



**Individualised Pharmaceutical Medicine Specialty Training (PMST) Programme**

**Completing the individualised PMST programme form**

It is important that before completing this form you refer to the ‘Specialty Training Curriculum for Pharmaceutical Medicine August 2010 (Amended 2014)’ [‘the PMST curriculum’], which you can download from the Faculty of Pharmaceutical Medicine website at the following web address:

<https://www.fpm.org.uk/trainingexams/pmst/curriculumassessment>

If you are completing this form as part of your enrolment on the PMST programme please ensure that you include the original copy of the form with your other enrolment documentation.

If you are completing this form following your move to a new pharmaceutical organisation please ensure that you also include your completed continuation of training endorsement application form, and a copy of your organisation’s completed Local Education Provider Agreement.

**Returning your completed individualised PMST programme form**

Please return your completed individualised PMST programme form together with any other documentation to:

Specialty Training Manager

Faculty of Pharmaceutical Medicine

19 Angel Gate

326a City Road

London

EC1V 2PT

**Section 1 – General Information**

|  |
| --- |
| Trainee Name:       |
| NTN (if applicable): ALL/PM/     / (e.g. ALL/PM/123/I) |
| Name of Educational Supervisor (ES):       |
| Name of Associate Educational Supervisor (AES):      (if applicable) |
| Name of Specialty Adviser (SA):       |
| Name and address of employer:       |
|       |
|       |
| Site address if different from above:       |
|       |
|       |
| Tel:       | Fax:       | E-mail:       |

**Signature of Trainee:** Date: / /

**Signature of ES:** Date: / /

**Signature of AES:** Date: / /

(if applicable)

**Section 2 – Specialty Knowledge-base of PMST**

Trainees must hold the Diploma in Pharmaceutical Medicine prior to completion of the PMST programme (i.e. before a CCT can be recommended). Information about the Diploma and details on the required syllabus are available on the Faculty website at <https://www.fpm.org.uk/trainingexams/exams/dippharmmed> or by calling the Faculty’s Examinations Administrator on 020 7831 7662. The syllabus sections are listed below.

Please indicated below whether you have passed or plan to sit the Diploma in Pharmaceutical Medicine examination:

1. I passed the Diploma in Pharmaceutical Medicine examination in:       (year)

**OR**

2. I plan to sit the Diploma in Pharmaceutical Medicine examination in:       (year)

If you do not hold the Diploma in Pharmaceutical Medicine, please tick those syllabus sections below for which you will gain knowledge *within your job* in order to sit the Diploma in Pharmaceutical Medicine examination.

[ ]  1. Discovery of Medicines

[ ]  2. Development of Medicines: Planning

[ ]  3. Non-Clinical Testing

[ ]  4. Pharmaceutical Development

[ ]  5. Exploratory Development (Molecule to Proof-of-Concept)

[ ]  6. Confirmatory Development: Strategies

[ ]  7. Clinical Trials

[ ]  8. Ethics and Legal Issues

[ ]  9. Data Management and Statistics

[ ]  10. Regulatory Affairs

[ ]  11. Drug Safety, Pharmacovigilance and Pharmacoepidemiology

[ ]  12. Information, Promotion and Education

[ ]  13. Economics of Healthcare

[ ]  14. Therapeutics

Please list below any courses you will take or are taking to gain the required specialty knowledge to sit the Diploma in Pharmaceutical Medicine examination.

|  |  |
| --- | --- |
| **Course name and location** | **Start date (if known)** |
|       |       |
|       |       |
|       |       |

**Section 3 – Practical competencies in PMST programme**

**3A Practical in-work experience**

Please tick ☑ on the tables which follow for each item whether you will acquire training by practical in-work experience (IWE), by item taught course (ITC) [mini course, internal or external] or by external module course (EMC) [approved by the Faculty].

The PMST curriculum requires that at least three modules should be completed substantially through practical experience in the workplace (IWE). Of these three, Interpersonal, Management and Leadership Skills (IML) is compulsory, although components of this may be supplemented by course work.

