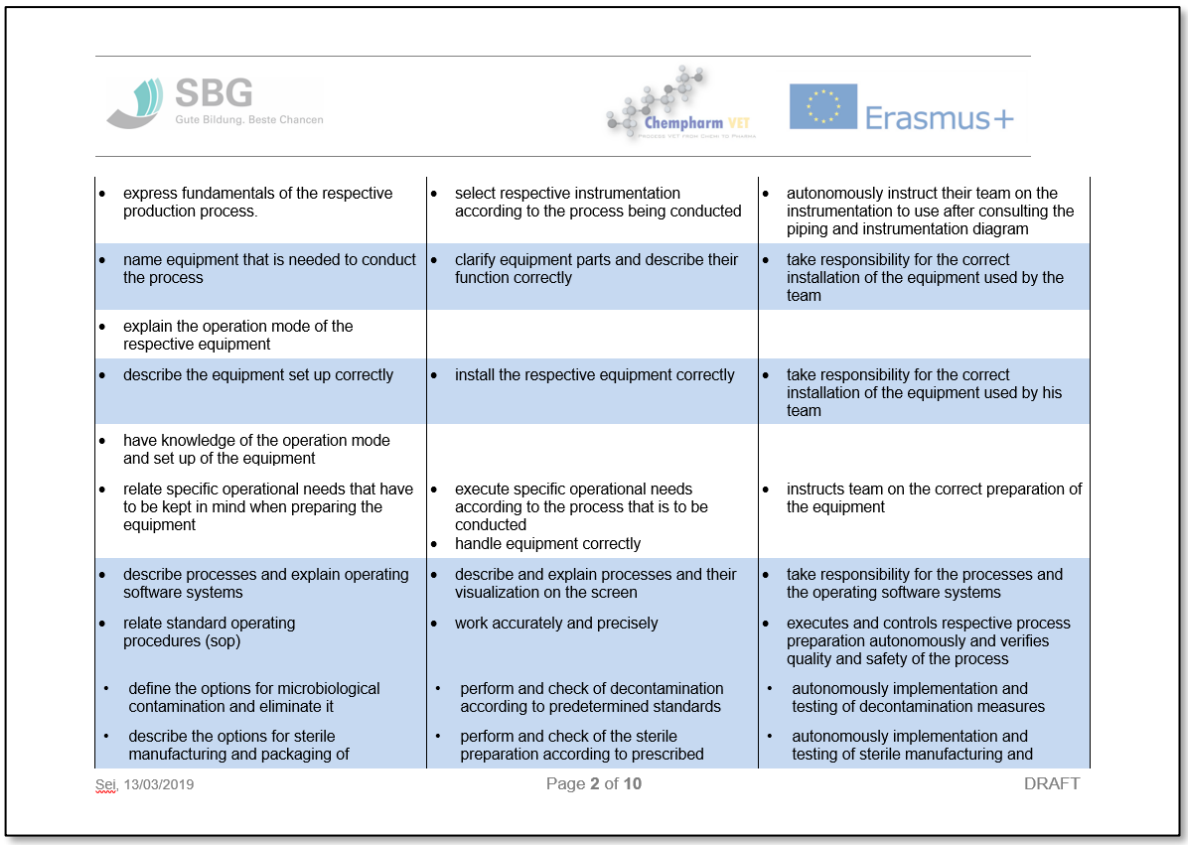

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• express fundamentals of the respective production process.	• select respective instrumentation according to the process being conducted	• autonomously instruct their team on the instrumentation to use after consulting the piping and instrumentation diagram
• name equipment that is needed to conduct the process	• clarify equipment parts and describe their function correctly	• take responsibility for the correct installation of the equipment used by the team
• explain the operation mode of the respective equipment		
• describe the equipment set up correctly	• install the respective equipment correctly	• take responsibility for the correct installation of the equipment used by his team
• have knowledge of the operation mode and set up of the equipment		
• 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	• perform and check of the sterile preparation according to prescribed	• autonomously implementation and testing of sterile manufacturing and

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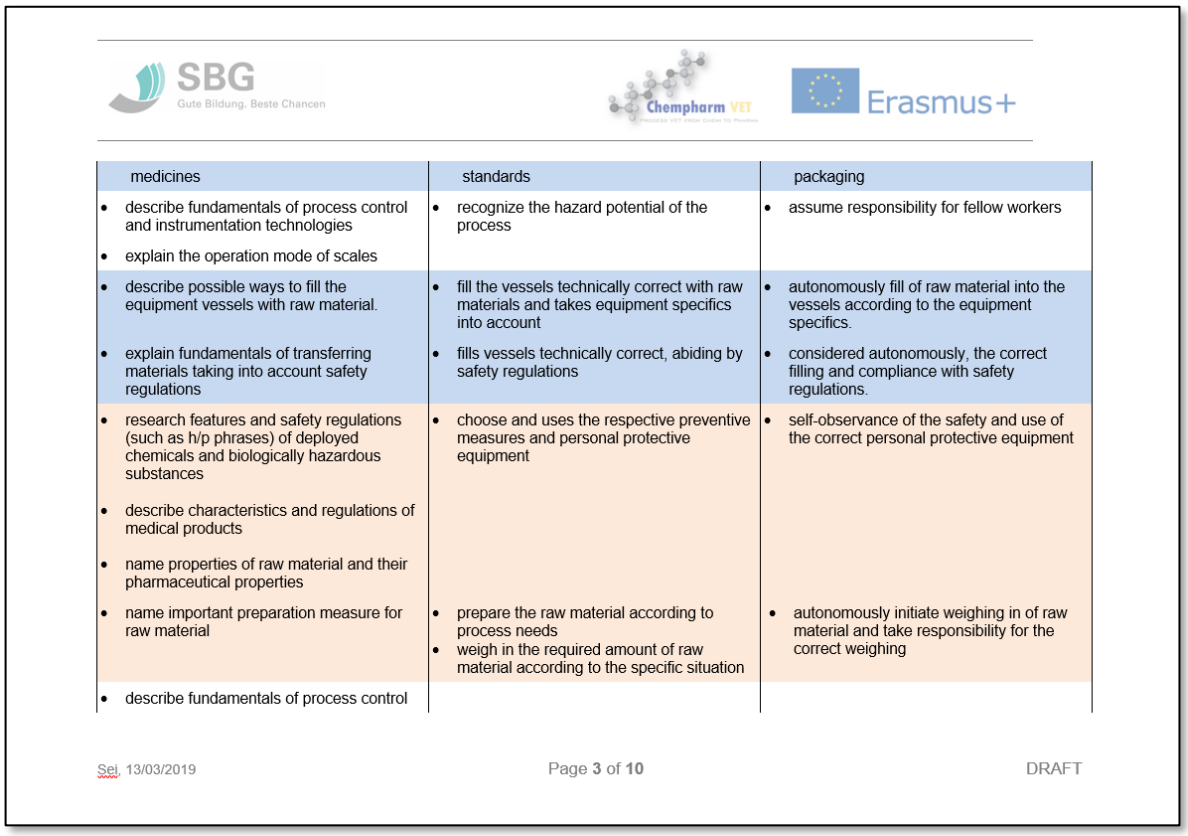
O2 Identification of relevant areas



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medicines	standards	packaging
• describe fundamentals of process control and instrumentation technologies • explain the operation mode of scales	• recognize the hazard potential of the process	• assume responsibility for fellow workers
• describe possible ways to fill the equipment vessels with raw material. • explain fundamentals of transferring materials taking into account safety regulations	• fill the vessels technically correct with raw materials and takes equipment specifics into account • fills vessels technically correct, abiding by safety regulations	• autonomously fill of raw material into the vessels according to the equipment specifics. • 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 • describe characteristics and regulations of medical products • name properties of raw material and their pharmaceutical properties • name important preparation measure for raw material	• choose and uses the respective preventive measures and personal protective equipment • prepare the raw material according to process needs • weigh in the required amount of raw material according to the specific situation	• self-observance of the safety and use of the correct personal protective equipment • autonomously initiate weighing in of raw material and take responsibility for the correct weighing
• describe fundamentals of process control		

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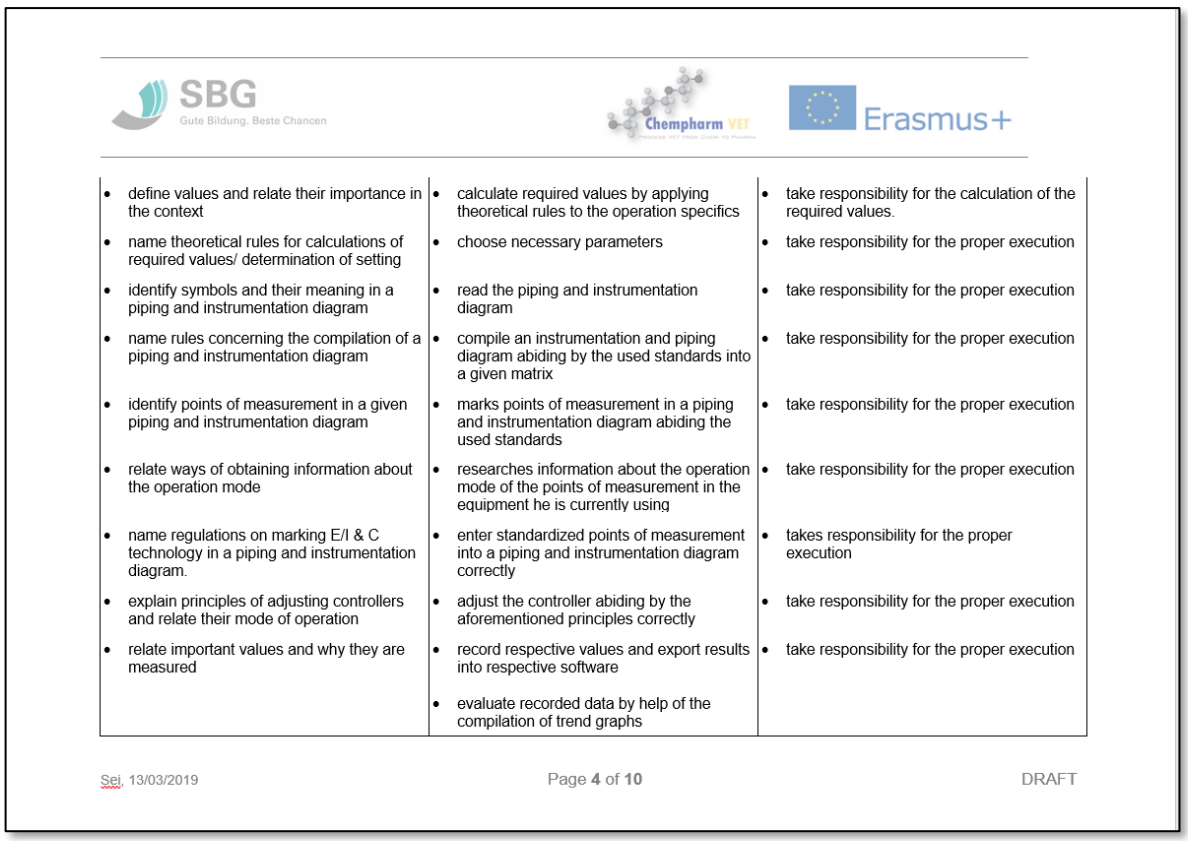

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• define values and relate their importance in the context	• calculate required values by applying theoretical rules to the operation specifics	• take responsibility for the calculation of the required values.
• name theoretical rules for calculations 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

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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 • express fundamentals of the production process and its ideal conduct	• carry out the task schedule as it is intended. • estimate requirements for material against suppliers stock levels to ensure production targets	• 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 • 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 • identify specific conditions of the start process according to current situation • identify possible ways of filling and emptying the vessels technically correct	• use correct materials and hardware according to 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 his and his colleagues' safety • autonomously decide on ramifications to start and stop the process safely • instruct fellow workers on these ramifications • assume responsibility for safety.
• 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

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• explain the operation mode of the equipment and know how to shut it down appropriately • 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	• write an appropriate protocol containing all results • correctly dismantle and reinstall the equipment • clean the equipment correctly and accurately abiding by safety regulations and plant intern standards	• take responsibility for the documentation • 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 • name possible by-products and contaminants for specific reactions	• purify/ finish the product correctly	• autonomously instruct team on how to purify the products correctly • 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

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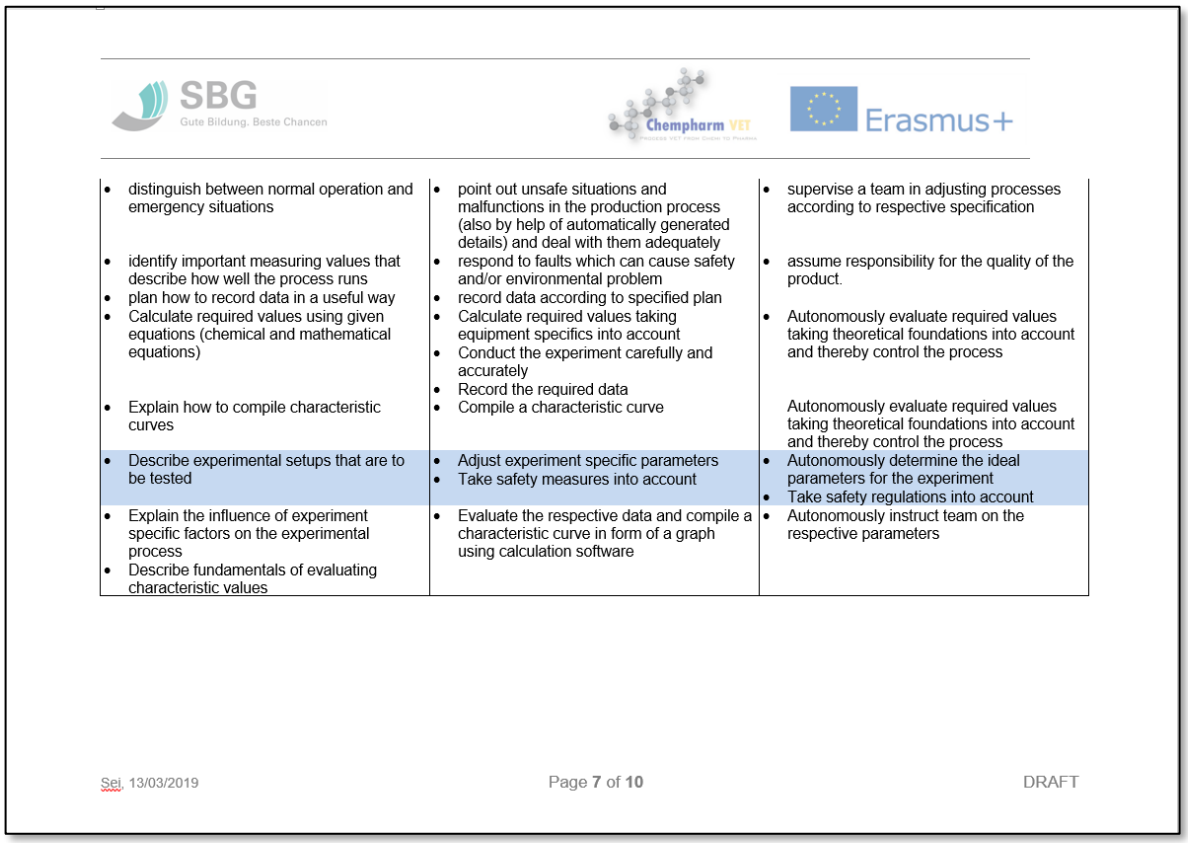
O2 Identification of relevant areas



• 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 • plan how to record data in a useful way • Calculate required values using given equations (chemical and mathematical equations)	• respond to faults which can cause safety and/or environmental problem • record data according to specified plan • Calculate required values taking equipment specifics into account • Conduct the experiment carefully and accurately • Record the required data	• assume responsibility for the quality of the product. • 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 • Describe fundamentals of evaluating characteristic values	• Evaluate the respective data and compile a characteristic curve in form of a graph using calculation software	• Autonomously instruct team on the respective parameters

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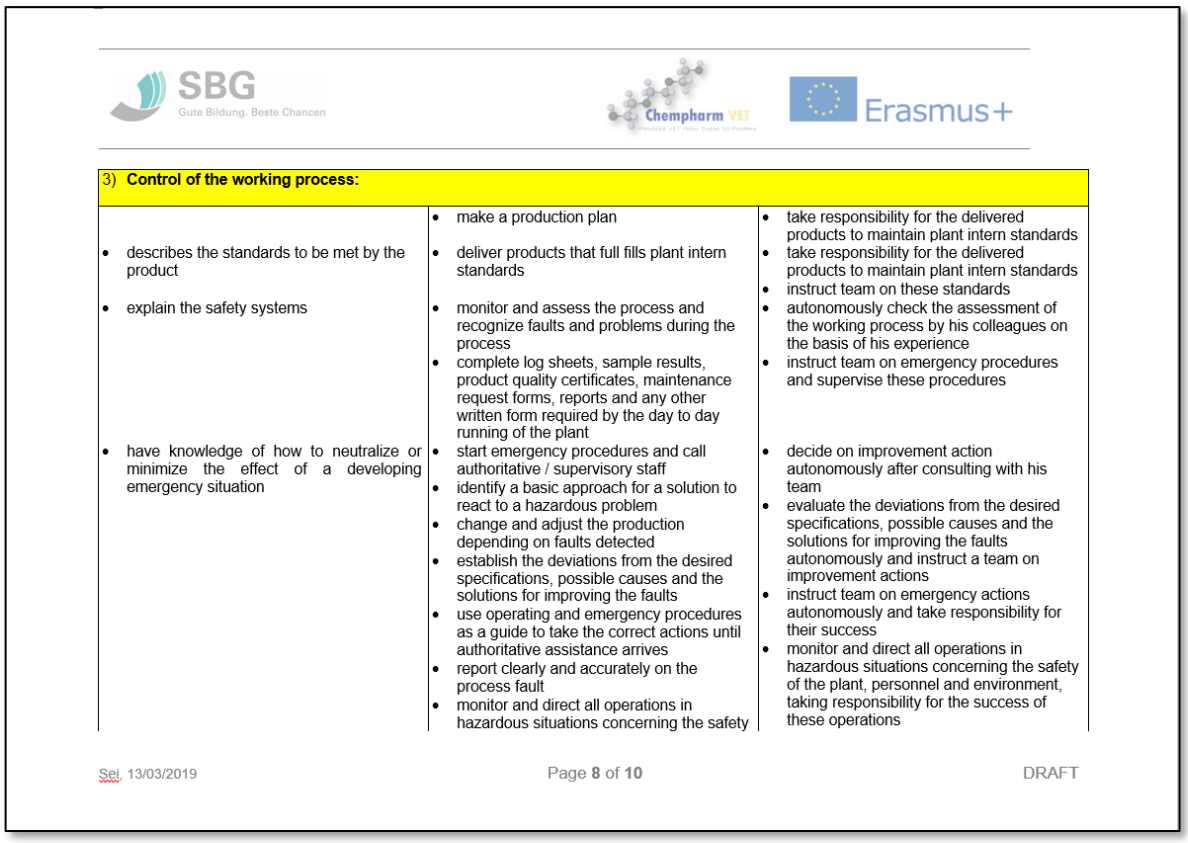

3) **Control of the working process:**		
	• make a production plan	• take responsibility for the delivered products to maintain plant intern standards
• describes the standards to be met by the product	• deliver products that full fills plant intern standards	• take responsibility for the delivered products 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	• 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

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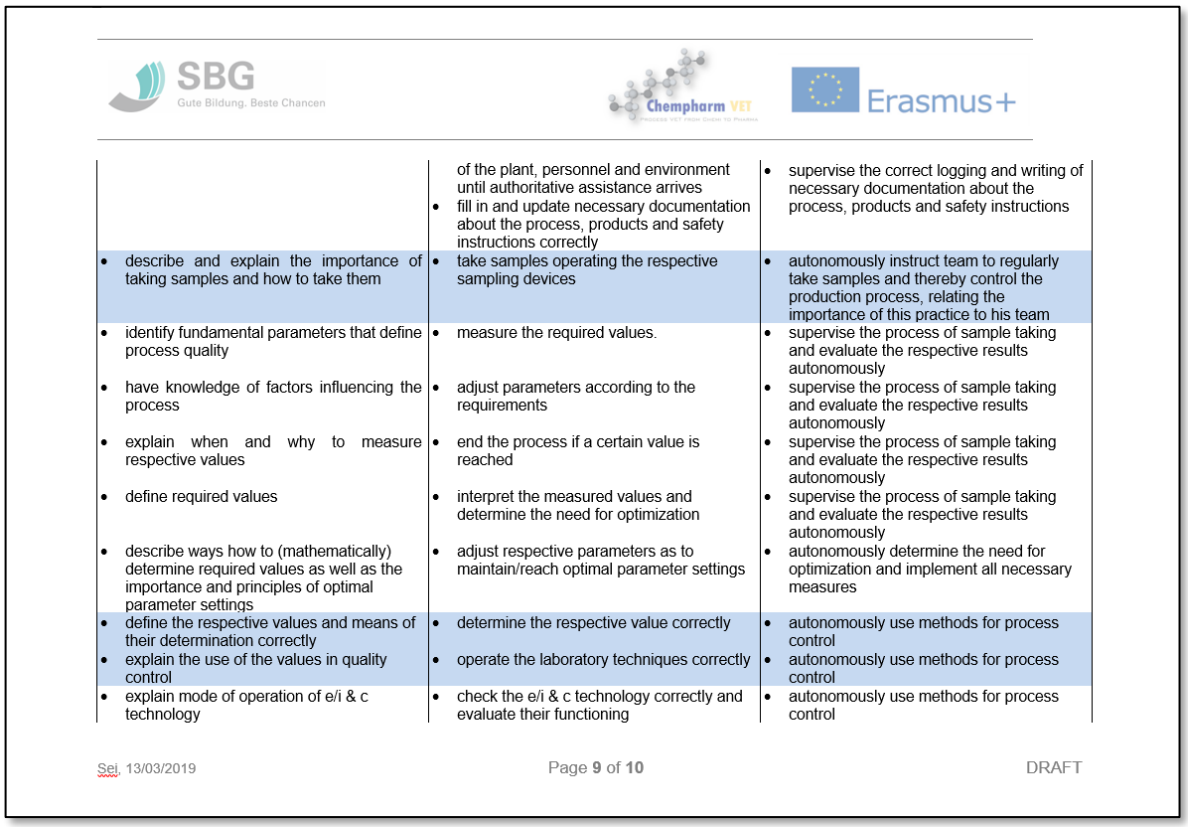

	of the plant, personnel and environment until authoritative assistance arrives • fill in and update necessary documentation about the process, products and safety instructions correctly	• supervise the correct logging and writing of necessary documentation about the process, products and safety instructions
• 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

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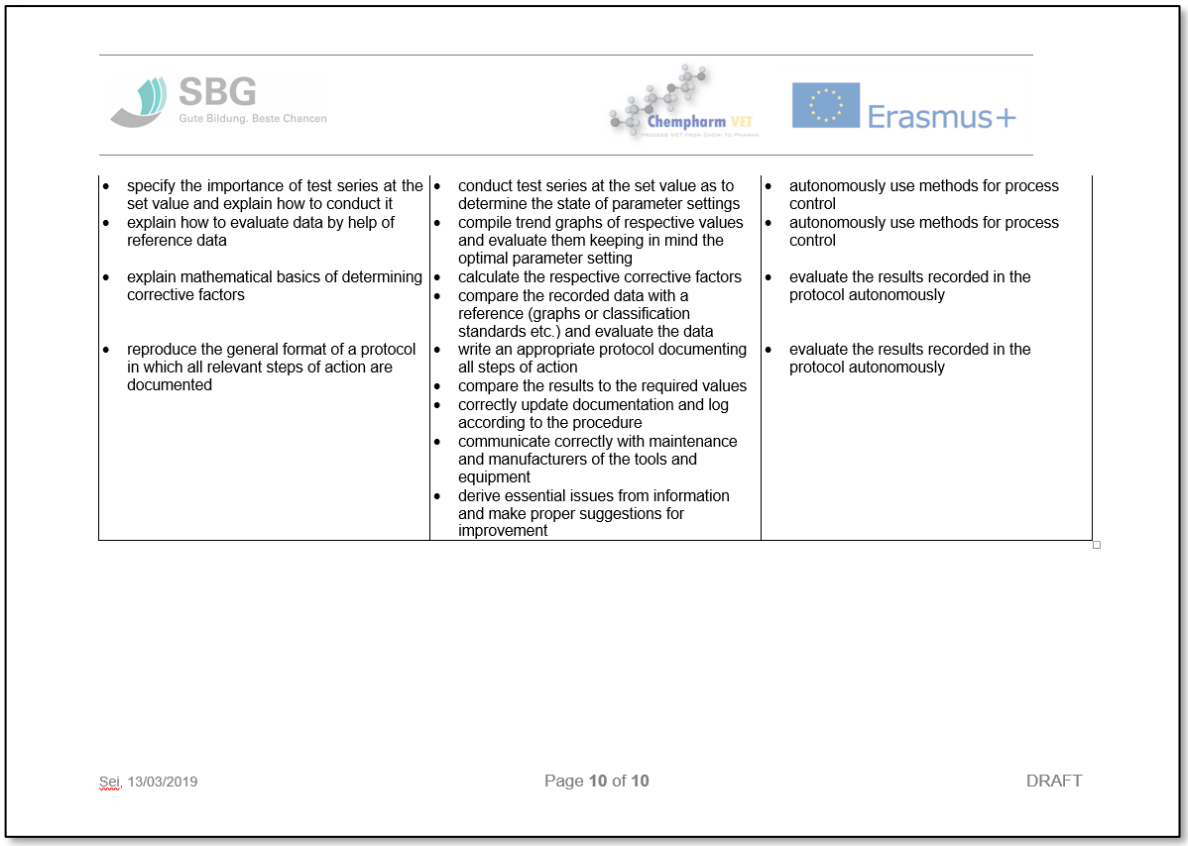

• specify the importance of test series at the set value and explain how to conduct it • explain how to evaluate data by help of reference data	• conduct test series at the set value as to determine the state of parameter settings • compile trend graphs of respective values and evaluate them keeping in mind the optimal parameter setting	• autonomously use methods for process control • 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

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Pharmaceutical Process Operator

ULO 3	Title of the unit: Participate in quality control	Date: 03/06/2016 Version: #1
Work tasks:	1. Taking samples 2. Sample analysis 3. Participating in quality control	
Technological context	Taking samples, methods of analysis, quality management,	

Learning Outcomes:

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

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• 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

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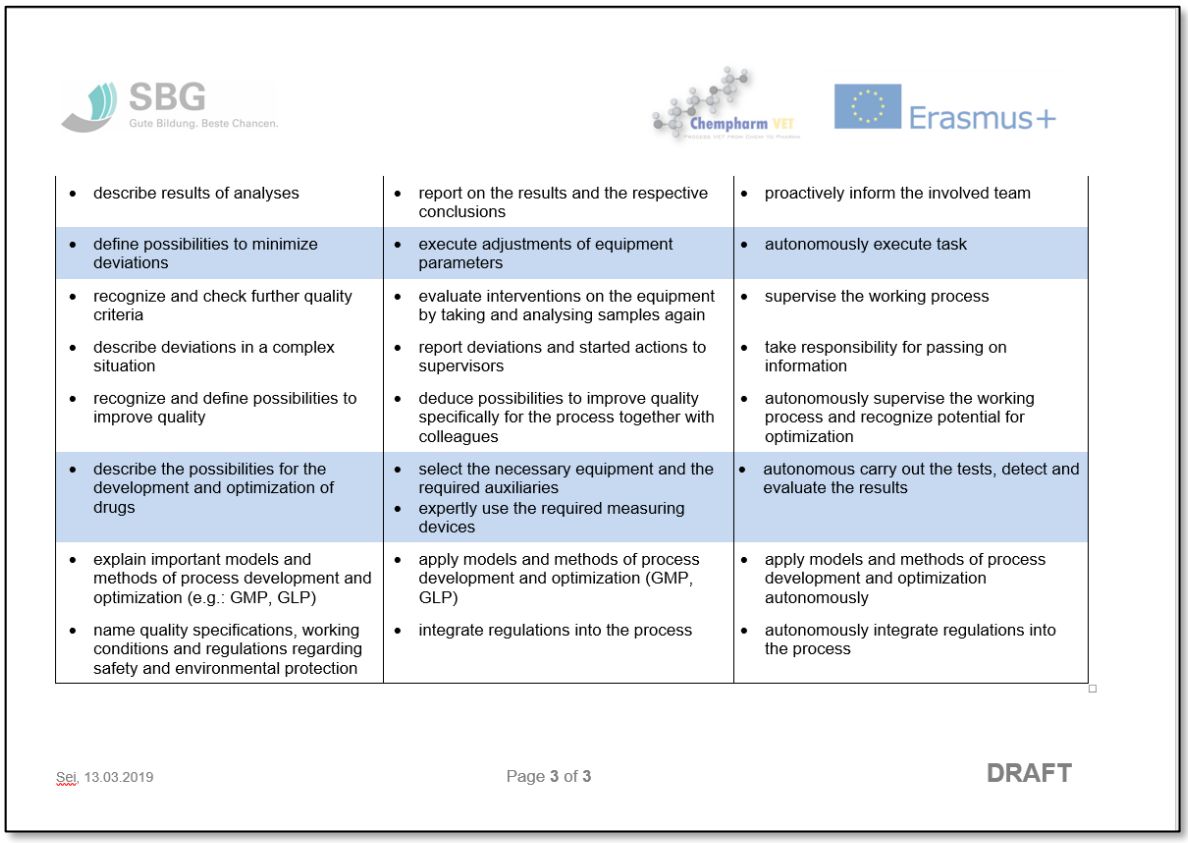
O2 Identification of relevant areas



• 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) • name quality specifications, working conditions and regulations regarding safety and environmental protection	• apply models and methods of process development and optimization (GMP, GLP) • integrate regulations into the process	• apply models and methods of process development and optimization autonomously • autonomously integrate regulations into the process

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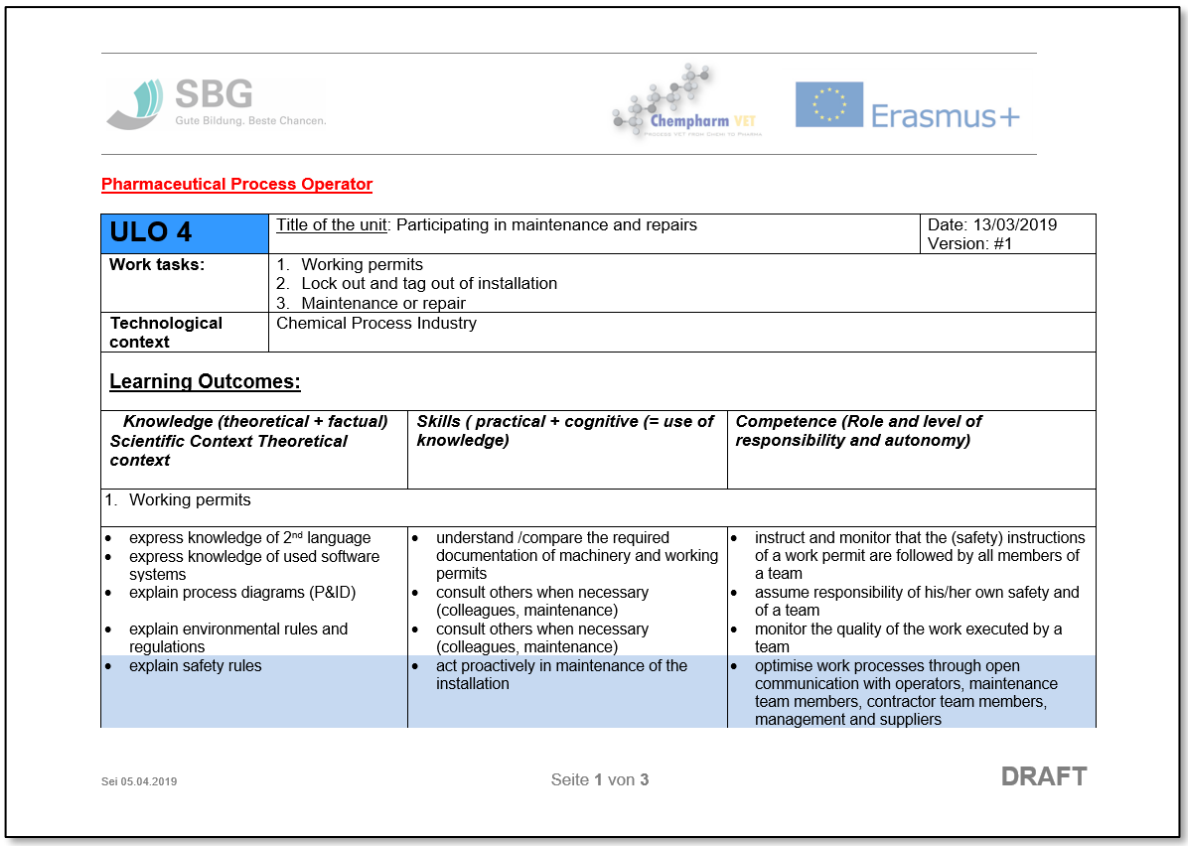

Pharmaceutical Process Operator

ULO 4	Title of the unit: Participating in maintenance and repairs	Date: 13/03/2019 Version: #1
Work tasks:	1. Working permits 2. Lock out and tag out of installation 3. Maintenance or repair	
Technological context	Chemical Process Industry	

Learning Outcomes:

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 • explain safety rules	• understand /compare the required documentation of machinery and working permits • consult others when necessary (colleagues, maintenance) • consult others when necessary (colleagues, maintenance) • act proactively in maintenance of the installation	• 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 • optimise work processes through open communication with operators, maintenance team members, contractor team members, management and suppliers

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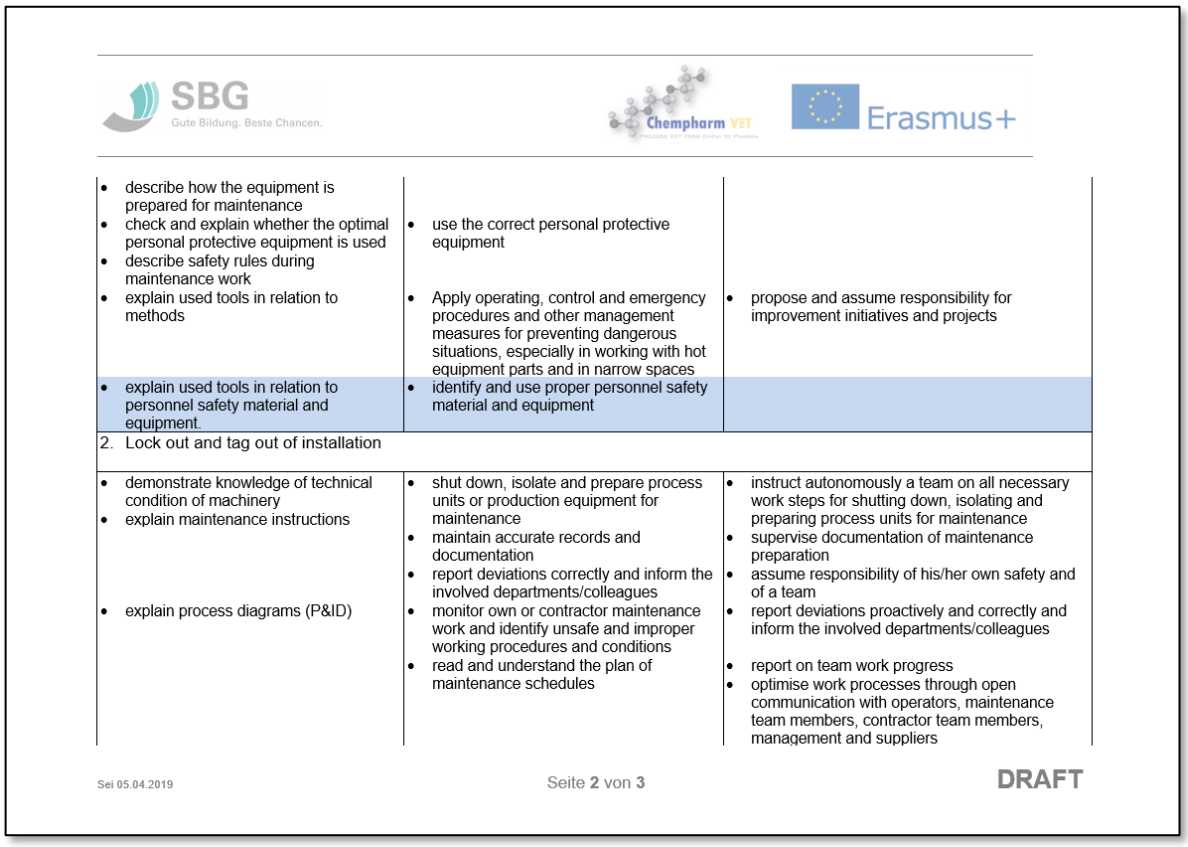
O2 Identification of relevant areas



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• 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	• 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	• propose and assume responsibility for improvement initiatives and projects
• explain used tools in relation to personnel safety material and equipment.	• identify and use proper personnel safety material and equipment	
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

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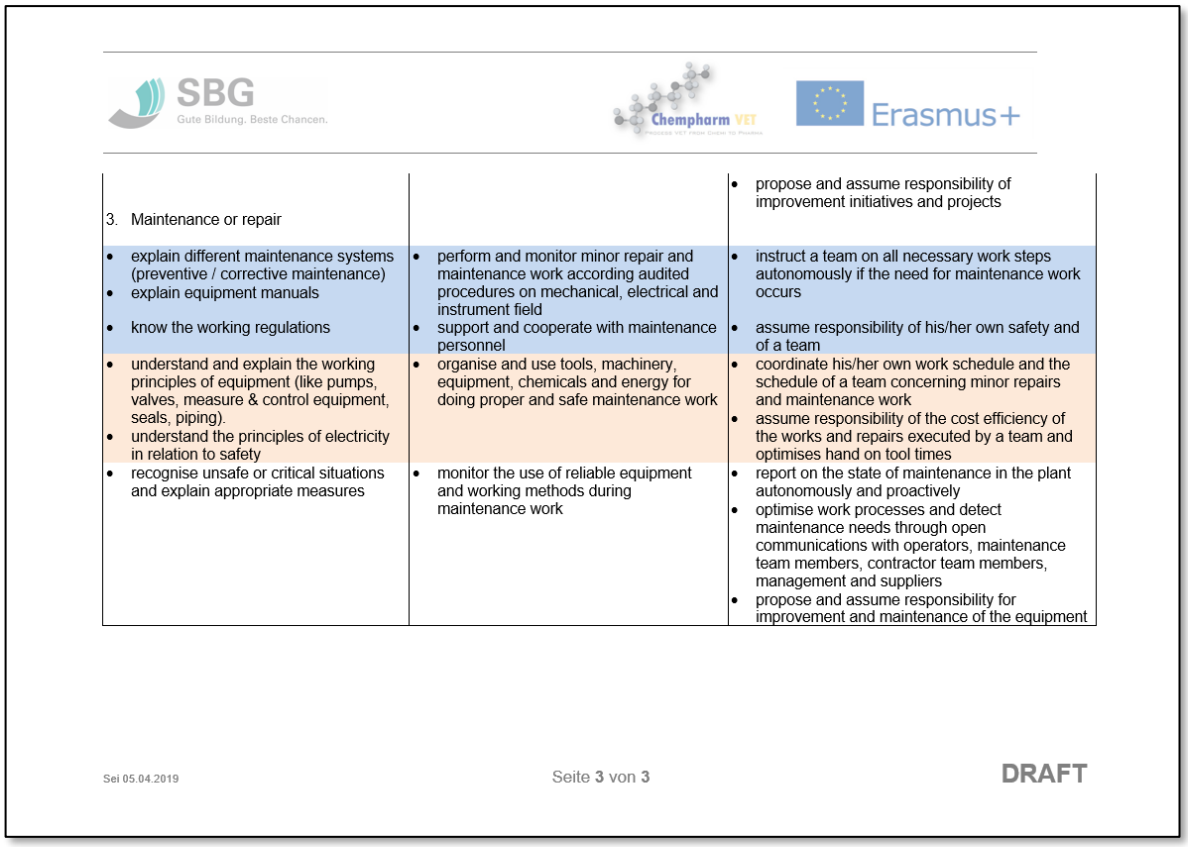

