EMA Workshop on Framework of Collaboration with Academia

Presentation, June 15, 2016, London UK

The System and Academic Impact

Hans H. Linden, EUFEPS

“Unless researcher education and training, no research...”

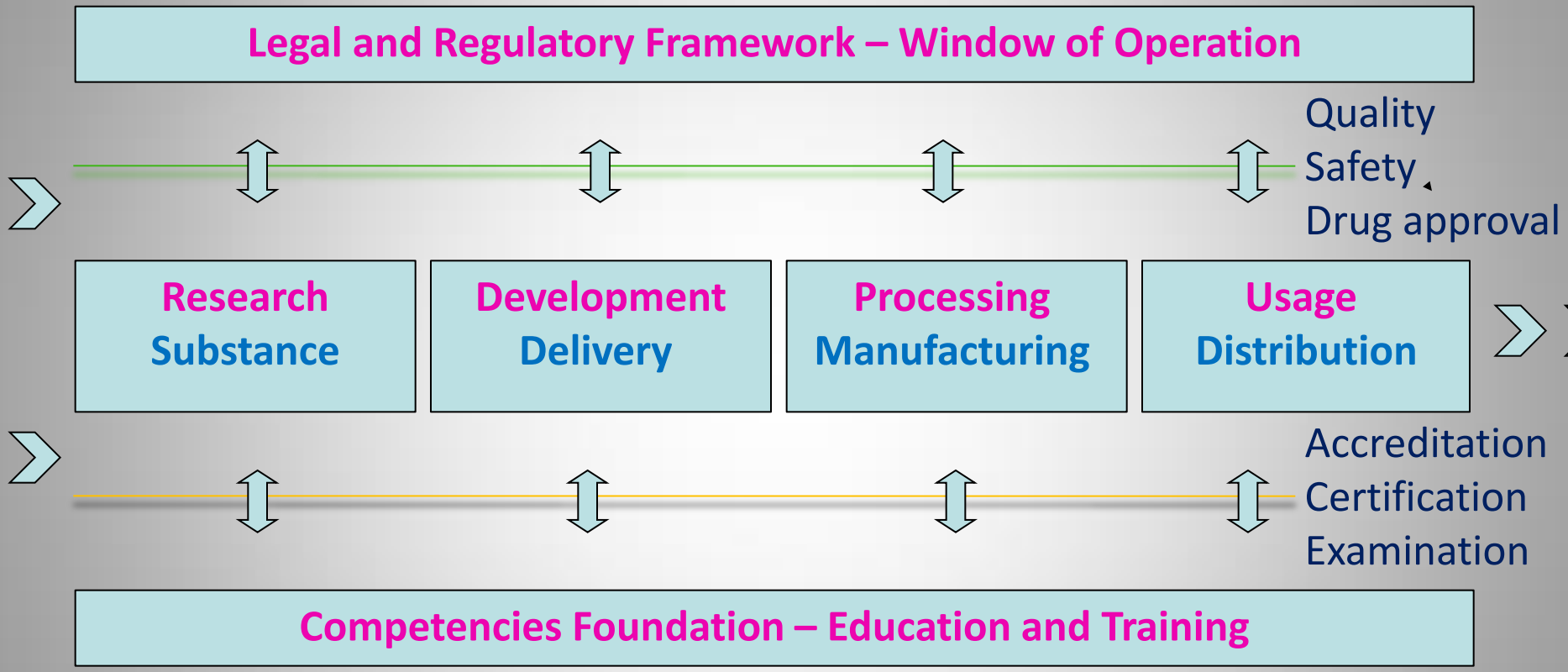
- **Academia provides the people, scientists and other professionals, with (start) competencies for many different roles**
- **Should academia also be even more active in participating in continuing professional development (CPD) to facilitate update and upgrade of future competencies needed?**
- **Should the “system” become more innovative as well; what would then be significant system approaches to make it happen?**
- **Or, would focus on one or a few components of it be sufficient?**
- **Either one, what old and new key competencies for whom when?**

➢ **Obviously, more focus on what competencies needed where, and on how to arrive there, in building an effective and efficient system for better medicines and health – in collaboration; takes leadership**

Medicines research, development, processing and usage …

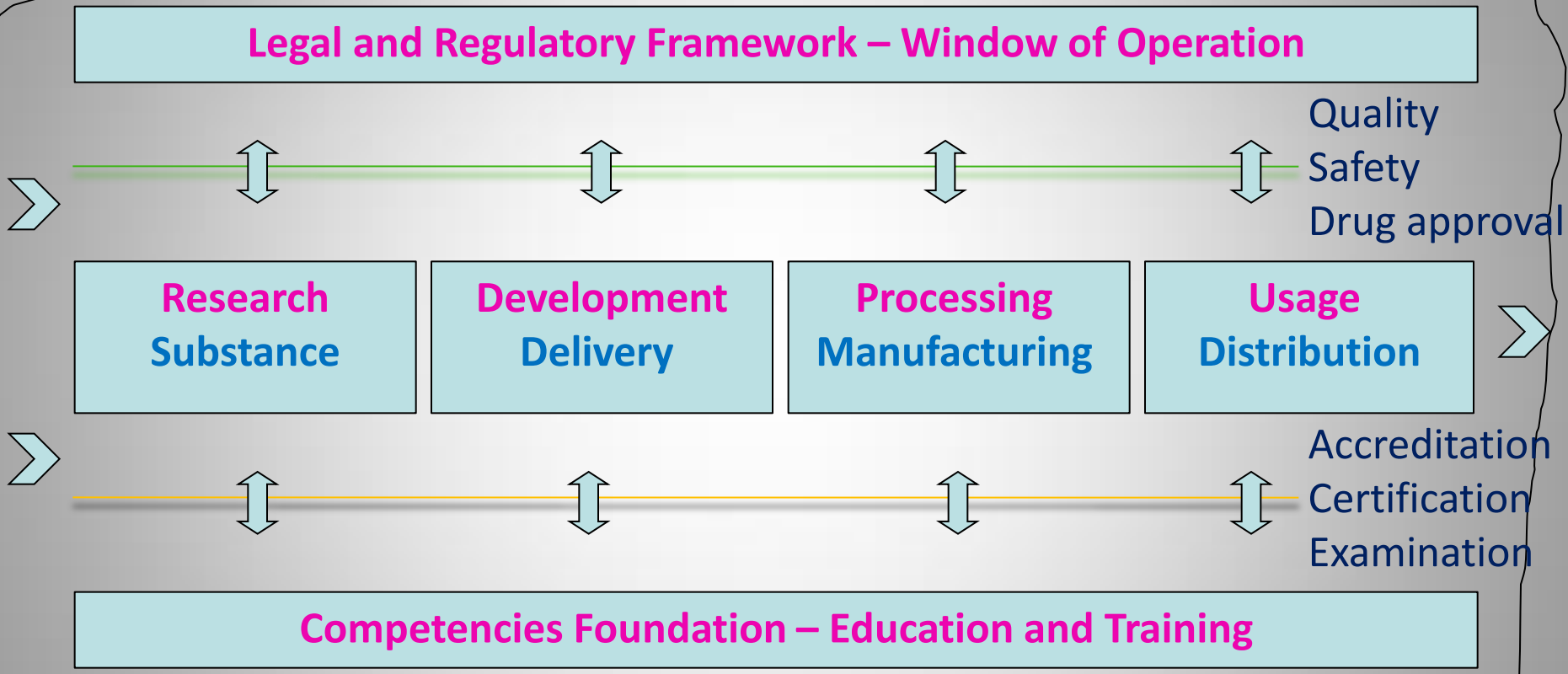
Research
Substance

Medicines research, development, processing and usage …



Qualitatively different phases and roles in drug discovery, development, processing and usage of medicines

Medicines research, development, processing and usage … … the system



Qualitatively different phases and roles in drug discovery, development, processing and usage of medicines

EUFEPS
European Federation for Pharmaceutical Sciences
the organisation

Associations of scientists/professionals in Europe (primarily) representing around 15.000 individuals

