NHS Aseptic Services Accreditations Working Group

Nationally Recognised Competency Framework for Pharmacists and Pharmacy Technicians:

The Assessment of Product Approval (Release) in Aseptic Services under Section 10 exemption

Version 1.1: April 2016

CONTENTS

The National Framework for the Assessment of Product Approval (Release)

Introduction

Welcome to the nationally recognised competency framework for the training, assessment and accreditation of individuals carrying out the role of Product Approval (release) in aseptic services, under section 10 exemption. This framework outlines the processes that must be followed for the training and assessment of pharmacists and pharmacy technicians involved in an accreditation programme.

This framework supersedes the previous 'Nationally Recognised Framework for Accreditation of Final Accuracy checking within Aseptic Services' published in Oct 2008.

Background

The MHRA, empowered by the Medicines Act 1968[1] and Human Medicines Regulations 2012[2], have the task of protecting the public from any hazards that arise from the preparation and production of medicines. Most of this work is carried out through a system of licensing where producers and products meet stringent standards. There is however an exemption to this degree of control whereby organisations may prepare products for individual patients against a prescription. These processes must be carried out under the supervision of a pharmacist, within a governance framework which should be open to internal and external audit. This is generally known as working under "section 10 exemption".

Detailed guidance for professionals and organisations is available through regional Quality Assurance Officers and the NHS standards contained in "Quality Assurance of Aseptic Preparation Services"[3]. Within these standards, three key roles are identified:

- Chief Pharmacist (CP)/Senior Pharmacy Manager (SPM)
- Accountable Pharmacist*
- Authorised pharmacist

*The standards of the "Quality Assurance of Aseptic Preparation Services (2006)" refer to the pharmacist responsible for all aspects of the services within an aseptic unit as the Responsible Pharmacist. Subsequently, however, within the Health Act 2006[4] (the publication that made amendments to the relevant sections of the

[1] Medicines Act (1968) http://www.legislation.gov.uk/ukpga/1968/67/contents
[2] The Human Medicines Regulations 2012 http://www.legislation.gov.uk/uksi/2012/1916/pdfs/uksi_20121916_en.pdf
[3] Quality Assurance of Aseptic Preparation Services, Ed A.M. Beaney Pharmaceutical Press (London)

[4] The Health Act 2006, http://www.legislation.gov.uk/ukpga/2006/28/pdfs/ukpga_20060028_en.pdf

Medicines Act 1968), the term 'Responsible Pharmacist' was used to define the "pharmacist appointed by the employer, who is responsible for securing the safe and effective running of the pharmacy". This is directly related to the sale and supply of medicines. Hence a revised term of ''Accountable Pharmacist" was adopted within technical services units as the pharmacist responsible for all aspects of the services. This is the term that is widely accepted and used within technical services now and consequently throughout this report.

There are some inconsistencies with this approach to pharmacist supervision however:

- There are instances where the pharmacist that carries out product approval has also been involved in checks carried out earlier in the process
- The training undertaken by pharmacists may be inconsistent and they may lack experience and confidence
- Placing the focus of pharmacist input on product approval sometimes means that the "clinical check", which should ideally be carried out at a very early stage of the process, is combined with the final step of "product approval"
- The pharmacist may not have sufficient knowledge or information about the contemporaneous conditions within the unit that has prepared the medicine or be in a position to take account of operational problems that may affect the integrity of the product.

It was recognised that developing a specific training package to address these issues was necessary, to at least maintain, and potentially improve, current levels of patient safety. For operational reasons it was also recognised that there are potential advantages to deploying suitably trained registered pharmacy technicians to carry out product approval. Some pharmacy technicians may have more technical and operational experience in this area of practice and it may also allow the use of an additional individual within the process which, according to the theory of safe systems, should add an additional barrier to errors. In order to introduce accredited pharmacy technician product approvers to a unit, it will be necessary for Accountable Pharmacists to address the way that the overall process is supervised and to ensure that the level of pharmacist supervision meets the standards of the Yellow Cover Document, 'Guidance on the definition of supervision as applied to section 10 aseptic preparation activities'. This Yellow Cover Document sits alongside the National Framework and is available to download from www.nhspedc.nhs.uk.