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3. Maintenance or repair		• propose and assume responsibility of improvement initiatives and projects
• explain different maintenance systems (preventive / corrective maintenance) • explain equipment manuals • know the working regulations	• perform and monitor minor repair and maintenance work according audited procedures on mechanical, electrical and instrument field • support and cooperate with maintenance personnel	• 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
• 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	• organise and use tools, machinery, equipment, chemicals and energy for doing proper and safe maintenance work	• 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

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4 Critical skills

4.1 Definition of critical skills

Critical skills as a concept, refers to the demand for an element of the practical, foundational or reflexive competence that allows for specialization within roles/professions or occupations and includes specific "top-up' skills. Particular specialization "top-up skills for roles/professions or occupations 'top-up' might have arisen as a result of changing technology or new forms of work organization. (https://www.agriseta.co.za/downloads/agm_presentations/Department_of_Labour_definitions.pdf, 2006)

Larry Kim, CEO of MobileMonkey. Founder of WordStream defined the critical skills that been needed for the year 2020 in the following picture:

(https://www.inc.com/larry-kim/10-critical-skills-you-ll-need-to-succeed-at-work-in-2020.html, 2019)

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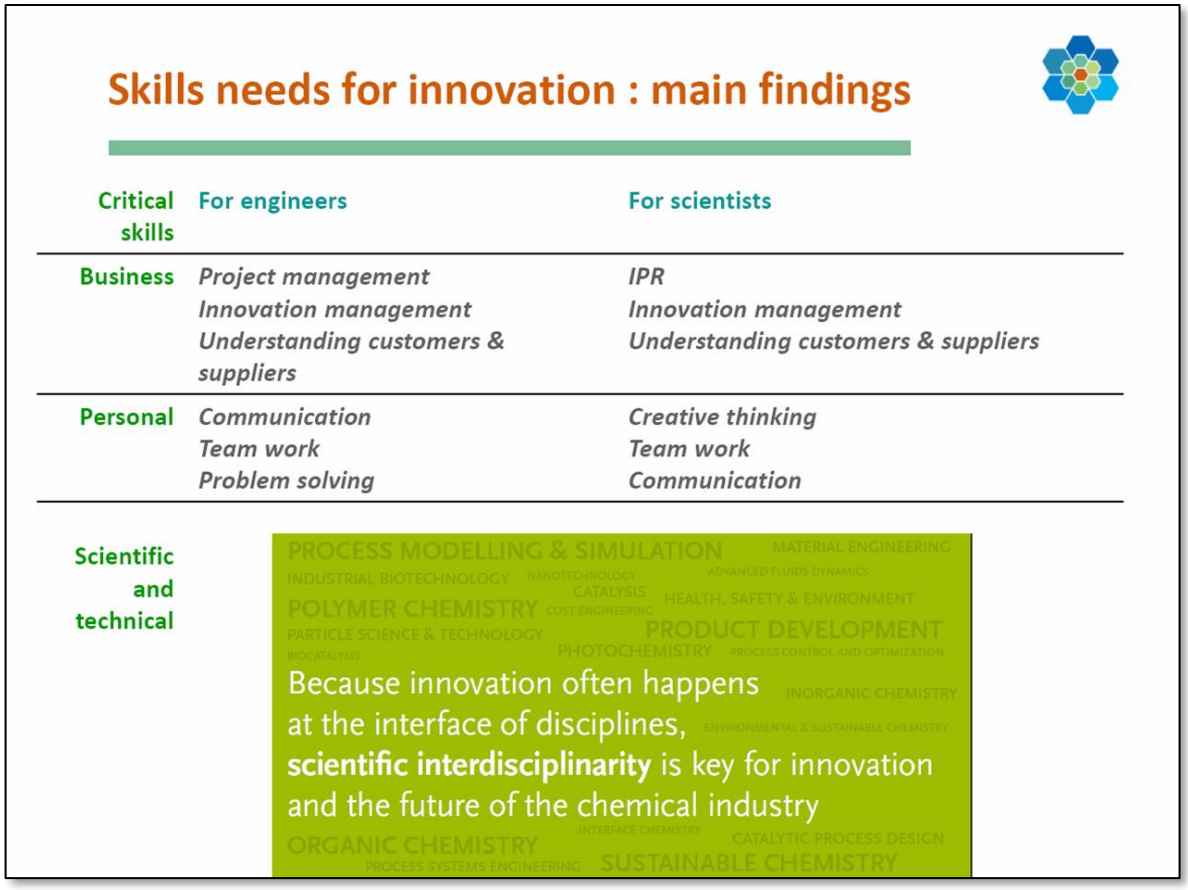
Similarly, the Cefic project "Skills for innovation the European chemical industry" names three critical skills for chemical engineers: Communication, team work and problem solving.



(CEFIC, 2014)

The critical skills could only be described by specific competences, competences needed for specific equipment, technical plant or company organisation and regulations that are not common to all operators.

4.2 Identification of relevant areas for critical skills

Analog to the procedure of identification of tacit knowledge, the contents of the ULOs that representing critical skills can be identified.

4.2.1 Example for critical skills in ULO 4

In ULO 4 "participating in maintenance and repairs" the following competence could be found as an example for critical skills.

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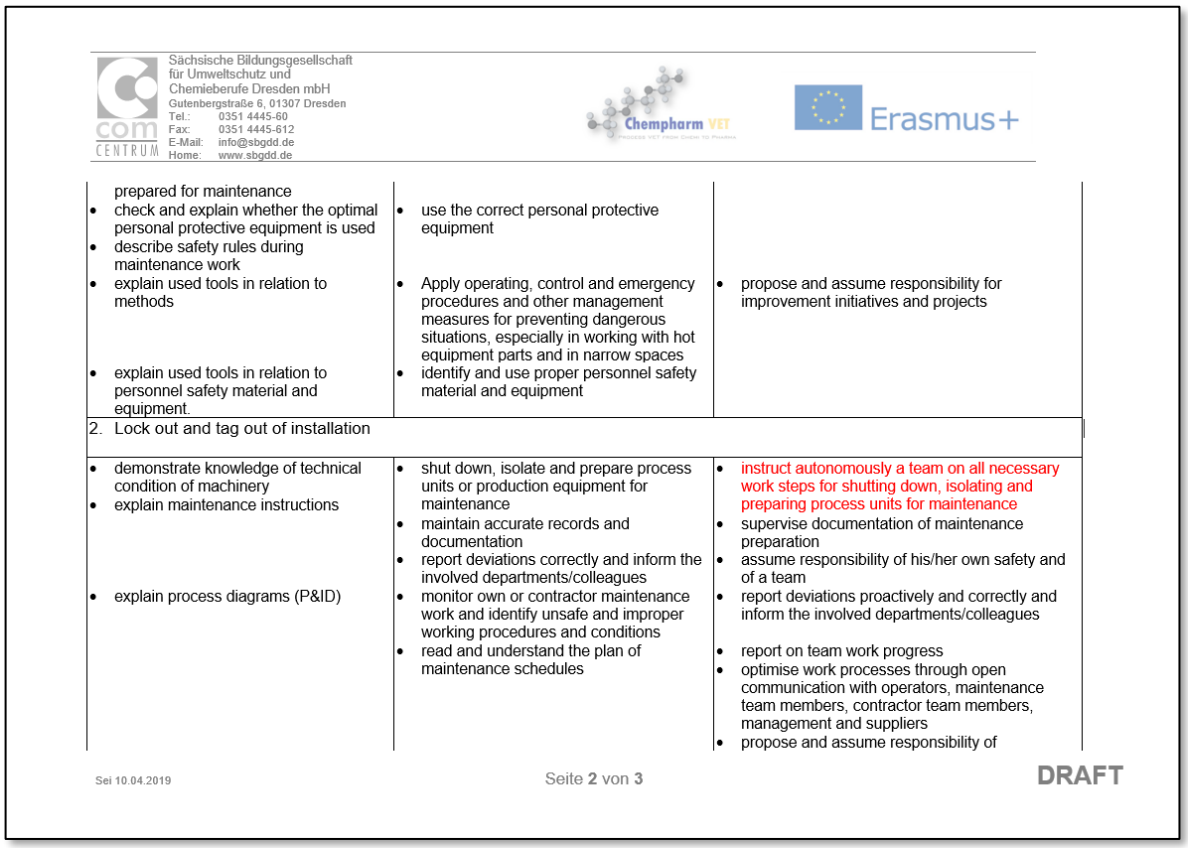

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prepared for maintenance • check and explain whether the optimal personal protective equipment is used • describe safety rules during maintenance work • explain used tools in relation to methods • explain used tools in relation to personnel safety material and equipment.	• 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	• 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

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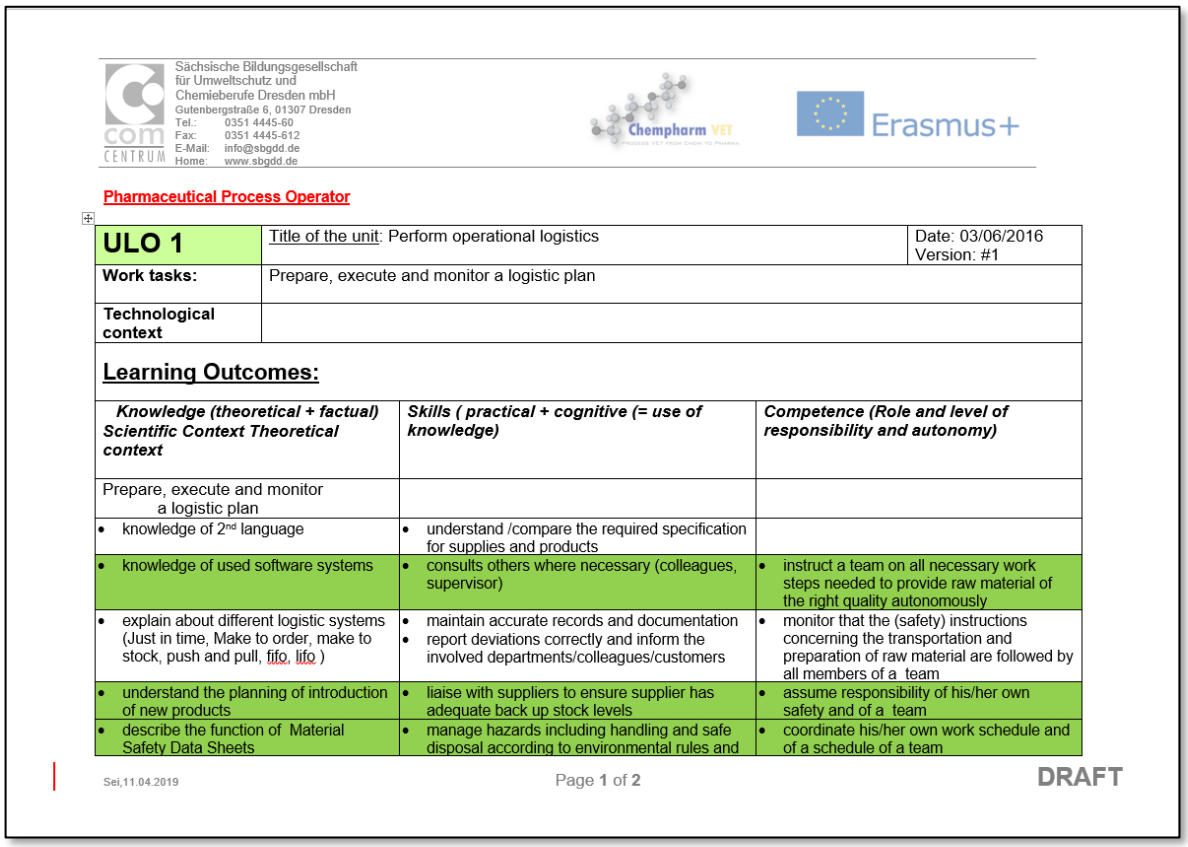
"Instruct autonomously a team on all necessary work steps for shutting down, isolating and preparing process units for maintenance" is an example for visualization of critical skills. Therefore, this competence is a typical specific competence, this could be an example how lock and tag out of installation should be done.

4.3 Summary and identification of relevant areas for critical skills

- For the identification of relevant areas for critical skills in the the competences, as described in the units of learning outcome, are divided into common and specific competences.
- The competences of the ULOs were analysed for contents containing parts of critical skills.
- The competences found are assigned corresponding work tasks.
- The work tasks were analysed to identify critical skills.

On the following pages the results of identification of relevant areas are shown. The **critical skills** are in green.