**Medicines Regulation (RGN)**

**Module Item Description Please tick as appropriate**

RGN 1 Legislative frame work for the [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 Development and registration

 of medicines

RGN 2 Post-authorisation safety [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 monitoring and regulatory

 reporting procedures

RGN 3 Product safety update reports [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

RGN 4 Unlicensed medicines [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

RGN 5 Marketing Authorisation [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

RGN 6 Clinical trials and global [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 Drug development

RGN 7 Wider availability of medicines [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 and product deregulation

RGN 8 Product defects, counterfeit [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 products, miscellaneous

 procedures and other

 requirements

**Clinical Pharmacology (CLP)**

**Module Item Description Please tick as appropriate**

CLP 1 Non-clinical pharmacology [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 and toxicology

CLP 2 Literature review and preparation [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 of manuscripts for publication

CLP 3 Clinical pharmacology and [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 toxicology evidence required

 in regulatory approval process

CLP4 Design, execution and analysis [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 of earl-phase studies in man

CLP 5 Ethical principles and practices [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 in clinical research with volunteer

 subjects

CLP 6 Good Clinical Practice (GCP) in [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 clinical pharmacology

CLP 7 Clinical pharmacology of new [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 medicine within the clinical

 development plan

CLP 8 Application of therapeutic area [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 knowledge to identify unmet

 therapeutic needs

**Statistics and Data Management (SDM)**

**Module Item Description Please tick as appropriate**

SDM 1 Statistical principles in design [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 of clinical studies

SDM 2 Clinical input and review of [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 Statistical Analysis Plan (SAP)

SDM 3 Statistical principles, methods for [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 analysis and presentation of data

 from clinical studies

SDM 4 Statistical principles for the design, [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 conduct, analysis and reporting of

 clinical, post-marketing and health

 economic studies

SDM 5 Statistical methods used and [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 presented in reports and

publications

SDM 6 Case Report Form (CRF) design [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 and clinical data management,

 including CDISC, Electronic Data

 Capture and MedDRA

**Clinical Development (CLD)**

**Module Item Description Please tick as appropriate**

CLD 1 Disease area analysis within [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 Industry clinical development

 environment

CLD 2 Evaluation of non-clinical and [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 Phase I data for CDP for a new

 drug

CLD 3 End-points used in clinical trials [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

CLD 4 Clinical Development Plan (CDP) [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

CLD 5 Development of clinical trials [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 protocol

CLD 6 Regulatory and ethical aspects [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 of clinical development

CLD 7 Management and conduct of [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 clinical trials

CLD 8 Evaluation of all suspected [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 adverse events in clinical trials

CLD 9 Clinical study reports and [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 manuscripts prepared for

 publication

**Healthcare Marketplace (HMP)**

**Module Item Description Please tick as appropriate**

HMP 1 Healthcare environment and [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 pharmaceutical medicine

 (‘The External Environment’)

HMP 2 Medical-marketing [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 communications with legal

and regulatory compliance

HMP 3 Pharmaceutical industry; [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

structure, function, stakeholders,

commercial drivers and impact of

these business elements on broader

healthcare market

(‘The Internal Environment’)

HMP 4 Commercial analysis of product [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 potential within industry business

 environment

HMP 5 Competitor environment [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

HMP 6 Interface of pharmaceutical [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 industry with broader healthcare

 environment

**Drug Safety Surveillance (DSS)**

**Module Item Description Please tick as appropriate**

DSS 1 Regulatory requirements for [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 pharmacovigilance (PV)

 and their historical background

DSS 2 Medical assessments and drug [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 Safety reporting

DSS 3 Spontaneous reporting [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 and signal detection

 methodologies and medical

 evaluation of ADRs for causality

 assessment

DSS 4 Evaluation of risk/benefit balance [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 and the Risk Management Plan

(RMP)

DSS 5 Regulatory actions to address [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 patient safety

DSS 6 Communications of safety issues [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

DSS 7 Issues and crisis management [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

DSS 8 Progress, major advances and [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 Future challenges in drug

 Safety and PV

**Interpersonal, Management and Leadership Skills (IML)**

**Module Item Description Please tick as appropriate**

IML 1 The managed environment [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 in which pharmaceutical

 medicine operates

IML 2 Principles and practices of [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 people management and

 leadership

IML 3 Interpersonal and communication [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 skills in pharmaceutical medicine

IML 4 Communicating the knowledge, [ ]  IWE | [ ]  EMC | [ ]  ITC | [ ]  N/A

 skills and behaviours of competent

 pharmaceutical medicine

**3B Taught course training summary (add extra pages if necessary)**

Each module or module item which is ticked as a taught course in section 3B must also be entered on the summary chart below detailing the training you plan to undertake.

This summary should be completed with the agreement of your ES and SA and can be updated if the situation changes.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date** | **Module or Module Item** | **Course Title and Provider**(this may be for a ‘mini’ course for item(s) or whole module course) | **Date Planned** | **Date Attended** |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |

**Section 4 – JRCPTB use only**

Q1. Is this individualised PMST programme approved?

□ Yes □ No

Q2. Is there a minimum of 3 **in-work** modules including the IML module?

□ Yes □ No

Comments:

Signature of SAC member: Date: / /

Print name: