



PharmaTrain Specialist in Medicines 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, 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, and on completion, receive a SMD Certificate from the PharmaTrain Certification Board.

Specialist in Medicines Development (SMD)

The principles and certification programme for the PharmaTrain SMD title for professionals involved in medicines development arise from the IMI PharmaTrain project. Multi-disciplinary professionals work in the complex environment of medicines development and are trained on-the-job in varied programmes leading to an array of job-related competencies across multiple domains, for which to date there is not a defined path nor qualification available which certifies this background or achievement in a structured process; the PharmaTrain SMD aims to fill this gap.

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 & learning experiences in competencies described by the SMD curriculum. Learning & teaching methods have been developed to meet the continuing education needs of postgraduate doctors, scientists & other professionals working with the research-based international industry, comprising pharmaceutical companies, contract research organisations, academic centres, clinical or pre-clinical research institutes, or 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 modality for adult learning and teaching has moved from didactic classroom lectures to interactive learning based in the workplace and assessed by outcomes.

SMD programme: organisation, management, administration & governance

The SMD programme is delivered under the auspices of the PharmaTrain Certification Board, through an SMD Executive Group, which conducts the practical delivery, monitoring & administration of the SMD programme, involving enrolment of trainees, approval of personalised training programmes, review & evaluation of achievement and progress, and award the SMD Certificate to successful trainees.

Requirements to obtain SMD certification:

- a. applicants for SMD must 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. applicants must hold a post in Pharmaceutical Medicine/Medicines Development, or intend to hold such a post for the practical competency-based, workplace-centred training component.

Award of the SMD certification:

- a. participants must complete theoretical training in the specialty knowledge base of medicines development in accredited course(s) covering the entire PharmaTrain Syllabus for Medicines Development, with assessments & certified outcome; this theoretical training can occur prior to enrolling in the SMD programme, or in parallel with the practical workplace-based training.
- b. participants must <http://www.pharmatrain.eu> provide evidence over a 4-year period of gaining practical training and competencies in medicines development in an institution (pharmaceutical company, 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.

Practical competency-based training in a personalised programme

The goal of training is to acquire competencies in the main areas of medicines development. There are seven specialty Domains (see Table) in the competencies curriculum covering 57 competencies in medicines development. Domain VII encompasses a general domain of Interpersonal, Management and Leadership (IML) skills relevant to the ethical & professional work involved in medicines development.

A minimum of three Domains, including Domain VII, comprise the real-life performance (competencies) and must be completed in the workplace, with continuous and performance-based assessments which enable trainees to demonstrate the breadth and depth of learning and experience achieved. The remaining domains can be completed in the workplace, or through interactive cognitive-competency-based courses covering the Domains, when the workplace does not provide appropriate learning opportunities.

The collection and recording of evidence of attainment and assessment of competencies is an important aspect of progress and completion of the SMD programme. Regular checks and verification of the appropriateness and veracity of this evidence are made, recorded and validated by the trainee's mentor. The SMD curriculum defines the standards of knowledge, skills and attitudes/behaviours required for a competency which must be demonstrated in order to achieve progressive competence for SMD certification.

Mentoring

Trainees in SMD will at all times have a named and qualified mentor, responsible for overseeing and facilitating their training. All elements of work in an SMD programme must be supervised to a level dependent on the trainee's experience, their exposure to and responsibility in projects and activities undertaken, and the level of their competence. The mentor will be trained in the responsibilities, skills and processes of SMD mentoring, for example, the conduct of appraisals, giving feedback and assessments of performance and competency.

Training Record

For SMD certification, a minimum of four years on-the-job training is required. To demonstrate acquisition of competencies, the projects and learning experiences and length of the involvement in the work should be documented and authenticated by the participant in the Training Record, which allows evidence to be built up to inform decisions on a participant's progress against the Training Plan and provides tools to support the trainee's education and development.

Mechanisms for feedback

Opportunities for feedback to trainees about their performance and acquisition of competencies will arise through the use of the workplace-based assessments, regular meetings with mentors, discussions with work supervisors, managers and colleagues, and feedback from the Annual Review. The results of feedback on competencies, assessments, standards reached as well as strengths and deficiencies will be discussed between trainee and mentor during meetings and appraisals.

Annual performance appraisal and Annual review

The annual performance appraisal enables participant and mentor to evaluate projects, assessments, achievements and progress against the training plan and renew the training plan for the coming year. This is the opportunity to consider what and how much has been achieved in the SMD against the set objectives for the year, and for new objectives to be set. Unlike regular educational meetings, annual performance appraisal is a summative evaluation, and its outcome and report informs the Annual Review. The Annual Review of trainees and their personalised SMD programme is an independent review of achievement and progress against the training plan and programme timetable of four years and the standards expected for the

demonstration of competencies. Annual reviews are conducted independently of the workplace and trainee/mentor. Outcomes of annual reviews determine whether a trainee continues with training as before or with re-directed training, additional intensive training or remedial activity before continuing training.

SMD certification

After a positive review of the application consisting of complete documentation of theoretical training with certified outcome and of the four years of competency-based training, the PCB will issue the SMD Certificate.

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:

- **Domain 1: Discovery medicine & early development.** 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 II: Clinical development & clinical trials.** To design, execute & evaluate exploratory & confirmatory clinical trials & prepare manuscripts or reports for publication & regulatory submissions.
- **Domain III: Medicines regulation.** 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 IV: Drug safety surveillance.** 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 V: Ethics & subject protection.** To combine the principles of clinical research & business ethics for the conduct of clinical trials & commercial operations within the organisation.
- **Domain VI: Healthcare marketplace.** 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 VII: Communications & management.** To interpret the principles & practices of people management & leadership, using effective communication techniques & interpersonal skills to influence key stakeholders & achieve the scientific & business objectives.