

# REPORT IO-8 RPL VALIDATION OF PRIOR LEARNING



Erasmus+

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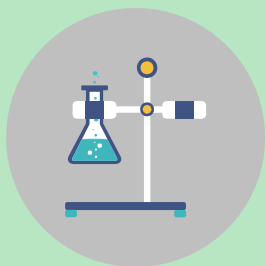
Annexes – examples of test procedures for Process Operator in the European Chemical and Pharmaceutical Industry (EQF 3-4):

**A. Preparation of ascorbic acid capsules**

- a. Work task
- b. Assessment tool

**B. Cleaning of the 826-application kettle including wax melt**

- a. Work task
- b. Assessment tool



# 1. BACKGROUND

With the chemical and pharmaceutical industries being very close as concerns content and procedures, learning experiences obtained in one area may be relevant in the other. It is therefore a need for an elaboration of procedures of recognition of prior learning (RPL) to bridge between them. This will secure better permeability and flexibility in career pathways and career changes as well. The RPL procedures described below constitute the basis for this type of professional mobility.

Traditional vocational education and training has documented practical performance as situational and linked to the certification of pre-described outcomes, in this project through the multilingual qualification matrixes. The target has also been to secure that an individual's portfolio of lifelong learning experiences can be taken care of and used as recognised input to CVs and personal qualification profiles and portfolios. The bridge from life experience and workplace learning to a more formal documentation of competences has in the project been taken care of through contextual (ChemPharmVET) developments of existing practices of RPL.

NTI-MMM has, in cooperation with OsloMet University (previously the Oslo and Akershus University College of Applied Science), developed practices of assessment and recognition using the Skillsbank services to integrate ECVET and RPL. These experiences have been further developed and transferred to ChemPharmVET together with experiences from earlier projects, especially the PileUp.



## 2. IMPLEMENTATION

The aim of the first part of this project was to give a better overview of how performed skills are treated in the partnership countries when defined through learning outcomes and to organise these learning outcomes in units which may be integrated in a ChemPharmVET qualification according to the ECVET principles. In practice this included the adaptation of the learning units for chemical and pharmaceutical operators according to the required, standardized format and including them in Skillsbank.

A final element was to elaborate RPL procedures which might bridge over national and/or cultural gaps in the perception and documentation of the required competences. This included also a review and adjustment of existing procedures of assessment and RPL to comprise VET for chemical and pharmaceutical operators to secure better permeability and flexibility in career pathways and career changes.

In this context work examples and test situations have been described and systematised to allow companies' work based learning and an individual's soft skills and transversal skills to be assessed within an ECVET framework.

This implied description of the smaller elements constituting a performance, including soft skills, in the form of learning outcomes. Accordingly, it gave the opportunity to exemplify assessment methods and routines to cover various forms of learning experiences, previous and present.

The aims of this work are therefore to


- Develop the procedures and principles of assessing and documenting in an ECVET setting
- Establish functioning RPL procedures
- Identify transfer options of ECVET documented competences into qualifications to open up for permeability and flexible pathways in career developments





## 3. ASSESSMENT

A range of assessment methods are established with RPL practices integrated in more general procedures of recognition and accreditation of prior learning as recommended by CEDEFOP and other European developments. For the assessment of a (unit of) learning outcomes a wide range of different instruments are therefore made available and possibly be used stepwise, such as:


### 1. Self assessment in Skillsbank




**Smith John**  
 European

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English (en) ▼



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SELECT QUALIFICATIONS ChemPharmVET Process Opera... ▼  
 SELECT QUALIFICATION UNIT ChempharmVET-U4 Participate i... ▼

COMPLETION

ChempharmVET-U4: Participate in maintenance and repairs										
4.3. Maintenance and repair										
4.3.1: Specific conditions										
a) I'm able to work according to audited procedures on mechanical, electrical instruments in the field						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b) I'm able to monitor minor repair and maintenance work						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c) I'm able to organise and use tools, machinery, equipment, chemicals and energy for doing proper and safe maintenance work						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d) I'm able to monitor the use of reliable equipment and working methods during maintenance work						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e) I'm able to support and cooperate with maintenance personnel						<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. Expert assessments in Skillsbank, based upon
  - a. Uploaded documentation in Skillsbank
  - b. Supported by video documentation (Skillstube in Skillsbank)
3. Expert assessments with optional input and requirements from a selection of examples from the European recommendations:
  - a. Theoretical tests /»quiz«
  - b. Written assignments
  - c. Practical tests / work samples
  - d. Computer simulation
  - e. Interview
  - f. Presentation
  - g. Simulated conversation
  - h. Role playing
  - i. Portfolio documentation
4. Validation and recognition against standards should be the next step to be implemented at national/sectorial level.

