Methodology: the initial approval of pharmacist foundation training year programmes delivered independently of an MPharm degree

November 2021

Contents

Introduction ............................................................................................................................................. 2
Background ............................................................................................................................................. 2
The accreditation of foundation training year programmes ................................................................. 2
The scope of this methodology ................................................................................................................. 3
What needs to be approved? ..................................................................................................................... 3
The role of the GPhC and the statutory education bodies (SEBs) ......................................................... 4
The legal basis of accreditation ............................................................................................................. 5
Making decisions ..................................................................................................................................... 5
Appeals .................................................................................................................................................... 5
Principles of approval ............................................................................................................................. 5
Methodology for initial approval by accreditation ................................................................................. 7
Summary of methodology for initial approval: ....................................................................................... 7
Tracking progress across all steps .......................................................................................................... 8
When should this be achieved? ............................................................................................................. 8
First step: confirmation of intent .......................................................................................................... 8
Second step: self-assessment ............................................................................................................... 9
Third step: demonstration to GPhC Accreditors .................................................................................. 12
Introduction

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in Great Britain. Part of its education function is to check the standards of courses leading to registration and annotation as a pharmacist. It assumed responsibility for this work on September 27th 2010. Prior to that, it was the responsibility of the Royal Pharmaceutical Society of Great Britain (RPSGB).

Background

Pharmacy is a regulated profession. This includes the regulation of education and training leading to registration and annotation as a pharmacist and registration as a pharmacy technician.

The GPhC has two related education quality processes: accreditation and recognition. Accreditation involves the approval of a course designed and delivered by a provider (for example, an MPharm degree designed and delivered by a university) whereas recognition involves the approval of a national qualification (for example, an NVQ) which is quality assured by a national qualifications body (for example, Ofqual).

The GPhC has historically accredited a number of different courses. This document adds foundation training year (also ‘FTY’) Programmes covering the fifth year of initial pharmacist education and training. These programmes replace the existing Pre-Registration Training Year and, which along with the MPharm degree, permit those who complete them successfully and pass the GPhC’s registration assessment, to register as a pharmacist in Great Britain.

The accreditation of foundation training year programmes

The introduction of the 2021 standards for the initial education and training of pharmacists (‘IETP standards’) made a number of reforms to the education and training process for pharmacy education including the introduction of a Foundation training year which, along with a reformed MPharm degree, would allow graduates to become prescribers on registration as pharmacist.

The foundation training year is subject to the 2021 IETP standards which cover:

- Standard 1: Selection and admission
- Standard 2: Equality, diversity and fairness
- Standard 3: Resources and capacity
- Standard 4: Managing, developing and evaluating Foundation Training Year programmes
- Standard 5: Foundation year design and delivery
- Standard 6: Assessment
• Standard 7: Support and development for student pharmacists and everyone involved in the delivery of the foundation training year
• Standard 8: The foundation training year
• Standard 9: The foundation training year supervision

By 2025/26, foundation training year programmes must have been assessed as meeting these standards through an accreditation (approval) process. Successful completion of an approved foundation training year programme and passing the registration assessment will allow the holder to register as a pharmacist and annotate as an independent prescriber.

The scope of this methodology

This methodology concerns the initial approval through accreditation of foundation training year programmes forming the fifth year of the initial education and training of pharmacists where this is not integrated into an MPharm degree. We require that all foundation training year programmes are in place and meet our standards by the academic year commencing 2025/26.

What needs to be approved?

The GPhC will approve Foundation training year programmes

We will approve, by accreditation, the foundation training year Programme proposed by the SEB and its partners.

The programme must meet all the standards for the foundation training year. ‘The programme’ means all the aspects of the delivery of the foundation training year to which GPhC standards apply. We will not approve organisations but the proposed programme of learning along with its assessments, arrangements for delivery and quality management.

Accreditation is an evidence-based process and requires providers to demonstrate evidence against the standards.

Approval of placements and supervisors will be delegated to SEBs in future

At present, we approve the foundation training placements and designated supervisors unless there is an agreement (MoU) to delegate this function to the SEB in the country. We intend to delegate this function entirely to SEBs as part of the approval of the foundation training year Programme, if not already done so. SEBs will quality manage placement sites and designated supervisors and provide the list of their approved placement sites and supervisors to the GPhC.

Outcomes

We have provided interim outcomes along with guidance on their management for the transition period to new standards. These are a subset of the full outcomes and as such we will accredit foundation training year programmes to the new standards; there will not be a transitional approval against the interim outcomes as their implementation is a precursor to the implementing outcomes in full.
The role of the GPhC and the statutory education bodies (SEBs)

The 2021 IETP standards state that:

- Foundation training year programmes will be delivered by the statutory education bodies, employers and higher-education institutions, all working together. The precise nature of this collaboration will be decided between these organisations and will be approved by the GPhC.
- The statutory education bodies will be responsible for foundation trainees in their respective jurisdictions\(^1\)

The standards also set out a structure in which:

- The GPhC quality assures SEBs and their partners against the standards for the delivery of the foundation training Year
- The SEBs and their partners carry out quality management and oversee the delivery of the foundation training year locally by employers and supervisors
- Employers and supervisors carry out and control the quality of the course day-to-day

We will seek assurance about the quality of the foundation training Year primarily from the SEB in each country. While we recognise that foundation training year programmes will be delivered by a range of partners working under agreement, the SEB will be primarily responsible for all foundation trainees in its jurisdiction and as such will be in an overall position to provide assurance to the GPhC about standards.

Who needs to bring forward a course for accreditation?

In this paper, the term ‘foundation training year provider’ is used to describe the body that designs and develops the foundation training year programme for approval and takes responsibility for its quality management to meet the standards. While it is possible that they may be identical with the statutory education body (SEB) in each jurisdiction, this arrangement allows the SEB to form a partnership to perform these functions, for example, with one or more pharmacy schools or employers in its jurisdiction to be accountable for the management of processes to design and manage the foundation training year programme. We would expect a dean within an SEB to hold overall responsibility for the quality of the programme.

The foundation training year provider will be expected to have formal agreements in place with employers of trainee pharmacists to provide the day to day delivery of the programme and ensure supervision by appropriately qualified supervisors who have met the foundation training year provider’s requirements.

\(^1\) With the exception of Foundation Training years delivered as part of an integrated MPharm.
The legal basis of accreditation

GPhC’s right to check the standards of pharmacy qualifications leading to annotation and registration as a pharmacist is the Pharmacy Order 2010. It requires the GPhC to ‘approve’ courses (approval being the generic term for accreditation and recognition) by appointing ‘visitors’ (accreditors and recognisers) to report to the GPhC’s Council on the ‘nature, content and quality’ of education as well as ‘any other matters’ the Council may require.

The foundation training Year will form part of the programme leading registration as pharmacist and, in future, to annotation as a prescriber. As such, our right to check and approve foundation training year programmes is consistent with the principles and functions set out in the Pharmacy Order 2010.

Making decisions

Accreditation decisions will be the responsibility of the GPhC’s Registrar on advice from accreditors. The exception is the refusal or withdrawal of accreditation, which is reserved to the GPhC’s Council.

Reports will be written after accreditation events which will be made public. Providers may choose to provide a written response to reports, which will also be made public.

Appeals

The Pharmacy Order describes the appeal mechanism for accreditation and recognition decisions, at the heart of which is the right of a provider to challenge a decision by, first, providing additional evidence and, second, by making an appeal to the GPhC’s independent Appeals Committee. The form and manner of an appeal is described in the Order.

Principles of approval

The GPhC will apply the following principles to the initial accreditation of foundation training year programmes:

- Proportionality: the process will aim to seek assurance using proportionate processes
- Evidence-based: we will seek evidence about the design and management of programmes
- Peer review: we will make use of the judgements of appropriately qualified and experienced experts in decision making
- Public: the outcome of QA will be accessible to all on our website
- Transparent: we will set out our requirements at each step clearly
- Flexibility: while some aspects of the process will be completed at specific times, the timing of other aspects will reflect the progress of providers in implementing standards
• Parity: while the methodology may vary, foundation training programmes will need to meet the same standards whether they are delivered as part of an integrated MPharm degree or independently.

NB our methodologies to date have included cyclical review as a principle. This is not included because this is a one-time methodology, and because the ongoing methodology is yet to be decided.
Methodology for initial approval by accreditation

Summary of methodology for initial approval:

Initial approval must be achieved no later than the foundation training Year intake starting in 2025/26. Each step will result in a summary report outlining progress across GB. At steps 1-2, the GPhC will provide optional feedback to the foundation training year provider about their plans and at step 3a and 3b, the GPhC will write and publish a report about each programme. Should it be appropriate and proportionate, we will consider delivering steps 3a and 3b as a single step. Such a decision would be at the discretion of the GPhC and based on the previous steps and discussion with the foundation training year provider.

