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Competences for industrial pharmacy practice in biotechnology – PHAR-IN

PHAR-IN: Competences for industrial Pharmacy practice in biotechnology

Under / Postgraduate courses for the future

Vrije Universiteit Brussel

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A project funded by the EU: October 2013 through October 2015
EACEA (Education, Audiovisual and Culture Executive Agency)
http://phar-in.eu/

PHAR-IN is a follow-up to PHARMINE:
pharmacy education and training in Europe
that produced:

- a survey of PET in Europe
- a position paper on competences for industrial pharmacy practice

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AIM OF PHAR-IN

1. To develop the Delphi methodology for establishing and evaluating a competence framework for biotechnology practice
2. To propose a framework of competences in biotechnology for future and current industrial employees
3. To develop courses necessary for the acquisition of such competences

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PARTNERS

P3: EIPG (European Industrial Pharmacists' Group)
Luigi Martini (King's College Londen) and Jane Nicholson

P4: Faculty of Pharmacy, University of Catania (Italy)
Giuseppe Ronsisvalle

P5: Genzyme Belgium (biotech big pharma)
Gunther Pauwels

P6: Areta International (biotech SME)
Maria Luisa Nolli and Vitor Sousa

Associated partner: Vivien Moffat (EFPIA)
Advisory board: Keith Wilson (Aston University, UK)
Andries Koster and Annie Marcincal (EAFP)
Svetlana Kolundžić (EPSA)
External reviewer: Chris Van Schravendijk (VUB / Medine)

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PHAR-IN FLOW-CHART SUMMARY

Stage 1

- Creation of web tools for survey of EU biotechnologists
- Find out what courses are needed for biotech competences (subjects, pre- and post-graduate…)

Stage 2

- Develop courses for biotech competences (local / distance learning)
- Run and evaluate courses

Stage 3

- Publish papers on methodology, results, proposed competences…
- Final report to EU funding agency; possible audit

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TASKS / 5 WORK PACKAGES

P1/VUB – coordinator university

- Coordination of consortium; coordination with EACEA
- Financial matters / budget
- Use of Basecamp for management

P2/pcn – director consultant

- Run consortium
- Develop website & other dissemination material
- Develop surveymonkey and other tools

P3/EIPG - P4/UniCt university (others to join – EACEA amendment request for University of Utrecht)

- Develop , run and evaluate courses
- Maintain PHAR-IN after EU funding

P3/EIPG – P5/Genzyme – P6/Areta industry (others to join)

- Develop competence framework through Delphi
- Maintain PHAR-IN after EU funding; advertise and promote university CPD courses

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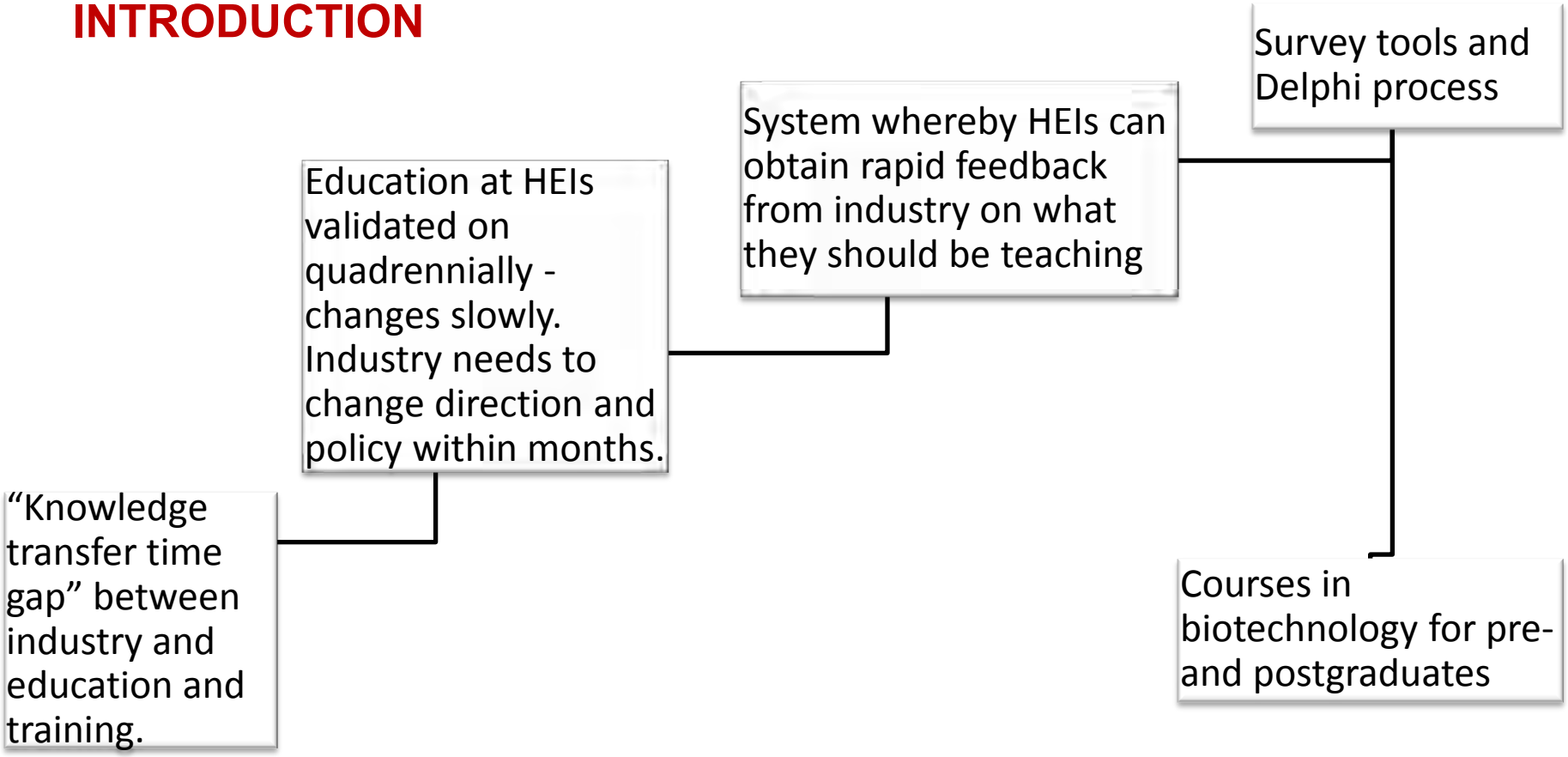
INTRODUCTION



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MAIN INNOVATIVE ASPECTS OF PHAR-IN

1. Interaction between universities, professional organisations and pharmaceutical industry,

⟹ both big pharma and biotechnological SMEs

2. Use of the Surveymonkey tool and Delphi methodology

3. Use of Basecamp for management

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APPLIED DELPHI METHODOLOGY

1	**INITIAL QUESTIONNAIRE**	- Production by **small expert panel** - Initial framework produced by Brian Gennery (King's College) and Patrick Crowley (Callum Consultancy) - Starting point to be modified in 3 consecutive rounds
2	**EVALUATION BY SMALL EXPERT PANEL**	- **Small expert panel** (consortium) - Panel providing rankings, comments [what is unclear, what is missing, in duplicate, etc…]
3	**MODIFIED QUESTIONNAIRE**	- Production of modified questionnaire based on rakings and comments of **small expert panel** in 3 rounds - 4th version for evaluation by large expert panel: **46 propositions for competences grouped into 13 categories**
4	**EVALUATION BY LARGE EXPERT PANEL**	- Large expert panel: industrialists, academia, pharmacists from other areas of the profession - Panel providing rankings and comments

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PHAR-IN SURVEY ON COMPETENCES FOR BIOTECHNOLOGY

1) Research and development
2) Preclinical sciences
3) Biological and advanced therapy
4) Clinical pharmacology
5) Clinical development
6) “Upstream” and “downstream” processing
7) Product development and formulation
8) Aseptic processing
9) Analytical methodology
10) Product stability
11) Regulation
12) Ethics and drug safety
13) Commercialisation

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METHODOLOGY LARGE EXPERT PANEL

- Internet / using Surveymonkey
- Participants came from all European countries
- To rank and comment upon the 46 proposed competences
- Using the uni-dimensional Likert method (scale 1-4)
- Score 1 (lowest) through 4 (highest)
- 'I am unable to rank this premise' / 'blank' (summed)
- Comments box at the end of each category (13)
- Evaluation between 10th July 2014 – 18th October 2014
- Statistics: ranking scores / non-parametric methods (Wilcoxon signed rank test)
- Comments were not analysed statistically

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The PHAR-IN survey on competences for biotechnology.

19. Aseptic Processing.

	1	2	3	4	I am unable to rank this premise
1. Understand microbiological principles as they apply to sterility assurance in biopharmaceutical manufacturing.	○	○	○	○	○
2. Understand unit operations in aseptic processing and design of facilities and utilities in sterile manufacturing suite.	○	○	○	○	○
3. Understand concepts of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) as applicable to the aseptic production, control, storage and handling of biopharmaceuticals.	○	○	○	○	○

Comments.