Disclaimer

No responsibility is accepted for the content of documents derived from this original publication. Training providers remain responsible for the training, assessment, accreditation and reaccreditation of individual candidates.

Definitions

These terms relate solely to the body of this document. Although some terms have been taken from national guidance, there may also be variations in definitions according to regional and national documentation.

Accountable Pharmacist (AP)	The pharmacist responsible for all aspects of the aseptic preparation unit. The duties of the Accountable Pharmacist include the approval of all systems of work and documentation used in the unit. This person is also an Authorised pharmacist.
Accredited Product Approver	An authorised pharmacist or pharmacy technician who has been approved through a nationally recognised accreditation programme for product approval.
Appropriate persons	Staff who have been identified as suitably trained and qualified to give guidance and make decisions regarding the assessment process.
Assessment period	The period during which assessments are carried out. This must be preceded by an adequate period of supervised training.
Authorised pharmacist	The person designated in writing by the Accountable Pharmacist to supervise the aseptic process and release or delegate the release of the product for use.
Trainee	The person undertaking the training and assessment.
Chief Pharmacist (CP)	The pharmacist responsible for the pharmacy service within a corporate body.
Clinical Governance	The system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care. [5]
Clinical screening	Clinical assessment of a patient's prescribed medicines for safety, efficacy and compliance with local and/or national guidelines.
Continuing Professional Development (CPD)	An ongoing process of reflection and learning focussing on an individual's area of practice to maintain currency and occupational competence.
Competence	An ability to consistently successfully perform a task or activity to an agreed standard.

[5] HSC 1999/065. (March 1999) Health Service Circular. Clinical Governance: Quality in the new NHS http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4004883

Educational Supervisor (ES)	A suitably experienced pharmacy technician or pharmacist responsible for support of the trainee and facilitation of their training.
Pharmacy technician	An individual who holds the appropriate and recognised pharmacy technician qualifications in the UK and is registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society of Northern Ireland (PSNI). Throughout the document, where the term 'pharmacy technician' is used, the framework assumes the definition 'registered pharmacy technician' (where registration is a requirement).
Pharmacist	A person who holds an appropriate university degree and is registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society of Northern Ireland (PSNI).
Ongoing competence	Recognition of revalidation of practice, to demonstrate that required standards of competence continue to be met.
Reflective practice	The process of reviewing a specific task or day-to-day practice, identifying successes and weaknesses, and planning and taking action to address areas for development.
Registered pharmacy technician	A pharmacy technician who is registered with the relevant regulatory body (where registration is a requirement), for example, in Great Britain registration is with the General Pharmaceutical Council (GPhC).
Standard Operating Procedures (SOPs)	Approved, written, step-by step instructions specifying how a task or process should be carried out.
Supervised practice period	A period of training under the direct supervision of a suitably trained/qualified person e.g. pharmacy technician, pharmacist, educational supervisor.
Training Provider	An organisation responsible for the training and assessment programme, including delivery of training, assessment and accreditation.

Aim

The aim of the National Framework for the Assessment of Product Approval (Release) is to:

- Enable training providers to develop and implement a fit for purpose training and assessment programme that will deliver enhanced skills, knowledge, and an appropriate level of confidence for pharmacists and pharmacy technicians to approve products prepared in aseptic services under Section 10 exemption of the Medicines Act (1968)
- Support appropriate skill mix within pharmacy aseptic services units
- Enable training providers to provide a nationally recognised and transferrable accreditation to successful candidates.

Learning Objectives

The table below outlines the learning objectives that must be covered within any Product Approval Accreditation Programme and how these learning outcomes can be delivered and assessed.