1. Confirmation
   • Provider identifies planned date to move to new standards in full
   • Provider confirms delegation of site/tutor approval or makes arrangements to do so

2. Self assessment
   • Self assessment: Provider identifies current status for each standard: Met/Some work needed/Significant work; implementation plan is provided its plan to do so

3. Peer review
   • Part A: GPhC accreditation team reviews evidence about quality programme design, assessment and QM and plans for implementation
   • Part B: GPhC accreditation team reviews implementation of SEB programme

Approval
• GPhC accreditation team recommends approval of the programme
• GPhC grants accreditation

steady state
• Programme enters steady state QA
Tracking progress across all steps

The GPhC will retain a record across all step about what assurance has been received against each standard. This will be updated following each assurance activity.

When should this be achieved?

- Foundation training year providers must complete the process and receive approval no later than the start of the foundation programme intake 2025/26 with the initial step carried out iteratively, starting in 2021/22.
- The initial steps (statement of intent and self-assessment) must be completed and submitted by the end of the academic year 2021/22 so that further activity can be scheduled at the appropriate point.
- The remaining steps will be flexible to reflect the different approaches of foundation training year providers. We have set some timing limits to when the final steps can take place to ensure issues can be resolved before the 2025/26 deadline and to manage logistics but otherwise we aim to tailor its approach to the needs of foundation training year providers.

First step: confirmation of intent

Purpose

This step is intended to establish the administrative relationship between the GPhC and the Provider to approve the course.

Content/format

Format

This step will be delivered entirely through a short form.

Content

The foundation training year provider would provide factual information on:

- the anticipated date to meet the standards in full, either by the start of the academic year 2025/26 or earlier
- How the foundation training year provider meets/will meet the requirement that it has responsibility for the totality of the foundation training year within its jurisdiction\(^2\) through:

\(^2\) Other than those delivered as part of an integrated MPharm degree programme. This does not preclude the SEB from being involved in such a programme.
confirming there is an MoU between the Provider and the GPhC covering to allow the
delegation of approval functions to the SEB in the foundation training year provider and
that the MoU is active or will come into force before the planned date meet standards in
full
o or, completing an additional step 1.a
  • Key contact details for the course: The dean and a quality management contact
  • Narrative on how regional variations in the programmes will be managed
  • Their approach to partnership arrangements around foundation training year delivery (both
    employers and universities providing MPharms)

Timing
Foundation training year provider should confirm their intentions and contacts to the GPhC by the end
of January 2022.

Delegation of approval functions
Where the Provider does not have control or funding for the totality of training, they should set out the
steps by which they will acquire responsibility for the totality of foundation training in their jurisdiction.
This should happen before the planned date to meet standards in full. They will need to:
  • Confirm intention to have such an arrangement in place
  • Identify target date to complete an MoU with the GPhC to govern the arrangement
  • Provide a short narrative
This step should result in the eventual completion of an MoU between the GPhC and the SEB in the
foundation training year provider covering delegation.

Data sharing
The MoU will need to conclude agreements to share the administrative data required to manage and
assure the foundation training year programme, including personal data, necessary to the effective
quality management and quality assurance of the foundation training year.

Outcome
The completed form would be published on our website.

Second step: self-assessment

Purpose
The purpose of this step is to:
  • Receive assurance the foundation training year provider is designing its programme to meet
    GPhC standards for the foundation training year
To demonstrate that the foundation training year provider has a credible plan and arrangements in place to meet their intended deadline
To provide a steer for the timing and format of the final steps of the review

Timing
The timing of this step is also relatively inflexible. Foundation training year providers should complete and submit the self-assessment template by the end of the academic year 2021/22.

Content/format

Format
The foundation training year provider will complete a templated self-assessment against each standard and provide supporting documentation.

Content
SEBs will need to submit:

- Updated narrative on plans for programme management and partnership arrangements
- A self-assessment of the extent to which their existing arrangements meet against the standards – for each standard, whether it has been
  - met, or whether
  - some work is required to meet the standard, or whether
  - significant work is required to meet the standard
- A plan to complete the implementation of their foundation training year to meet the new standards
- Supporting documents (not new documentation) about their curriculum, assessment, QM strategy, trainee support and concerns processes, requirements and support for/training of supervisors and agreements around to provide training places
- An assessment of current capacity against that required to deliver the programme (placements and supervisors)

Outcome

Analysis and publication
Self-assessment outcomes would be summarised into:

- Confirmation that the GPhC has received self-assessment and key support documents (curricula, assessment, QM strategy, trainee support arrangements)
• Total numbers of standards met/some work required to meet to meet the standards/significant work required to meet the standard
• Key themes in terms of challenges and barriers summarised

We will publish an aggregated progress report, summarising the status of foundation training year programmes and challenges.

