Towards a Common Framework for Continuing Professional Development in the Biomedical Sciences*: A Concept Paper Based on the First IMI Education and Training LifeTrain Workshop, Manchester, 4-5 October 2011

Introduction

In recent years Europe has been struggling to prevent further erosion of its research infrastructure against a background of increasing competition from North America and Asia. Europe is spending 0.8% of GDP less than the US and 1.5% less than Japan every year on Research & Development (R&D). Thousands of our best researchers and innovators have moved to countries where conditions are more favourable. Although the EU market is the largest in the world, it remains fragmented and is not sufficiently innovation-friendly [1]. The Innovative Medicines Initiative (IMI) [2] and the European Strategy Forum on Research Infrastructures (ESFRI) in Biomedical Sciences (BMS) [3] were established to help Europe retain its position in biomedical research and development. There is still an urgent need to do more, and to do it more quickly.

One of the critical success factors is to strengthen the skills and competencies of European biomedical scientists and professionals in a rapidly changing environment (IMI Strategic Research Agenda) [4]. It is clear that in order to meet the demands for new cross-disciplinary skills, (e.g. bioinformatics, continuous processing, personalised medicine and modelling & simulation) and to adapt to increasing industry-academia collaborations, a different approach is required. This is being addressed by the IMI Education and Training projects, and an innovative strategy has been proposed; developing a European common framework for Continuing Professional Development (CPD) in the biomedical sciences*.

The development of such a framework requires close collaboration among relevant European professional/scientific bodies, employers, the ESFRI BMS, and relevant course providers. Owing to its strong relationships with the pharmaceutical industry, the relevant professional/scientific bodies, higher education institutes (HEIs) delivering QF-EHEA-compliant degrees [14] in the biomedical sciences, and professional course providers in academia and industry, IMI Education and Training is uniquely placed to work with these stakeholders towards a common framework for Continuing Professional Development (CPD) for medicines research. This initiative, which we call the LifeTrain initiative, is led by EMTRAIN in conjunction with the other IMI Education and Training projects. More information on the IMI Education and Training projects is available under www.emtrain.eu, www.eu2p.org, www.pharmatrain.eu, www.safescimet.eu.

The details of the proposed new European partnership for developing a common framework for CPD will be described below. This concept paper describes the outcome of the first IMI Education and Training LifeTrain workshop held in Manchester in October 2011. This workshop was attended by a broad range of European professional/scientific bodies (see Table 6 for list of participants, other contributors and the IMI Education and Training key players). Subsequent workshops will be held with the other stakeholder groups (employers, and academia/course providers) during 2012.

*) "Biomedical sciences" includes ALL science disciplines involved in the discovery, development, processing and usage of medicines research.

What do we mean by a common framework for CPD?

There is no standard definition of Continuing Professional Development. However, there is reasonable agreement about the overall principles. "Continuing Professional Development (CPD) is the means by which members of professional/scientific associations maintain, improve and broaden their knowledge and skills and develop the personal qualities required in their professional lives" [5].

There is an imperative for all scientists in the field of medicines' research and development to maintain their professional competency. This is driven by the rapid changes in science, the cross-disciplinary, team-working nature of modern science and the need for greater communication and collaboration across traditional boundaries. There is also huge variation in the types of scientists [6] required, yet traditional scientific training tends neither to recognise, nor to cater for, these differences. Successful scientists overcome these hurdles by taking responsibility for their own professional development. Traditionally in academia, publication of papers provided a record of the individual's contribution to a field. However, in fields that rely on collaboration among many players, whether in academia or in industry, we need more agile ways of tracking professional development than the accumulation of a publication record.

The way that CPD is currently addressed varies considerably across the different organisations and associations in Europe. It ranges from highly regulated, mandatory and comprehensive programmes of regular revalidation e.g. registered toxicologists [7], through similar, but voluntary programmes e.g. European Professional Biologist [8], to a range of programmes with greater or lesser degrees of guidance and control e.g. in learned societies. The range of different CPD activities and their value also varies considerably. CPD can include formal training courses, attendance at conferences, publications and mentoring; indeed, many professional/scientific bodies consider a mixed portfolio of activities to be indicative of well-rounded professional development. This works well for those who remain in a single profession, but presents quite a challenge for those who move discipline or change responsibilities. The lack of a common quality standard for developing new skills or competencies is a barrier to mobility and mutual recognition – pre-requisites for successful implementation of the European Research Area (ERA) [9]. Because there is no means of recognising prior learning, highly competent researchers moving from one setting to another often have to repeat training, at cost both to them and to their employers.