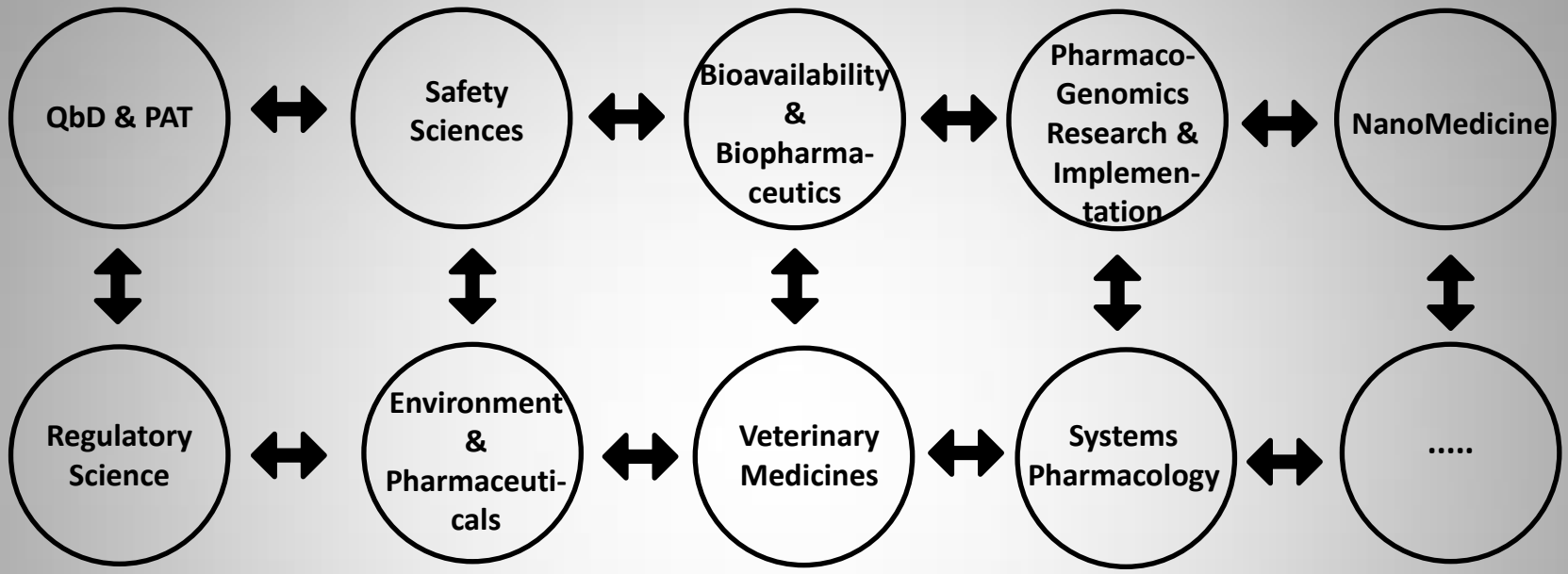
- **Member Societies**
- **Member Institutions**
- **Individual Members**

EUFEPS
the mission

"Advancing Sciences for Better Medicines and Health"

- Organisation of meetings and events
- Establishment of research networks
- Coordination of education and training
- Continuing scientific/professional development
- For a European research infrastructure of infrastructures
- Voice of scientists in medicines and health research
- Liaison with international organisations

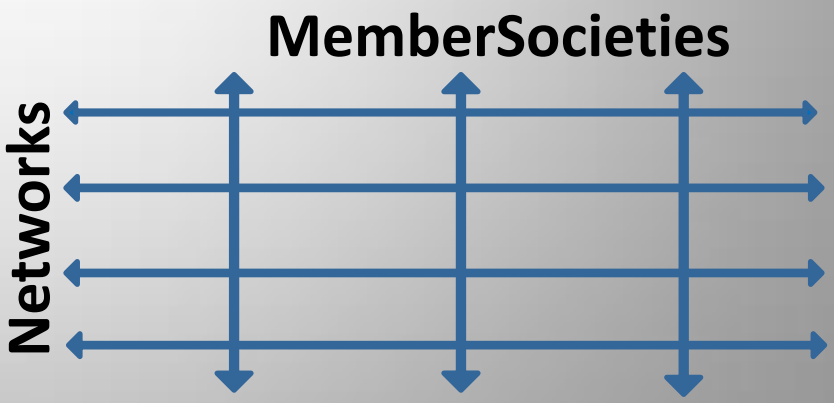
EUFEPS & networks



roles developing

- platforms for scientific exchange
- basis for research collaboration
- application for joint research grants
- collaborative education & training programs
- forum for strategy discussion and decision
- influence on science policy

towards a matrix organisation



Sample Regulatory Related Meetings

academia • industry • regulatory

EUFEPS aaps® Conference on

The Global Bioequivalence Harmonization Initiative: EUFEPS/AAPS Second International Conference

September 15–16, 2016

Hilton Washington DC/Rockville Hotel & Executive Meeting Center
Rockville, Md.

