

INTELLECTUAL OUTPUT 1: STATUS REPORT WITH GAP ANALYSIS FOR VET



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This project has been funded with support from the European Commission. This publication reflects the views only of the author, and the Commission cannot be held responsible for any use, which may be made of the information contained therein.

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Comparison between Pharmaceutical Operator and Chemical Operator

Europass certificates by the German Federal Institute for Vocational Education and Training:

Pharmaceutical Operator profiles of skills and competences	Chemical Operator profiles of skills and competences
<ul style="list-style-type: none"> • Produce and package drugs including planning, carrying out, checking and documenting stages of work • Operate and monitor technical pharmaceutical equipment and packaging lines • Ensure a smooth production process by instigating measures for the servicing, preventive maintenance, error detection and troubleshooting on the equipment, machinery and plants deployed • Ensure product quality through strict application of the good practice rules for drug production • Determine substance properties and constants and monitor process parameters within the framework of in- process control • Use computers and process control systems for machine and plant control, data retrieval and processing as well as for documentation purposes, for obtaining information and for logistical and organisational purposes • Exercise "responsible care" in according due consideration to the latest health and safety at work, environmental protection and health protection regulations when dealing with substances and equipment • Ensure environmentally compatible disposal and recycling of waste. 	<ul style="list-style-type: none"> • Carry out chemical processing technology, process control and plant engineering works, interdisciplinary cooperation along the process chain • Monitor, control and document chemical production flow and processing steps • Plan, check and document the steps necessary for the production and processing of different products • Work within a team to ensure processes run smoothly • Cooperate with other qualified staff (e.g. industrial mechanic, electronics technician for automation technology) in servicing, troubleshooting and preventive maintenance • Determine substance parameters and properties in a process oriented manner • Use computers and process control systems for machine and plant control, data retrieval and processing as well as for documentation purposes, for obtaining information and for logistical and organisational purposes • Act within the framework of "responsible care" by according due consideration to regulations concerning health and environmental protection, health and safety at work, plant safety and quality assurance • Environmentally compatible disposal and recycling of waste.



Hypothesis

The two professions do not differ in their basic features. The units of learning outcomes, developed in the PileUp project for chemical operator can also be adopted for the pharmaceutical operator.

ULO 1

Perform operational logistics

ULO 2

Conduct processes

ULO 3

Participate in quality control

ULO 4

Participating in maintenance and repairs

The ULOs reflect the work flow of the chemical and pharmaceutical operator

Steps of Gap Analysis

First Step:
Analysis of vocational education

Second Step:
Analysis on the job work tasks

National Curriculae



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Task: LEE3-1.2.2 Work task from production: Taking samples from tanks

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.		
Provide sample tin and lid.	Choosing the right sample tin.		
Printing a label with date, charge number, number of the tank, name of the operator.	Using the labelling function of the equipment's program controller.		Using a program controller.
Paying attention to special orders concerning sampling. Stirring for 20 min. before taking the sample.	Applying plant intern regulations on taking samples.	Ensuring to take samples from homogenized matter.	Using the stirrer.
Activating stirrer interlock.	Abiding by plant intern safety regulations.		Interlocking the stirrer against turning on again.
Taking samples with a ladle. Filling the sample tin completely.	Technically correct sample taking. Packaging the sample.		
Cleaning the tin if necessary and closing the lid.	Technically correct packaging.	Conserving a sample.	



German Vocational Training for Pharmaceutical Operators

Ein Service des Bundesministeriums der Justiz und für Verbraucherschutz
in Zusammenarbeit mit der juris GmbH - www.juris.de

Verordnung über die Berufsausbildung zum Pharmakanten/zur Pharmakantin

PharmAusbV 2009

Ausfertigungsdatum: 10.06.2009

Vollzeit:

"Verordnung über die Berufsausbildung zum Pharmakanten/zur Pharmakantin vom 10. Juni 2009 (BGBl. I S. 1374)"

x) Diese Rechtsverordnung ist eine Ausbildungsordnung im Sinne des § 4 des Berufsbildungsgesetzes. Die Ausbildungsordnung und der damit abgestimmte, von der Ständigen Konferenz der Kultusminister der Länder in der Bundesrepublik Deutschland beschlossene Rahmenlehrplan für die Berufsschule werden demnächst als Beilage zum Bundesanzeiger veröffentlicht.