In the appendixes examples of structured work situations are described – with links to the respective learning outcomes. Due to the degree of detailing these examples are given in English, the “master language” of the project deliverables.

In the development of the next steps of self-assessment it may be necessary to invite to a fine tuning of questions after longer use with partner feedback, also with the necessary translations of revised/added questions into partner languages. An optional development of possible additional «quiz»/test questions with the corresponding translation into partner languages and implementation in Skillsbank could be part of a project follow-up.



## 4. ANNEXES: EXAMPLES OF TEST PROCEDURES



## A. Preparation of ascorbic acid capsules

### a. Work task

Work Task: ULO2- Preparation of ascorbic acid capsules			
<b>Practical Knowledge</b> Characterization of the workflow		<b>Expertise</b> 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.		
Operator is aware of the potential dangers of the chemicals used and uses the appropriate personal safety equipment	Compliance with occupational safety. Knowing the hazard potential. Selection of PSE	Hazard potential of the raw materials.	
Use a mortar mill to rub filler through to a particle size of less than 180µm	Operation mortar grinder and sieve set	Determination of grain size.	Crushing and sieving of material.
	Open the capsule and fill the base with filler, then determine the volume	Volume determination.	
The operator sizes raw materials.	Transfer of the recipe and the resulting quantities in consideration of the plant.		Specifics of the equipment.
The operator weighs in the required quantities.	Operating a scale.	Basics of EI&C-technology.	Operating a scale.

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Transfer of raw materials to the mortar mill.	Professional transfer in compliance with occupational safety.	Hazard potential of the raw materials.	
The operator starts the crushing and mixing process.	Recognition of basic procedural processes and their analysis.	Crushing and mixing of solids	Setting the mortar mill
Checking the mill setting.	Professional adjustment of the mill		Setting the mortar mill
Removal of the mixture from a mortar mill and transfer into a sieve.	Operation mortar mill and sieve set	Determination of grain size.	Sieve of material.
Assembly of the semi-automatic capsule filling machine with the empty capsules	Operation capsule filling machine.		Specifics of the equipment.
Filling the mixture in the semi-automatic capsule filling machine	Professional transfer in compliance with occupational safety.	Hazard potential of the raw materials.	Specifics of the equipment.
Filling and closing the capsules.	Operation capsule filling machine.		Specifics of the equipment.
Dedusting of the capsules.	Operation capsule filling machine.		Specifics of the equipment.
Packing the filled capsules in cans of 10 pieces	Operation capsule filling machine.		Selection of right storage.
Taking a sample for quality control.		Taking a sample.	
The operator writes a protocol.	Documentation of results.		
The operator cleans the equipment.			Selection of the right cleaning method.
The operator shuts down the equipment.			

## b. Assessment tool: Preparation of ascorbic acid capsules

Name Applicant:	Company / Department:	Personal-ID:
Name Assessor:	Test Location:	Date Assessment:

Work assignment (company related)	Evaluated criteria	judgement	
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Assessment ULO 2		Conduct processes		EQF level 4	EQF level 3	failed	Test method* (S/E/I)
Work task ULO2-4.1 Preparation of ascorbic acid capsules							
Time available : . . . . . minutes							
Label of Learning Outcome	Competence		Work steps (to be filled in by the company)				
	Knowledge	Skills					
2.1 Process preparation	Autonomously execute all steps of the adapted work plan/ task schedule		The operator analyses the current task schedule.				
	Outline fundamental basics of production planning (including process optimization, work safety, quality	Evaluate the task schedule/work plan according to the current situation of the plant					

