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Appendix 12.8 to PharmaTrain Manual

PHARMATRAIN SPECIALIST IN MEDICINES DEVELOPMENT (SMD) PROCEDURAL DOCUMENT

SMD CERTIFICATION PROCESS & CURRICULUM PATH

INTRODUCTION, BACKGROUND & OVERVIEW

1. Introduction

The development of the 'Specialist in Medicines Development (SMD) certification programme, developed within the IMI JU Education & Training project PharmaTrain, and its implementation are described in this document.

The document applies to professionals involved in the development of medicines who want to become a Specialist in Medicines Development (SMD).

Why do we need a PharmaTrain Specialist in Medicines Development?

Medicines development is changing rapidly. Currently, academically-qualified people working in this complex environment are trained on the job, undertake continuing professional development (CPD), and participate in university training courses to achieve a secondary diploma and/or master degree. This leads to an individual acquiring a certain array of competencies across multiple domains. So far, there is no qualification / degree / title available which certifies this described background or achievement, and the PharmaTrain SMD aims to fill this gap.

The primary objective of this document is to describe SMD certification for professionals involved in medicines development. The aim of the process is to produce certified specialists in medicines development, who are equipped with specialist knowledge, comprehensive skills and competencies to practise to the highest ethical and professional standards in the development and maintenance of medicines, and to ensure consistent education and training of these individuals to enhance the quality of medicines research and development.

2. Background

As mentioned in the introduction, medicines development is changing rapidly.

There is currently a lack of standardisation and harmonisation of the training of those involved in medicines development, making it difficult and complex to assess if the required skills and expertise are available for high-quality development of medicines and there is, to our knowledge, no qualification available which certifies this described background or achievement.

The proposed certification process is partially based on that for certification for Specialist in Pharmaceutical Medicine (SPM) for MDs, existing in CH, UK and IRE (note: in Belgium the process of recognition of SPM is ongoing). The processes leading to specialist recognition in these countries have the following in common: prior experience; a theoretical part (tested with an examination); a practical part (on-the-job training). Once awarded, maintenance of the SPM is through Continuing Professional Development (CPD).

Teaching and learning methods in medicines development have been developed to meet the training and continuing education needs of postgraduate doctors, scientists and other professionals working in a dynamic, research-based, regulated international industry, comprising autonomous and competitive pharmaceutical companies, academic centres, contract clinical research organisations, and competent authorities.

Scientists work in local and international multidisciplinary teams with requirements for both general and very specific learning. As a result, teaching has moved from the familiar didactic lectures in a classroom setting, to an interactive learning modality with a reliance on expert scientists from industry and academia, clinicians from hospital medicine and general practice, and on senior industry personnel to present, share and discuss the latest research and its impact in the clinical setting and on medicine development life-cycle management and monitoring.

3. Overview of the SMD programme

The programme leading to SMD comprises the PharmaTrain Syllabus for Medicines Development, 'The PharmaTrain Syllabus' (Appendix 1), which prescribes the theoretical knowledge base for medicines development and the SMD, which must be acquired in full prior to the award of SMD. This is accompanied by competency-based (practical) training in an individualised programme centred on an approved workplace training environment, to meet the requirements of the competencies curriculum (Appendix 2). The SMD is a

4-year programme in which acquisition of the knowledge-base and the demonstration of competencies can run concurrently.

Practical SMD comprises a modular programme in six Domains of medicines development; 1.Discovery of medicines & early development; 2.Clinical development & clinical trials; 3.Medicines regulation; 4.Drug safety surveillance; 5.Ethics & subject protection; and 6.Healthcare marketplace. A seventh general Domain in medicines development encompasses 7.Communications, management & leadership skills - relevant to the professional work in medicines development.

A minimum of two of the six operational Domains and the general Domain (7) comprise the core practical programme and must be completed in the workplace. The remaining Domains can be completed also in the workplace, or through approved whole-Domain or Domain-Item (competency-based, interactive) courses or activities, or through a mix of in-work and course/activity-based training.

Practical SMD training with continuous and performance-based assessments enable trainees to demonstrate the breadth and depth of learning and experience that they have achieved in acquiring the competencies of medicines development, over the four years of the SMD programme.

Each trainee has an allocated, trained & approved mentor (educational supervisor), usually based in their workplace, throughout the SMD programme; the mentor is responsible for the overall supervision and management of a trainee's educational progress, and for facilitating opportunities for training and resources so that the requirements of the curriculum can be met on-site as far as possible.

