GOOD MEDICAL PRACTICE – 2024

Supporting Information examples for the four domains

This document is written for physicians employed by or working independently in the Pharmaceutical and allied industries (e.g. CROs, Consultancies etc.).

It gives examples of activities that can be provided as Supporting Information (SI) for FPM revalidation appraisals to demonstrate compliance with various attributes of the 4 GMP Domains.

Please note that this is not an exhaustive list of Supporting Information (SI). Please also refer to GMC's Guidance on supporting information for revalidation. If you would like additional SI examples added to this document, please send the same to a.khan@fpm.org.uk.

You don't need to provide Supporting Information (SI) and related evidence for each of the 31 attributes of the 4 GMP domains at every appraisal meeting. However, it is expected that you will provide a wide variety of SI covering the whole scope of your practice.

The Supporting Information (SI) provided at each appraisal meeting must demonstrate your ongoing compliance with the 4 domains of the GMP.

The six types of Supporting Information (SI) you must collect and reflect on, and discuss at your appraisal, over your revalidation cycle are:

1. Continuing professional development (CPD)
2. Quality improvement activity (QIA)
3. Significant events
4. Feedback from patients or those to whom you provide medical services (if applicable)
5. Feedback from colleagues
6. Compliments and complaints

Please also refer to FPM guidance entitled, How to Complete Your Input Form

Domain 1: Knowledge, Skills and Development

	Attributes	Supporting Information
1	Being competent	(a) Evidence of involvement in appropriate CPD, QI and other activities falling within the domains of the GMP (b) Client feedback (c) Company appraisals / performance reviews (d) Appraisee feedback reports (for appraisers only) (e) Review of your PDP (f) any significant event analyses and complaints, accompanied by discussion and reflection (g) feedback from lectures / trainings / presentations
2	Providing good clinical care	Relevant for Pharmaceutical physicians who are in direct patient or clinical research participant (including healthy volunteers) facing roles. Refer to FPM Clinical Review Policy
3	Offering remote consultations	As above
4	Considering research opportunities	Involvement in the development, review and approval of clinical trial protocols, investigator-initiated studies and other research protocols e.g. RWE, studies within trials
5	Maintaining, developing and improving your performance	(a) CPD activities (b) Quality Improvement Activities (QIAs) Refer to FPM guidance entitled, How to Complete Your Input Form for details
6	Managing resources effectively and sustainably	(a) Evidence of working in a role with line management and budgetary responsibilities (b) Evidence of taking part in company sustainability workstreams / initiatives, e.g. low carbon inhalers (c) Examples of work-related sustainability initiatives, e.g., paperless office, virtual meetings, travel cuts etc. (d) Examples of function (clinical development, medical affairs, drug safety etc.) specific sustainability initiatives

Domain 2: Patients, Partnership and Communication

	Attributes	Supporting Information
1	Treating patients fairly and respecting their rights	Participation in development, review, roll out and / or monitoring of: (a) Outer packaging – braille (b) Patient / carer support materials (c) Data protection activities e.g. patient registry (d) Involvement in GCP, GDP, GPVP activities (e) Compliant use of patient case studies or visual and audio recordings of patients (f) Ensuring diversity in clinical research participants to reflect population, especially women, ethnic minorities etc. (g) appropriate agreement terms for patient engagement activities including consideration of appropriate remuneration (h) other ethical considerations when there is a direct interface with patients
2	Treating patients with kindness, courtesy and respect	(a) Formal / Validated or Informal patient feedback (b) Actual examples, such as consideration of practical patient needs in activities involving patients (c) Demonstration of participant burden in clinical study protocols
3	Supporting patients to make decisions about treatment and care	Participation in development, review, roll out and / or monitoring of: (a) Informed consent; documentation and procedure (b) Awareness of relevant law on capacity and mental health – research consent (c) Patient Information Leaflets (d) Patient Education Materials (e) Disease Awareness Campaigns (f) Social media campaigns (g) any other material or activity co-created with patients / carers
4	Sharing information with patients	Participation in development, review, roll out and / or monitoring of: (a) Patient Information Leaflets (b) Patient Education Materials (c) Disease Awareness Campaigns (d) Summaries of Product Characteristics (SmPCs) (e) Outer Packaging – Braille (f) Additional Risk Minimisation Materials (g) Patient / Carer Support Materials (h) Medical Information Enquiry From Patients / Carers (i) Research Information for the Research Participants (j) Clinical Trial Registration (k) Patient Clinical Trial (or Lay) Summaries (l) Patient and public involvement in drug development and life cycle management (m) Collaborative work with patient advocacy groups (n) Involvement in GCP, GDP, GPVP

		activities involving sharing information with patients (o) Compassionate Use Programme / Early Access / Named Patient Supply (p) Making and using visual and audio recordings of patients (q) Expert patient consultant / patient advisory boards (r) patient meetings (s) patient websites
5	Communicating with those close to a patient	(a) Participation in development, review, roll out and / or monitoring of materials for carers (b) Collaborative work with patient advocacy groups and carer organisations
6	Caring for the whole patient	Direct: Relevant for Pharmaceutical physicians who are in a patient or clinical research participant facing roles. Refer to FPM Clinical Review Policy Indirect: Websites / Apps for patients; various patient materials / activities described in (4) above in this Domain
7	Safeguarding children and adults who are at risk of harm	(a) Participation in Paediatric investigation plans (b) Participation in informed consent procedures for vulnerable populations
8	Helping in emergencies	Actual examples
9	Making sure patients who pose a risk of harm to others can access appropriate care	Actual examples
10	Being open if things go wrong	(a) Participation in development, review, roll out and / or monitoring of: Dear HCPs and other safety communications (b) Declaring complaints, significant events and ABPI Code breaches & engaging in investigation and corrective action

Domain 3: Colleagues, Culture and Safety

	Attributes	Supporting Information
1	Treating colleagues with kindness, courtesy and respect	(a) 'Thank you' communications, compliments, company rewards and recognitions (b) Mentorships (c) Onboarding support (d) Handover plans (e) Equality, Diversity, Inclusion training (f) Validated colleague 360 feedback (g) laying people off with due respect and care (h) Involvement in hiring with evidence of fair and kind participation (i) maintaining courtesy and respect in investigation of complaints and breaches
2	Contributing to a positive working and training environment	(a) Training delivered (b) Advice provision (c) SOP writing (d) Development and review of training materials e) mentoring and contributing to others' development
3	Demonstrating leadership behaviours	(a) Organising trainings for the team (b) Personal soft skills, management and leadership trainings (c) Actual examples of demonstrating leadership behaviours e.g. decision making; managing conflict within the team; development and communication of strategy and plans
4	Contributing to continuity of care	(a) Keeping up to date with latest developments in the relevant area of practice (b) Completion of all mandatory trainings (SOPs, Policies, PV training etc.) (c) Copy review and approvals (d) Ensuring cover during absence
5	Delegating safely and appropriately	Actual examples
6	Recording your work clearly, accurately, and legibly	Presentation of the PReP portfolio, SI and supporting evidence in the form of written documents etc.
7	Keeping patients safe	Actual examples of contributions to product safety e.g. safety reporting; update of safety information; product quality issues etc.
8	Responding to safety risks	a) Safety communications e.g., Dear HCP Letters (b) Updating Company Core Data Sheets, SmPCs and Prescribing Information due to safety concerns (c) Actual examples

9	Managing risks posed by your health	(a) Looking after your own health and work-life balance (b) Ensuring you receive all relevant vaccinations (c) Registration with a GP / primary healthcare practitioner

Domain 4: Trust and Professionalism

	Attributes	**Supporting Information**
1	Acting with honesty and integrity	(a) Involvement in declaration of transfers of value in accordance with the ABPI Code requirements (b) Declaration of Conflicts of Interest (c) Equality, Diversity, Inclusion training (d) Declaration of complaints / significant events / ABPI code cases / Police and other investigations
2	Acting with honesty and integrity in research	(a) Keeping GCP trainings up to date (b) Involvement in GCP audits and inspections (c) speaking up when ethical concerns arise (d) ensuring that research findings are communicated accurately
3	Maintaining professional boundaries	(a) Having appropriate indemnity and insurance for the work undertaken (b) Actual examples (c) Not treating / prescribing for staff or close family members
4	Communicating as a medical professional	(a) Actual examples of involvement in external and internal communications, e.g., company spokesperson, media talks, presentations, publications (b) Feedback – both formal and informal
5	Managing conflicts of interest	Actual examples
6	Cooperating with legal and regulatory requirements	(a) Completion of all mandatory training (SOPs, Policies, PV training, ABPI code, GCP, Life Support etc.) (b) Participation in audits and inspections (c) taking action when legal or regulatory requirements are not respected by others