Fußnote

(+++ Textnachweis ab: 1.8.2009 +++)

Eingangsformel

Auf Grund des § 4 Absatz 1 in Verbindung mit § 5 des Berufsbildungsgesetzes vom 23. März 2005 (BGBl. I S. 931), von denen § 4 Absatz 1 durch Artikel 232 Nummer 1 der Verordnung vom 31. Oktober 2006 (BGBl. I S. 2407) geändert worden ist, verordnet das Bundesministerium für Wirtschaft und Technologie im Einvernehmen mit dem Bundesministerium für Bildung und Forschung:

§ 1 Staatliche Anerkennung des Ausbildungsberufes

Der Ausbildungsberuf Pharmakant/Pharmakantin wird nach § 4 Absatz 1 des Berufsbildungsgesetzes staatlich anerkannt.

§ 2 Dauer der Berufsausbildung

Die Ausbildung dauert drei Jahre und sechs Monate.

§ 3 Struktur der Berufsausbildung

Die Berufsausbildung gliedert sich in:

1. Pflichtqualifikationen nach § 4 Absatz 2 Abschnitt I Nummer 1 bis 10,
2. vom Auszubildenden festzulegende Wahlqualifikationen nach § 4 Absatz 2 Abschnitt II Nummer 1 bis 16 im Umfang von insgesamt 72 Wochen; dabei sind aus den Wahlqualifikationen nach den Nummern 1 bis 3 mindestens zwei und aus den Wahlqualifikationen nach den Nummern 4 bis 6 mindestens eine auszuwählen.

§ 4 Ausbildungsrahmenplan, Ausbildungsberufsbild

(1) Gegenstand der Berufsausbildung sind mindestens die im Ausbildungsrahmenplan (Anlage) aufgeführten Fertigkeiten, Kenntnisse und Fähigkeiten (berufliche Handlungsfähigkeit). Eine vom Ausbildungsrahmenplan abweichende sachliche und zeitliche Gliederung des Ausbildungsinhaltes ist insbesondere zulässig, soweit betriebspraktische Besonderheiten die Abweichung erfordern.

(2) Die Berufsausbildung zum Pharmakanten/zur Pharmakantin gliedert sich wie folgt (Ausbildungsberufsbild):

Abschnitt I: Pflichtqualifikationen nach § 3 Nummer 1

§ 2 Duration of training

The training lasts three years and six months.

§ 3 Structure of vocational training

The training is divided into:

1. Required qualifications according to § 4, number 2, Section I, number 1 to 10 ,
2. be determined by companies choice qualifications according to § 4, number 2, Section II, number 1 to 16 amounting to a total of 72 weeks Taking part from the electoral qualifications set out in numbers 1 to 3 and at least two of the electoral qualifications set out in paragraphs 4 to 6 to select at least one .

§4 education frame plan, vocational training requirements

Object of the professional training is at least the skills performed in the education frame plan (arrangement), knowledge and abilities (professional legal capacity). An objective and temporal arrangement deviating from the education frame plan of the education contents is in particular allowed, as far as company-practical specific features require the divergence.

The professional training to the pharmaceutical operator is made up as follows (vocational training requirements):

Assignment of the Content to the ULOs of Chemical Operator

Content	ULO 1 Perform operational logistics	ULO 2 Conduct processes	ULO 3 Participate in quality control	ULO 4 Participating in maintenance and repairs
1. Vocational training, labour legislation and rate right,	✓	✓	✓	✓
2. Construction and organisation of the education company,	✓	✓	✓	✓
3. Operational measures to the responsible action (Responsible Care):	✓	✓	✓	✓
3.1 Security and health protection at the work,	✓	✓	✓	✓
3.2 Environment protection,	✓	✓	✓	✓
3.3 Quality management,	✓	✓	✓	✓
3.4 Start from energy sources,	✓	✓	✗	✓
3.5 Handle with working devices and means including care and servicing,	✓	✓	✓	✓
3.6 Costs-oriented action;	✓	✓	✓	✓
4. Labour organisation and communication:	✓	✓	✓	✓