On completion of the SMD programme, trainees are expected to be competent in all aspects of the curriculum.

The (international) SMD programme is delivered by the PharmaTrain Certification Board (PCB), responsible for the implementation, monitoring, standards and quality of the SMD certification programme. The work of the PCB is delegated to Certification Board Delegates (CBD) responsible for overseeing training environments (workplaces) and SMD programmes.

SMD education and training takes place within a framework of continuous assessment, educational & performance appraisal and periodic review of achievement and progress, to enable trainees to complete the programme and gain the award of SMD.

The SMD programme is conducted within a quality management system with an ethos of quality improvement, renewal and maintenance of the high standards

befitting such an endeavour in the interests of better medicines' development and patient care and well-being.

ORGANISATION OF THE SMD CERTIFICATION PROGRAMME

3. LEARNING & TEACHING

3.1 Learning experiences, sources and methods

The SMD programme is based around the workplace and much of the learning comes from experience on-the-job, governed by the individual's job description(s) and exposure to projects and learning opportunities in the seven (7) Domains of the SMD curriculum.

Acquisition of the specialty knowledge base (theoretical) also comes from the workplace experience, attendance at structured courses, available through the PharmaTrain Diploma (Base) course, extension Master or integrated Master modules, and/or PharmaTrain approved Short Courses, and in the workplace through dedicated group seminars, in-company and external lectures, meetings and conferences, self-directed and distance learning (journals, textbooks and the internet).

Learning methods include:

a. experiential learning (apprenticeship);
b. structured postgraduate academic courses in medicines development e.g. university-based;
c. interactive structured courses for practical curricula (competency-based);
d. problem-based and case-based scenarios;
e. national and international symposia and conferences;
f. personal study, self-directed and distance learning (journals, textbooks and internet);
g. formal themed training at local, national, international levels;
h. courses and study days;
i. in-company training programmes;
j. reflective practice and commentary;
k. self-assessment;
l. small-group seminar learning with peers.

Practical training:

The goal of the training is to acquire competencies in the main areas of medicines development.

The applicant must provide evidence of practical training in medicines development in an institution (pharmaceutical company, contract research organisation, clinical or pre-clinical research institute, or competent authority) which offers the candidate the appropriate opportunity to gain practical experience in medicines development.

A training plan must be submitted to the PharmaTrain Certification Board at the start of the practical training for evaluation and approval. Modifications to the plan have to be communicated to the PharmaTrain Certification Board.

The training will take place under close supervision of a qualified mentor. A qualified mentor has to provide documentation of his/her training to substantiate his/her qualification as a mentor. Alternatively in those countries where applicable, training can be performed in recognised training sites or under the supervision of an experienced tutor selected from the teaching staff of a PharmaTrain accredited course.

In any case the type of projects the applicant has been working on, the length of the involvement, and the work setting should be documented. The practical training must be recorded in the Training Record *(www.pharmatrain.eu).* The completed practical training must be validated in writing by the applicant's mentor or alternatively where applicable by the recognised training site. In toto, on-the-job-training of a minimum of four (4) years is required.
The theoretical training and the practical training for the SMD will run concurrently (over the 4-year period), or will greatly overlap.

External full-Domain courses are PharmaTrain-approved, competency-based (cognitive competency), interactive, quality assured courses provided under contract to PharmaTrain by independent organisations and course providers. These are available for trainees to attend if they have no exposure in the workplace to a whole SMD Domain.

The courses are approved by PharmaTrain (curricular content, delivery, assessments, assignments), which also underpins the quality management of the courses.

As further described, there is a maximum of four (4) Domain courses permitted for an individual SMD programme.

3.2 Practical competency-based training in an individualised programme.

Principles:

Provide evidence over a 4-year period of gaining practical training and competencies in medicines development in an institution (pharmaceutical company, contract research organisation, clinical or pre-clinical research institute, or competent authority) which offers the appropriate opportunities to gain such experience in medicines development. The practical training must be recorded in the PharmaTrain Training Record/e-portfolio (www.pharmatrain.eu).

Practical SMD training in seven (7) Domains of medicines development parallels or follows the theoretical training. At the end of the programme trainees are expected to be competent:

- To identify unmet therapeutic needs, evaluate the evidence for a new candidate for clinical development and design a Clinical Development Plan for a Target Product Profile. (Domain I)
- To design, execute & evaluate exploratory & confirmatory clinical trials and prepare manuscripts or reports for publication & regulatory submissions. (Domain II)
- To interpret effectively the regulatory requirements for the clinical development of a new medicine through the product life-cycle to ensure its appropriate therapeutic use & proper risk management. (Domain III)
- To evaluate the choice, application & analysis of post-authorisation surveillance methods to meet the requirements of national/international agencies for proper information & risk minimization to patients & clinical trial subjects. (Domain IV)
- To combine the principles of clinical research & business ethics for the conduct of clinical trials & commercial operations within the organization. (Domain V)
- To appraise the pharmaceutical business activities in the healthcare environment to ensure that they remain appropriate, ethical & legal to keep the welfare of patients & subjects at the forefront of decision-making in the promotion of medicines & design of clinical trials. (Domain VI)
- To interpret the principles & practices of people management & leadership, using effective communication techniques & interpersonal skills to influence key stakeholders & achieve the scientific & business objectives. (Domain VII)

The curriculum for the practical modules showing the competencies (n=60) across the seven Domains of medicines development is available on www.pharmatrain.eu, and as Appendix 2.

A minimum of two operational Domains and the general, IML, Domain VII comprise the core practical competencies / performance and must be completed in the workplace.

Practical SMD training with continuous and performance-based assessments enables trainees to demonstrate the breadth and depth of learning and experience that they have achieved in acquiring competencies in medicines development.

In addition, throughout their 4-year SMD program, trainees should:

- maintain knowledge and awareness of the need to move on from the scientific and technological challenges in the medicines development industries to addressing industry bottlenecks and resolving healthcare and societal challenges, through prevention and therapy, focused, for example, on health priorities and priority medicines and diseases as outlined in the 2004 WHO report;
- acquire a thorough understanding of the management and administration of those organisations in which they work or with which they are affiliated within medicines development, including an understanding of the business model(s) used for the development of medicines.

On completion of SMD training trainees are expected to be competent in all Domains of the SMD curriculum.

The individual SMD programmes are undertaken by trainees who are both working and learning within a managed environment undertaking medicines development; this comprises pharmaceutical companies, contract clinical research organisations, clinical or pre-clinical research institutes, or competent authorities. This is a disparate environment comprising organisations of very varied size, culture, aims & objectives, management ethos and attitude to the needs of workplace-based training and continuing professional development.

The SMD programme has a requirement for monitoring the progress and achievement of trainees, for establishing a valid and verifiable outcome of the training, and, through quality management of the programme, for providing public assurance of the excellence of the learning and academy, of transparency, of fairness and of non-discrimination.

PharmaTrain must maintain and assure standards for the delivery and outcomes of the SMD programme so that the award of SMD can be made

reliably and PharmaTrain specialist certification for competent professionals can be achieved and upheld.

These requirements for the SMD programme are approached through the development and maintenance of a support network (framework) both within and external to the SMD programme itself.

4. ACQUISITION OF THE SPECIALIST OF MEDICINES DEVELOPMENT (SMD) CERTIFICATION

4.1 General requirements to obtain the SMD

Prerequisites (Entry criteria):

a. Candidates must have completed a formal education (BSc, MSc or equivalent) in a discipline in life science or healthcare e.g. medical doctors, pharmacist, biologist, chemist, biometrician, certified nurse.

b. Hold a post in Pharmaceutical Medicine/Medicines Development Science, or intend to hold such a post for the practical competency-based, workplace-centred training towards the SMD Award.

c. Candidates with exceptional circumstances outlying a. & b. will be considered by the PCB on a case-by-case basis.

Theoretical training/knowledge assessment:

Theoretical training must be documented and be through a postgraduate training programme comprising PharmaTrain-recognised modules and courses. This training can be started in parallel to practical workplace-based training.

Theoretical training can occur prior to enrolling in the SMD programme, or whilst undertaking the practical workplace–based training. The theoretical training must be documented in the PharmaTrain Training Record/e-portfolio *(www.pharmatrain.eu).*

Specialty knowledge base: The PharmaTrain Syllabus for Medicines Development

The PharmaTrain Syllabus for Medicines Development is available on www.pharmatrain.eu, www.fpm.org.uk and other websites.

The Syllabus is the specialty knowledge base of the SMD programme.