Objective By the end of the Product Approval Accreditation Programme the trainee should be able to:		**Learning/Training delivery**	**Assessment Method**
1. Overarching principles of aseptic preparation	a. Demonstrate an appropriate level of knowledge of Good Manufacturing Practice in aseptic preparation	Pre-course reading Taught course	Written assessment Viva voce
	b. Demonstrate an appropriate level of knowledge of Quality Assurance in aseptic preparation.	Pre-course reading Taught course	Written assessment Viva voce
	c. Demonstrate knowledge of aseptic products and the principles and processes in aseptic preparation.	Pre-course reading Taught course	Written assessment Viva voce
	d. Demonstrate knowledge of the facilities, environment and maintenance in aseptic preparation.	Pre-course reading Taught course	Written assessment Viva voce
2. Aseptic products	a. Demonstrate an understanding of the main types of aseptic products in terms of their technical characteristics, e.g. stability, clinical use and risks. i. CIVAS ii. Parenteral nutrition iii. Cytotoxics iv. Others, e.g. “Biologicals”	Pre-course reading Taught course	Written assessment Viva voce
3. Identifying Errors	a. Demonstrate a thorough knowledge of the sources of human errors in aseptic presentation and steps that can be taken to identify them.	In-house experience and tuition Pre-course reading Taught course	Practice based evidence Written assessment Viva voce
	b. Demonstrate a thorough knowledge of the sources of system error in aseptic preparation and steps that can be taken to identify them.	In-house experience and tuition Pre-course reading Taught course	Practice based evidence Written assessment Viva voce
4. Legal and professional framework	a. Demonstrate a thorough knowledge of relevant legislation and professional guidance.	Pre-course reading Taught course	Written assessment Viva voce
	b. Demonstrate a thorough understanding of the professional responsibilities and accountabilities surrounding section 10 exempt aseptic preparation.	Pre-course reading Taught course	Written assessment Viva voce

Legal and professional framework cont..	c. Demonstrate a thorough understanding of pharmacist supervision of section 10 exempt aseptic preparation.	Pre-course reading Taught course	Written assessment Viva voce
	d. Demonstrate an appropriate professional attitude to the role of Product Approval.	In-house experience and tuition Pre-course reading Taught course	Practice based evidence Written assessment Viva voce
	e. Demonstrate competence and an appropriate level of confidence in carrying out product approval on aseptically prepared items.	In-house experience and tuition Pre-course reading Taught course	Practice based evidence Written assessment Viva voce
	f. Demonstrate a clear understanding of their personal professional capabilities and scope of practice.	In-house experience and tuition Pre-course reading Taught course	Practice based evidence Written assessment Viva voce

Entry Criteria

Criteria for Participating Sites

Note that for pharmacists to go forward in the training programme there are no site specific criteria and participation is encouraged from all aseptic services units. For a unit wishing to go forward with accredited pharmacy technician product approvers then the following will apply:

- The site is able and willing to operate the required pharmacist supervision model
- The site has a commitment from the Chief Pharmacist to approve and support trainees to undertake training
- The Accountable Pharmacist has sufficient experience and understanding of the legal issues and the model for supervision
- The site is approved by their Regional QA specialist / EL Auditor who will consider the following criteria:
  a) All relevant SOPs are in place and all worksheets approved by the Accountable Pharmacist
  b) Risk management arrangements are satisfactory, including robust change control processes
  c) Suitable staff training programmes and resources are available
  d) Clinical checking is carried out by suitably trained pharmacists in line with organisational procedures
  e) Prescription verification is carried out by authorised pharmacists
  f) A robust in-house system of dealing with errors including monitoring, reporting, managing and trending of errors is in place and the reviewing of data from the National Error Reporting Scheme.
  g) Sites should report to the National Error Reporting Scheme
  h) There must be data to support the baseline error rate. Error rates must be part of the acceptance criteria for the Change Control when introducing the change to allow accredited pharmacy technicians to carry out final product approval
  i) Robust Quality Management Systems including deviations and untoward events reporting and investigation are in place
  j) The management structure is compliant with the nationally agreed definition of supervision.

Criteria for trainees

The following criteria will apply:

Pharmacists

The pharmacist is allocated to an aseptic unit for a suitable minimum period of time sufficient to complete the programme (3 months).

The individual should be committed to the process.

Pharmacy Technicians

The pharmacy technician is allocated to an aseptic unit for a suitable minimum period of time sufficient to complete the programme (3 months).

They should have at least 2 years full-time or 3 years rotational aseptic experience and be accredited, in line with the national framework, to perform pre-process or pre and in-process checks in aseptic preparation.

The individual should be committed to the process.

Accountable Pharmacist Approval

Each trainee must be approved by the Accountable Pharmacist ahead of registration for a programme.

Exclusions from the process

The process applies to aseptically prepared pharmaceuticals only and with the following exemptions:

1) Radiopharmaceuticals
2) Products made under MA, MS or MA (IMP) licences
3) Clinical Trials prepared under Paragraph 37 exemption of the Clinical Trials regulations
4) Batch prepared products made in anticipation of a prescription
5) One off products made without a fully approved worksheet or those necessarily made for a clinical emergency
6) Advanced Therapy Medicinal Products
7) Intrathecal products

Management of the Scheme and the Role of the Training Provider

The training provider will:

- Ensure that the training and assessment programme is regularly reviewed and updated, and meets the standards of the national legislation and national framework regarding product approval under section 10 exemption
- Accept nominations for the training courses and facilitate places
- Ensure that a learning agreement has been completed for each trainee outlining the responsibilities of the trainee, the Accountable Pharmacist and the Chief Pharmacist
- Ensure that the Accountable Pharmacist has ascertained any specific training needs the trainee may have, and the support and guidance they may require when working towards completion of the accreditation
- Co-ordinate, quality assure and mark the pre-course assessments
- Provide a face to face induction programme to ensure the trainee fully understands the requirements of the programme
- Provide regional assessment of the portfolio
- Co-ordinate, quality assure and mark the summative practical exam
- Facilitate the summative viva voce
- Issue certificates to trainees upon successful completion of all aspects of assessment for the accreditation
- Maintain a regional register of trainees accredited through the scheme
- Ensure that an equal opportunities and appeals procedure is in place and is invoked when necessary
- Provide advice and information to hospitals and organisations implementing the required supervision model to facilitate the training
- Ensure high standards of training delivery are maintained through regular reviews of trainee evaluation.

The Role of the Employer (Chief Pharmacist)

It is the responsibility of the Chief Pharmacist to:

- Take local action to ensure that the organisation recognises the task of product approval by accredited pharmacy technicians (where appropriate) and that the extension to the pharmacy technician's role is documented in their current job description, to ensure that they are covered by the vicarious liability of the employing organisation following accreditation

  NB: Individuals will only be covered if practicing within accredited scope of practice and professional limitations
- Ensure that a learning agreement is read, agreed and signed by all stakeholders
- Ensure that there is an overarching procedure or policy defining the responsibilities of each individual in the process.

Guidance on issues for local administration

It will be necessary for the Chief Pharmacist to:

- Establish clear departmental policies/procedures for the roles and responsibilities of the accredited product approver prior to the trainee embarking on this role
- Ensure that all staff whose work may be affected by the implementation of the scheme are fully informed of the process and clearly understand their own responsibilities
- Identify an appropriate area in which to base the trainee
- Identify the product types it will be appropriate for the trainee to cover locally
- Identify an appropriate educational supervisor to support the trainee through the training period.

The Role of the Educational Supervisor

This information is for educational supervisors of trainees undertaking a Product Approval Accreditation Programme.

What is an Educational Supervisor?

"Educational supervision" in pharmacy involves overall supervision and management of a specified trainee's educational progress during a programme (or series of periods of training), as opposed to a single period of training. Educational supervisors are responsible for ensuring that trainees are making the necessary practice-based and educational progress, through the use of appraisals and review meetings. The ability to effectively review a trainee's entire portfolio will also be necessary. This will require a holistic approach, rather than assessing single pieces of evidence.

An "educational supervisor" in pharmacy is someone who is selected and appropriately trained to be responsible for the overall supervision and management of a specified trainee's educational progress during a period of a training placement or series of placements. The educational supervisor is responsible for the trainee's educational agreement or plan. This will include formal assessment and sign off. The educational supervisor should have an understanding of the range of learning, assessment and support opportunities for learning in the workplace, work collaboratively with colleagues to monitor and support the trainee's progression and foster learner autonomy. They should also be able to identify and support trainees in difficulty, including interfacing with employment performance management procedures [6]

Role of the Educational Supervisor

The educational supervisor's role is to facilitate the local implementation of the training and assessment programme, to provide support and guidance, and to assess performance and provide feedback to the trainee whilst they undertake the accreditation programme.

Who can be an Educational Supervisor?

