The Specialist in Medicines Development (SMD) A Global Certification Programme by PharmaTrain Federation

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Rationale:

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.

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 (PCB).
The programme has been developed by IMI-PharmaTrain and PharmaTrain Federation*, a European follow-up programme (and is endorsed and supported by imi-train *),. Currently a European pilot has been started in Italy and subsequently in Portugal and Belgium in close cooperation with IFAPP**. Further global rollouts are planned for Latin America and Asia.

*) IMI-PharmaTrain and imi-train : a European Teaching and Education programme within the framework of IMI (Innovative Medicine Initiative), supported by the EU-commission and EFPIA (European Federation of Pharmaceutical Industries and Associations) PharmaTrain Federation – the follow up organisation of IMI-PharmaTrain
**) IFAPP: International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine

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.

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 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. 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.

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.

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.

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.

Annual performance appraisal and 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.

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.