PharmaTrain Specialist in Medicines Development Certification Programme: SMD Curriculum Path & Certification Process.

Summary
The Specialist in Medicines Development (SMD) is a competency-based, workplace-centred 4-year education and training certification programme in Medicines Development, comprising a knowledge base covering the PharmaTrain Syllabus for Medicines Development Science, delivered and assessed through modular curricula, and the acquisition and demonstration of competencies for medicines development across seven domains of the competency curriculum. Participants in this mentored programme acquire knowledge and competencies within a framework of assessment, appraisal and annual review of progress and achievement. On completion, participants receive the SMD Certificate from the PharmaTrain Certification Board.

Background

This document outlines the principles & certification programme for the new 'PharmaTrain Specialist in Medicines Development' (SMD) title for professionals involved in medicines development and pharmaceuical medicine, which arises from the IMI PharmaTrain project to be implemented by its successor, the PharmaTrain Federation (PTF). Professionals working in the complex and changing global environment of medicines development are trained on-the-job, participate in university courses to achieve a 2nd-training cycle, diploma and/or master degree, and undertake continuing professional development (CPD). This vocational & academic education leads to an informal acquisition of an array of job-related competencies across multiple domains. To date, there is not a defined path nor qualification available for any professional in medicines development which certifies this described back-ground or achievement in a structured process; the PharmaTrain SMD aims to fill this gap.

Teaching & learning methods have been developed to meet the continuing education needs of postgraduate doctors, scientists and other professionals working with the research-based international pharmaceutical and related industries undertaking medicines development, contract research organisations, universities and competent authorities. Executives work in local & international multidisciplinary teams with requirements for both general and very specific competencies, and therefore learning. As a result, outcomes (competency) based education is emerging as a suitable alternative for adult learning and thus teaching has moved from didactic lectures in a classroom to interactive learning modalities based in the workplace, and assessed by outcomes. The SMD programme is based around the workplace with learning coming from experience on-the-job, governed by the individual's job description(s) and

exposure to projects and learning experiences in competencies described by the SMD curriculum.

SMD programme: organisation, management, administration & governance

The SMD programme is delivered under the auspices of the PharmaTrain Certification Board (PCB), the standard-setting body for the SMD programme, appropriately constituted by the PharmaTrain Federation. The PCB has an SMD Executive Group (SEG), which reports to the PCB, and conducts the practical delivery, monitoring and administration of the SMD Programme.

Documentation

The main documents relating to the SMD programme are:

a. The PharmaTrain Certification Board Charter;
b. The PharmaTrain Syllabus for Medicines Development;
c. The PharmaTrain SMD Competencies Curriculum (KSA Content) (developed by PharmaTrain & IFAPP);
d. The PharmaTrain Manual;
e. SMD Certification Programme;
f. SMD Mentor Criteria and Standards;
g. SMD Workplaces Criteria and Standards;
h. QMS SMD Programme (work in progress);
i. SMD Governace Document (work in progress);

These describe in detail all aspects of the SMD programme content and organisation, rules and regulations, personnel roles and responsibilities, minimum standards and financial matters. These aim to inform the PCB in the conduct of its duties which *inter alia* are to admit participants, approve training programmes, review and evaluate achievement and progress, and award the SMD Certificate to successful participants. All documents are available via *www.pharmatrain.eu*.

Requirements to obtain the SMD Certificate

Pre-requisites: potential participants must:

a. Have completed a formal education (BSc, MSc, MD, PharmD, RN, DV, PhD or equivalent) in a discipline in life science or healthcare e.g. medical doctors, pharmacists, biologists, chemists, biometricians, certified nurses.

b. Hold a post relating to researching, developing and/or medico-marketing of medicinal products, or intend to hold such a post for the practical competency-based, workplace-centred training towards the SMD Certificate.

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

For award of the SMD Certificate, participants must:

a. Complete theoretical training (specialty knowledge base) in medicines development in accredited course(s) covering the entire PharmaTrain Syllabus, with assessments and certified outcome. The contents of the theoretical training should 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 (PharmaTrain Centre; Centre of Excellence).
- An equivalent* Postgraduate degree (*covering the entire PharmaTrain 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) offered by the IFAPP National Member Associations in collaboration with local academic institutions or other accredited education providers.

Theoretical training can occur prior to enrolling in the SMD programme, or in parallel with the practical workplace–based training. The theoretical training must be documented in the PharmaTrain Training Record.

b. Provide evidence over a 4-year period of gaining practical training and competencies in medicines development in an organisation where medicines development is part of its work such as a company in the pharmaceutical or related industries, or a contract research organisation, academic centre, 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.

Practical competency-based training in a personalised programme

The goal of training is to acquire competencies in the main areas of medicines development. A training plan must be submitted to the PCB for evaluation and approval before the start of training. Practical training can run in parallel with theoretical training, over the 4-year duration of the SMD programme.

There are seven specialty Domains in the curriculum covering medicines development (see Table below); Domain VII encompasses a general domain of Interpersonal, Management and Leadership (IML) skills relevant to the ethical & professional work of individuals involved in medicines development. The curriculum for the Domains showing the Competencies (n=60) is available on *www.pharmatrain.eu*.

A **minimum** of three (3) Domains, including Domain VII, comprise the practical competencies / performance and must be completed in the workplace. Practical SMD training with continuous and performance-based assessments enables participants to demonstrate the breadth and depth of learning and experience that they have achieved in acquiring competencies in medicines development. The remaining domains can be completed in the workplace, or through attendance on interactive (cognitive-competency based) courses covering the Domains, which are necessary when the workplace does not provide opportunities to cover the curricular content of a Domain.

Table: SMD Competencies Curriculum.
On completion of SMD training a participant is expected to be competent in all Domains of the curriculum, and needs to be able:

- To identify unmet therapeutic needs, evaluate the evidence for a new candidate for clinical development & design a Clinical Development Plan for a Target Product Profile.
  Domain 1: Discovery medicine & early development.
- To design, execute & evaluate exploratory & confirmatory clinical trials & prepare manuscripts or reports for publication & regulatory submissions.
  Domain II: Clinical development & clinical trials.
- To interpret effectively the regulatory requirements for the clinical development of a new drug through the product life-cycle to ensure its appropriate therapeutic use & proper risk management.
  Domain III: Medicines regulation.
- To evaluate the choice, application & analysis of post-authorisation surveillance methods to meet the requirements of national/international agencies for proper information & risk minimisation to patients & clinical trial subjects.
  Domain IV: Drug safety surveillance.
- To combine the principles of clinical research & business ethics for the conduct of clinical trials & commercial operations within the organisation.
  Domain V: Ethics & subject protection.
- 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: Healthcare marketplace.
- 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: Communications & management.

The Workplace-based competencies learning environment

The personalised SMD programmes are undertaken by participants who are both working and learning within a managed environment undertaking medicines development; this comprises pharmaceutical company, contract research organisation,

academic centre, clinical or pre-clinical research institute, or competent authority. The workplace offering the SMD practical training must be recognised as an appropriate learning environment by the PCB.

Supervision; mentored programme

Participants in SMD will at all times have a named and qualified Mentor, responsible for facilitating and monitoring their training. A Mentor must provide documentation of his/her training to substantiate his/her qualification as a Mentor. The Mentor is who knows the SMD training programme and the individual SMD programme and Training Plan of the participant. The Mentor may be employed in the participant's own work-place or may be independent and external to the organisation. In some circumstances, the designated Mentor may delegate all or selected supervision to an associate Mentor, whilst retaining overall responsibility for supervision of training.

All elements of work in an SMD programme must be supervised to a level dependent on the experience of the participant, their exposure to and responsibility in projects and activities undertaken, and the level of their competence. The responsibilities of Mentors have been defined by PharmaTrain within the document *'Quality Management Handbook PharmaTrain'.* The Mentor (and Associate Mentors) must be willing to undergo induction and training in the responsibilities, skills and processes of mentoring in the SMD; for example, the conduct of educational and performance appraisals and assessments of performance and competency.

The PharmaTrain Regional Adviser (PRA)

The PRA is an advisory role which has responsibility for overseeing the SMD programmes followed by participants in the workplace and ensures appropriate quality management. The PRA is responsible to and acts on behalf of the PCB, to whom s/he has a duty of responsibility, diligence and care. The PRA is assigned to workplaces (company; CRO; competent authority) within their geographical orbit (national, regional, urban) to provide advice on SMD and to participants and Mentors on their individual SMD programmes, and to oversee their progress and achievement in the SMD programmes. The PRA, appointed by the PCB, will be experienced in pharmaceutical medicine / medicines development science operating at a senior level in pharmaceutical / regulatory medicine as well as in staff supervision, assessment and appraisal. The PRA must undergo induction into the role and training into SMD and the background to responsibilities of the PRA with the expected duties and activities in undertaking this advisory role.

The Training Record

To demonstrate acquisition of competencies the learning experiences the participant has worked on, and the length of the involvement, the work should be documented and authenticated by the participant. The completed practical training must be validated in writing by the Mentor. For the SMD certification, a minimum of four (4) years on-the-job training full-time equivalence is required. The Training Record allows evidence to be built up to inform decisions on a participant's progress and provides

tools to support the education and development of SMD participants. The participant'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 the Training 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.

SMD Certification

After a positive review of the application consisting of complete documentation of theoretical training and of the four years of practical competency-based training, the PCB will issue the PharmaTrain SMD Certificate; signatories of the Certificate are the President of the PTF and the President of IFAPP.

Continuing Professional Development (CPD)

The holders of a PharmaTrain SMD Certificate 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. All aspects of development important for the specialty should be addressed, for example, using the PharmaTrain modular training platform, as well as topics in science & medicine, in pharmaceutical medicine & in personal / professional development. The request for renewal of the SMD certification should be submitted every five years to the PCB by the holder.

Mechanisms for feedback

Opportunities for feedback to participants about their performance will arise through the use of the workplace-based assessments, regular appraisal meetings with mentors, discussions with work supervisors, managers 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 the SMD, which is, in the main, a formative, developmental process. Feedback to the participant on progress and achievements in the SMD, including acquisition of competencies, assessments made and standards reached, as well as strengths and deficiencies can be made throughout SMD, through educational meetings, appraisals and reviews, and written procedures. The results of feedback will be discussed between participant and Mentor during appraisals. Evidence that feedback has been sought and responded to will form part of the Annual Review of SMD training.

Participant – Mentor meetings

A formal process of appraisals and reviews underpins training. This process ensures adequate supervision during training, provides continuity between posts and different mentors and associate mentors, and is one of the main ways of providing feedback to participants. All appraisals should be recorded in the Training Record. Educational appraisal is a formative, developmental process which allows the participant and

Mentor to meet regularly to review how the requirements of the curriculum are being met and to discuss successes and deficiencies of participant and training in a confidential setting. Such meetings 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 & personal matters both to the participant on performance, and to the Mentor on how facilitation of training is progressing.

SMD Performance Appraisal and Annual Review

The SMD Performance Appraisal is the opportunity to consider what and how much has been achieved in the SMD programme against the set objectives for the year; and for new objectives to be set. Unlike educational appraisal, SMD Performance Appraisal is a summative evaluation, and its outcome and report informs the Annual Review process. The SMD Performance Appraisal enables participant and Mentor to discuss projects, assessments, achievements and progress against the Training Plan and preparation for the new Training Plan for the coming year. The SMD Performance Appraisal is normally conducted annually, but this should be according to workplace policy on appraisal cycles and may be subject to national legislation. Whenever it is conducted, the SMD Performance Appraisal will inform the Annual Review of the participant.

The Annual Review of participants and their individualised SMD programme is the opportunity for independent evaluation of achievement and progress in the acquisition of competencies for the SMD, against the annual Training Plan and the standards expected for the demonstration of competencies. Annual reviews will be conducted by independent panels, established by the PRAs, unrelated to the workplace and participant. Outcomes of annual reviews determine whether a participant continues with training as before or with additional intensive training requirements or a time-based mandate to complete remedial activities before continuing training.

Participants' responsibilities for curriculum implementation

One of the basic principles of a workplace-centred competency-based education and training programme is that the participant 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 specialty advisers, universities and bodies such as the PCB 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 participant with the motivation, drive and enthusiasm to undertake SMD training who must ensure that the circumstances are present and appropriate for their full participation, giving them the best chance for a timely and successful outcome.

Tracking evidence and assessment of competencies

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 required for a competency which must be demonstrated in order to achieve progressive acquisition of competence towards the SMD Certificate.

Managing curriculum implementation

The introduction of a structured competency-based training programme for SMD certification and the adoption of competency assessment procedures into outcome-based curricula represent a major departure from the former approach to postgraduate training. It is essential that there should be an explicit partnership between participants and those responsible for training, so that participants receive adequate support and guidance throughout the training period. In turn there is a new responsibility placed on participants to evaluate their own strengths and weaknesses, and to seek out the educational opportunities that they require to correct any deficiencies. The coordination, verification, monitoring and evaluation of all of these activities and undertakings can be implemented by the PRAs accountable to the PCB.

Equality and diversity

The SMD will be in compliance with the requirements of relevant legislation and codes of ethical conduct concerning all aspects of equality and diversity. SMD quality management will ensure equality & diversity (ED) compliance in all aspects of the SMD programme – all recruitment; participant enrolment, examination & assessment; availability of ED training & reporting. Compliance with anti-discriminatory practices will be assured through upholding national and international pharmaceutical industry and academic institution anti-discriminatory policies and practices.

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