O2 Identification of relevant areas



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Pharmaceutical Process Operator

ULO 1	Title of the unit: Perform operational logistics	Date: 03/06/2016 Version: #1
Work tasks:	Prepare, execute and monitor a logistic plan	
Technological context		

Learning Outcomes:

Knowledge (theoretical + factual) Scientific Context Theoretical context	***Skills (practical + cognitive (= use of knowledge)***	***Competence (Role and level of responsibility and autonomy)***
Prepare, execute and monitor a logistic plan		
• 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	• coordinate his/her own work schedule and of a schedule of a team

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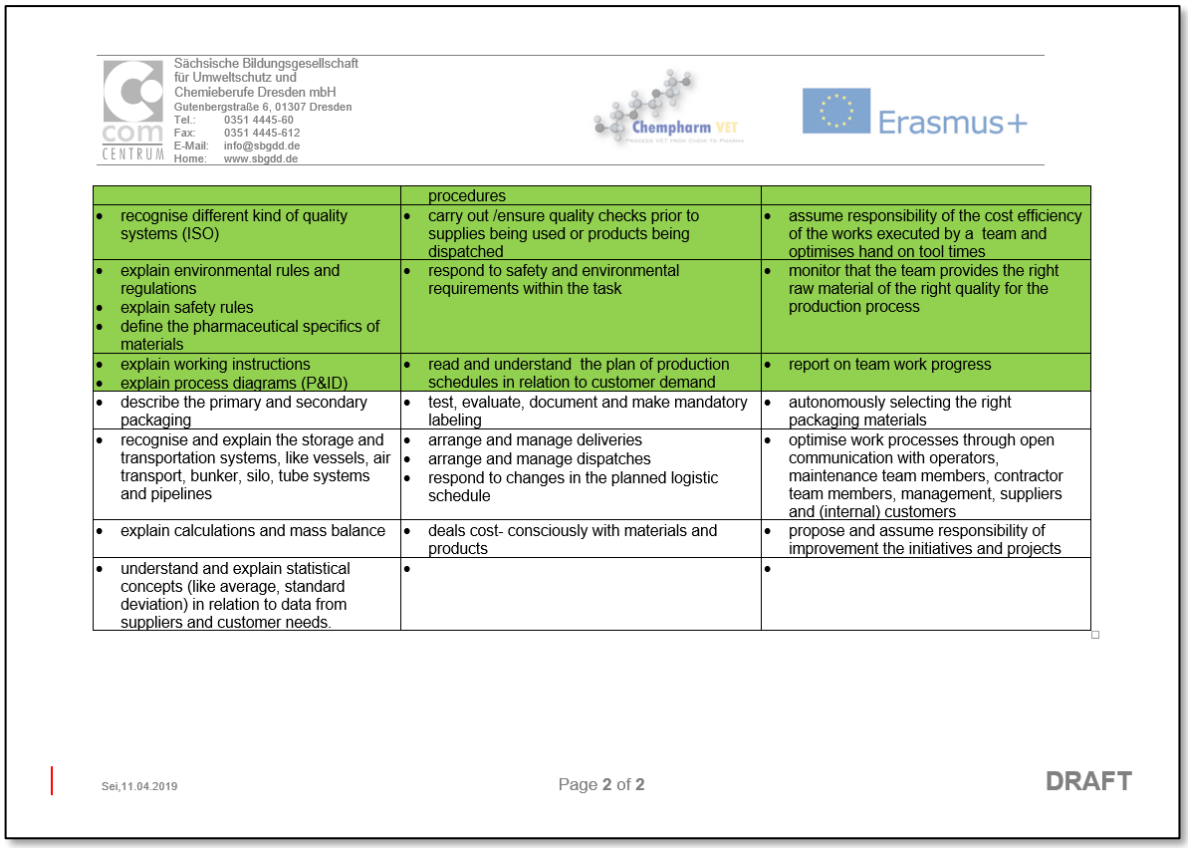

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	procedures	
• recognise different kind of quality systems (ISO)	• carry out /ensure quality checks prior to supplies being used or products being dispatched	• assume responsibility of the cost efficiency of the works executed by a team and optimises 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.	•	•

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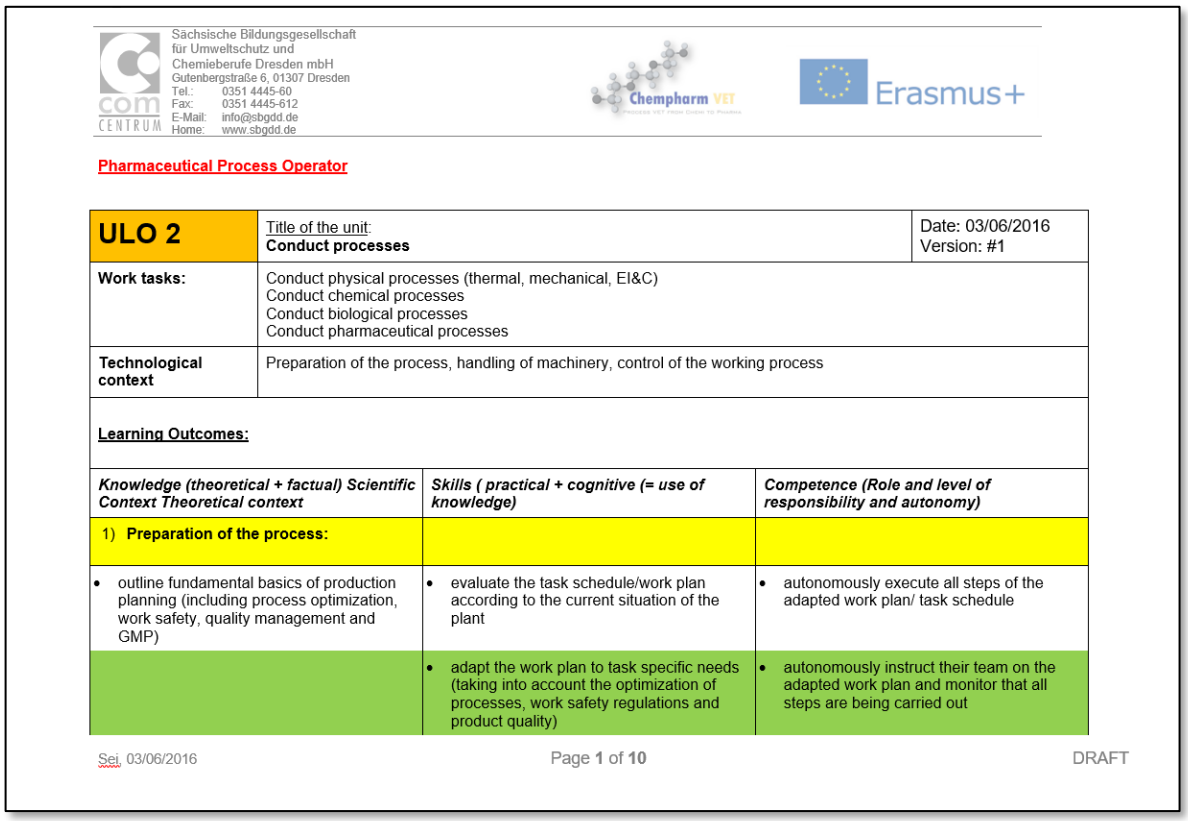

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Pharmaceutical Process Operator

ULO 2	Title of the unit: **Conduct processes**	Date: 03/06/2016 Version: #1
Work tasks:	Conduct physical processes (thermal, mechanical, EI&C) Conduct chemical processes Conduct biological processes Conduct pharmaceutical processes	
Technological context	Preparation of the process, handling of machinery, control of the working process	

Learning Outcomes:

Knowledge (theoretical + factual) Scientific Context Theoretical context	***Skills (practical + cognitive (= use of knowledge)***	***Competence (Role and level of responsibility and autonomy)***
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

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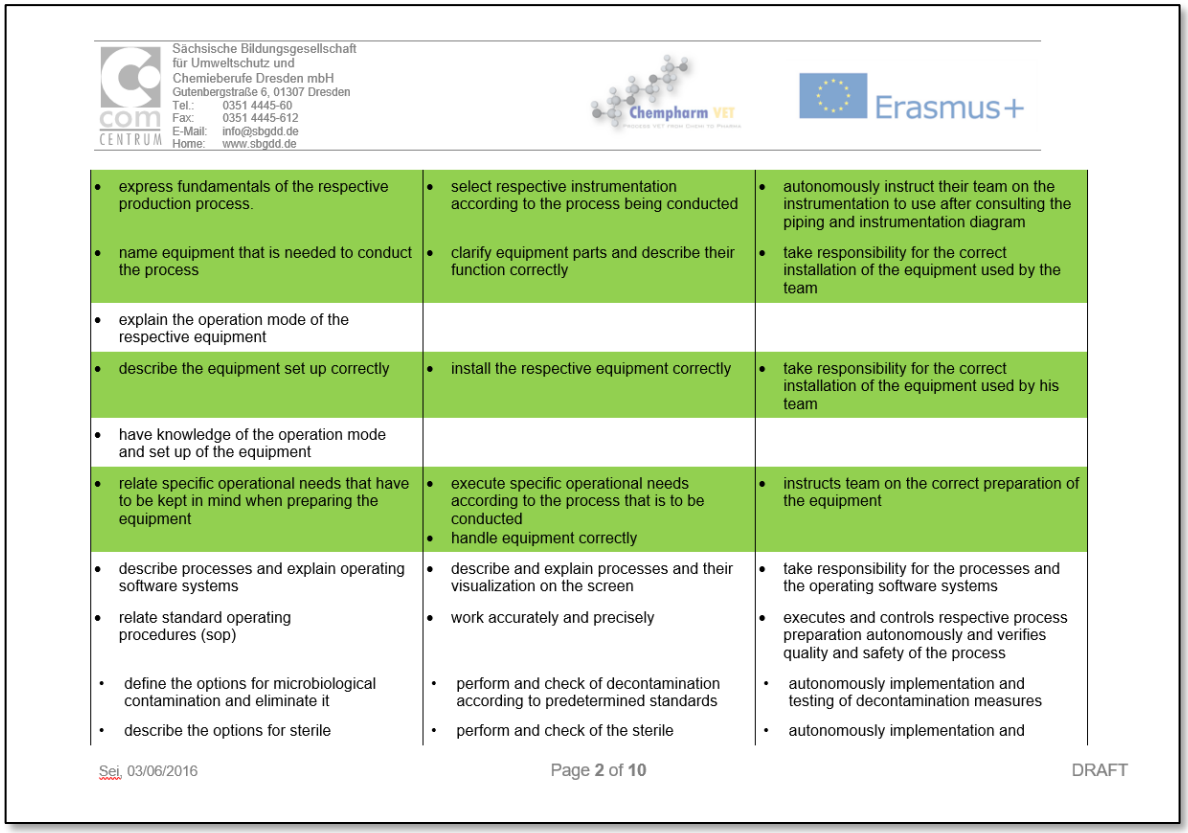

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• express fundamentals of the respective production process. • name equipment that is needed to conduct the process	• select respective instrumentation according to the process being conducted • clarify equipment parts and describe their function correctly	• autonomously instruct their team on the instrumentation to use after consulting the piping and instrumentation diagram • take responsibility for the correct installation of the equipment used by the team
• explain the operation mode of the respective equipment		
• describe the equipment set up correctly	• install the respective equipment correctly	• take responsibility for the correct installation of the equipment used by his team
• have knowledge of the operation mode and set up of the equipment		
• 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 • relate standard operating procedures (sop)	• describe and explain processes and their visualization on the screen • work accurately and precisely	• take responsibility for the processes and the operating software systems • executes and controls respective process preparation autonomously and verifies quality and safety of the process
• define the options for microbiological contamination and eliminate it • describe the options for sterile	• perform and check of decontamination according to predetermined standards • perform and check of the sterile	• autonomously implementation and testing of decontamination measures • autonomously implementation and

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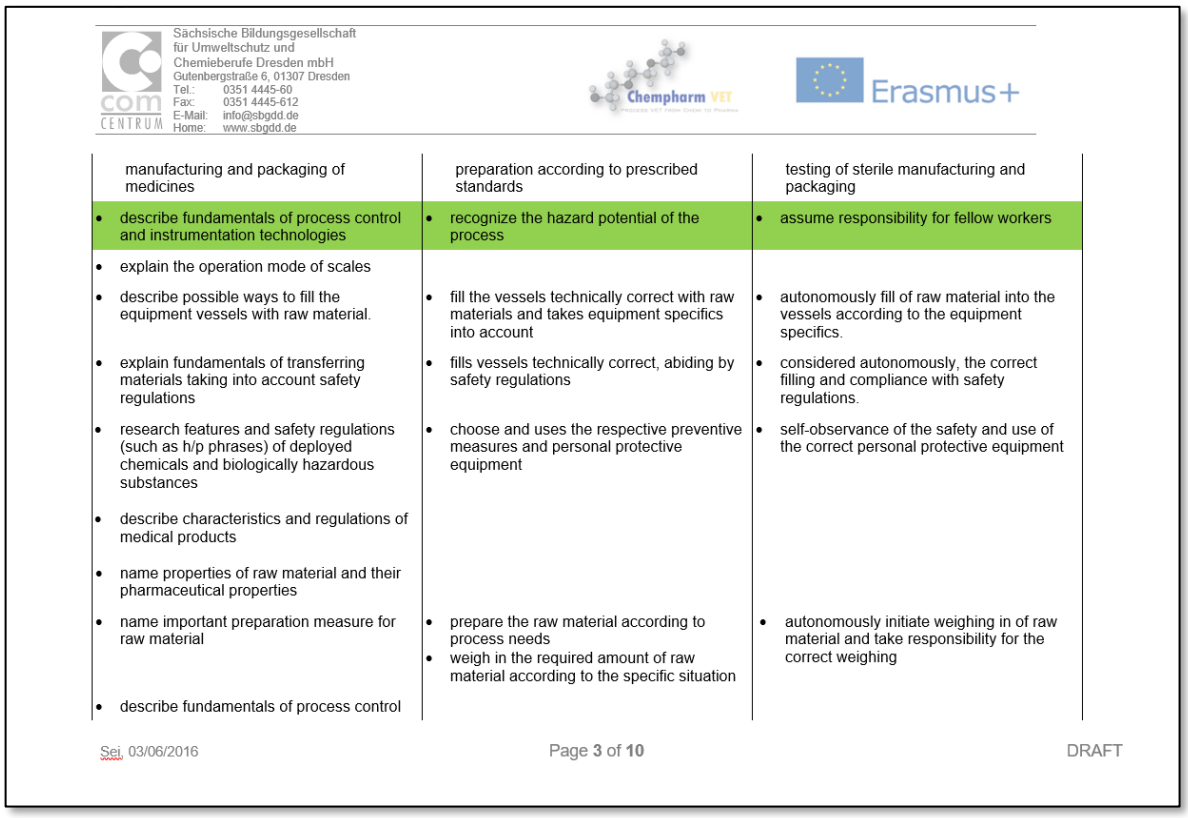
O2 Identification of relevant areas



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manufacturing and packaging of medicines	preparation according to prescribed standards	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		