EBF

EBF & EUFEPS Workshop on:

EUFEPS

EMEA Draft Guideline on Validation of Bioanalytical Methods

April 15-16 • 2010 • Sheraton Hotel Brussels • Brussels • Belgium

Sample Regulatory Related Meetings

- academia
- industry
- regulatory

EUFEPS in IMI Education and Training

EMTRAIN

European Medicines Research Training Network

Eu2P

EUROPEAN PROGRAMME IN PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY

EUPATI

European Patients Academy on Therapeutic Innovation

PharmaTrain

MASTERING MEDICINES DEVELOPMENT

Pharmaceutical Medicine Training Programmes

SafeSciMET

European Modular Education and Training Programme in Safety Sciences for Medicines

IMI-TRAIN
Common Portal
Joint Project
2015-16
www.imi-train.eu

Safety is critical in launching and in using medicines

Meeting safety requirements calls for

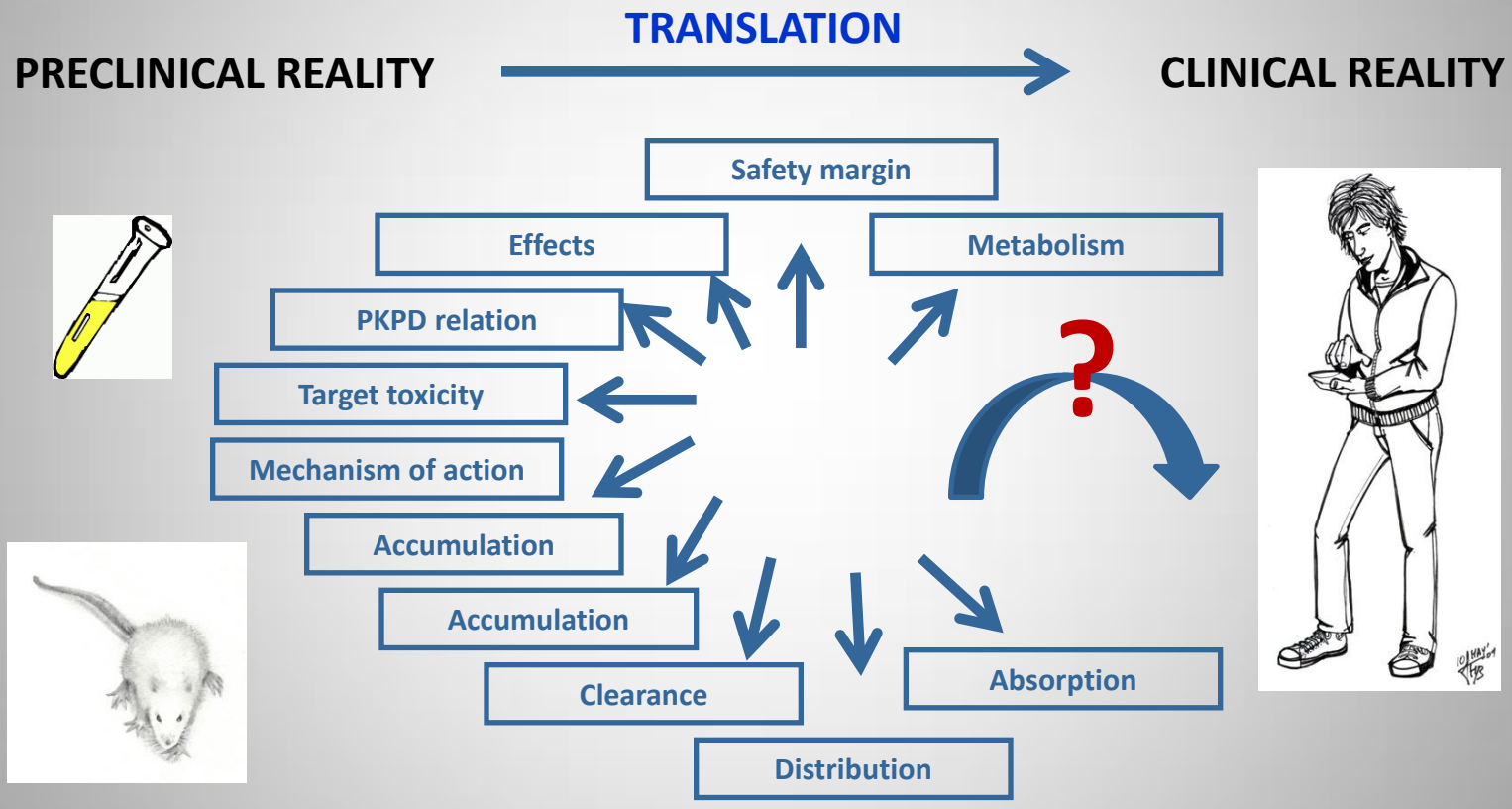
- **people with competencies in safety sciences**
- **taking advantage of cutting-edge knowledge**
- **applying it – and performing as individuals and teams**
- **in real-life situations**
- **all through the medicines' value chain**