The educational supervisor can be:

- The Accountable Pharmacist or an experienced and designated authorised pharmacist based in the trainee's unit
- An experienced accredited product approver

Educational supervisors must be approved by the Chief Pharmacist and Accountable Pharmacist.

It is recommended that the educational supervisor is someone who has the opportunity to meet regularly with the trainee to discuss progress and give feedback.

---

[6] *Jubraj, B, Fleming, G, Wright, E, et al. Say goodbye to clinical tutors: standardising the terminology in education. Pharmaceutical Journal 2010; 285:21-28.*

Duties of the educational supervisor include:

- Ensuring that a learning agreement is read, agreed and signed by the Chief Pharmacist, the educational supervisor and the trainee
- Discussing the essential reading - Professional standards and code of conduct produced by the regulatory body, e.g. GPhC 'Standards on Conduct, Ethics and Performance'[7]- to ensure that the trainees have understood all important issues relevant to their role
- Encouraging trainees to read any recommended publications and discussing any relevant details from these publications
- Confirming that trainees have a clear understanding of all relevant policies and procedures
- Supporting the trainee to complete the pre-course activities and tasks, and providing any additional support necessary
- Ensuring the trainee completes the pre-course assessments, including the pre-course viva voce carried out by the Accountable Pharmacist, as instructed by the training provider
- Facilitating the post-course training and assessment period
- Assessing the trainees objectively against the standards set in the scheme
- Assisting with identifying opportunities for trainees to cover the agreed range of product types
- Coaching and supporting the trainee regarding their approach
- Documenting the progress of the trainee by performing regular appraisals
- Facilitating and invigilating the practical exam, as instructed by the training provider
- Preparing trainees for the summative viva voce
- Liaising with the training provider
- Assisting the trainee with assembling the portfolio of documentation as evidence for accreditation.