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5 GROUPS WITHIN THE LARGE EXPERT PANEL (n = 257)

- **54% (n = 140) were industrial employees**
- **36% industrial employees worked in SME, 35% in big pharma (29% others)**
- **76% pharmacy degree, 20% science degree, 4% medical degree**

Industrial employees in biotechnological environment (n = 82 ; 32%)	Other industrial employees (not biotech) (n = 58 ; 23%)	Persons working in regulatory affairs departments (n = 50 ; 19%)
Hospital pharmacists (n = 32 ; 12%)	Academics (n = 35 ; 14%)	

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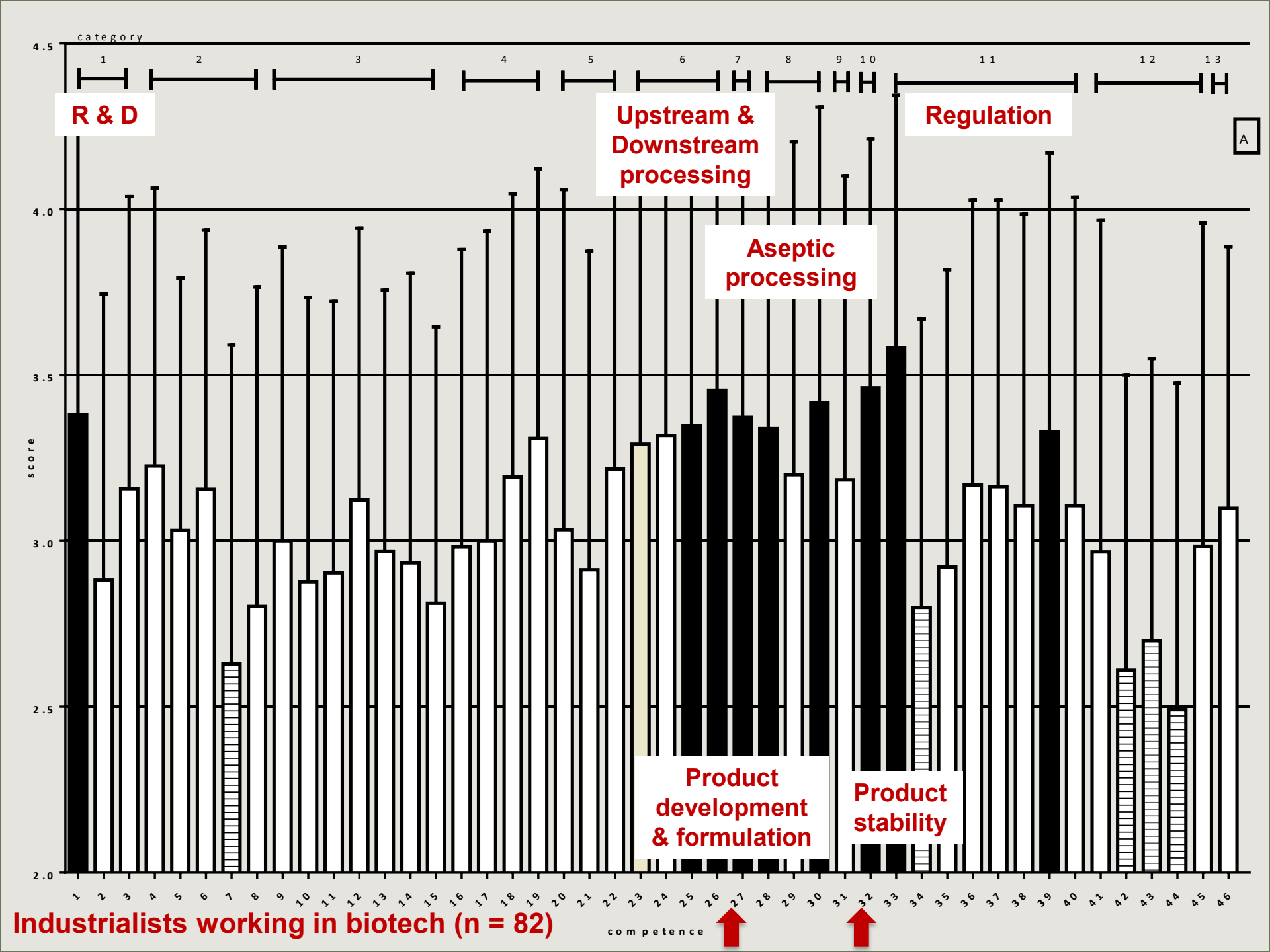
category
1
2
3
4
5
6
7
8
9
10
11
12
13
R & D
Upstream & Downstream processing
Regulation
A
Aseptic processing
Product development & formulation
Product stability
score
4.5
4.0
3.5
3.0
2.5
2.0
competence
Industrialists working in biotech (n = 82)