	management and GMP)						
2.1.1.2 Equipment	Take responsibility for the correct installation of the equipment used by the team		Use a mortar mill to rub filler through to a particle size of less than 180µm				
	Name equipment that is needed to conduct the process	Clarify equipment parts and describe their function correctly					
	Explain the operation mode of the respective equipment						
2.1.1.3 Equipment setup	Take responsibility for the correct installation of the equipment used by his team						
	Describe the equipment set up correctly	Install the respective equipment correctly					
2.1.2.1 Calculation	Take responsibility for the calculation of the required values		Determining the capsule fill volume.				
	Define values and relate their	Calculate required values by applying theoretical rules to					

	importance in the context	the operation specifics	The operator sizes raw materials.				
	Name theoretical rules for calculations of required values/ determination of setting	Choose necessary parameters					
2.1.7 Handling of raw material	Knows the properties of raw material and their pharmaceutical properties and operates in compliance with safety regulations		Operator is aware of the potential dangers of the chemicals used and uses the appropriate personal protective equipment				
	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	Transfer of raw materials to the mortar mill.				
		Autonomously fill of raw material into the vessels according to the equipment specifics.					
	Explain fundamentals of transferring	Fills vessels technically correct,					

	materials taking into account safety regulations	abiding by safety regulations					
		Self-observance of the safety and use of the correct personal protective equipment					
	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	Operator is aware of the potential dangers of the chemicals used and uses the appropriate personal safety equipment				
	Name important preparation measure for raw material	Prepare the raw material according to process needs					
		Initiate weighing in of raw material and take responsibility for the correct weighing	The operator weighs in the required quantities.				

		Weigh in the required amount of raw material according to the specific situation					
2.2 Handling of machinery in process	Take responsibility for the task schedule being carried out by the team according to specifications and instruct team on the correct handling of chemicals and equipment/laboratory techniques according to safety regulations		The operator starts the crushing and mixing process.				
	Fundamentally understand the basics of production planning (including process optimization, work safety, quality management etc.)	Carry out the task schedule as it is intended in the process plan					
	Outline the process and name the task steps						
	Explain basics of process balancing						



2.2.1 Production process	Supervise and autonomously adjust equipment settings to situational needs of the process and instructs co-workers in the process		Checking the mill setting				
	Express fundamentals of the production process and its ideal conduct	Estimate requirements for material against suppliers stock levels to ensure production targets					
2.2.1.1 Preparing production	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					
	Identify possible ways of filling and emptying the vessels technically correct	Instruct team on the prescribed way of operation of the equipment	Removal of the mixture from a mortar mill and transfer into a sieve.				
		Supervise that the equipment is used					

		in the prescribed way					
2.2.1.2 Starting production	Autonomously decide on ramifications to start and stop the process safely		Assembly of the semi-automatic capsule filling machine with the empty capsules				
	Identify basic operations and basic functions of the software	Instruct fellow workers on the ramifications					
		Use correct materials and hardware according to situation					
		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					
2.2.1.3 Closing down	Take responsibility for the closing and the required documentation						
	Explain the operation mode of the equipment and know how to shut it down appropriately	Write an appropriate protocol containing all results					
2.2.2 Production quality standards	Take responsibility for the keeping of respective in-plant standards and autonomously instruct his team on these standards regarding the cleanliness of the equipment						
	Name production standards and relate the importance of clean equipment to reach these standards	Supervise that these standards are maintained by his team					
		Correctly dismantle and reinstall the equipment					

	Define Clean-in-place (CIP), Wash-in-place (WIP) and Sterilisation-in-place (SIP) technology	Clean the equipment correctly and accurately abiding by safety regulations and plant intern standards	The operator cleans the equipment.				
2.2.2.1 Purification and contamination	Take responsibility for the correct and accurate purification of products and the resulting quality						
	Explain how to safely transfer and add raw material into the equipment	Handle chemicals and equipment according to safety regulations					
		Instruct his team on the correct handling of chemicals					
	Explain how and why to purify/ finish the product	Transfer/ add the raw material into the equipment correctly, taking specific safety regulations into account					