In an area such as medicines research and development, where success depends on the ability to cross disciplinary boundaries and understand the contributions that many fields make to the whole, there needs to be a shared understanding of professional competency among all the stakeholders. These stakeholders include: individual scientists; professional bodies; employers; academia and other course providers. In Europe, the emerging research infrastructures in the biomedical sciences (ESFRI BMS) represent a significant stakeholder group, both as course providers and as employers. Below we summarise the potential benefits of a common framework for CPD to each of the major stakeholder groups.

Individual scientists

Individual scientists are ultimately responsible for their own professional and career development. They have to plan for their current positions and for future career positions. However, to achieve this they need support from the other stakeholders. They would benefit by being able to identify training that is (1) relevant to their needs, (2) recognised by professional/scientific bodies of which they are members or potential members, and (3) meaningful to their employers, potential employers and peers.

Professional/scientific bodies and learned societies

Professional/scientific bodies support their members in a variety of ways. One of their activities is to provide guidance about their CPD requirements. As described above, these requirements differ between professional/scientific bodies, thus presenting a barrier to mutual recognition and mobility. Furthermore, there are no European quality standards for CPD courses. Unlike the European Credit Transfer and Accumulation System (ECTS) [10] for academic degrees, and The European Credit System for Vocational Education and Training (ECVET) [11] there is no mutually recognised 'currency' for CPD in the fields of interest of these professional/scientific bodies. Were such a 'currency' to be developed, professional/scientific bodies would be able to contribute towards shaping qualifications and competencies that are appropriate for scientists and professionals and relevant to industry and other employers. By working with academic course providers to provide such training, the bodies might guide members at an early stage of their career towards a successful career path, and empower established members with a strong track record to adapt to the changing needs of their professions. Other scientific bodies, associations and federations including learned societies, the European Science Foundation (ESF) and ESFRI BMS develop and provide guidance on state-of-the-art, cross-discipline science and achievements. The benefits of a common framework for CPD were discussed with representatives of 13 professional/scientific bodies and other key players at the first LifeTrain workshop in October 2011. Of the many potential benefits identified, the most widely agreed upon are summarised in table 3.

Employers

Employers need to be able to define the competency profile for individual jobs. A common framework for CPD would enable employers to identify new postholders with prior learning that was relevant to their role. They would also be able to send existing staff members on e.g. short courses that would fill immediate skills gaps and would not entail employees taking large periods of time out of the workplace.

Course providers

Course providers have to be able to provide flexible, high quality courses to address the needs of industry, regulatory authorities, academic staff and other contributors. **Universities** have centuries of experience of providing high quality education and training that prepares individuals for their chosen vocation. If similar quality principles could be applied to CPD, this could enhance the attractiveness of Europe to high-calibre professionals. Although the European Universities signed a

charter for Lifelong Learning in 2008 [12] this has not yet been fully implemented. The charter includes the following chapter:

> *"2. Providing education and learning to a diversified student population.*
>
> *European universities will respond positively to the increasingly diverse demand from a broad spectrum of students – including post secondary students, adult learners, professionals who seek to up-grade skills for the workplace, senior citizens taking advantage of their increasing longevity to pursue cultural interests, and others – for high quality and relevant higher education throughout their lifetime."*

A common framework for CPD in the biomedical sciences would encourage sharing of expertise among Higher Educational Institutes (HEIs) and between professional/scientific bodies and HEIs. This would help HEIs to fulfil their agreements in the Charter for Lifelong Learning and could also bring welcomed revenue to HEIs. More importantly, it could help to forge interactions between students at the beginning of their career and mid-career students, with benefits to both.

The emerging **Research Infrastructures** [3] in biomedical science will all provide training for their users. They also need to train scientists and professionals to run the infrastructures, all of which constitute a significant pan-European expansion of existing infrastructures. The ESFRI-BMS projects recognise that a common framework for CPD would enable them to collaborate better with each other, sharing the burden of education and training and developing appropriate learning pathways for users of the infrastructures.