Group	Competences with scores above global mean according to category								Global means ± StDev (n)
	1 R&D	4 Clinical pharma-cology	6 Upstream and Downstream Processing	7 Product develop ment and formu-lation	8 Aseptic pro-cessing	10 Product stability	11 Regu-lation	13 Commer-cialisation	
Industrialists working in biotech (n = 82)	1		25, 26	27	28, 30	32	33, 39		3.09 ± 0.91 (n = 2926)
Industrialists not working in biotech (n = 58)	3	19	25		30	32	33, 40		2.95 ± 0.99 (n = 1909)
Regulatory affairs (n = 50)			23, 24, 25, 26	27	28, 29, 30	32	33		3.06 ± 1.00 (n = 1828)
Hospital pharm (n = 32)	3				30	32		46	2.93 ± 0.99 (n = 751)
Academics (n = 35)	NA	NA	NA	NA	NA	NA	NA	NA	3.12 ± 0.83 (n = 1305)

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RANKING OF COMPETENCES: HIGHEST SCORES

Category 1: "Research and Development – early phase studies"	Category 6: "Upstream and downstream processing"	Category 7: "Product development and formulation"
Category 8: "Aseptic processing"	Category 10: "Product stability"	Category 11: "Regulation"

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LOW SCORES FOR:

1) Research and development
2) **Preclinical sciences**
3) **Biological and advanced therapy**
4) Clinical pharmacology ***(high percentages of unable to score)***
5) **Clinical development**
6) "Upstream" and "downstream" processing
7) Product development and formulation
8) Aseptic processing
9) **Analytical methodology**
10) Product stability
11) Regulation
12) **Ethics and drug safety** ***(high percentages of unable to score)***
13) Commercialisation

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COMMENTS

Less than 2% - Comments were made on:

1) The clarity of the survey, e.g. regarding preclinical sciences *"your question is not clear enough to provide an answer"*
2) The context, e.g. regarding R&D *"I am not clear in what context you are asking these to be ranked"*
3) The specificity of biotechnology, e.g. regarding R&D *"not really specific to biotech products"*
4) The level in terms of foundation or specialist, e.g. *"I find the topics listed in each section to lack consistency in terms of 'general' and 'specialist' knowledge"*
5) The balance between the relative importance of different areas, e.g. regarding regulatory affairs *"fascinating that someone thinks there is more to discuss in regulation than in all other areas of development"*

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01/2014-12/2014

- Partners produce a list of **46 outcomes and competences divided into 13 categories** from their evaluation of the skills required for future developments and challenges in the biotechnology
- This is the basis for initial learning outcomes and competences in the first Delphi round
- Simultaneously PCN will produce
  a. **surveymonkey questionnaire**
  b. tools for **data output and analysis**
- An **expert panel** from EUFEPS, EAFP, EIPG and EFPIA will rank outcomes and competences, suggest changes to wording and missing outcomes or competences
- Evaluation between 10th July 2014 – 18th October 2014
- Consortium meeting early December 2014

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MAIN DELIVERABLES / OUTPUT SO FAR

1. Production of a framework for competences needed in biotechnology practice
2. Evaluation of this framework by industrialists
3. Published papers on PHAR-IN project:
   - European Industrial Pharmacy, issue 18, October 2013
   - European Industrial Pharmacy, issue 24, March 2015
4. Investigation into the ways of producing and delivering courses allowing participants to acquire the competences outlined in the final framework
5. Successful Delphi methodology (anonymous; no limitation on the possibility to participate; recruiting with a snowballing effect)

   → Avoiding that replies find their origin in the competences of the experts chosen

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- Development of courses by KCL / UniCt / Utrecht
- Necessary to further identify and specify the courses, needed for education and training of biotechnologists with respect to the selected competences
- To organize a round of (semi-)structured interviews
  - **Upstream/downstream processing**
  - **Product development and formulation**
  - **Aseptic processing**
  - **Analytical methodology**
  - **Product stability**
- Interviewees are being selected from both big pharma and SME in different European countries; including pharmaceutical technologists working in academia
- 15-20 interviewees

01/2015-06/2015

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INTERVIEW QUESTIONS

Introductory questions

1. Describe your own position in your own organization. What are your responsibilities with respect to the discovery, development and/or production, testing and dealing with regulatory matters related to biologicals?
2. Are you responsible for continuous professional development (CPD) activities for biotechnologists in your organization? If so, briefly describe these in-house CPD activities.