Appointment of accreditors
The GPhC will appoint a team leader for the next step who will work with the provider

Discussion with providers
GPhC staff will review the submission to:
• Identify any early concerns or issues about progress identified by staff
• Set out arrangements and timing for the peer review step (review by accreditors)

The team leader will be present for the discussion and contribute to the discussion about the timing and format of the third step.
Third step: demonstration to GPhC Accreditors

The final step will be to discuss and triangulate information through peer review, meaning discussion with GPhC accreditors. We have suggested that this step may take place through two activities some time apart, reflecting that arrangements for implementation may be evolving until 2026/26.

In line with our intention to deliver flexible and proportionate assurance processes, we will consider a high degree of flexibility at this step: in some cases, we may consider delivering both these activities in a single step or other significant adaptations that may reduce the amount of activity required for step 3b. Any such decision will be made on the basis of the evidence provided in steps 1-2 and the subsequent discussion with the provider, and will be at the discretion of the GPhC. We will consider this where the foundation training year provider is able to demonstrate progress towards implementation of the standards by its intended date that would make this an appropriate and proportionate approach.

Part a: first check with GPhC accreditors

Purpose

The purpose of this step is to receive assurance that:

- Curricula and assessment strategies have been developed in line with the standards
- That policies to underpin training and support have been developed and that systems to deliver this are in development
- That the SEB is making adequate progress with the establishment of QM systems to govern the programme
- To explore arrangements about partnership working

Timing

The timing would be dictated at the request of the SEB following their self-assessment but should take place no less than 12 months before the SEB’s latest planned date to move to new standards. We would aim to adapt the timing to the needs of the SEB. For example, where an SEB may have a single curriculum and assessment but with regional organisation management and QM, we would work with the SEB to review common components in one activity.

Content/format

Format

Flexible but with some in person content, on site or remotely depending on the assessment of the visiting team. The exact format and content would be flexible to accommodate needs of the SEB and accreditors.
Measurable components

The provider will demonstrate that:

- Updated assessment of numbers of placements and designated supervisors required and numbers of completed agreements are adequate
- That the SEB is collecting data to support the quality management of the foundation training year placements, likely including:
  - The name of trainees
  - The location of placements/planned placements
  - Supervisors and their registration and training status (have they completed the foundation training year providers requirements for their role such as training and induction)
  - Whether trainees are making expected progression, or requires/are subject to remediation
- Progress in the training and approval of prescribing supervisors (DPPs)
- An update to their self-assessment if a significant amount of time has passed

Dialogue components

A small team of accreditors would be appointed to review the submission of the team and review documentation submitted to date. They would plan questions based on their scrutiny of the document but intended to focus on the following areas:

- Progress/project management towards implementing systems to achieve full compliance with the standards for foundation training year
- Development of quality management systems and process including partnership arrangements to deliver the foundation training year programme with employers and others; the foundation training year provider should be able to demonstrate progress towards a quality management system that can identify, track and resolve quality issues in all training sites
- Supervision- recruitment of supervisors, training and support
- Curriculum and assessment
- Tracking trainee progression and providing remediation where appropriate
- That partnership arrangements to manage the transition from MPharm to foundation training year are in place/ demonstrate that the student/trainee’s journey through from MPharm to foundation training year is reflected in the design of the foundation training year programme (years 1-4 will be covered in MPharm accreditation)
Outline event programme:

<table>
<thead>
<tr>
<th>When</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>After discussion with GPhC:</td>
<td>Set out likely dates for first check with GPhC:</td>
</tr>
<tr>
<td>12 weeks to check in</td>
<td>• No less than 16 weeks after than meeting with GPhC and later the GPhC’s discretion (to accommodate scheduling and logistical issues)</td>
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<tr>
<td></td>
<td>• No more than 12 months before the planned full implementation date</td>
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<td></td>
<td>• Appoint 2-3 further team members with appropriate experience (NB requirements for accreditor appointment to this role TBC)</td>
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<td></td>
<td>• Training on purpose and format of event</td>
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<td></td>
<td>• Provide background documentation to team</td>
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<tr>
<td>8 weeks to check in</td>
<td>Team provides:</td>
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<tr>
<td></td>
<td>• key lines of enquiry</td>
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<tr>
<td></td>
<td>• any requests for further information</td>
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<tr>
<td>6 weeks to check in</td>
<td>• Provider responds to further requests for evidence</td>
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<td></td>
<td>• Confirm attendees (NB if representation from pharmacy schools is to be included)</td>
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<tr>
<td>4 weeks to check in</td>
<td>Team provides further comments/further key lines of enquiry with detailed questions</td>
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<tr>
<td>2 weeks to event</td>
<td>GPhC collates and circulates agenda and key lines of enquiry</td>
</tr>
<tr>
<td></td>
<td>• team received detailed questions</td>
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<tr>
<td></td>
<td>• SEB receives key lines of enquiry</td>
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<tr>
<td>1 day before the event</td>
<td>Team meets and reviews questions</td>
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<tr>
<td>Event</td>
<td>Event: covering</td>
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<td></td>
<td>• Update on management of programme/ progression</td>
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<td></td>
<td>• Progression against plans</td>
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<td>• Risks and challenges to implementation</td>
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<td></td>
<td>• Development of partnership arrangements</td>
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<td></td>
<td>• Curricula and assessment development</td>
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<tr>
<td></td>
<td>• Quality management process</td>
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<td></td>
<td>• Discussion with sample of supervisors and employers covering:</td>
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<td></td>
<td>• involvement in course development</td>
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<td></td>
<td>• development of agreements and QM structures in respect of local placements</td>
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<td></td>
<td>• support and training from the foundation training year provider</td>
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<td></td>
<td>• Supervision meeting</td>
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</tbody>
</table>
**Outcomes**