	Name possible by-products and contaminants for specific reactions	Purify/ finish the product correctly	Dedusting of the capsules.				
		Instruct team on how to purify the products correctly					
2.2.2.2 Product characteristics and handling	Describe characteristics and regulations of medical products						
	Describe solid, semisolid and liquid medicines regarding the pharmaceutical peculiarities						
2.2.2.3 Product packing and storing	Assume responsibility for the correct packaging and storing of products						
	Describe possible ways for packaging the products	Instruct team on the right containers for respective products					
		Package the product technically correct according to product and equipment	Assembly of the semi-automatic capsule filling machine with the empty capsules				

		specifications and required regulations	Filling the mixture in the semi-automatic capsule filling machine				
	Explain requirements on the container according to respective stored product	Choose the right container for the respective product, abiding by work place safety regulations	Packing the filled capsules in cans of 10 pieces				

2.3.3 Quality control	Supervise the process of sample taking and evaluate the respective results autonomously		Taking a sample for quality control.				
	Identify fundamental parameters that define process quality	Measure and assess the required values.					
2.3.3.1 Sampling control	Autonomously instruct team to regularly take samples and thereby control the production process, relating the importance of this practice to his team						
	Have knowledge of factors influencing the process	Adjust parameters according to the requirements					
	Describe and explain the importance of taking samples and how to take them	Take samples operating the respective sampling devices					
		Supervise the process of sample taking and evaluate the respective results					
	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	The operator writes a protocol.				

		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				



**B. Cleaning of the 826-application kettle including wax melt**  
**a. Work task**

Work Task: ULO2-Cleaning of the 826 application kettle including wax melt			
<b>Practical Knowledge</b> Characterization of the workflow		<b>Expertise</b> Characterization of the work system	
workflow	skills/abilities	scientific context	technological context
The operator analyzes the current state of the system.	Reflection of the acquired knowledge. Plan the process	Acid-base reaction. pH-values in position.	Control of the inlet valve via pH electrode.

The operator determines process water.	Knowledge of the SOP and the resulting cleaning water volumes for the respective system	Properties of the 4 water types	System specifics.
Operator informs himself about the potential dangers of the materials used and uses the appropriate personal protective equipment	Compliance with occupational safety. Knowing the hazard potential. Selection of PSE	Hazard potential of the feedstock.	
Dosage of the appropriate amount of water	Operation of raw material dosing systems	Basics of EMSR technology.	Structure of dosing systems ..
The operator starts the process by starting the plant. Tempering.	Recognition of basic procedural processes and their analysis.		Driving the plant, using the existing EMSR and process control technology.

Control of the controller setting.	Professional adjustment of the controller		Controller setting.
Rinse water transport between wax melt and batch kettle			
Homogenizing and stirring from the point of cleaning the whole inside of the container	Operation of the system using suitable speeds	Heat transfer, dissolving behavior of product and dyes	Function of stirrer and homogenizer
Emptying the system		Properties of surfactants and water	Handling foaming in the stirred vessel
Rinse the system	Operation of the system using suitable speeds	Properties of the 4 water types	System specifics.

Visual inspection of the vessel	Knowing the critical areas inside the vessel		
Log the cleaning	Handling SAP-based protocol		
The operator shuts down the system.			

## Assessment tool: Cleaning of the 826-application kettle including wax melt

<b>C. Name Applicant:</b>	<b>Company / Department:</b>	<b>Personal-ID:</b>
<b>Name Assessor:</b>	<b>Test Location:</b>	<b>Date Assessment:</b>

Work assignment (company related)	Evaluated criteria	judgement			
<b>Assessment ULO 2</b>  <b>Work task ULO2- Cleaning of the 826 application kettle including wax melt</b>  <b>Time available : . . . . . minutes</b>	<b>Conduct processes</b>	<b>EQF level 4</b>	<b>EQF level 3</b>	<b>failed</b>	<b>Test method* (S/E/I)</b>

Label of Learning Outcome	Competence		Work steps (to be filled in by the company)				
	Knowledge	Skills					
2.1 Process preparation	Autonomously execute all steps of the adapted work plan/ task schedule		The operator analyzes the current state of the system.				
	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	The operator determines process water				
	Express fundamentals of the respective production process	Select respective instrumentation according to the process being conducted					
2.1.2.1 Calculation	Take responsibility for the calculation of the required values		The operator determines process water.				