Much professional training is performed by **training companies**, which are often SMEs. It is hard for employers to identify appropriate trainers, and harder still to judge the quality of the training that they offer without investing significant time and effort in running pilot courses. Participation in a common framework, with recognised quality standards, might make this process more reliable and straightforward.

Funders, policymakers and society

The EU has invested significant time and effort in developing qualifications frameworks for higher education (HE) and for vocational education and training (VET). By basing its own recognition system on European reference frameworks for qualifications, the Innovative Medicines Initiative (IMI) would capitalise on this existing experience. There would be no need to reinvent the wheel, and the IMI Education and Training framework for CPD would be compatible with national and pan-European frameworks in both the VET and HE arenas. The framework would be extensible to new IMI Education and Training initiatives with different target audiences. IMI Education and Training could provide a compelling success story for Europe by contributing towards a mobile workforce and economic success.

A customised new proposal

We propose a 4-pronged approach to support individual scientists. The four prongs are:

1. The Professional/Scientific bodies
2. The Research Infrastructures
3. The Employers
4. Academia and other Course Providers

The IMI Education and Training projects have developed a comprehensive strategy to address the above points. A set of quality standards for CPD courses has been developed and published [13] We propose a series of draft charters (shown in tables 1, 4 and 5), in which these quality standards can be included, and which should be further developed in partnership with the relevant stakeholders. A core feature would be the individual's competency portfolio which would, as presented by the individual, become transparent to all stakeholders by virtue of the quality standards and a 'currency' for CPD. We believe that these are of fundamental importance in building the foundation for CPD which would help Europe retain its position in biomedical research and development and bring new, better and safer medicines to patients more quickly.

What is needed to develop the framework?

Extensive consultation with stakeholders

Our first step towards shaping a common framework for CPD is extensive consultation with the major stakeholder groups identified above. The first LifeTrain workshop provided an excellent opportunity to gather input from 13 professional/scientific bodies and additional contributors and key players, listed in Table 6. Over the coming year, we plan to hold similar events with other major stakeholder groups. Each group will construct a charter, outlining their agreed position regarding the common framework.

Course quality: the bedrock of the framework

Another important factor in making the framework operable is a shared understanding of what we mean by course quality. The current IMI Education and Training projects have already contributed to our thinking in this regard, by defining a set of quality standards (Table 2). These were initially developed to help the IMI Education and Training programmes identify units of training developed elsewhere that might contribute to IMI Education and Training curricula. They are now gaining wider use in IMI EMTRAIN's course catalogue, on-course®. Any course provider entering information into on-course® is asked to indicate which of the nine quality criteria apply to their courses. This information is then transparent to course seekers.

Currency for mutual recognition of training

Another element to the framework, which will be essential if different course providers, employers and professional/scientific bodies are to recognise an individual's portfolio of competencies, is either a common 'currency' for training credits, or a 'currency converter' that allows comparison of the local credit system with course credits gained elsewhere.

Such systems already exist in Europe: the European Qualifications Framework (EQF) [14] acts as a translation device to make national qualifications more readable across Europe, promoting workers' and learners' mobility between countries and facilitating their lifelong learning. The EQF aims to relate different countries' national qualifications systems to a common European reference framework. Its goal is to help individuals and employers to better understand and compare the qualifications levels of different countries and different education and training systems. The core of the EQF concerns eight reference levels describing what a learner knows, understands and is able to do – 'learning outcomes'. Levels of national qualifications are placed at one of the central reference levels, ranging from basic (Level 1) to advanced (Level 8). This facilitates comparison between national qualifications and should also mean that people do not have to repeat their learning if they move to another country. The EQF applies to all types of education, training and qualifications, from school education to academic, professional and vocational. For higher education, the Qualifications Framework of the EHEA (QF-EHEA or Bologna Framework) [15] performs a comparable role, covering the top three levels of the EQF. The credit transfer currency of the QF-EHEA is the European Credit Transfer and Accumulation System (ECTS) [10].

Many professional/scientific bodies have their own credit systems and these encompass a wide range of different activities providing evidence that an individual maintains their competency. Whilst some of this might involve formal learning, informal learning is considered to be an important part of the equation: attending conferences, writing papers and teaching others are typical examples.

What is missing here is the ability to translate (and transfer) these credit points in any meaningful way – either among different national professional/scientific bodies, or among bodies that serve different, but closely related fields. Both are necessary if we are to achieve Europe's goals for geographical and inter-disciplinary mobility. Another much cited shortfall of current systems is that they do little to differentiate the excellent from the average, hence IMI Education and Training's emphasis on mutual recognition of **high quality** professional development.

Testing the framework

Once we have reached a shared understanding, among all major stakeholders, of the concept of a common framework for CPD in the biomedical sciences, we will need to provide support for them to understand, pilot and adopt the framework, and a means for it to evolve in line with the needs of its stakeholders.

Outcomes of Discussions with Professional/Scientific Bodies:
Summary of the First LifeTrain Workshop

Background:

Since the IMI Education and Training projects began in 2009 we have had extensive informal discussions with representatives of all our stakeholder groups. The first LifeTrain workshop gathered training experts from professional/scientific bodies relevant to all stages of medicines research and development. Wherever possible, we invited professional/scientific bodies with a pan-European and/or international outlook, reflective of our goals to improve the mobility of professionals and researchers. The goals of the workshop were:

1. Explore and agree an overall strategy for CPD, which we would then incorporate into a draft charter for professional/scientific bodies
2. Discuss and agree on the use of the IMI Education and Training shared standards for course quality and on how certified courses will be identified in the on-course® catalogue
3. Identify the benefits to professional/scientific bodies of the common framework. (Table 3)

Achievements:

Although we had already begun to identify some of the building blocks of the common framework, our discussions began to lay the foundations. The draft charter for professional/scientific bodies outlines the principles that the majority of participants in the workshop agreed upon:

1. Explored and agreed the overall strategy for CPD
    1. As described in the underlying concept paper

2. Discussed and revised the draft charter for Professional /Scientific Bodies (Table 1)

Table1. Draft Charter for Professional/Scientific Bodies

- The professional/scientific bodies present at the workshop support the development and implementation of a European common framework for continuing professional development in lifelong learning. The framework should facilitate the all-round professional development of the individual by recognising learning in a range of different contexts (formal and informal), and by encouraging the development of leadership skills in addition to scientific competency.
- They will encourage maintenance of professional competency as a pre-requisite for continuing membership, including continuing certification/registration
- They will support their members to develop and maintain a competency portfolio.
- They will recognise the importance of trans-disciplinary and generic competencies.
- They will mutually recognise competencies from all partner professional/scientific bodies.
- They will implement the shared IMI Education and Training standard for course quality and certify courses that fulfil the appropriate criteria.
- They will include a rigorous process to monitor compliance.

3. Discussed and agreed the use of the IMI Education and Training Quality Standards (Table 2) in the on-course® course catalogue (www.on-course.eu)

    a. Not all the quality standards are equally important to all professional/scientific bodies
    b. on-course® will indicate which standards are met by each course

In a breakout session during the workshop, delegates explored the shared IMI Education and Training standards for course quality and voted on those that they felt were most important. This process revealed that not all the quality standards were equally important to the professional/scientific bodies represented at the workshop. Table 2 highlights the quality standards that received support from the majority of participants. The session concluded that the common framework for CPD should be sufficiently broad to cover all types of professional development, not just formal learning in the context of courses. The participants recognised that the IMI shared standard on course quality had been developed specifically for courses and acknowledged that a subset of these criteria might also be applicable to other types of CPD. They agreed that, as on-course® will indicate which standards are met by each course, professional/scientific bodies would certify courses according to the standards that are agreed upon. The session also concluded that compliance with the framework would have to be reviewed or audited, with loss of credit for non-compliance.

Table 2. IMI Education and Training Quality Standards

A formalised and transparent QA/QC policy that includes the following:

- University accreditation OR a suitable system for approving, monitoring and reviewing the training offered.
- A system for quality assurance of teaching staff.
- Regular review of the QA/QC process and demonstration that the training is further developed in light of this review.

A set of documented criteria for individual modules, courses or course programme that include the following:

- Defined and transparent admission criteria.
- A predefined set of teaching objectives, leading to defined learning outcomes.
- The facilities, infrastructure, leadership and competencies available for the support of student learning should be adequate, appropriate and up to date for the training offered.
- Assessment of the students' achievement in accordance with the agreed learning outcomes of the training offered.
- A system for collecting, assessing and addressing feedback from learners, teachers, technical/administrative staff and programme/course/module managers.
- Availability of appropriate and updated reference material (e.g. Published articles, links, book chapters, scripts, etc)

4. Discussed and agreed the identification of certified courses in the on-course® catalogue

    a. Where consensus is not critical, professional/scientific bodies can certify courses according to which standards are important to them

5. Identified the benefits for the professional/scientific bodies (Table 3)

    A second breakout session identified the stakeholders for the common framework and began mapping the benefits to them, with an emphasis on the benefits to professional/scientific bodies. The group identified the following as the highest priority benefits to professional/scientific bodies:

Table 3. Benefits to Professional/Scientific bodies

Benefit to Professional/Scientific bodies
Partnership in the common framework would provide the critical mass for dialogue with other stakeholders (for example, employers and course providers) and would build a pan-European platform for exchange of expertise in professional development.
A set of agreed standards for CPD courses would in itself be a benefit of the framework as it would allow mutual recognition of competencies among the key players in professional development.
The framework would allow a better match of professional competencies and skills with the needs of the business sector; this would improve the attractiveness of medicines research and development careers for the brightest and best individuals.
The framework would help to protect and improve reputation of professions in the field.
A shared currency for CPD would facilitate trans-disciplinary recognition and support change and mobility.
The framework would provide comprehensive support for members of professional/scientific bodies, enabling professional/scientific bodies to flexibly meet the needs of the individuals.
Professional/scientific bodies would be supported to advance their professions in line with developments in science and technology, and to look after the interests of scientists and other relevant professionals throughout Europe.

6. Agreed the next steps for implementation

    a. Development of a concept paper to describe the views of the professional/scientific bodies and gain additional input

    b. Cascade information to the individual member associations

    c. Plan a follow-up workshop in 2012 where all relevant stakeholder groups will come together to develop the European common framework for CPD.

Questions for consultation

1. **Does your organisation want to be involved in the further development of the common framework for CPD?**
2. **Which elements of the draft charter (Table 1) do you agree with, in principle, and which do you not agree with?**
3. **Which elements of the charter would your organisation not be able to implement now?**
4. **Which elements of No. 3 above would you be prepared to discuss internally and see if you could support in the future?**
5. **Any further comments**

Conclusion

This concept paper reflects the outcome of the workshop. It does not indicate that all the professional/scientific bodies agreed with, or are able to implement, all the elements of the revised charter. This will form the basis for broader consultation.

In the first LifeTrain workshop we established there was a common desire across the professional/scientific bodies to work together to support all scientists in Europe, working in the area of medicines research and development. The charter was amended and will continue to be developed after further consultation with the individual partner and member organisations.

A number of small working parties will be set up to address specific challenges.

The IMI Education and Training quality standards were discussed and their use in the on-course® database was agreed.

The professional/scientific bodies and associations were supportive of the use of on-course® and can indicate which courses fulfil their requirements for CPD and can be identified in on-course® as certified* courses.

Further work is underway to develop the common framework which will include all relevant aspects of CPD and not just be restricted to courses.

In parallel, work is being undertaken with the other stakeholder groups (employers, academia/course providers, learned societies and the ESFRI BMS). All of this will be brought together in the next IMI Education and Training LifeTrain workshop planned for October 2012.

*certified in this context refers to the current process by which a professional/scientific body indicates that a course fulfils its requirements for CPD. This will be indicated in on-course®

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Appendix

Table 4. Draft Charter for Employers

- Provide input to the development of life-long learning requirements, to ensure employer needs are addressed
- Recognise the requirements of professional/ scientific bodies and support staff in maintaining life-long learning competency portfolios
- Include life-long learning in individual development plans and as part of the performance appraisal
- Recognise the value of high quality IMI Education and Training and preferentially recommend them for training
- Advise future employees about the importance of maintaining professional competency and include life-long learning requirements in job adverts
- Recognise the value of competency portfolios in career development and reward accordingly

Table 5. European Universities Charter on Lifelong Learning (2008) www.eua.be

- Embedding concepts of widening access and lifelong learning in their institutional strategies
- Providing education and learning to a diversified student population
- Adapting study programmes to ensure that they are designed to widen participation and attract returning adult learners
- Providing appropriate guidance and counselling services
- Recognising prior learning
- Embracing lifelong learning in quality culture
- Strengthening the relationship between research, teaching and innovation in a perspective of lifelong learning
- Consolidating reforms to promote a flexible and creative learning environment for all students
- Developing partnerships at local, regional, national and international level to provide attractive and relevant programmes
- Acting as role models of lifelong learning institutes

Table 6. Participants and other Contributors

1. **EACPT** European Association of Clinical Pharmacology and Therapeutics*
2. **EAFP** European Association of Faculties of Pharmacy*
3. **EAPB** European Association of Pharma Biotechnology
4. **ECRIN** European Clinical Research Infrastructure Network
5. **EFMC** European Federation of Medicinal Chemistry
6. **EMBO** European Molecular Biology Organization*
7. **EPHAR** Federation of European Pharmacological Societies *
8. **EMRC/ESF** European Medical Research Council/European Science Foundation*
9. **EUFEPS** European Federation for Pharmaceutical Sciences*
10. **EUROTOX** European Federation of Toxicologists & European Societies of Toxicology
11. **IFAPP** International Federation of Associations of Pharmaceutical Physicians*
12. **ECBA** European Countries Biologists Association*
13. **RSC** Royal Society of Chemistry*
14. **Society of Biology***
15. **TOPRA** The Organisation for Professionals in Regulatory Affairs*
16. **EIPG** European Industrial Pharmacists Group*
17. **PSI** Statisticians in the Pharmaceutical Industry*
18. **ISOP** International Society of Pharmacovigilance
19. **ISPE** International Society for Pharmacoepidemiology*
20. **EFB** European Federation of Biotechnology
21. **ISPE** International Society for Pharmaceutical Engineering
22. **ESCP** European Society of Clinical Pharmacy
23. **GA** Society of Medicinal Plant Research
24. **EPSA** European Pharmaceutical Students Association

EMTRAIN*, SafeSciMET*, PharmaTrain* and Eu2P* key players

*Represented at the first LifeTrain Workshop, Manchester, 4-5 October 2011

Glossary

BBMRI: Biobanking and Biomolecular Resources Research Infrastructure.

Biomedical sciences: include **ALL** science disciplines involved in the discovery, development, processing and usage of medicines research and development

CPD: Continuing Professional Development

Certified: The process by which professional/scientific bodies indicates that a course fulfils its requirements for CPD

ECRIN: European Clinical Research Infrastructure Network

EATRIS: European Advanced Translational Research Infrastructure

ECTS: European Credit Transfer and Accumulation System

ELIXIR: European infrastructure for biological information to support life science research

EMRC: European Medical Research Council

EMTRAIN: European Medicines Research Training Network

EQF: European Qualification Framework

ERA: European Research Area

ESFRI BMS: European Strategy Forum on Research Infrastructures in Biomedical Sciences

ESF: European Science Foundation

Eu2P: European Programme in Pharmacovigilance and Pharmacoepidemiology

GDP: Gross Domestic Product

HEI: Higher Education Institutes

IMI: Innovative Medicines Initiative

Infrafrontier: European Infrastructure for Phenotyping and Archiving of Model Mammalian Genomes

INSTRUCT: Integrated Structural Biology - Research Infrastructure

LifeTrain: IMI Education &Training Lifelong Learning project

on-course®: is an EU registered trade mark belonging to the Medical University of Vienna for a pan-European course catalogue and resource centre for biomedical and drug development sciences

PharmaTrain: Pharmaceutical Medicines Training Programme

QA: Quality Assurance

QC: Quality control

QF-EHEA: Qualifications Framework of the European Higher Education Area

R&D: Research and Development

SafeSciMET: European Modular Education and Training Programme in Safety Sciences for Medicines

VET: Vocational Education and Training