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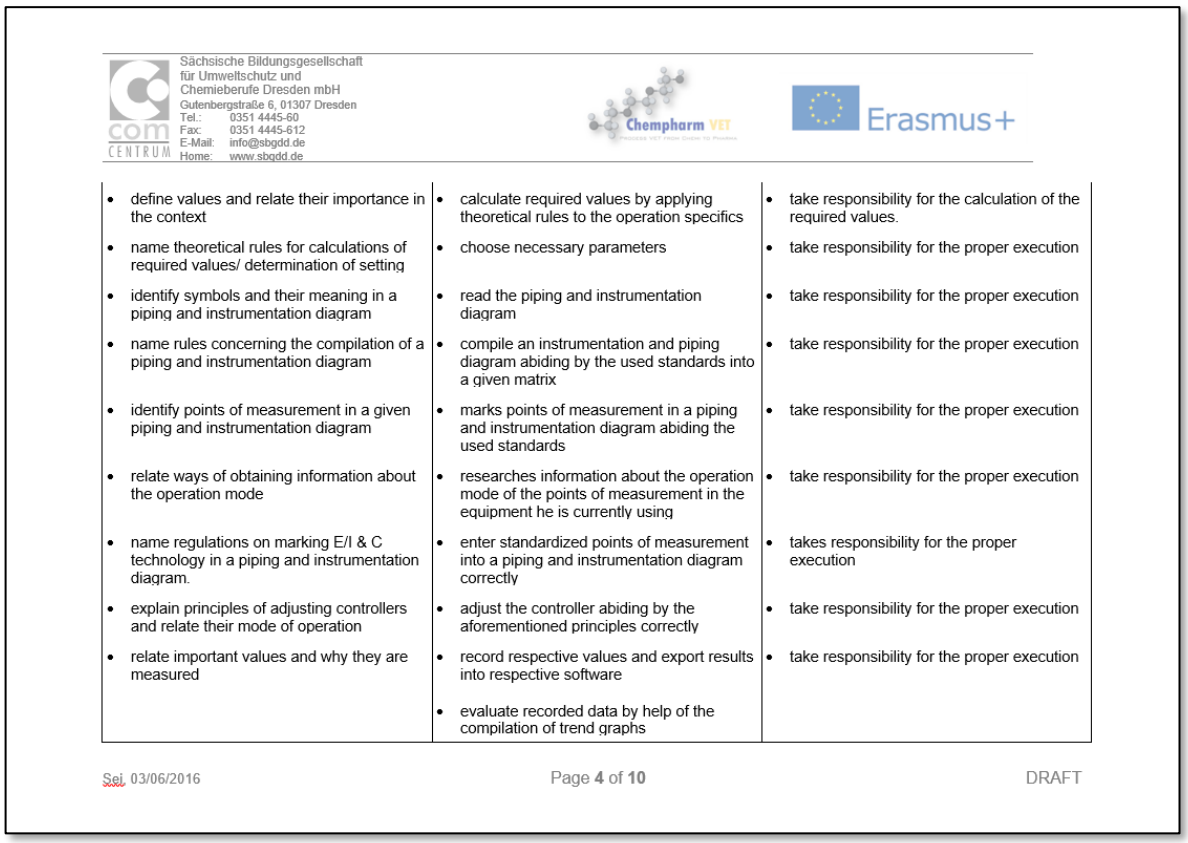

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• define values and relate their importance in the context	• calculate required values by applying theoretical rules to the operation specifics	• take responsibility for the calculation of the required values.
• name theoretical rules for calculations 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	• take responsibility for the proper execution
	• evaluate recorded data by help of the compilation of trend graphs	

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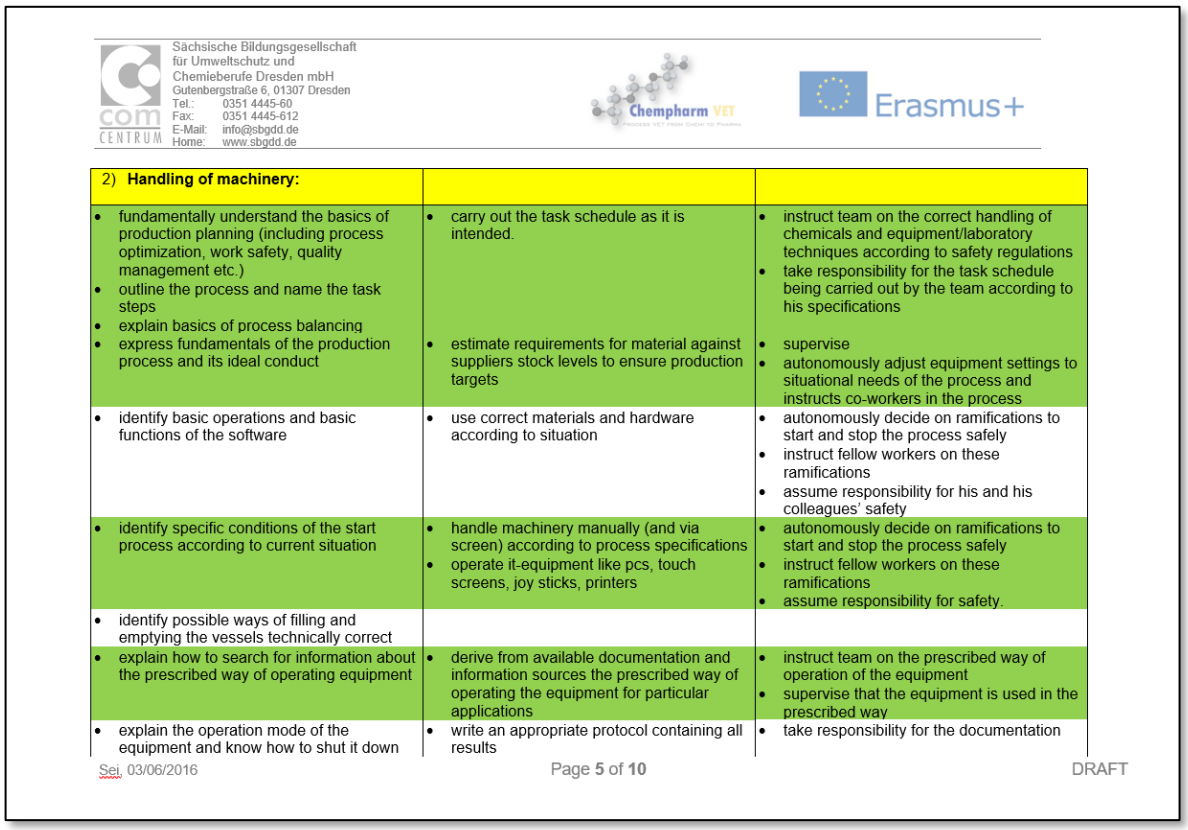

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2) **Handling of machinery:**		
• fundamentally understand the basics of production planning (including process optimization, work safety, quality management etc.) • outline the process and name the task steps • explain basics of process balancing	• 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	• write an appropriate protocol containing all results	• take responsibility for the documentation

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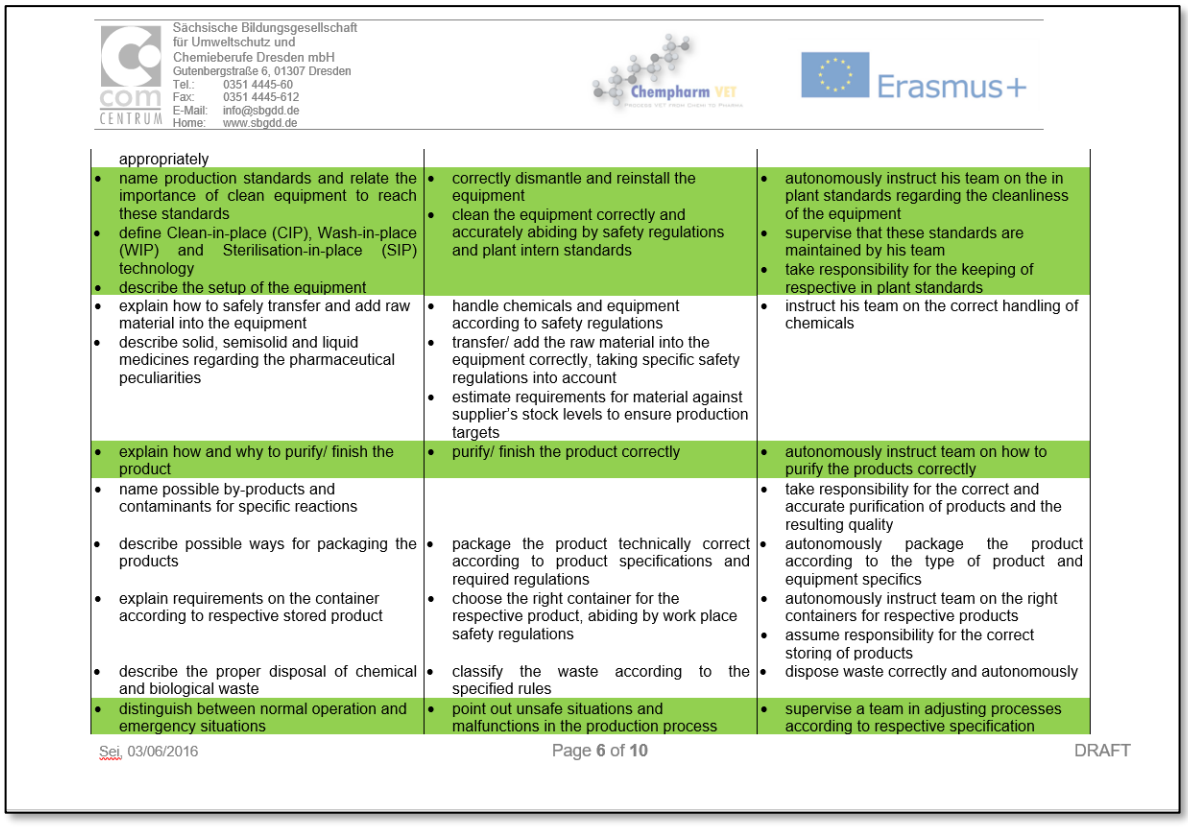

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appropriately		
• name production standards and relate the importance of clean equipment to reach these standards • define Clean-in-place (CIP), Wash-in-place (WIP) and Sterilisation-in-place (SIP) technology • describe the setup of the equipment	• 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	• supervise a team in adjusting processes according to respective specification

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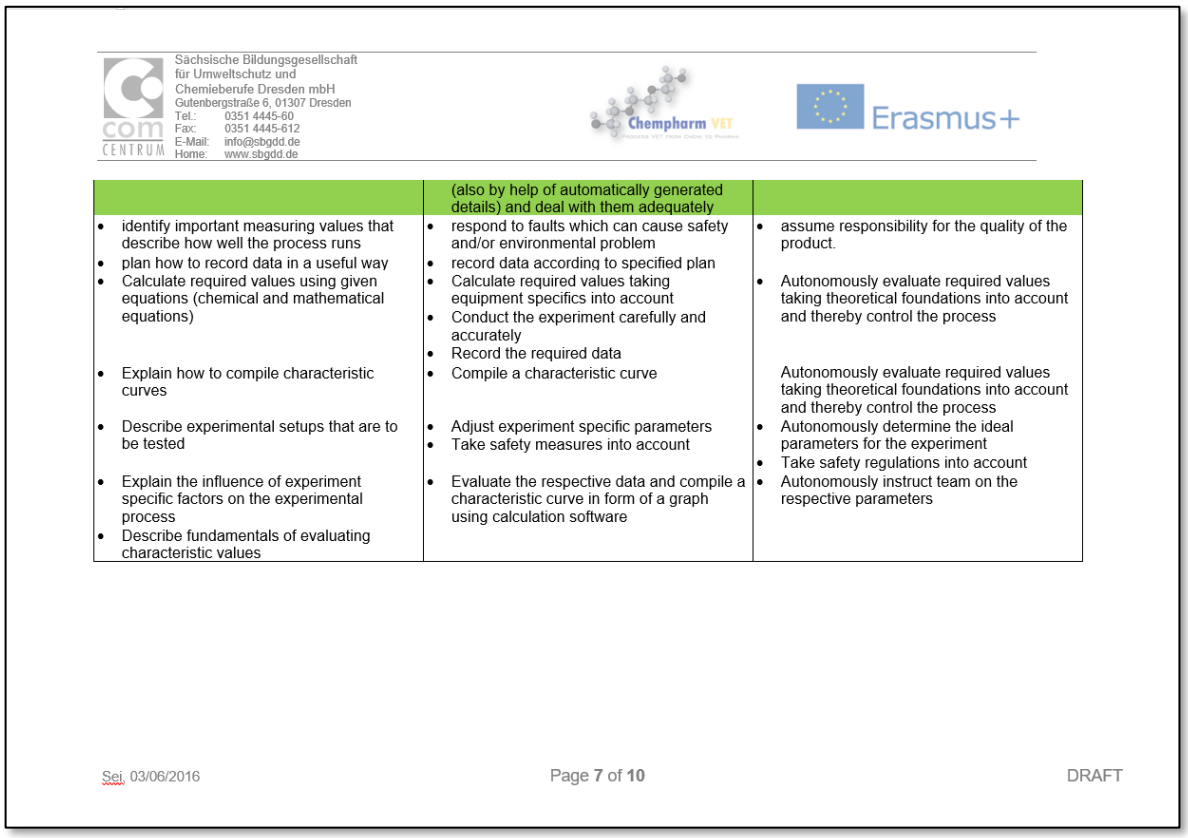