	Define values and relate their importance in the context	Calculate required values by applying theoretical rules to the operation specifics					
	Name theoretical rules for calculations of required values/ determination of setting	Choose necessary parameters					
	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	Operator informs himself about the potential dangers of the materials used and uses the appropriate personal protective equipment				
	Name important preparation	Prepare the raw material according to process needs					

	measure for raw material	Initiate weighing in of raw material and take responsibility for the correct weighing				
		Weigh in the required amount of raw material according to the specific situation				
2.2 Handling of machinery in process	Take responsibility for the task schedule being carried out by the team according to specifications and instruct team on the correct handling of chemicals and equipment/laboratory techniques according to safety regulations					
	Fundamentally understand the basics of production planning (including process optimization, work safety, quality	Carry out the task schedule as it is intended in the process plan				



	management etc.)						
	Outline the process and name the task steps						
	Explain basics of process balancing						
2.2.1 Production process	Supervise and autonomously adjust equipment settings to situational needs of the process and instructs co-workers in the process						
	Express fundamentals of the production process and its ideal conduct	Estimate requirements for material against suppliers stock levels to ensure production targets					
2.2.1.1 Preparing production							
	Explain how to search for information about the prescribed way	Derive from available documentation and information sources the prescribed way of operating the equipment					

	of operating equipment	for particular applications					
	Identify possible ways of filling and emptying the vessels technically correct	Instruct team on the prescribed way of operation of the equipment	Dosage of the appropriate amount of water				
		Supervise that the equipment is used in the prescribed way					
2.2.1.2 Starting production	Autonomously decide on ramifications to start and stop the process safely						
	Identify basic operations and basic functions of the software	Instruct fellow workers on the ramifications					
		Use correct materials and hardware according to situation					
		Assume responsibility for his and his colleagues' safety					
	Identify specific conditions of the start process	Handle machinery manually (and via	The operator starts the process by starting the plant. Tempering.				

	according to current situation	screen) according to process specifications				
		Operate it-equipment like pcs, touch screens, joy sticks, printers	Control of the controller setting.  Rinse water transport between wax melt and batch kettle			
2.2.1.3 Closing down	Take responsibility for the closing and the required documentation					
	Explain the operation mode of the equipment and know how to shut it down appropriately	Write an appropriate protocol containing all results	The operator shuts down the system.			
2.2.2 Production quality standards	Take responsibility for the keeping of respective in-plant standards and autonomously instruct his team on these standards regarding the cleanliness of the equipment					

	Name production standards and relate the importance of clean equipment to reach these standards	Supervise that these standards are maintained by his team				
		Correctly dismantle and reinstall the equipment				
	Define Clean-in-place (CIP), Wash-in-place (WIP) and Sterilisation-in-place (SIP) technology	Clean the equipment correctly and accurately abiding by safety regulations and plant intern standards	Homogenizing and stirring from the point of cleaning the whole inside of the container			
	Describe the proper disposal of chemical and biological waste	Classify the waste according to the specified rules				
		Conduct the experiment carefully and accurately record the required data				

2.3.1 Standards compliance	Take responsibility for the delivered products to maintain plant intern standards						
	Describes the standards to be met by the product	Instruct team on these standards					
		Deliver products that full fills plant intern standards	Rinse the system				
2.3.3.2 Measurements	Autonomously determine the need for optimization and implement all necessary measures						
	Explain when and why to measure respective values	End the process if a certain value is reached	Visual inspection of the vessel				
	Define required values	Interpret the measured values and determine the need for optimization					
	Describe ways how to (mathematically) determine required values as well as the	Adjust respective parameters as to maintain/reach optimal parameter settings					

	importance and principles of optimal parameter settings						
2.3.3.3 Test series in process control	Autonomously use methods for process control						
	Define the respective values and means of their determination correctly	Determine the respective value correctly					
	Explain the use of the values in quality control	Operate the laboratory techniques correctly					
	Explain mode of operation of e/i & c technology	Check the e/i & c technology correctly and evaluate their functioning					
	Specify the importance of test series at the set value and	Conduct test series at the set value as to determine the state of parameter settings					

	explain how to conduct it						
	Explain how to evaluate data by help of reference data	Compile trend graphs of respective values and evaluate them keeping in mind the optimal parameter setting					
2.3.3.4 Quality analysis and reporting	Evaluate and analyse the results recorded in the protocol autonomously						
	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					
	Reproduce the general format of a protocol in which all relevant steps of	Write an appropriate protocol documenting all steps of action	Log the cleaning				

	action are documented	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					