ChemPharmVET

Content	ULO 1 Perform operational logistics	ULO 2 Conduct processes	ULO 3 Participate in quality control	ULO 4 Participating in maintenance and repairs
4.1 Planning and controlling of process , operations and workflows	✓	✓	✓	✓
4.2 Duties solve in the team,	✓	✓	✓	✓
4.3 Procurement of information,	✓	✓	✓	✓
4.4 Communication systems and information systems;	✓	✓	✓	✓
5. Handle with pharmaceutical-specific working materials,	✓	✓	✓	✓
6. Determine from material constants and material qualities,	✓	✓	✓	✗
7. Pharmaceutical process engineering,	✗	✓	✗	✗
8. Measuring technology, control technology and control engineering,	✗	✓	✓	✗
9. Producing and packing of medicaments,	✗	✓	✗	✗
10. Storage	✗	✓	✗	✗

ChemPharmVET

Content	ULO 1 Perform operational logistics	ULO 2 Conduct processes	ULO 3 Participate in quality control	ULO 4 Participating in maintenance and repairs
1. Production and packaging of solid dosage forms,	✗	✓	✗	✗
2. Producing and packaging semi- solid and liquid dosage forms,	✗	✓	✗	✗
3. Producing and packaging of sterile dosage forms,	✗	✓	✗	✗
4. Galenics for solid dosage forms,	✗	✓	✓	✗
5. Galenics for semi-solid and liquid dosage forms,	✗	✓	✓	✗
6. Galenics for sterile dosage forms,	✗	✓	✓	✗
7. Maintenance of production equipment and control devices,	✗	✗	✗	✓
8. Instrumental analysis,	✗	✗	✓	✗
9. Planning, developing, organizing and ensuring of quality assurance measures,	✗	✗	✓	✗
10. Electrical work,	✗	✗	✗	✓
11. Examining and developing of packaging,	✗	✗	✓	✗
12. Logistics and storage,	✗	✓	✗	✗
13 production and packaging of diagnostic products,	✗	✓	✗	✗
14. Biotechnological drug recovery,	✗	✓	✗	✗
15. Producing and packaging therapeutic systems,	✗	✓	✗	✗
16. International competence.	✓	✓	✓	✓

Example of the Analysis of the Defined Paragraphs of the German Curricula

Line no.	Vocational training requirements	To be provided skills, knowledge and abilities	Temporal approximate values during weeks in the education		
			1. – 12. Month	13. – 18. Month	19. – 42. Month
1	2	3	4		
I.7	Pharmaceutical process engineering (§4 paragraph 2 Segment I Number 7)	a) Perform basic operations of pharmaceutical process technology, especially crushing, classifying, drying, filtration, distillation, extraction, homogenize, mix b) Apply microbiological techniques and methods for the bacterial count reduction	12		

a) Perform basic operations of pharmaceutical process technology, especially crushing, classifying, drying, filtration, distillation, extraction, homogenize, mix