[7] www.pharmacyregulation.org

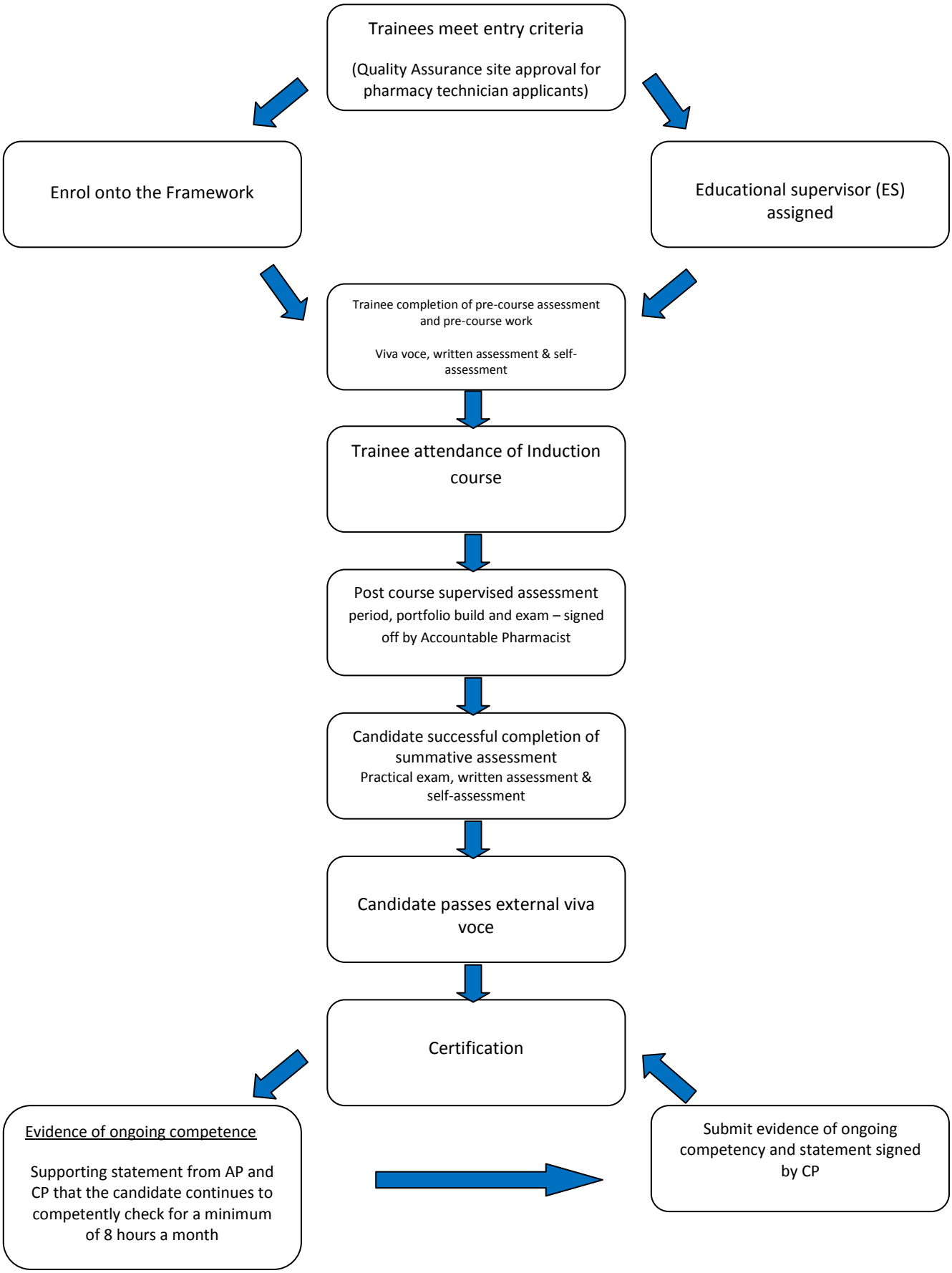
The Role of the Trainee

This information is for trainees undertaking a Product Approval Accreditation Programme.

It is the responsibility of the trainee to:

- Ensure an application form is completed and submitted to the training provider
- Complete and sign a learning agreement outlining the responsibilities of the trainee, the Accountable Pharmacist and the Chief Pharmacist
- Inform their educational supervisor of any specific training needs they may have, and agree the support and guidance they may require when working towards completion of the scheme
- Read and comply with the 'Standards on Conduct, Ethics and Performance[3]' (or equivalent) produced by their professional regulatory body
- Complete all the necessary pre-course work prior to attending the face to face study days
- Fulfil all responsibilities outlined in their job description and comply with all organisational and departmental policies and procedures relating to the role they will be undertaking
- Attend any face to face teaching sessions or courses as required by the scheme on a day/block release basis
- Inform the educational supervisor/line manager of any concerns/issues around the product approval role
- Meet regularly with their allocated educational supervisor
- Take responsibility for their own learning and actively seek opportunities to cover the range of product types and gather the required evidence
- Act upon feedback received from educational supervisor and other colleagues to improve learning and practice
- Ensure that all evidence submitted is entirely their own work
- Complete the scheme within the agreed timescales as set by the training centre
- Be aware of the training provider's appeals procedure.

Framework of the Training and Assessment Programme



Pre-course Assessment

Viva Voce

In order to gain acceptance on the course, the trainee must successfully meet the criteria of the pre-course viva voce carried out by their Accountable Pharmacist. The main objectives of the pre-course viva voce are:

- To assess the trainees potential to successfully complete the training period and to develop the correct professional approach to the role of product approval
- To assess the current knowledge, skills and attitudes with the aim of agreeing the key areas for the individual to address during the training period
- To assess the trainee's commitment to the role.

The outcome of the pre-course viva voce will be reviewed by the training provider and any concerns or questions raised will be forwarded to a regional QA Officer to seek their views and approval.

Assessment of knowledge and self-assessment

In addition to the viva voce each trainee will be asked to complete a self-assessment questionnaire and a written assessment of knowledge. These will help the Accountable Pharmacist and the training provider establish the trainee's baseline knowledge, skills and attitudes and will be repeated at the end of the programme.

The initial pre-course viva voce should take into account the trainee's self-assessment against the learning objectives.

Pre-course Work

Prior to attending the induction, it is important that all trainees have been adequately introduced to the product approval programme at their base hospital/organisation, and have received an appropriate induction into the product approval role.