meaning from discovery to pre-clinical development, onto clinical development and finally into end usage

The very endpoint of this "system approach" is good patient care and population health – and healthy health care systems as well

Safety Sciences

integration and translation



need to know, know how to - and do

Competencies at Work

Know – knowledge

Know how – applied knowledge

Show how – simulations

Do – real life performance

"A competency profile captures the knowledge, skills and behaviours that an individual requires to perform his or her role, i.e. in our case, in the position in the pharmaceutical value chain. By defining competency requirements, we will be better equipped to provide training that meets the needs of the professionals – (medicines) safety scientists becoming a recognised profession."

"What learning outcomes of courses and programmes contribute to update and upgrade of the competencies of an individual?"

Chaotic Behaviour

In addressing the competency issue – where to start?

A double rod pendulum animation showing chaotic behavior. **Starting the pendulum from a slightly different initial condition would result in a completely different trajectory.** The double rod pendulum is one of the simplest dynamic systems that has chaotic solutions.

http://en.wikipedia.org/wiki/File:Double-compound-pendulum.gif

IMI-TRAIN Task Force for Competencies in Safety Sciences for Medicines and Devices

Cath Brooksbank (EMTRAIN), European Bioinformatics Institute (EBI), Cambridge, United Kingdom

Philippe Detilleux (SafeSciMET), Sanofi, Paris, France

Sanja Dragovic (SafeSciMET), VU University, Amsterdam, The Netherlands

Annie Fourier-Réglat (Eu2P), University of Bordeaux, Bordeaux, France

Claire Johnson (EMTRAIN), European Bioinformatics Institute (EBI), Cambridge, United Kingdom

Hans H. Linden (SafeSciMET), European Federation for Pharmaceutical Sciences (EUFEPS), Stockholm, Sweden

Shirley Price (SafeSciMET), University of Surrey, Guildford, United Kingdom

Peter Stonier (PharmaTrain), King's College, London United Kingdom

Nico Vermeulen (SafeSciMET), VU University, Amsterdam, The Netherlands

Roles and Positions for
competencies in the pharmaceutical value chain

✓ Investigative toxicologist	Throughout value chain
✓ Other investigative scientist (e.g. discovery biologist; computational biologist)	Throughout value chain
✓ ADMET specialist (Absorption, Distribution, Metabolism, Excretion, Toxicity)	Throughout value chain
✓ Safety pharmacologist	Throughout value chain
✓ Study toxicologist (study director)	Throughout value chain
✓ Toxicologic pathologist	Throughout value chain
✓ Regulatory toxicologist	Throughout value chain
✓ Preclinical safety integrator/ Project toxicologist	Throughout value chain

Roles and Positions for competencies in the pharmaceutical value chain

✓ Safety physician	Development
✓ Chief Safety/Medical Officer, safety scientist, safety officer	Development and post-approval
✓ Safety nurse/pharmacist, associate pharmacovigilance officer, assistant pharmacovigilance officer	Development and post-approval
✓ Pharmacovigilance officer/Clinical assessment officer	Development and post-approval
✓ QP/PV (qualified person, pharmacovigilance)	Development and post-approval
✓ Pharmacoepidemiologist	Post-approval
✓ Medical director	Post-approval
✓ Regulatory Affairs Professional	Throughout value chain