It is mapped through learning outcomes to the PharmaTrain Diploma (Base) and Masters (Extension & Integrated) Courses, and to Short Courses (1-4 ECTS credits) approved by PharmaTrain.

Demonstration of acquisition of the theoretical training (specialty knowledge base):

Trainees must complete theoretical training in medicines development in accredited course(s) covering the entire PharmaTrain Syllabus, with assessments & certified outcome.

The contents of the theoretical training should be aligned with & cover the PharmaTrain Syllabus for Medicines Development, for example:

- The PharmaTrain Diploma Base Course or Master programme; i.e. A postgraduate Diploma or Master of Science degree in Medicines Development offered at one of the PharmaTrain approved training centres (Centre of Excellence, Centre Recognition).
- An equivalent* Postgraduate degree (*covering the entire PhT Syllabus).
- PharmaTrain-recognised Short Courses, either a combination of Short Courses alone, or in combination with the PharmaTrain Diploma (Base) course & Master Modules (to cover the entire PharmaTrain Syllabus).

The theoretical training programme, regardless of how it is comprised must:

a. be documented;

b. cover the entire PharmaTrain Syllabus for Medicines Development;

c. receive overall approval of satisfactory completion & meeting standards by:
   i. a PharmaTrain centre university, or
   ii. a pass in an examination, approved by PharmaTrain, covering the entire PharmaTrain Syllabus, or
   iii. The PharmaTrain Certification Board (pending/to be approved).

All courses (Short, Diploma(Base), Masters) making up the theoretical training programme, must fulfil the following criteria:

d. be approved by PharmaTrain,

e. fulfil the 9 IMI E&T quality criteria,

f. cover a stated part of The PharmaTrain Syllabus,

g. have Learning Outcomes which are assessed on a modular basis (by examination or marked assignment(s) or both).

***Practical Training*:**

Trainees must provide evidence over a 4-year period of gaining practical training and competencies in medicines development in an institution (pharmaceutical company, contract research organisation, clinical or pre-clinical research institute, or competent authority) which offers the appropriate opportunities to gain such experience in medicines development. The practical training must be recorded in the PharmaTrain Training Record/e-portfolio (www.pharmatrain.eu).

Practical SMD training parallels or follows the theoretical training.

4.2 Specialist in Medicines Development (SMD) title & Continuing Professional Development (CPD).

The holders of a PharmaTrain specialist title commit themselves to CPD, in which a minimum of 250 credit points (250 hours of work) will need to be assembled over a 5-year period. An attempt should be made to cover all aspects of development important for the specialty, for example, using the entire PharmaTrain modular (face-to-face as well as e-) training platform, as well as topics in science & medicine, in pharmaceutical medicine & in personal / professional development.

The request for renewal of the specialist title should be submitted every five years by the specialist to the PCB. If certification for CPD is not obtained during five successive years the PharmaTrain SMD title will be revoked.

4.3 Awarding the Specialist title

After a positive review of the application consisting of satisfactory documentation of four years of practical training as per the above definition, the PCB will issue the PharmaTrain specialist title of Specialist in Medicines Development (SMD).

On completion of SMD training trainees are expected to be competent in all Domains of the SMD curriculum.

4.4 Applications for SMD (Specialist) Certification & Declarations of Continuing Professional Development (CPD)

Applications should be submitted electronically to the PCB. Incomplete submissions will be returned to sender (an administrative fee might be applicable).

After receipt of payment of the relevant fees, submissions will be evaluated by at least one qualified reviewer appointed by the PCB. In case of a negative opinion, a PCB Member will re-evaluate the submission. Both evaluations need to be in agreement in case of a final negative opinion. If the two opinions are divergent a third evaluation will be required by another PCB Member to come to a final conclusion on acceptability.

Applicants will be notified by the PCB in writing within three months of the outcome of their application: either accepted, accepted with conditions or rejected. In case of rejection of an application, the PCB will provide a written explanation.

Any appeals must be sent to the PCB within 30 days after being notified of a decision. The PCB will present the appeal to the PharmaTrain Federation Executive Board for a final decision.

5. PharmaTrain Certification Board (PCB)

The role of the board is to manage the certification process and to certify Specialists in Medicine Development.

The PCB member selection criteria are:

1. Holder of postgraduate qualification in Pharmaceutical Medicine, Biomedical Sciences, or Pharmaceutical Sciences (or equivalent qualification);
2. Involvement in postgraduate training and education activities e.g. Teaching Faculty, Examination Board, Education Quality Assessment Board, CPD/E&T Director;
3. Current or past board level participation in professional bodies e.g. IFAPP, FPM;
4. Experience in accreditation, certification and quality assurance processes;
5. Any of 2-4 when from outside of Pharmaceutical Medicine / Pharmaceutical Industry / medicine / science.

6. PharmaTrain Certification Advisory Group

The PharmaTrain Certification Advisory Group will advise the PCB on scientific questions that might arise during the certification process. It will be composed of members of academia, industry, regulatory agencies and professional organisations. Its composition will be determined by the PCB.

7. The Training Record

On enrolling with PharmaTrain, trainees will be given a personal Training Record for SMD. The Training Record allows evidence to be built up to inform decisions on a trainee's progress and provides tools to support the education and development of SMD trainees.

The Training Record could be paper-based (hard-copy) or electronic (e-Portfolio) [to be determined].

The trainee's responsibilities are to ensure the Training Record is kept up to date, arrange assessments and ensure they are recorded, prepare drafts of appraisal forms, maintain their personal development plan, collate (against Items of the curriculum) the validated and authenticated evidence of competency, record their reflections on learning and record progress through the curriculum by completion of a Training Log.

The Training Log will be used at an annual review to gauge the progress of competency attainment and programme completion against the expected (and published) SMD progress criteria.

8. Assessment

The Curriculum for SMD defines the standards of knowledge, skills and attitudes/behaviours which must be demonstrated in order to achieve progressive development towards the award of SMD.

Competencies and their knowledge, skills and attitudes/behaviours (KSAs) take time and systematic practice to acquire and become embedded in regular performance. Implicit therefore in a competency-based programme of training must be an understanding of both the minimum level of frequency of experience, and the time required to acquire competencies and confirm performance in the processes and practices of medicines development.

Assessment strategies for SMD must not deliver just snapshots of skills and competencies, but must deliver a programme of assessment which looks at the sustainability of competencies and the professional performance of trainees in everyday practices and activities in medicines development.

Trainees gain competence at different rates, depending on their abilities, their determination and their exposure to situations which enable them to develop the required competencies. The rate of progress in acquisition of the competencies in SMD is defined in the curriculum so that all are clear as to what is acceptable progress in SMD. This also enables a limit for remediation to be set and trainees to be aware of the boundaries within which remediation can and will be offered.

9. Supervision and feedback

All elements of work in an SMD programme must be supervised to a level dependent on the experience of the trainee, their exposure / responsibility in projects & activities undertaken, and the level of their competence. Trainees in SMD will at all times have a named mentor (educational supervisor), responsible for overseeing their education and training.

The responsibilities of mentors have been defined in the PharmaTrain Quality Handbook.

A mentor who is appropriately qualified is responsible for the overall facilitation and oversight of a trainee's educational progress. The mentor supervises a trainee undertaking an SMD programme on a regular basis and through personal contact in a centre approved for training. The mentor is responsible for facilitating opportunities for training and resources so that the requirements of the curriculum can be met on-site as far as possible.

The training will take place under close supervision of a qualified mentor. A qualified mentor has to provide documentation of his/her training to substantiate his/her qualification as a mentor. Alternatively in those countries where applicable, training can be performed in recognised training sites or under the supervision of an experienced tutor selected from the teaching staff of a PharmaTrain accredited course.

The mentor‘s main responsibilities are to use evidence from the Training Record such as outcomes of assessments, reflections and personal development plans to inform educational and annual performance appraisal meetings. They are also expected to update the trainee's record of progress through the curriculum, write end-of-post (exit) appraisals and provide supervisor reports.

Attainment of competencies by trainees, which includes project / task completion, assessment of competency and filing of authenticated and validated evidence in the Training Record, will be recorded through completion of the Training Log. This involves dated sign-off by trainee and by mentor against the relevant competency (curricular Item), and recording how the competency was achieved. To provide supervision during the SMD programme, the mentor should be in regular contact with the trainee on at least a 4-weekly basis. More formal meetings, with a written record, should occur in the early stages of training at least quarterly and might be more often.

In some circumstances, with approval of the PCB or its delegate, a Certification Board Delegate (CBD), the designated mentor may delegate overall or selected supervision to an associate, whilst retaining overall responsibility for supervision of training.

The mentor (and any associate mentors) must be willing to undergo induction and training in the responsibilities, skills and processes of supervision of SMD; for example, the conduct of educational and annual performance appraisals and assessments of performance and competency. PharmaTrain will offer or facilitate any appropriate training that it considers necessary or is requested.

Mechanisms for supervision:

Each trainee has an assigned mentor who facilitates an SMD programme at the workplace. The mentor will normally be the trainee's manager and work on the same site, being familiar with and overseeing the trainee's work.

Trainees should work with a level of supervision appropriate to their experience and competence, and know that they must limit their work to within their level of competency and seek help and support without hesitation.

The trainee and mentor should meet on a regular basis (frequency is their decision) to discuss the SMD programme, but undertake more formal Educational Appraisals (e.g. 4-monthly basis) and a formal Annual Performance Appraisal prior to the planned Annual Review of achievement and progress in SMD.

The mentor should keep the PharmaTrain Certification Board Delegate (CBD) who acts on behalf of the PharmaTrain Federation, informed about: significant problems that arise in the provision of educational components, such as a trainee experiencing difficulties in achieving educational objectives, their performance not reaching the required standard, and problems relating to the professional and personal development of the trainee, as they relate to the SMD programme. Such issues should be discussed with the trainee in the first place and remedial measures adopted as soon as possible.

The mentor will be involved in assessments and appraisals of SMD trainees:

a. SMD meetings / advisory / educational (on-going);
b. educational appraisals (usually four-monthly);
c. annual performance appraisal;
d. performance and competency assessments (as necessary for SMD curricular Items).
   (Sections c. and d. above will form part of the Annual Review.)

Mechanisms for feedback:

Opportunities for feedback to trainees about their performance will arise through the use of the workplace-based assessments, regular appraisal meetings with mentors, other meetings and discussions with supervisors and colleagues, and feedback from the Annual Review.

Receiving regular and timely feedback on learning and performance is an essential part of the work-based experiential learning of SMD, which is, in the main, a formative, developmental process.

Feedback to the trainee on progress and achievements in SMD, including acquisition of competencies, assessments made and standards reached, strengths and deficiencies can be made in a number of ways in a variety of circumstances throughout SMD, such as educational meetings, appraisals and reviews, and written procedures. The results of feedback will be discussed between trainee and coach/mentor during appraisals. Evidence that feedback has been sought and responded to will form part of the Annual Review of SMD training.

10. Appraisal

A formal process of appraisals and reviews underpins training. This process ensures adequate supervision during training, provides continuity between posts and different supervisors and is one of the main ways of providing feedback to trainees. All appraisals should be recorded in the Training Record.

Educational Appraisal:

Educational appraisal is a formative, developmental process which allows the trainee and coach/mentor to meet at regular intervals (4-monthly) to review how the requirements of the curriculum are being met and to discuss successes and deficiencies of trainee and training in a confidential setting. Educational appraisals present an opportunity for deviations and deficiencies to be addressed, and are a major opportunity for feedback on learning, learning objectives, projects, proposals, plans, problems and personal matters both to the trainee on performance, and to the coach/mentor on how facilitation of training is progressing.

Annual Performance Appraisal:

Annual performance appraisal is a summary evaluation of progress and achievement of the preceding period, and its outcome and report feeds into the annual review process. Annual performance appraisal enables trainee and mentor/educational supervisor to discuss projects, assessments, achievements and progress against the Training Plan and preparation for the new Training Plan. Reviewing progress through the curriculum will help trainees to compile an effective Personal Development Plan (PDP) of objectives for the coming period.

Exit Appraisal:

Prior to changing job or post, trainees should review their SMD curriculum progress and PDP with their mentor using evidence from the Training Record. Specific concerns may be highlighted from this appraisal. The end of post appraisal form should also record the areas where further work is required to overcome any shortcomings that have been identified. Further evidence of competency in certain areas may be needed, such as planned workplace-based assessments, and this should be recorded. If there are significant concerns following the exit appraisal then the CBD should be informed.

11. Annual Review (of progress and achievement in SMD programme)

Structured postgraduate training, including SMD, is dependent on having a curriculum, which sets out clearly the standards and competencies of practical work, an assessment strategy to know whether these standards have been achieved and an infrastructure which supports a training environment within the context of the requirements of the job description and expectations for work delivery.

The three key elements which support trainees in this process are appraisal, assessment and annual planning. Together these contribute to the Annual Review of progress and achievement. The Annual review is the formal method by which a trainee's progression through the training programme is monitored and recorded. The Annual Review is not an assessment; it is the review of evidence of training and assessment.

The PCB is responsible for organising and conducting Annual Review, usually by delegation to an appropriately constituted and composed Annual Review Panel which reviews the SMD programme of the trainee in person, or through some other appropriate means (TC, VC, written submission, e-portfolio review) [to be determined], and declares an outcome which in turn determines whether a trainee continues in the programme, requires remedial training or additional time, or some other outcome [to be determined].

12. The PharmaTrain Certification Board Delegate (CBD)

The CBD has responsibility for overseeing the SMD programme followed by trainees at the work place and ensures appropriate quality management.

The position CBD is an appointment of PharmaTrain Federation. The CBD will normally be an experienced medicines developer operating at a senior level in any function in medicines development as well as in staff supervision, assessment and appraisal, and is committed to continuing professional development in general, with a particular emphasis on SMD.

The CBD must undergo induction into the CBD role & responsibilities and training, organised by PharmaTrain Federation, into the background and scope of SMD, and the duties and activities of the CBD position. The CBD is accountable to and acts on behalf of the PharmaTrain Certification Board, to whom s/he has a duty of responsibility, diligence and care.

The CBD is assigned to oversee workplaces (company; CRO; competent authority*) within their geographical orbit (national, regional, urban) to provide advice on SMD and to trainees on their SMD programmes, and to oversee (quality manage) the workplace in terms of support for and the provision of E&T opportunities and the nature, progress and outcome of individual SMD programmes.

13. Evidence and Assessment of Competency

The proper collection and recording of evidence of attainment and assessment of competencies in SMD is an important aspect of progress and completion of the competency-based training programme in medicines development. Regular checks and verification of the appropriateness and veracity of this evidence are made, recorded and validated by the mentor.

The curriculum for SMD defines the standards of knowledge, skills and attitudes/behaviours (KSAs) which must be demonstrated in order to achieve progressive acquisition of competencies towards completion of the SMD programme.

Competencies take time and systematic practice to acquire and become embedded in regular performance. Implicit therefore in a competency-based programme of training must be an understanding of both the minimum level of frequency of experience, and the time required to acquire competency and confirm performance in the practices and operations of medicines development.

Assessment strategies for SMD must not deliver only snapshots of skills and competencies, but must deliver a programme of assessment which looks at the sustainability of competencies and the professional performance of trainees in everyday work in medicines development.

14. Managing curriculum implementation

The introduction of a structured competency-based training programme for the SMD certification and the adoption of competency assessment procedures represent a major departure from the former approach to postgraduate training. It is essential that there should be an explicit partnership between trainees and

those responsible for training, so that trainees receive adequate support and guidance throughout the training period.

In turn there is a new responsibility placed on trainees to evaluate their own strengths, shortcomings and knowledge/competency gaps and to seek out the educational opportunities that they require to correct any deficiencies.

15. Trainees' responsibilities for curriculum implementation

One of the basic principles of a workplace-centred competency-based education and training programme is that the trainee is firmly at the centre, not only as the apprentice and "raison d'être" for the programme, but as the initiator and responsible person to ensure that education and training takes place and has a successful outcome. The curriculum for a competency-based programme puts the emphasis on learning rather than teaching.

Whilst CBDs and education & training bodies (PharmaTrain Federation) can set curricula and lay down standards to be achieved, and mentors and other trainers can facilitate the availability of learning opportunities and resources, it is the trainee with the motivation, drive and enthusiasm to undertake specialty training who must ensure that the circumstances are present and appropriate for their full participation, giving them the best chance for a successful and timely outcome to the SMD certification programme.

16. Curriculum review and updating

The responsibility for curriculum review and updating lies with the PCB.

Evaluation of the curriculum will take place during the initial stages of curriculum implementation and during the first two years of full implementation. Evaluation will continue, as indicated from early and on-going evaluations, during the full cycle of SMD. Evaluation will continue thereafter on a rolling basis, contingent on PharmaTrain Federation requirements and guidance.

Appendix 1: The PharmaTrain Syllabus for Medicines Development.
(= Appendix 12.1 to the PharmaTrain Manual)

Appendix 2: The SMD Competencies Curriculum.
(=Appendix 13.4 to the PharmaTrain Manual)