

## PharmaTrain Certification Board Charter

### I. PURPOSE & AIMS

The PharmaTrain Certification Board (PCB) is the standard-setting body for the PharmaTrain Specialist in Medicines Development (SMD) education and training programme.

The aim of the PCB is to implement and oversee the SMD programme, and to recognise those who complete it successfully by awarding them the PharmaTrain SMD Certificate.

The PCB aims to enhance the standards, quality and excellence of the work in medicines development through the SMD programme of professional competence progression and SMD certification.

The basis and framework of the SMD programme, curriculum and assessment are specified in approved curricular documents (*Annexes* to this Charter). The PCB oversees delivery, acquisition and completion of individual SMD programmes.

### 2. DEFINITION OF TERMS

**Global PharmaTrain Certification Board (gPCB).** As defined in this Charter there is one gPCB, established by the PharmaTrain Federation (PTF) as the standard-setting body for the SMD programme.

**National PharmaTrain Certification Board (nPCB).** As defined in this Charter a nPCB is established by the gPCB on a country basis to meet the requirements of local SMD programmes, legal or regulatory requirements, geography or culture. The constitution, composition, terms of office and modus operandi of the nPCBs shall be those of the gPCB, as appropriate to local conditions.

**PCB.** The term 'PCB', as used in this Charter, applies to both gPCB and nPCB, unless these are specified.

**PTF Board.** The term ‘PTF Board’, as used in this Charter, means the PharmaTrain Federation (PTF) Board with its constituent member, the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP). The PTF Board is the approval body for decisions of the PCB requiring such approval. Decisions of the PTF Board are endorsed by imi-train (through WP3).

**SMD Executive Group (SEG).** A group established by the PCB to undertake the executive actions of the PCB to implement, monitor and administrate the SMD programme. There is no prescribed composition of a SEG, which will depend on their tasks, local circumstances, and expectations of the PCB. The SEG will report to the PCB.

**PharmaTrain Regional Adviser (PRA).** An experienced professional in Medicines Development Science / Pharmaceutical Medicine who will be appointed by and be responsible to the PCB for oversight of workplaces where SMD programmes are conducted, for being the point of contact between workplaces, participants & their mentors, PharmaTrain Centres & Centres of Excellence and the PCB. The PRA will seek to represent, promote & facilitate the uptake of the SMD programme, to ensure its organised introduction and orderly conduct to its high and shared quality standards. PRAs oversee geographical territory, as agreed with them by the PCB, and all SMD activities within it. PRAs act in an advisory capacity and have no executive authority over the SMD programme.

**Mentor.** A Mentor facilitates the education & training of an SMD participant. Mentors are nominated by an SMD stakeholder, and are approved and trained by the PCB. Mentors are usually based in the workplace of the SMD participant, as their manager or senior colleague. However, where necessary, Mentors may be appointed who are external to the workplace of the participant. The Person Specification and Role & Responsibilities of Mentors are described in a separate document (*Annexed*).

### 3. CONSTITUTION

This Charter represents the constitution of the global PCB (gPCB).

National PCBs (nPCB) will also be constituted and will adhere to this Charter as appropriate to local conditions. nPCBs will report to the gPCB.

*[The first PCB, instituted for the SMD Pilot in Italy, will act for the period of the Pilot as the gPCB, the nPCB (Italy) and the SMD Executive Group (Italy). These three functions will be separated as the SMD programme develops beyond the Pilot country(ies)]*

#### **4. COMPOSITION**

The gPCB shall be composed of ten (10) members. There will be eight (8) individual members nominated by SMD stakeholders for approval by the PTF Board, endorsed by imi-train (through WP3). Two (2) of the eight (8) individual members, the Executive Chair and Vice-Chair will be nominated by SMD stakeholders for those specified positions for approval by the PTF Board, endorsed by imi-train (through WP3). The remaining two (2) members of the gPCB will be, ex officio, the President of PTF and President of IFAPP as signatories; occupation of these positions changes as the office-holders are replaced.

All ten (10) members of the gPCB shall have equal voting rights.

#### **5. NATIONAL CERTIFICATION BOARD (nPCB)**

A nPCB may be formed to meet the requirements of local SMD programmes, legal or regulatory requirements, geography or culture.

The constitution, composition, terms of office and modus operandi of the nPCBs shall be those of the gPCB, as appropriate to local conditions.

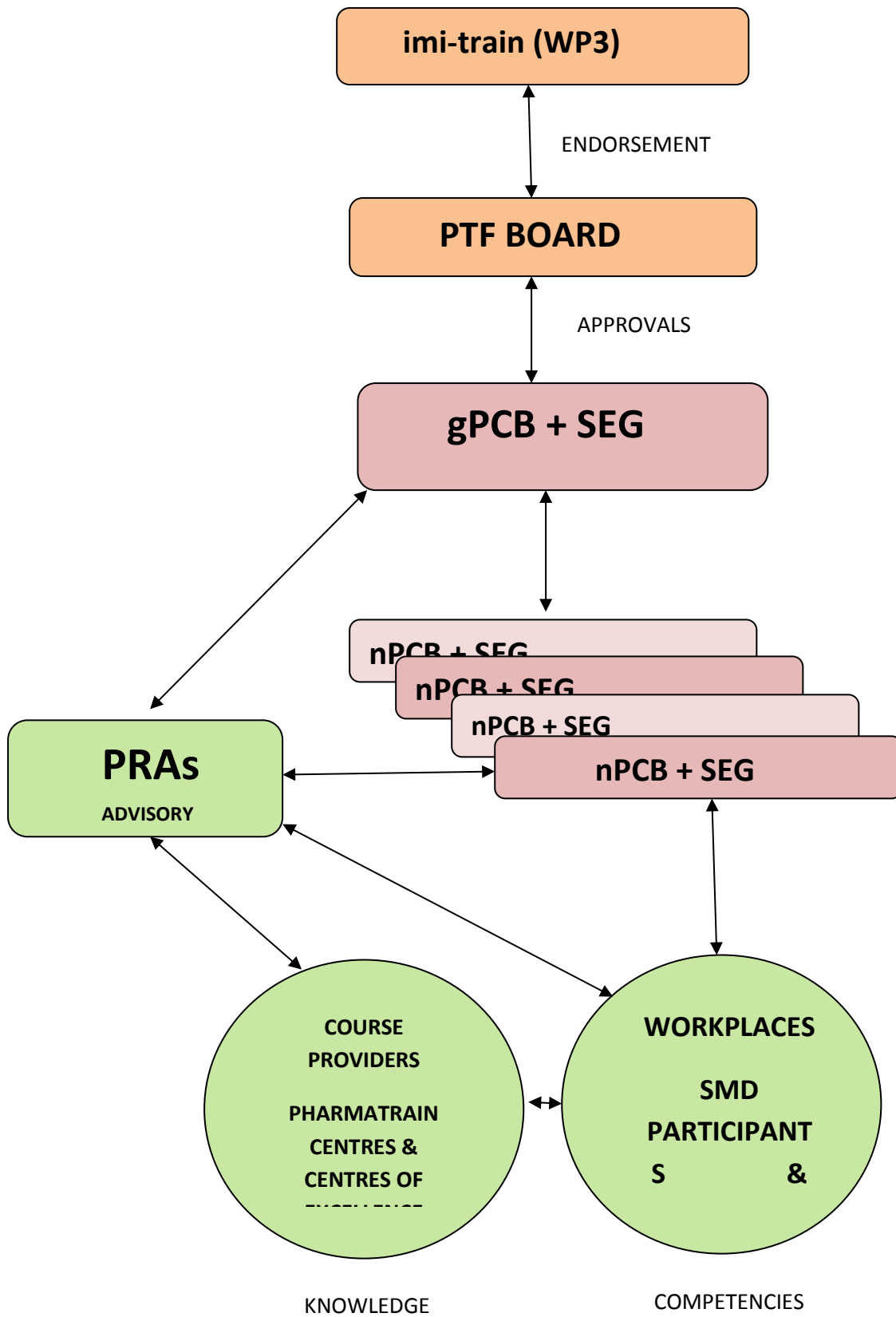
*(The positions of Presidents of PTF & IFAPP apply only to the gPCB. These places on nPCBs will be filled by national representatives of the PTF and of the IFAPP national Member Association, as appropriate.)*

#### **6. TERMS OF OFFICE**

The term of office of all nominated members of the PCB is three (3) years with the possibility for re-appointment for one further term.

PCB nominated members, excluding the Executive Chair and Vice-Chair, may be represented by an Alternate on prior approval by the PCB Executive Chair.

### Reporting within the SMD Certification Programme



## 7. MEANS OF OPERATION

The gPCB will meet through monthly teleconferences called by the Executive Chair to address a pre-circulated agenda. A quorum for a decision-making meeting is for 50% of the gPCB to be present including three (3) nominated members, the Chair or Vice Chair and either PTF President or IFAPP President.

The gPCB will also have at least one (1) face-to-face meeting per annum.

Matters for decision will be by simple majority of those present, with the meeting Chair having the casting vote.

All gPCB decisions will be ratified by the PTF Board, endorsed by imi-train (through WP3).

Members of the gPCB are expected to attend at least 50% of the monthly TCs per annum and all of any face-to-face meetings called, unless extenuating circumstances prevail and are accepted by the Executive Chair.

## 8. PERSON SPECIFICATION

**Any member of the PCB shall meet the following essential criteria:**

- a. Qualification to Masters level or above in a life science or medical field.
- b. Actively working in or consulting in the field of medicines development science / pharmaceutical medicine.
- c. Experienced in at least two (2) specialty domains of the SMD competency curriculum over a period of not less than 10 years.
- d. Actively undertaking Continuing Professional Development in their own field.

**...and if possible meet the following desirable criteria:**

- e. Two (2) publications in the scientific / medical literature in the past 5-8 years, as first or joint author.

- f. Experience of supervision / mentoring of students / trainees, including assessing, examining, appraising, reviewing.
- g. Experience or demonstrable interest in education and training in the field of pharmaceutical medicine / medicines development science.

## **9. RESPONSIBILITIES OF THE PCB**

- a. The PCB works closely with its SEG which monitors, manages and administrates the SMD programme.
- b. SMD Governance. The PCB maintains liaison with all stakeholders in SMD and, on the basis of feedback and stakeholder input, makes recommendations with respect to changes to the rules, regulations, processes & procedures governing the SMD programme to the PTF Board for approval.
- c. SMD Curriculum. The PCB evaluates all input and proposed changes to the SMD curriculum, and to the competencies curriculum, and after review on a regular (3-yearly) basis will submit proposed updates to the PTF Board for approval.
- d. Through the SMD curriculum, the PCB oversees, monitors and promotes good practices and competence in medicines development.
- e. The PCB will confirm that applicants fulfil the eligibility and entry criteria to the SMD.
- f. The PCB will approve the individual SMD programmes and their workplace posts, and will confirm the provisional completion date of all individual SMD programmes.
- g. The PCB will oversee the progress of all SMD participants through the SMD programme. The SEGs will monitor the progress of SMD participants through individual SMD programmes.
- h. The PCB will ensure that appropriate assessments of knowledge and competencies are in place, and that they are valid, reliable and comprehensive.
- i. The PCB will satisfy itself that all SMD participants have opportunities for regular appraisal.

- j. The PCB will ensure arrangements are in place for the annual review of progress of SMD participants and that outcomes for continuation (and / or remediation) of training are communicated.
- k. The PCB will be responsible for the appointment and training of Mentors for the SMD participants.
- l. The PCB will be responsible for appointment and training of PharmaTrain Regional Advisers (PRA).
- m. The PCB will approve all those named and eligible participants who have completed the SMD programme for the award of the SMD Certificate. Signatories of the SMD Certificates will be the gPCB members who are President of PTF and President of IFAPP.
- n. The gPCB will be responsible to the PTF Board for matters relating to the proper management of the SMD programme. These will include:
- i. Management of the budget agreed by the PTF Board.
  - ii. Appointment and supervision of administrative staff, in close collaboration with the PTF administration and President/Executive Director.
  - iii. The publication of an Annual Report.
- o. Acting on behalf of the PTF Board the gPCB will address all matters relating to appeals.
- p. The gPCB will be responsible for establishing a system for quality management of the SMD and enable its implementation.
- q. The PCB will assume other roles and responsibilities as may from time to time be required by the PTF Board in connection with the SMD programme.
- r. The PTF Board will determine the extent to which roles & responsibilities of the gPCB may be delegated to the nPCBs, SDM Executive Group(s), PharmaTrain Regional Advisers, President/Executive Director (PTF admin).

## **10. EQUALITY AND DIVERSITY**

The PCB will comply with, and ensure compliance throughout the SMD Programme 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.

## **11. GENERAL RULES**

- a. This Charter is effective upon approval by the PTF Board and endorsed by imi-train (through WP3). It shall be reviewed for re-adoption at least every five (5) years from the date of the most recent revision.
- b. Interim proposed changes to the Charter shall be submitted for approval to the PTF Board and endorsed by imi-train (through WP3).

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## **Annexes:**

- i. PharmaTrain Syllabus V1.0
- ii. PharmaTrain SMD Competencies Curriculum (KSA Content) V3.0
- iii. PharmaTrain Manual V2.0
- iv. SMD Certification Programme V1.0
- v. SMD Mentor Criteria and Standards V1.0
- vi. SMD Workplaces Criteria and Standards V1.0



vii. Quality Management System SMD Programme V0.2 (*Work in Progress*)

viii. SMD Governance Document V0.1 (*Work in Progress*)

#### Record of Version Control and Revisions

Revision Date	Version	Responsible for Version control/change	Description	Sections Affected
8 Dec 2014	V0.1	P D Stonier	Initial Draft	All
12 Dec 2014	V0.2	P D Stonier	Revisions following review by IPCB Task Force	All
19 Dec 2014	V0.3	P D Stonier	Revisions following review by IPCB Task Force	New 10, 8, 11
29 Dec 2014	V1.0	P D Stonier	Final V1.0 released to imi-train WP3	All