Competency Levels & Reporting

Required competency level inidcated for each role

1 No Specific competency required

2 Cognitive competency required

3 Full competency required

Competency Domains or Areas

Common

1 Data analysis, interpretation and evaluation

2 Application of methods, procedures and standards

3 Interpersonal, management and leadership

Specific

4 Non-clinical science

5 Clinical science

6 Regulatory science

7 Safety surveillance and evaluation

Of these domains 1, 2 and 3 can be considered as common competencies. Domains 4, 5, 6 and 7 are more specifically related to safety sciences.

Competency Work Progress

- 37 competencies in safety sciences for medicines (in the medicines value chain) in 16 job roles identified and listed, categorised to 7 domains or areas
- In two consultation rounds, 150 experts and specialists have been invited to comment and provide input, in November 2015 and in early June 2016. Broad publicity of the outcomes being planned.
- Good input has been received – a few additional competencies, one additional job role, and competency level suggestions
- To take it one step further, professional bodies, employers, and individuals should be invited to join forces for a “safety sciences for medicines” certification body or system, ideally

Maintaining Professional Competence

Also suggests that every professional in the biomedical sciences needs to **develop and maintain** an optimal level of professional competence, to speed up the development of better medicines for patients

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Thank you!

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www.eufeps.org

European Federation for Pharmaceutical Sciences

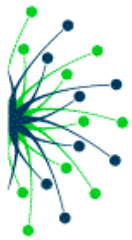
Established in 1991

Back up slides…

Competency

What is competency?

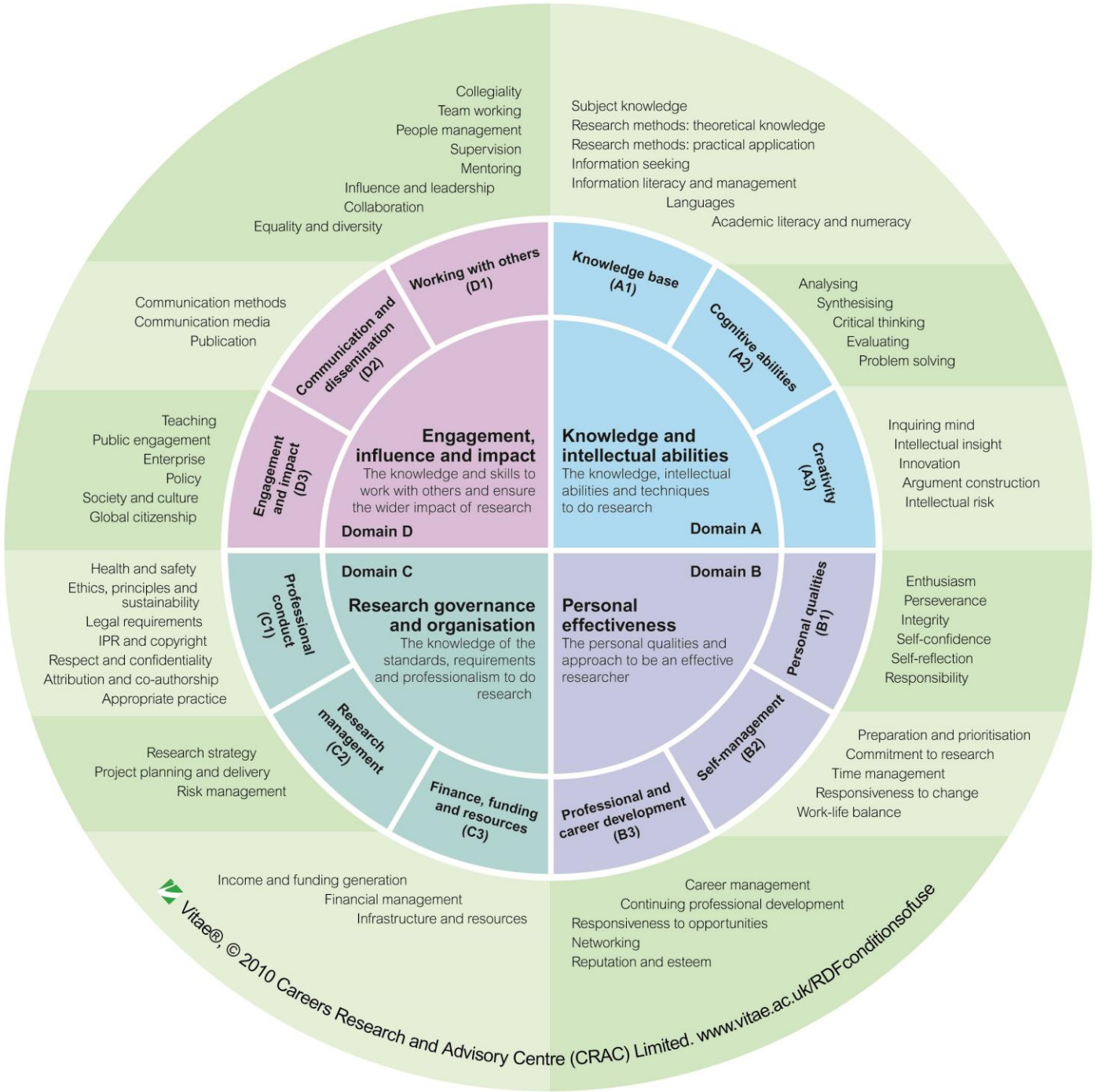
Competency is defined as “an observable ability of any professional, integrating multiple components such as knowledge, skills, values and attitudes.” Because competencies are observable, their acquisition can be validated objectively.



