



**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)** |
|  |  |
|  |  |
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**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** |
|  |  |  |  |  |
|  |  |  |  |  |
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**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: