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European initiative towards quality standards in education and training for discovery, development and use of medicines ☆

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ABSTRACT

This position paper recommends a set of standards for quality assessment of continuing professional development (CPD) for medicines research and development (R&D). We have developed these standards to help us achieve the education and training goals of the Innovative Medicines Initiative (IMI; www.imi.europa.eu/), which is developing courses to address the skills gaps in European medicines R&D. The IMI shared standard for course quality will enable professionals in medicines R&D to create a personalized portfolio of education and training that best suits their needs. Individuals already working in the pharmaceutical industry will be able to select modules for study on an as-needs basis, which may be combined to gain a qualification that is recognized throughout Europe. By seeking input from the medicines R&D community, especially professional bodies involved in the career development of biomedical scientists, we hope to initiate the creation of a mutually recognized framework for lifelong learning in medicines R&D. The shared standards call for defined and transparent admission criteria, a predefined set of teaching objectives leading to defined learning outcomes, assessment of the students' achievement, a system for collecting, assessing and addressing feedback, and provision of appropriate and updated reference material. This framework will make it easier for professionals to develop the skills required by industry, and easier for employers to recognize professionals with appropriate skills. It will obviate some of the need for retraining personnel who have already developed appropriate skills in a different setting, thereby saving the industry additional effort. Fulfilment of quality standards by course providers will be made transparent within the IMI's catalogue of courses, on-course (www.on-course.eu), which will be made publicly available during 2012

1. Introduction

The pharmaceutical industry needs highly skilled professionals who understand cutting-edge technologies and life sciences disciplines to adequately perform and deliver their research and development (R&D) activities. Industry also needs to be able to support the continued professional development (CPD) of employees, who often have to re-skill in a rapidly moving business. Uptake of new science in academic teaching is not happening quickly enough. As a result of this, some pharmaceutical companies have individual initiatives to establish training courses to address their needs; others simply relocate to where they have access to the right skills. This is expensive for industry, and does not address the fact that

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individuals trained in one company often need to be retrained when they move jobs because skills acquired in one setting are not recognized in another. If this problem can be addressed on a European level it will increase the critical mass of scientists underpinning the industry, and consequently Europe will be increasingly attractive for industry as they make decisions on where to locate and/or expand their R&D facilities.

The Innovative Medicines Initiative (IMI; http://www.imi.europa.eu/) is a unique and large-scale public–private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA; http://www.efpia.org). IMI runs a €2 billion research programme aiming to speed up the discovery and development of safer and more effective drugs for patients, and to reinvigorate the biopharmaceutical sector in Europe. IMI receives €1 billion funding from the European Commission's Seventh Framework programme. The EFPIA member companies match this amount with at least equal in-kind contributions, consisting of research-related activities and resources.

European leadership in innovative biomedical research requires highly skilled, experienced researchers in many different disciplines. The IMI's education and training projects aim to substantially improve expertise in biomedical science, tools and technologies (such as biomarkers, imaging techniques and knowledge management platforms to name a few) that will enable the faster and more efficient development of safe and effective medicines for patients. Education and training is one of the IMI's four current 'pillars'; the other three pillars being predicting safety, predicting efficacy and knowledge management.

The four IMI Education and Training projects (Box 1) have convened a Cross-Project Task Force on Course Quality to address the need for shared quality standards in training for European medicines R&D. This position paper reflects the Task Force's joint understanding and recommends a shared set of standards to develop a framework for quality assessment of the courses listed and offered through this initiative and more broadly throughout the European Research and Education Areas.

Box 1. IMI Education and Training Projects:

IMI EMTRAIN (www.emtrain.eu)

The European Medicines Research Training Network (EMTRAIN) will establish a sustainable, pan-European platform for education and training, covering the whole life-cycle of medicines research, from basic science and pre-clinical development through clinical development to marketed products, including pharmacovigilance. This will be achieved by making use of and integrating the strengths and competencies of all the IMI Education and Training Partners.

IMI Eu2P (www.eu2p.org)

The European Programme in Pharmacovigilance and Pharmacoepidemiology (Eu2P) will address training needs for both life science specialists and non-specialists. It is being developed by a unique faculty of highly qualified professionals in these disciplines, who have combined experienced from academia, industry and regulatory agencies. The curriculum will offer a range of qualification levels (certificate, master and PhD) and allow part or full time study by those in employment as well as graduate students. There will be a high level of course flexibility and use of innovative and interactive e-learning tools. Its first courses will be delivered in autumn 2011.

IMI PharmaTrain (www.pharmatrain.eu)

The Pharmaceutical Medicines Training Programme (PharmaTrain) aims at fostering the overall understanding and competence for successful execution of integrated drug development and life cycle management of medicines through innovative training methods and Europe-wide agreed programme content. It will identify needs and build and implement new education and training programmes in the field, including related areas such as regulatory sciences and clinical trial practices. It began delivering its first courses in autumn 2010.

IMI SafeSciMET (www.safescimet.eu)

European Modular Education and Training Programme in Safety Sciences for Medicines (SafeSciMET) will develop and deliver a pan-European education and training programme on drug safety that emphasizes integrative and translational aspects, from pre-clinical phases to clinical ones, lacking largely in today's educational programmes. By this, it should deliver a new 'breed' of drug safety scientists, also embracing new technologies to enhance innovative approaches to drug discovery and development. SafeSciMET's first course on Drug Discovery and Development was delivered in November 2010 at the University of Copenhagen, Denmark – the remaining nineteen courses in the programme will be delivered throughout 2011 and 2012.

IMI Education and Training Projects address CPD for professionals in medicines R&D. CPD is the means by which professionals maintain, improve and broaden the knowledge and skills required in their professional lives. It is a conscious updating of professional knowledge and improvement of professional competence throughout an individual's working life, building on a commitment to being professional, keeping up to date and continuously seeking to improve. It is the key to optimizing career opportunities, both today and for the future.

The quality standards recommended in this paper align with pan-European initiatives to harmonize course quality standards, both in higher education (the European Standards and Guidelines for Quality Assurance in the European Higher Education Area) (Association for Quality Assurance in Higher Education et al., 2009) and in vocational education and training (European Quality Assurance Reference Framework to promote and monitor continuous improvement of national systems of vocational education and training).(European Parliament And The Council Of The European Union et al., 2009) We have also mapped the IMI Education and Training shared quality standards to those used by professional bodies of relevance to medicines R&D, and are working with these professional bodies to develop a mutually recognized framework for lifelong learning in medicines R&D.

Our ultimate goal is to move towards a more unified system for recognizing individuals with the necessary knowledge, skills and competences to excel in medicines R&D, and therefore to enhance European competitiveness in this area, in line with IMI's goals. These goals align strongly with the European Commission's Strategic Framework for European Cooperation in Education and Training (ET2020; http://ec.europa.eu/education/lifelong-learning-policy/doc1120_en.htm).

2. Drawing on existing European standards for education and training

In line with the Bologna Declaration and process (Declaration on the European Higher Education Area: http://www.ond.vlaand-

eren.be/hogeronderwijs/bologna/2010_conference/documents/Budapest-Vienna_Declaration.pdf., 0000), the IMI Education and Training Cross-Project Task Force on Course Quality encourages European co-operation in quality assurance of higher education and training programmes, with a view to developing comparable high quality criteria and methodologies. The Task Force adheres to the European Standards and Guidelines for Quality Assurance in the European Higher Education Area (Association for Quality Assurance in Higher Education et al., 2009) when formulating IMI quality assessment policies for the courses listed and offered through the IMI Education and Training projects. We have mapped the IMI shared quality standards to the European Standards and Guidelines.

The IMI's Education and Training projects, which include pan-European Master's programmes in safety sciences, medicines development and pharmacovigilance and pharmacoepidemiology, all follow the Bologna process (Declaration on the European Higher Education Area: http://www.ond.vlaanderen.be/hogeronderwijs/bologna/2010_conference/documents/Budapest-Vienna_Declaration.pdf., 0000). The Bologna Process aims to create a European Higher Education Area, in which students can choose from a wide and transparent range of high-quality courses and benefit from smooth recognition procedures. On 28 and 29 April 2009, the ministers responsible for higher education in the then 46 countries of the Bologna Process met in Leuven and Louvain-la-Neuve to establish the priorities for the European Higher Education Area until 2020. They highlighted the importance of lifelong learning, widening access to higher education, and mobility.

We make the assumption that universities offering Bologna-compliant master's courses have already taken steps to assure the quality of their courses and have documented accreditation in place. We have no intention of interfering with this process or creating additional hurdles.

The IMI's Education and Training pillar addresses the training needs of professionals already working in medicines R&D. We therefore considered not only the European Standards and Guidelines for Quality Assurance in the European Higher Education Area (Association for Quality Assurance in Higher Education et al., 2009), but also those put in place by international professional bodies of relevance to medicines R&D, among others. Where no international organization exists, or where the representative international organization does not have a policy on quality assurance, we chose a representative national organization with a European view (for example, for basic biomedical research we selected the UK-based Society of Biology). We drew on guidelines from different areas of the medicines research spectrum, from basic research through clinical development to medical practice. We have used them to derive (1) a set of principles upon which existing quality standards are based and (2) the criteria used by these bodies to set their own quality standards. We also consulted with representatives from each of the IMI Education and Training projects to gain an understanding of whether these principles and standards had already been incorporated into their quality assessment processes. We derived a condensed set of quality standards by grouping closely related criteria and considering carefully which ones related specifically to course quality.

3. Core principles

The IMI shared standard on course quality is based on the following principles. These principles are summarized in Box 2

Box 2. The principles upon which the IMI shared standard on course quality is based In brief, the IMI shared quality standard is based on the following **principles**:

(1) Trainees are supported to acquire the necessary knowledge and skills.
(2) Course structures encourage exchange and multidisciplinary approaches.
(3) Facilities, infrastructure, leadership and competences are adequate to deliver the approved curriculum.
(4) Training is offered on the basis of equality principles.
(5) Teaching methods appropriate to the goals of the course.
(6) Transparency regarding potential conflicts of interest.

3.1. Trainees are supported to acquire the necessary knowledge and skills

The IMI shared quality standards address this principle by requesting that course providers publish clear information about each course, provide training materials for the students and an evaluation mechanism that enables the course provider to respond to student feedback.

3.2. Course structures encourage exchange and multidisciplinary approaches

Stimulating mobility is an important driver of the IMI Education and Training pillar. This encompasses geographical mobility, intersectoral mobility (between academia and industry) and scientific mobility, including fostering a translational approach to medicines R&D (the ability to apply skills learned in, for example, a drug discovery environment to drug development, regulatory affairs and clinical settings). The decision to offer electives outside the institutions offering IMI Education and Training curricula is motivated by this principle, and the IMI shared quality standards have been selected with this in mind. We envisage that the European Credit Transfer System (ECTS)Anon. and ECTS Users' Guide: Office for Official Publications of the European Communities, 2009 will be a frequent, if not yet universal, means of achieving recognition of elective courses by the degree-awarding university.

3.3. Facilities, infrastructure, leadership and competences adequate to deliver the approved curriculum

Whilst an excellent curriculum is a prerequisite to delivering excellent training, on its own, it is not sufficient. The IMI shared standard on course quality must therefore incorporate a means by which the course provider demonstrates that it can deliver on the curriculum.

3.4. Training is offered on the basis of equality principles

Education and training should be fair and based on principles of equality. Course places should be awarded to candidates regardless of gender, racial or ethnic origin, religion or belief, disability, age or sexual orientation.

3.5. Teaching methods appropriate to the goals of the course

The skills necessary to perform medicines R&D are varied and complex; the teaching methods appropriate to learn how, for

Table 1
Mapping of the European standards and guidelines for internal quality assurance within higher education institutions onto the IMI Education and Training standards for course quality.

IMI Education and Training standard for course quality	European standards and guidelines for internal quality assurance within higher education institutions (ENQA) Association for Quality Assurance in Higher Education et al., 2009
(1) A formalized and transparent quality assurance/quality control policy that includes the following:	1.1 Policy and procedures for quality assurance: Institutions should have a policy and associated procedures for the assurance of the quality and standards of their programmes and awards. They should also commit themselves explicitly to the development of a culture which recognizes the importance of quality, and quality assurance, in their work. To achieve this, institutions should develop and implement a strategy for the continuous enhancement of quality. The strategy, policy and procedures should have a formal status and be publicly available. They should also include a role for students and other stakeholders. 1.7 Public information: Institutions should regularly publish up to date, impartial and objective information, both quantitative and qualitative, about the programmes and awards they are offering.
a. University accreditation or an equivalent system for approving, monitoring and reviewing the training offered.	1.2 Approval, monitoring and periodic review of programmes and awards: Institutions should have formal mechanisms for the approval, periodic review and monitoring of their programmes and awards.
b. A system for quality assurance of teaching staff	1.4 Quality assurance of teaching staff: Institutions should have ways of satisfying themselves that staff involved with the teaching of students are qualified and competent to do so. They should be available to those undertaking external reviews, and commented upon in reports.
c. Regular review of the quality assurance/quality control process and demonstration that the training is further developed in light of this review.	
(2) A set of documented criteria for individual modules, courses or course programmes that include the following:	
a. Defined and transparent admission criteria.	
b. A predefined set of teaching objectives, leading to defined learning outcomes.	
c. The facilities, infrastructure, leadership and competences available for the support of student learning should be adequate, appropriate and up to date for the training offered.	1.5 Learning resources and student support: Institutions should ensure that the resources available for the support of student learning are adequate and appropriate for each programme offered.
d. Assessment of the students' achievement in accordance with the agreed learning outcomes of the training offered.	1.3 Assessment of students: Students should be assessed using published criteria, regulations and procedures which are applied consistently.
e. A system for collecting, assessing and addressing feedback from learners, teachers, technical/administrative staff and programme/course/module managers.	1.6 Information systems: Institutions should ensure that they collect, analyse and use relevant information for the effective management of their programmes of study and other activities.

example, to use a bioinformatics resource are completely different from those necessary to learn how to take a case history for a patient enrolling on a clinical trial. Another consideration is the proportion of face-to-face versus distance learning. A high proportion of distance learning may be appropriate for the development of some competences (for example, modelling of biological systems) but inappropriate for others (for example, ethical considerations surrounding taking samples from patients or healthy volunteers).

3.6. Transparency regarding potential conflicts of interest

In an environment in which industry is funding and supplying training, special care needs to be taken regarding conflicts of interest. Steps should be taken to ensure that any potential conflict does not inappropriately influence the structure or content of the training and, where there might be a risk of this, the trainees and accrediting bodies should be made aware of this risk.

4. Shared standards

We applied the above-described principles to derive the following standards for course quality. The standards are summarized in Table 1, where they are mapped to the European Standards and Guidelines for Quality Assurance in the Higher Education Area (Association for Quality Assurance in Higher Education et al., 2009).

1. A formalized and transparent quality assurance/quality control policy that includes the following:

   a. University accreditation or an equivalent system for approving, monitoring and reviewing the training offered. An important goal of this is to encourage universities to provide CPD in addition to classical higher education, in accordance with the European Universities' Charter on Lifelong Learning (Anon. and European Universities' Charter on Lifelong Learning, 2008).
   b. A system for quality assurance of teaching staff. Although assessing the quality of the curriculum is an important part of quality assurance, it is also vital that the teaching staff have the appropriate skills to teach the curriculum.
   c. Regular review of the quality assurance/quality control process and demonstration that the training is further developed in light of this review. This is important to ensure that quality assurance procedures are not merely a box-checking exercise, but address any concerns that the students, teaching staff or other stakeholders may have, with the goal of continually improving course quality.

The IMI Cross Project Task Force on Course Quality will, in the future, provide standard operating procedures for implementation of these policies. Any guidelines provided will be voluntary as we do not wish to interfere with established quality assurance/quality control review systems. The quality assurance/quality control policy may either form part of the course provider's statutes (typical for higher education institutes) or be put in place by a professional body or professional course provider (typical for continuing professional development). In principle, if the training offered by an organization is accredited by an agency that is recognized by the European Association for Quality Assurance in Higher Education (ENQA, www.enqa.org), this organization will already satisfy the IMI shared quality standards.

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

a. Defined and transparent admission criteria. We do not wish to interfere with the admission criteria of universities and course providers; however, we feel that transparency is essential: if a candidate is not admitted to a course, s/he should be able to find out why.
b. A predefined set of teaching objectives, leading to defined learning outcomes. Learning outcomes and objectives are often used synonymously, although they are not the same. Learning outcomes are statements of what a learner is expected to know, understand and/or be able to demonstrate after completion of a process of learning. Learning outcomes must be accompanied by appropriate assessment criteria that can be used to judge that the expected learning outcomes have been achieved. Learning outcomes, together with assessment criteria, specify the requirements for the award of credit, while marking is based on attainment above or below the requirements for the award of credit. Objectives, on the other hand, distil the aims of the course into statements of what the course provider is setting out to teach (or, put another way, what the course provider intends the students to learn). The aims are almost certainly more than the sum of the objectives, but the objectives serve the purpose of adding clarity (see http://www.learningandteaching.info/teaching/objectives.htm#ixzz1SowwbB5u for definitions of aims, objectives and outcomes).
c. The facilities, infrastructure, leadership and competences available for the support of student learning should be adequate, appropriate and up to date for the training offered. This includes, but is not limited to, provision of up-to-date course material. We encourage (but do not require) course providers to make training materials (e.g. scripts, links, book chapters and up-to-date publications) available to reviewers, and to share course materials among trainers on the same course to avoid inconsistencies and duplication of effort. Depending on the nature of the training, appropriate facilities may vary enormously, from a room with chairs and a flip-chart to highly specialized equipment. The important principle here is that the facilities are adequate for the type of course. Finally, we emphasize the importance of both subject-matter knowledge and teaching ability, in addition to the support of strong programme leaders, in delivering a high quality curriculum.
d. Assessment of the students' achievement in accordance with the agreed learning outcomes of the training offered. Modular assessment and final exams have different goals; in the Bologna criteria, a module is assessed and then given an appropriate number of ECTS points. The most important principle here is that students are awarded their certificate once they have demonstrated that they have improved their skills/knowledge/competence in accordance with the stated learning outcomes. The Bologna Process recommends that assessment is modular; this is important for individuals to accumulate a portfolio of CPD throughout their career.
e. A system for collecting, assessing and addressing feedback from learners, teachers, technical/administrative staff and programme/course/module managers. Feedback, and demonstration that feedback is responded to with the aim of improving course quality, are an essential part of quality control and should involve all stakeholders in the learning process.
f. Availability of appropriate and updated reference material (e.g. published articles, links, book chapters and scripts). This differs from the notion of providing these materials to reviewers and peers discussed in point C; here we address the need for trainers to provide adequate reference material to their trainees.

5. Next steps

5.1. IMI Education and Training electives

The IMI Education and Training Programmes (Box 1) have agreed to abide by the IMI shared standard on course quality and, where appropriate, to use it to identify courses outside of the IMI Education and Training programme that are suitable for use as elective modules for an IMI Master's degree.

5.2. Use of the standards to flag the quality of CPD courses

We anticipate that many of the master's modules provided by the IMI Education and Training programmes, or flagged by them as appropriate elective modules, will also be offered individually as standalone CPD courses. The quality of the IMI Education and Training master's courses is therefore inextricably linked to the quality of CPD, and also provides a natural route for offering quality-assured standalone CPD courses.

On behalf of the IMI Education and Training Projects, EMTRAIN, with significant input from the other three IMI Education and Training Projects, is developing an online course portal, 'on-course', which will list Master's, PhD and CPD courses of relevance to medicines R&D. Course providers will be asked to select the IMI shared standards for course quality that apply to each of their courses/modules, and course seekers will be able to search for courses that meet these standards.

We also plan to flag those courses that are approved by professional bodies whose quality standards accord with IMI's. In our discussions with professional bodies, we plan to seek their agreement to flag courses approved by them, to seek their input on the IMI shared standards for course quality, and to agree how best to flag those courses that are not approved by any professional body and yet that meet all (or a high proportion of) the IMI quality standards.

5.3. Towards a shared understanding of CPD quality

By working with bodies that are already in the business of monitoring and awarding CPD credits to individual professions involved in medicines R&D, we hope to move towards a widely accepted system for recognizing and rewarding the acquisition and renewal of skills necessary for effective medicines R&D. Until now, this has been impossible because each profession in each European country has a different system for doing this, and there is little mutual recognition, either from one country to another, or from one profession to another, of the professional skills necessary to succeed in medicines R&D.

In this way, we hope to move towards a more unified system for recognizing individuals with the necessary knowledge, skills and competences to excel in medicines R&D, and therefore to enhance European competitiveness in this area, in line with IMI's goals and with those of the European Commission's ET 2020 Directive.

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