The pre-course work is divided into 5 areas:

a) Pre-course assessment

b) Defining the scope of role and completion of the Learning Agreement

c) Essential and recommended reading

This has been included to develop the trainee's background knowledge of the role

d) Knowledge of policies and procedures

This is important to ensure that the trainee familiarises themselves with local procedures

e) Pre-course tasks

The pre-course tasks are designed to prepare the candidate for the product approver role

Each trainee attending the course will be expected to have completed **all** the pre-course work prior to attending the induction course.

The educational supervisor must ensure that a pre-course work certificate is issued and signed by the Accountable Pharmacist upon completion of the pre-course work and that a copy is forwarded to the training provider. A trainee's place on an induction course will be dependent on the receipt of this confirmation.

The pre-course work must be included in the final portfolio of evidence and will be assessed by the training provider.

Pre-course Reading

Essential Reading

It is essential that all trainees read:

1. The 'Standards on Conduct, Ethics and Performance'[1] provided by the GPhC (or equivalent), and
2. The relevant chapters of the current edition of 'Quality Assurance of Aseptic Preparation Services, Ed A.M. Beaney Pharmaceutical Press (London)

Each trainee is then required to reflect on the aspects of these documents that will be specifically relevant to the product approval role.

An example of a Reading Log is provided within this document (Appendix 2). Trainees should complete a reading log for each of the above publications to acknowledge that these have been read and understood. The Reading Logs should then be included in the portfolio.

Recommended Reading

The following list of publications provides interesting information on issues relating to the product approval role. These articles are recommended but it is also advisable to check for any new articles too.

*Reading Logs should be completed for at least **two** articles to demonstrate for the purposes of the accreditation that the articles have been read. Completed Reading Logs should then be included in the portfolio.*

Recommended Reading List:

1. Bateman R. Determining the rates and types of errors in pharmacy-managed aseptic preparation units. Hosp Pharm 2003; **10:496**–8.
2. Bateman R & Donyai P. Errors associated with the preparation of aseptic products in UK hospital pharmacies: Lessons from the national aseptic error reporting scheme. Quality and Safety in Health Care 2010. doi:10.1136/qshc.2009.034751
3. Dixon R, Forsey P, Morrison L. NHS technical specialists—strengthening the career path. Hosp Pharm 2007; **14**:337.

Additional Reading/References

4. Guidance to the NHS on the Licensing Requirements of the Medicines Act 1968, Medicines Control Agency, September 1992
5. Current edition of Medicines, Ethics and Practice
6. The current version of MHRA: Rules and Guidance for Pharmaceutical Manufacturers and Distributors, The Stationery Office

Pre-course Tasks

The pre-course tasks are designed to prepare the candidate for the product approver role. As a result, the candidate must complete all the following pre-course activities prior to attending the induction course.

The pre course tasks will make up part of the portfolio of evidence and must be included in the portfolio and submitted for regional assessment at the end of the scheme.

1. Observe an authorised pharmacist or an accredited product approver carrying out the inspection and final product approval (release) process on at least 10 different products. What things do they look for when checking the product? What other factors are they considering when determining if the product is appropriate and fit for human use?
2. Discuss with other accredited or experienced product approvers, their approach to checking. Reflect on what you have learned from these discussions. How might this affect your practice as an accredited product approver?
3. Examine a variety of local preparation or checking error/incident reports. Discuss with your Accountable Pharmacist what impact these errors had on the patient and how they may or may not have led to a change in practice and why. Reflect on what you have learned from this.

- Reflection on the pre-course tasks must be recorded and included in the portfolio for assessment.

  An example of a Pre-course Work Reflective Log is provided within this document (Appendix 3).

Knowledge of policies and procedures

It is essential that policies and procedures are prepared for this role, to ensure that the trainees involved have clear guidelines regarding:

- Role and duties to be performed
- Professional and local responsibilities and limitations
- Local practice requirements

Initially the Accountable Pharmacist should identify all the procedures relevant to the trainee.

It is important that there is evidence provided to show that the trainee understands the relevant policies and procedures. The trainee must demonstrate their understanding to the Accountable Pharmacist prior to commencing the evidence collection. In order to do this trainee must:

1. Collect and read ***all*** relevant procedures

   and

2. Provide answers to a minimum of three questions for each procedure, demonstrating that they know how to interpret and apply local policies and procedures to different scenarios.