Sample Key Competencies

Chief Safety/Medical Officer, safety scientist, safety officer

Access, integrate and critically analyse data from multiple sources…
Identify research challenges and provide an independent perspective…
Demonstrate statistical and data analysis skills appropriate to the role…
Recognise the impact of medicines R&D on the well-being of patients…
Work autonomously, and as a team member…
Demonstrate initiative, capacity to work under pressure, and leadership...
Maximise utility of resources, fostering a culture of high standards…
Interact effectively with scientists in other functional areas…
Convey appropriate information about benefit–risk balance…
Participate in external collaborations as in the scientific community…
Foster a culture of training, mentoring and sharing of best practices…
Demonstrate familiarity with principles of product safety + application…
Contribute to development and validation of relevant new technologies…
Demonstrate high-level knowledge of global regulations…


Collegiality
Team working
People management
Supervision
Mentoring
Influence and leadership
Collaboration
Equality and diversity
Subject knowledge
Research methods: theoretical knowledge
Research methods: practical application
Information seeking
Information literacy and management
Languages
Academic literacy and numeracy
Working with others (D1)
Knowledge base (A1)
Communication methods
Communication media
Publication
Communication and dissemination (D2)
Cognitive abilities (A2)
Analysing
Synthesising
Critical thinking
Evaluating
Problem solving
Teaching
Public engagement
Enterprise
Policy
Society and culture
Global citizenship
Engagement and impact (D3)
Engagement, influence and impact
The knowledge and skills to work with others and ensure the wider impact of research
Domain D
Knowledge and intellectual abilities
The knowledge, intellectual abilities and techniques to do research
Domain A
Creativity (A3)
Inquiring mind
Intellectual insight
Innovation
Argument construction
Intellectual risk
Health and safety
Ethics, principles and sustainability
Legal requirements
IPR and copyright
Respect and confidentiality
Attribution and co-authorship
Appropriate practice
Professional conduct (C1)
Domain C
Research governance and organisation
The knowledge of the standards, requirements and professionalism to do research
Domain B
Personal effectiveness
The personal qualities and approach to be an effective researcher
Personal qualities (B1)
Enthusiasm
Perseverance
Integrity
Self-confidence
Self-reflection
Responsibility
Research strategy
Project planning and delivery
Risk management
Research management (C2)
Finance, funding and resources (C3)
Professional and career development (B3)
Self-management (B2)
Preparation and prioritisation
Commitment to research
Time management
Responsiveness to change
Work-life balance
Income and funding generation
Financial management
Infrastructure and resources
Career management
Continuing professional development
Responsiveness to opportunities
Networking
Reputation and esteem
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