**Reporting and feedback**

QA is run on the principles of transparency and that it takes place in public and we will report the outcome of this step in public. This would take the form of:

- Simple narrative description of activities
- Feedback of any concerns about progress short of conditions or recommendation
- Identification of conditions for achieving accreditation or recommendations

**Action plan for the final step of the review**

The main outcome for the review will be the identification of:

- Remaining areas in which further assurance/triangulation is required
- Any further evidence requests required to gain this assurance
- Key lines of enquiry to explore in the final step

This should be written up into an action plan covering the updates, discussions and other evidence that the team requires in order to receive final assurance leading to accreditation. While there is likely to be some standard or expected content, the accreditation team will have flexibility about exactly what is covered and how.

**Part B: second check-in with GPhC accreditors**

**Purpose**

The purpose of this step is to:

- Triangulate the assurance received at earlier step including hearing from partnership organisations where appropriate
- Check progress against targets, issues or concerns identified at the previous step
- Provide a final check of in-practice arrangements and overall readiness to deliver the foundation training year
Timing
The step is intended to provide a final check before a recommendation for accreditation is made. It should take place close to the planned full implementation date of the new standards in the year prior to the proposed date with enough time to act on any concerns, suggested to be no later than three months before the start of the academic year in which the training would be delivered against the standards in full for the first time.

Content/format

Content
This would be the most flexible step of the process and would be the result of consideration of the following three previous step. In most cases it will involve the following components:

Progress updates
- Update of the self-assessment by the foundation training year provider
- Update to the numbers of placements and designated supervisors required secured and the status of the supervisors in terms of mandatory training and inductions
- Updates on any open issues or concern identified at previous step along with supporting evidence

Discussion
- Exploration of readiness to roll out the new programme in full the following academic year
- Discussion of the progress update
- Partnership arrangements for delivery of the foundation training year
- Discussion of issues identified in quality management, their identification and resolution.

Other assurance- focussing on triangulation and testing arrangements.
The team may seek further assurance through other means. We will discuss with foundation training year providers on what this is likely to be but we anticipate that in addition to seeking evidence from the provider from discussion and reporting updates, the team would consider whether assurance should be triangulated from employer and supervisors locally.

Possible step four programme
The following programme is suggested as an indicative programme for this step.
### Activity

**Updates/readiness meeting**

- Progress since last meeting
- Preparation full delivery of foundation training year programme to standards
- Resolution of any open conditions, recommendations or other outstanding concerns from previous activity

**QM meeting**

- Discussion - review of QM processes
- Discussion of numbers of placements agreed
- Updates and questions on agreements with employers
- Plans for evaluation and review post implementation

**Partnerships meeting**

- Updates on agreements reached around course delivery
- Update and questions on HEI partnerships (pharmacy schools (NB employers will be covered in QM above))

**Teleconference meeting with sample of supervisors /employers**

- Test employer/supervisor views on agreements, training and support provided by the SEB in respect of programme
- Triangulation of any other issues identified by team

### Outcome

The outcome of this step will be a recommendation to:

- Approval with or without conditions
- Decline to approve with conditions:
  - We do not anticipate this situation from taking place as we would work with providers to resolve any concerns earlier in the process. However, if significant gaps in the ability to meet standards remain, and there is little prospect of their resolution for the 2025/26 cohort, we will consider the implications of a decision to decline approval.

The approval would result in an addition to the list of approved providers.