Identification of education and training needs

3. What are the major needs for education and training of biotechnologists in your organization, related to the competences 6-10 (see Introduction)?
4. What are the major training needs of individuals working in this area ('biopharmaceuticals'), when they have experienced little or no formal training in the field fo biopharmaceuticals?
5. Can these needs be met by in-house CPD activities? Do you think that there is a need for education and training programmes, organized by outside organizations (universities or European professional groups such as EIPG or EAFP)?
6. Supposing that EIPG and/or EAFP were offering education and training courses, would you be willing to stimulate and facilitate participation of your personnel in these courses?
7. What – in your opinion – is the most suitable institution (professional organization, university?) for accreditation of such courses?

Identification and specification of required courses

8. Do you have suggestions for the content of individual courses, which may be useful for the biotechnologists in your organization? Mention maximally three different courses.

If you have specified more than one course in question 8, the questions 9-12 are preferably answered for each course separately.

9. Do you have a preference for your staff to attend short, focussed courses or for more comprehensive, broader courses, or for them to aim at a Diploma or Master in Biotechnology? Please specify the anticipated study load (in hours or days).
10. Do you have a preference for lecture-based or interactive courses with teacher-participant and participant-participant interaction or for a mixture of both? Please specify your arguments.
11. Do you have a preference for face-to-face meetings (teachers and participants meet in person) or for online education (each participant follows his/her own trajectory)? Alternatively, 'blended education' a combination of online (with or without interaction) and face-to-face education can be used. Please specify your arguments.
12. What would be your preferred balance between theoretical aspects (theoretical concepts being presented, usually in the form of lectures) and practical aspects of the course (particants are involved in solving authentic problems or in designing and discussing real protocols)? Please specify your arguments.

Required competence level of recent graduates

13. Are you satisfied with the competency level (with respect to the competences, specified in the Introduction) of recently hired Pharmacy (M.Pharm., Pharm.D.) graduates?
14. If you are not completely satisfied, what is/are – in your opinion – the major deficit(s) in their training?
15. Are you of the opinion that these deficits can and/or must be remedied by changes in the (under)graduate curriculum?

Concluding questions

16. Are you willing to give feedback on more concrete course proposals, later this year?
17. Are you willing to give a short (filmed) interviewed for inclusion in the Phar-IN website, later this year?

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03/2015-09/2015

- Development of courses KCL / UniCt / Utrecht
- All course elements available online
- Two types of courses will be developed, run and evaluated:
  - Pre-graduate course (UniCt / Utrecht) – that can be integrated in a master programme
  - Post-graduate course (CPD) by KCL and staff of EIPG partner – that can be incorporated into various industrial topics offered by KCL. Suggestion of 2 modules: 1) Product development; and 2) Manufacture of biopharmaceuticals. Both modules can also build towards a master degree in biotechnology at KCL

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IMPORTANT ELEMENTS FOR ONLINE COURSES (MOOCs)

- Filmed lecture talks
- Availability slides
- Suggested reading (books, papers, online)
- Tutorials / homework
- Discussion board (interaction with and amongst students)
- Examination with validation

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TAKE HOME MESSAGE

The aim of PHAR-IN is to produce a panel of industrialists and educationalists that will propose the competences and outcomes required for education in biotechnology, of future and current employees of the pharmaceutical industry.

This project will have a substantial impact on employees of the drug industry providing them with the skills they need in a fast-changing world. This will impact on the competitivity of the European pharmaceutical industry.

The PHAR-IN consortium consisting of academics with a deep interest in industry and vice versa, will pave the way for more in-depth cooperation between industry telling academia which skills it requires in the future and academia producing people with such skills.

PHAR-IN will produce employees whose higher education will allow them to further enhance innovation and competitivity in the European pharmaceutical industry.

Ultimately the project will impact on the well-being of the European population through the R&D and production of safer, more effective, modern-day medicines.

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IN HONOR OF BART ROMBAUT†

He was Professor, Head of the school of Pharmacy and vice dean of the Faculty; but above all, a true and dear colleague who inspired the younger generation with his vision for the development of pharmacy education.

At our monthly FI meetings – as Chairman of the Educational board of Pharmacy – he always spoke enthusiastically about PHARMINE and PHAR-QA and PHAR-IN, and kept us updated about every project meeting.

Educational innovation, implementation of new curricula, research in PET, including gaming, problem based learning, project learning and line projects; were always on top of his priority list.

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