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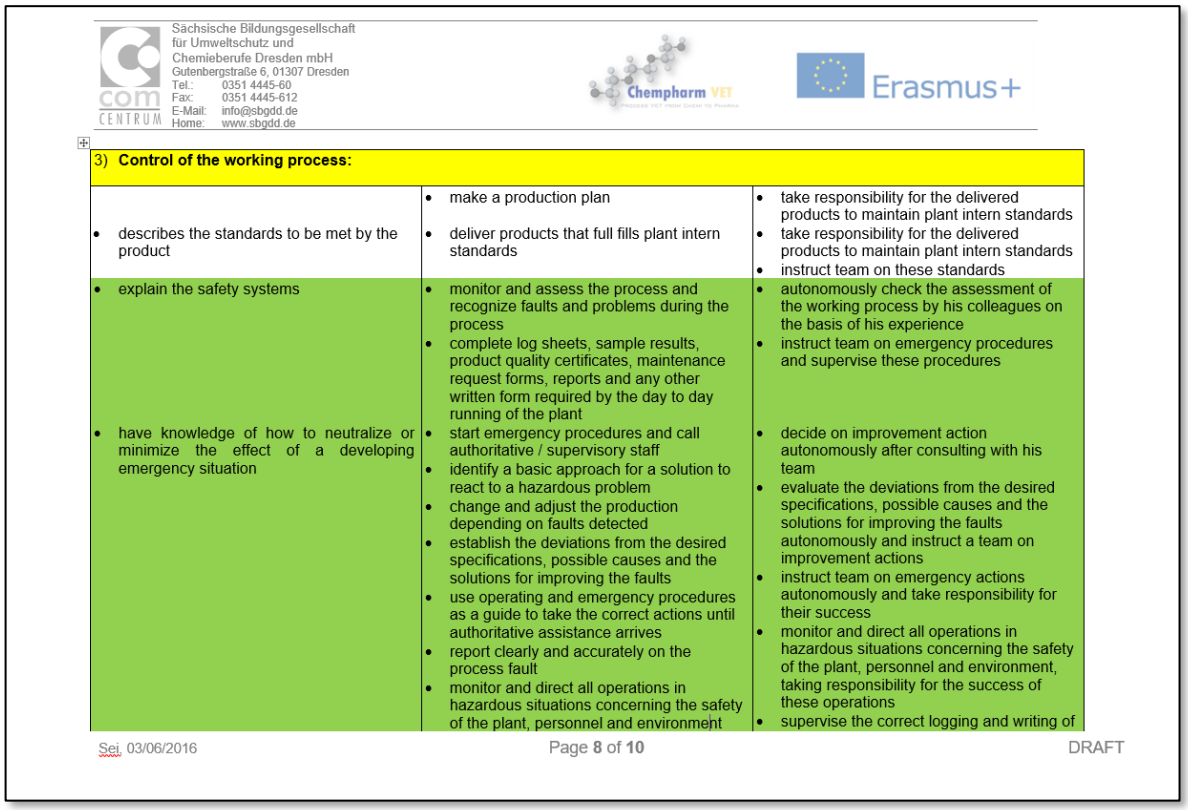
	(also by help of automatically generated details) and deal with them adequately	
• identify important measuring values that describe how well the process runs • plan how to record data in a useful way • Calculate required values using given equations (chemical and mathematical equations)	• respond to faults which can cause safety and/or environmental problem • record data according to specified plan • Calculate required values taking equipment specifics into account • Conduct the experiment carefully and accurately • Record the required data	• assume responsibility for the quality of the product. • 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 • Describe fundamentals of evaluating characteristic values	• Evaluate the respective data and compile a characteristic curve in form of a graph using calculation software	• Autonomously instruct team on the respective parameters



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3) **Control of the working process:**		
• describes the standards to be met by the product	• make a production plan • deliver products that full fills plant intern standards	• take responsibility for the delivered products to maintain 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	• 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

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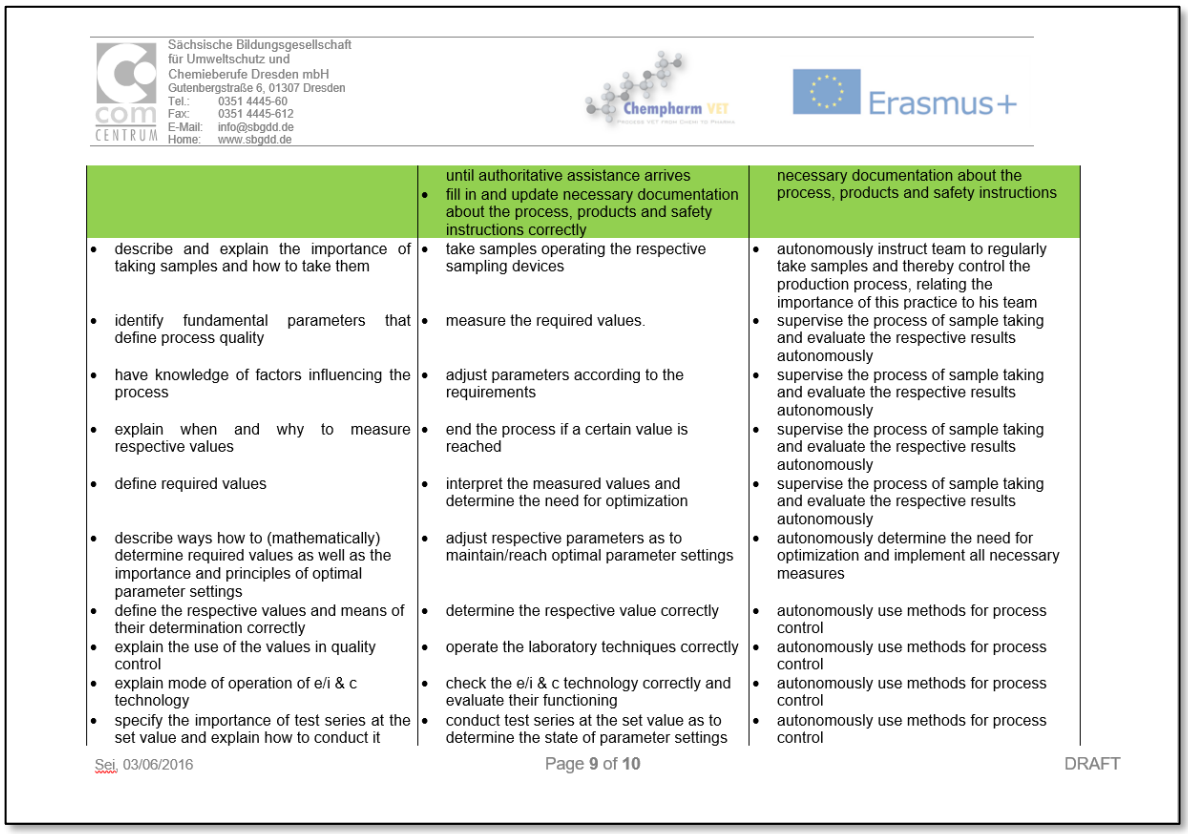
O2 Identification of relevant areas



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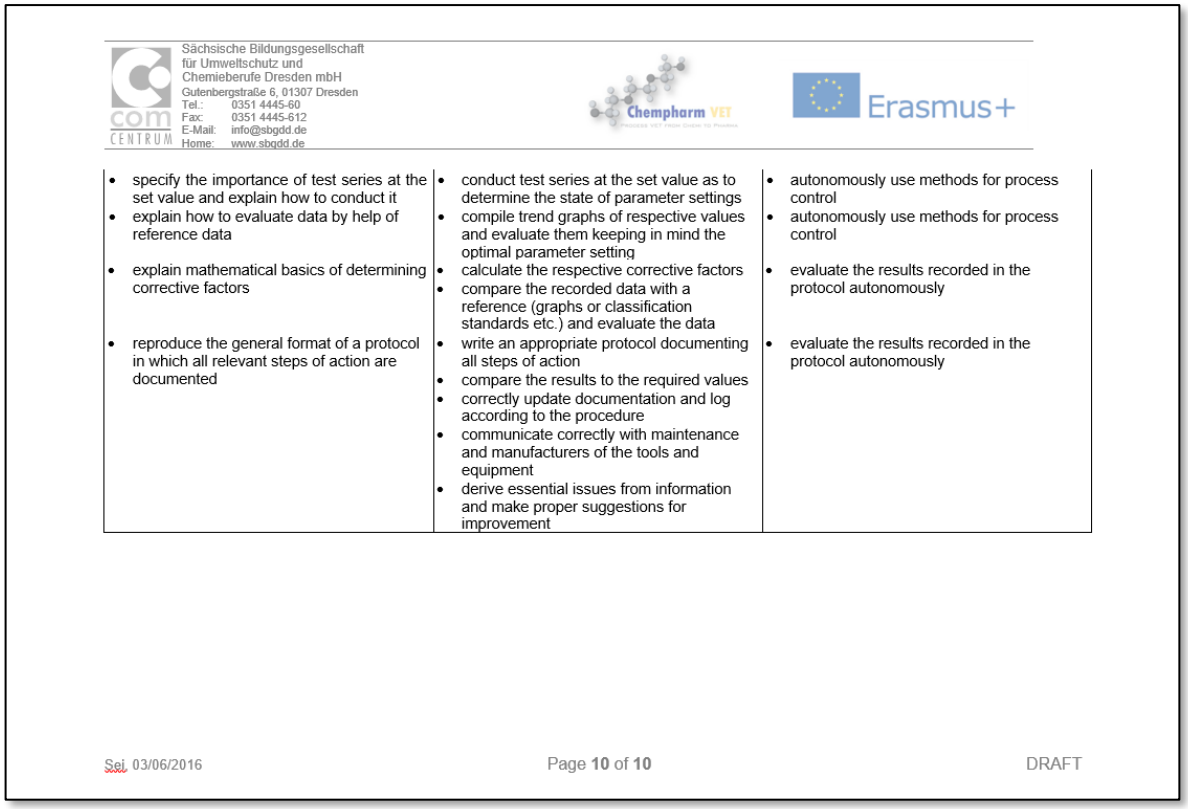
	until authoritative assistance arrives • fill in and update necessary documentation about the process, products and safety instructions correctly	necessary documentation about the process, products and safety instructions
• describe and explain the importance of taking samples and how to take them	• 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



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• specify the importance of test series at the set value and explain how to conduct it • explain how to evaluate data by help of reference data	• conduct test series at the set value as to determine the state of parameter settings • compile trend graphs of respective values and evaluate them keeping in mind the optimal parameter setting	• autonomously use methods for process control • 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

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Pharmaceutical Process Operator

ULO 3	Title of the unit: Participate in quality control	Date: 03/06/2016 Version: #1
Work tasks:	1. Taking samples 2. Sample analysis 3. Participating in quality control	
Technological context	Taking samples, methods of analysis, quality management,	

Learning Outcomes:

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

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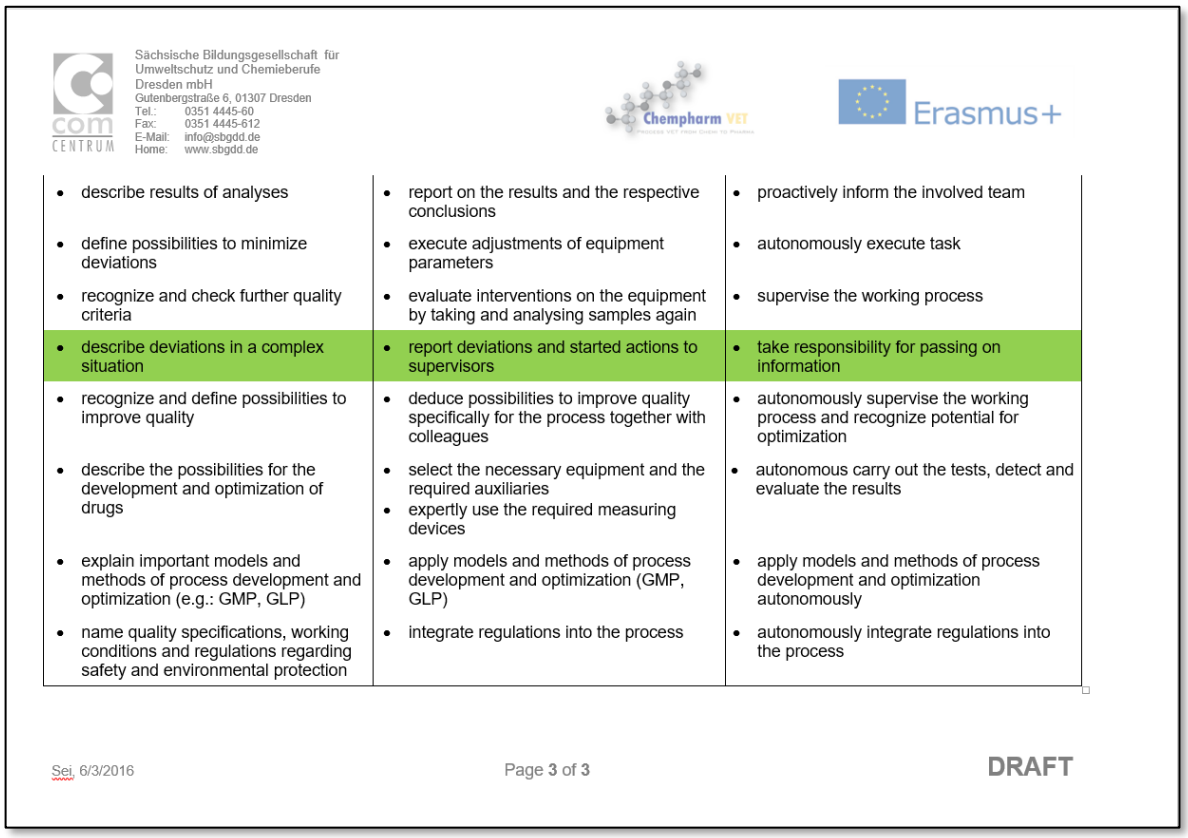

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• describe results of analyses	• report on the results and the respective conclusions	• proactively inform the involved team
• define possibilities to minimize deviations	• execute adjustments of equipment parameters	• autonomously execute task
• recognize 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

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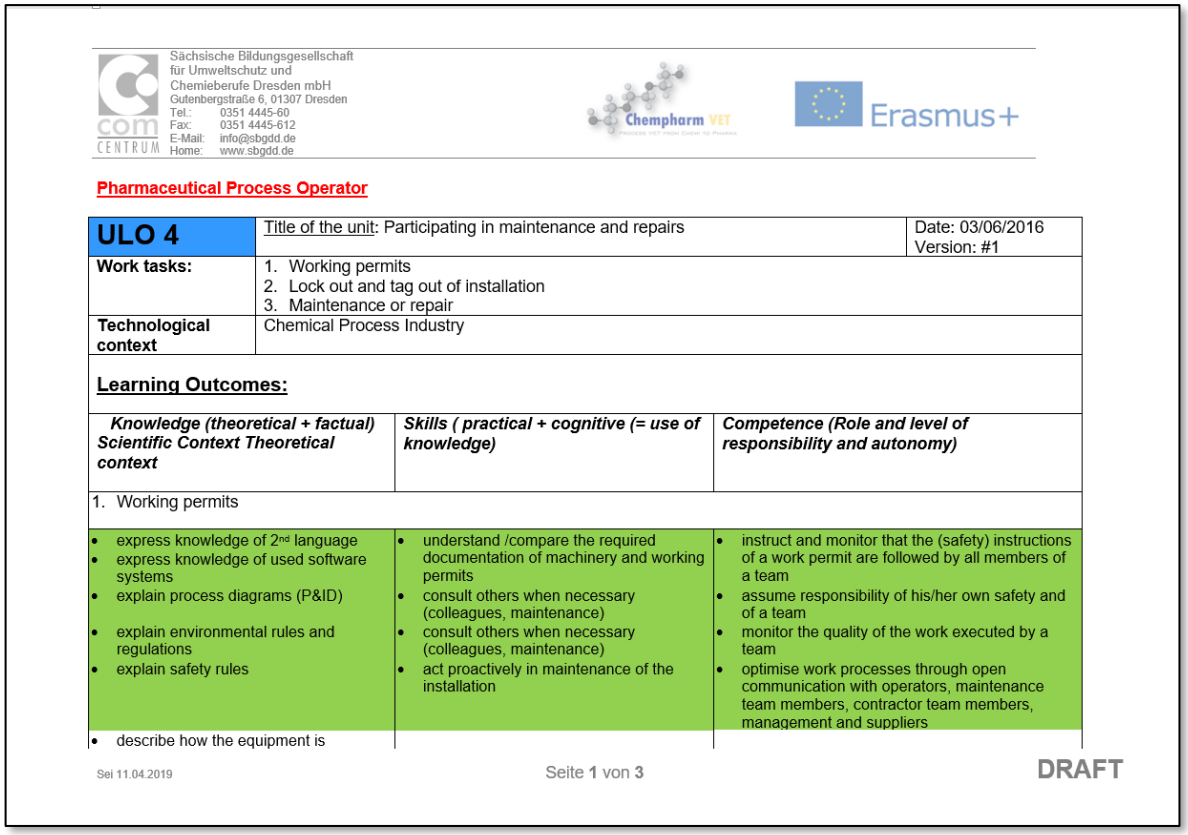

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Pharmaceutical Process Operator

ULO 4	Title of the unit: Participating in maintenance and repairs	Date: 03/06/2016 Version: #1
Work tasks:	1. Working permits 2. Lock out and tag out of installation 3. Maintenance or repair	
Technological context	Chemical Process Industry	

Learning Outcomes:

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 • explain safety rules	• understand /compare the required documentation of machinery and working permits • consult others when necessary (colleagues, maintenance) • consult others when necessary (colleagues, maintenance) • act proactively in maintenance of the installation	• 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 • optimise work processes through open communication with operators, maintenance team members, contractor team members, management and suppliers
• describe how the equipment is		

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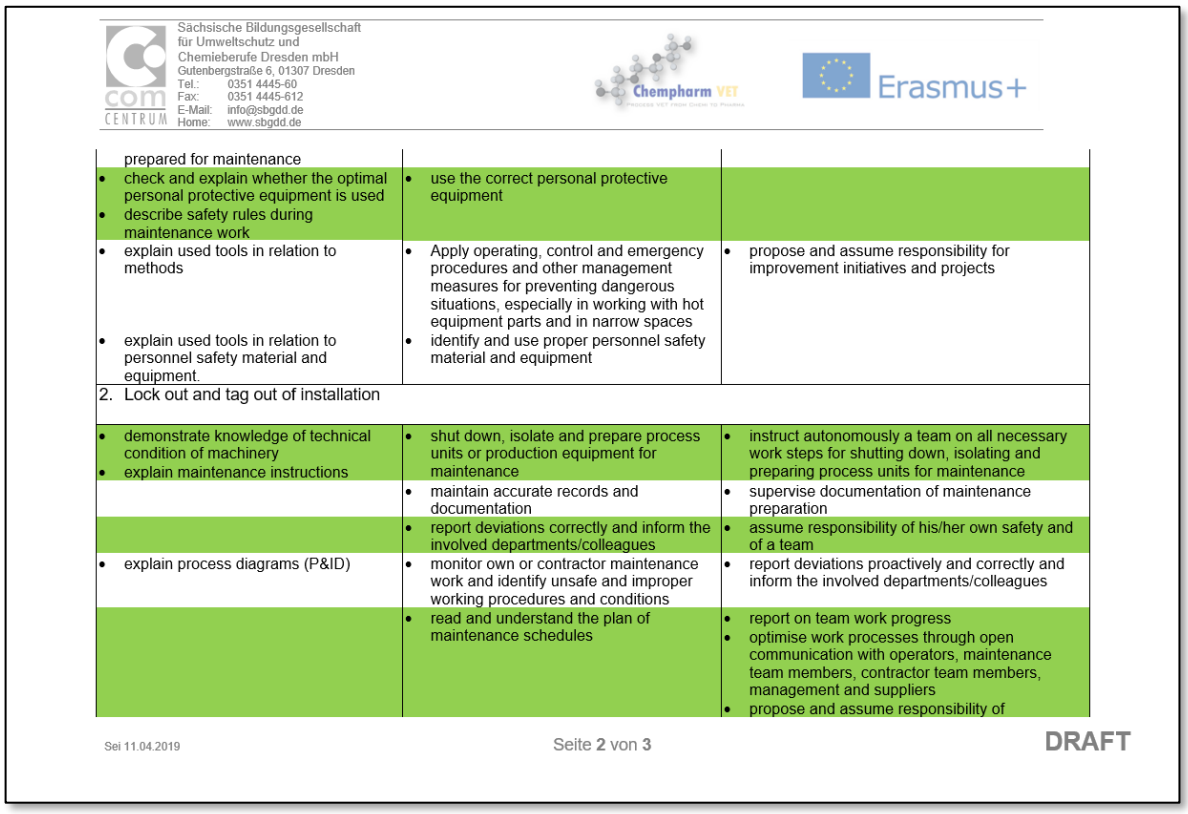
O2 Identification of relevant areas



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prepared for maintenance		
• check and explain whether the optimal personal protective equipment is used • describe safety rules during maintenance work	• use the correct personal protective equipment	
• explain used tools in relation to methods • explain used tools in relation to personnel safety material and 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	• 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	• shut down, isolate and prepare process units or production equipment for maintenance	• instruct autonomously a team on all necessary work steps for shutting down, isolating and preparing process units for maintenance
	• maintain accurate records and documentation	• supervise documentation of maintenance preparation
	• report deviations correctly and inform the involved departments/colleagues	• assume responsibility of his/her own safety and of a team
• explain process diagrams (P&ID)	• monitor own or contractor maintenance work and identify unsafe and improper working procedures and conditions	• report deviations proactively and correctly and inform the involved departments/colleagues
	• read and understand the plan of maintenance schedules	• 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

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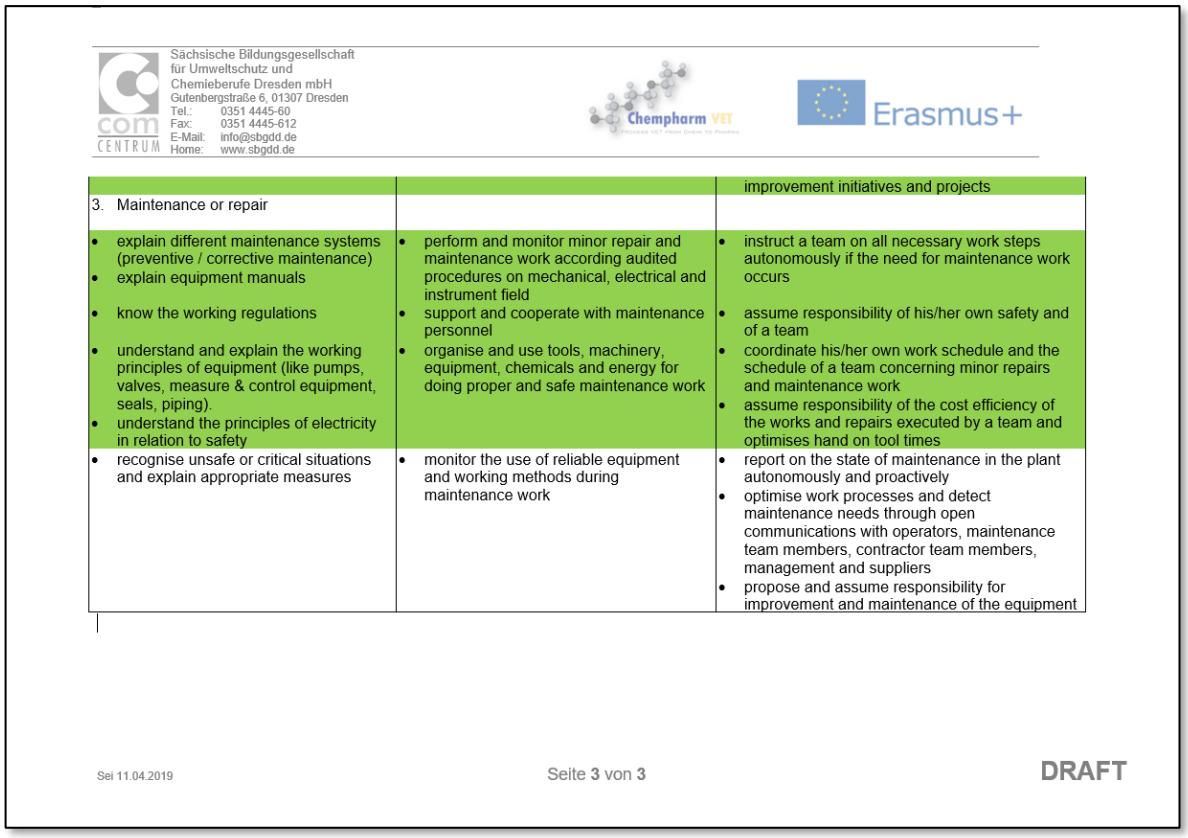

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		improvement initiatives and projects
3. Maintenance or repair		
• explain different maintenance systems (preventive / corrective maintenance) • explain equipment manuals	• perform and monitor minor repair and maintenance work according audited procedures 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	• support and cooperate with maintenance personnel	• assume responsibility of his/her own safety and of a team
• 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	• organise and use tools, machinery, equipment, chemicals and energy for doing proper and safe maintenance work	• 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

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5 Conclusion and Recommendation

For tacit knowledge as well as for critical skills, areas were identified in the units of learning outcome that were developed by the project ChemPharm. Tacit knowledge was divided into common and specific competences. Critical skills only belong to the specific competences.

After selecting the appropriate work task, it is possible to determine content to visualize tacit knowledge and critical skills.

Next step is to find examples in the work task that are parts of tacit knowledge or critical skills. Then script had to be produced and a film of the competence would be recorded.

The films should be placed to Skillsbank, so that Skillsbank's users have an idea of the expected competencies in practicing the profession of chemical and pharmaceutical operator.

Because the work on the units of learning outcome will not be finalized, due to future changes in the requirements of the chemical and pharmaceutical operator, the identification of relevant areas of tacit knowledge and critical skills cannot be concluded conclusively, since the changes in the job profile are also reflected here.

6 Bibliography

CEFIC, Skills for innovation in the European chemical industry. (2014)
ChemPharm VET, Final Report. (2017).
Chugh, R. “Do Australian Universities Encourage Tacit Knowledge Transfer?”. In Proceedings of the 7th International Joint Conference on Knowledge Discovery, Knowledge Engineering and Knowledge Management. (2015).
CREDCHEM – Entwicklung und Erprobung eines Leistungspunktesystems zur Verbesserung der Mobilität im Chemiesektor, Final Report. (2012).
http://steveo1967.blogspot.com/2013/06/tacit-and-explicit-knowledge-and.html. (1967).
https://www.agriseta.co.za/downloads/agm_presentations/Department_of_Labour_definitions.pdf. (2006).
https://www.inc.com/larry-kim/10-critical-skills-you-ll-need-to-succeed-at-work-in-2020.html. (2019).
PileUp Process Industry LEarning Unit Project, Final Report. (2013).
Polanyi, M. The Tacit Dimension University of Chicago Press. (1966).
Sensky, T. "Knowledge Management". Advances in Psychiatric Treatment. (2002).
Wikipedia. Retrieved 2019, from https://en.wikipedia.org/wiki/Tacit_knowledge#cite_note-1 (2019).

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