ULO 2
Conduct processes



2) Handling of machinery:		
<ul style="list-style-type: none"> fundamentally understand the basics of production planning (including process optimization, work safety, quality management etc.) outline the process and names task steps explain basics of process balancing express fundamentals of the production process and its ideal conduct 	<ul style="list-style-type: none"> carry out the task schedule as it is intended. 	<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> identify basic operations and basic functions of the software 	<ul style="list-style-type: none"> estimate requirements for material against suppliers stock levels to ensure production targets use correct materials and hardware according to situation 	<ul style="list-style-type: none"> supervise autonomously adjust equipment settings to situational needs of the process and instructs co-workers in the process 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
<ul style="list-style-type: none"> identify specific requirements of the starting process according current process and situation 	<ul style="list-style-type: none"> handle machinery manually (and via screen) according to process specifications operate it-equipment like pcs, touch screens, joy sticks, printers 	<ul style="list-style-type: none"> autonomously decide on ramifications to start and stop the process safely instruct fellow workers on these ramifications assume responsibility for safety.
<ul style="list-style-type: none"> identify possible ways of filling and emptying the vessels technically correct relate how a research for application ranges is conducted 	<ul style="list-style-type: none"> research the application range of equipment on the internet and in reference books 	<ul style="list-style-type: none"> instruct team on the application range of the respective equipment supervise that the equipment is used in the prescribed way
<ul style="list-style-type: none"> relate the operation mode of the equipment and know how to shut it down 	<ul style="list-style-type: none"> write an appropriate protocol containing all results 	<ul style="list-style-type: none"> take responsibility for the documentation

Gap Analysis Example

1	2	3	4
II.1	Producing and packing firm medicament forms (§4 paragraph 2 Segment II Number 1)	<ul style="list-style-type: none"> a) describe solid drugs according to their pharmaceutical forms regarding development and application b) Grinding, screening, mixing and dispensing systems differ, operate and maintain by their Purpose c) Granulators, tablet presses, coating and painting plants and equipment d) different to make the capsules according to their capabilities, operate and maintain e) different devices for packaging of drugs in solid form, operate and maintain, check for monitoring and control facilities f) perform in-process control in the production and packaging of solid dosage forms 	12

Packaging

↓
inaccurately reported in the ULOs 

↓
Supplementary units of learning outcomes required

ULO 2 Conduct processes

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:

2.) Handling of machinery:

3.) Control of the working process:

4.) Finish process:

<i>Knowledge (theoretical + factual) Scientific Context Theoretical context</i>	<i>Skills (practical + cognitive (= use of knowledge)</i>	<i>Competence (Role and level of responsibility and autonomy)</i>
1.) Preparation of the process:		
2.) Handling of machinery:		
3.) Control of the working process:		
4.) Finish process:		

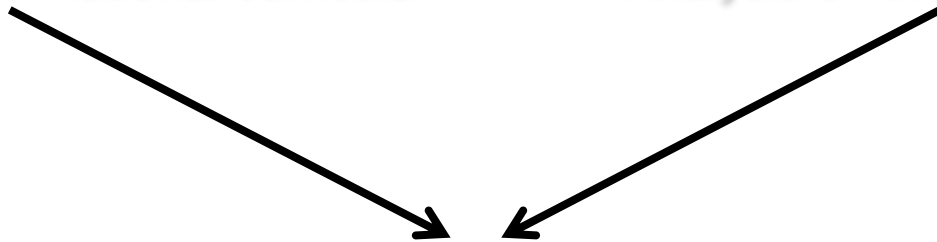
Example for Supplementary ULOs

<i>Knowledge (theoretical + factual) Scientific Context Theoretical context</i>	<i>Skills (practical + cognitive (= use of knowledge)</i>	<i>Competence (Role and level of responsibility and autonomy)</i>
4.) Finish process:		
<ul style="list-style-type: none"> • describe possible ways for packaging the products. 	<ul style="list-style-type: none"> • package the product technically correct according to product specifications and required regulations. 	<ul style="list-style-type: none"> • autonomously package the product according to the equipment specifics.
<ul style="list-style-type: none"> • relate requirements on the container according to respective stored product 	<ul style="list-style-type: none"> • choose the right container for the respective product, abiding by work place safety regulations 	<ul style="list-style-type: none"> • autonomously instruct team on the right containers for respective products • assume responsibility for the correct storing of products
<ul style="list-style-type: none"> • relate how and why to clean/ finish the product 	<ul style="list-style-type: none"> • clean/ finish the product correctly 	<ul style="list-style-type: none"> • autonomously instruct team on how to clean the products correctly

Next Steps

Completing analysis of national curricula

Analysis on the job work tasks



Mapping the results to the units of learning outcome and any necessary supplements



Defined units of learning outcome for pharmaceutical operator