The Accountable Pharmacist should document that the trainee has demonstrated the required working knowledge of the procedures and this should be included in the portfolio along with a copy of the questions asked. An example of a Working Knowledge of Procedure Log is provided within this document **(**Appendix 4).

If the trainee fails to answer any of the questions correctly or satisfactorily, the Accountable Pharmacist should provide feedback on why the answers are insufficient or incorrect and the trainee should be given an opportunity to answer the questions correctly after some time for reflection.

The Induction Course

After completing all areas of the pre-course work, trainees must attend and complete a face to face taught course.

The course should contain a series of sessions, each comprising of a mixture of didactic and participative teaching using a range of tutors, e.g. service managers, specialist regional QA, local QA and Accountable Pharmacists and specialist pharmacy technicians. The following areas should be covered:

Overarching principles of aseptic preparation

- Protecting the public
- Medicines Act and section 10 exemption
- QA of APS
- GMP/Orange Guide
- The need for internal and external audit
- Principal aspects of design of premises and equipment in aseptic preparation units
- Legal and professional framework
- The need for environmental monitoring and deviation reporting

Aseptic products

- Processes in aseptic preparation
- Key product types; common and “occasional”
- Pharmaceutical issues, including stability
- Main clinical uses
- Common problems
- Identifying and reporting errors

Errors

- Theory of origins of errors, e.g. James Reason – person and system faults
- Consequences of errors; risk assessment and risk management
- Common person errors and their identification
- Common system faults and their identification
- Inspection and checking techniques
- Reflecting on and learning from errors
- Reporting to the national error reporting scheme

Legal and Professional Frameworks

- How Medicines Act and Section 10 Exemption is put into practice in aseptic preparation
- Aspects of responsibility, liability and negligence.
    - Corporate governance
    - Personal responsibility; GPhC standards, conduct, ethics and performance
- Exerting professional independence; when to refer
- Working within personal scope of practice and standard operating procedures

Post-Course Supervised Assessment

During the first week of the post-course supervised assessment period, trainees should familiarise themselves with the documentation and reflect on the learning needs that have been identified through the:

- Pre Course self-assessment
- Pre Course viva voce
- Pre course written assessment

The Learning Plan

After a trainee has attended the induction course, they should spend some time with their educational supervisor formulating a plan for the training and assessment period. A Learning Plan should outline details such as:

- Timeframes
- Learning needs identified from pre-course assessment
- Product types that will be included in the evidence collection
- Product types that will be excluded
- Numbers of products to be inspected (see Evidence Collection for number of items)
- Plan for the competency based assessments

Please note: Once a decision has been made regarding what products the trainee will be able to "approve" subject to a second check, the Accountable Pharmacist and educational supervisor must ensure that the team within the department is aware of the assessment being undertaken and its scope

An example of a Learning Plan is provided within this document (Appendix 5).

Evidence Collection

In order to demonstrate evidence of ongoing competence, the trainee will compile a log of products that have been assessed for approval. The products assessed will reflect the product mix of the trainee's local unit taking into account any products that are excluded from the programme.

In order to demonstrate competence, **50 inspections** must be performed for all product types (i.e. CIVAS or CTYOs) with the exception of Parenteral Nutrition (PN), where **25 inspections** must be performed.

'Inspection' in this case refers to the complete product approval process, not merely the visual inspection.

NB: Clinical Trials whether made under an IMP licence or paragraph 37 exemption of the Clinical Trials regulations cannot be included within these product types.

Please note: Trainees must NOT be involved in any part of the preparation of the product prior to RECOMMENDING approval of the product.

Documenting Evidence

A Recommend for Approval Log Form must be used to document **every** product that the trainee inspects as part of their training period. Trainees must sign to indicate their decision regarding the recommendation for approval of the product, and the log must remain with the product until the authorised pharmacist has approved (or rejected) the product for its intended use.

The log sheets must be signed by the authorised pharmacist alongside each product line to ensure a clear audit trail.

An example of a Recommend for Approval Log Form is provided within this document (Appendix 6).

At the end of each day where trainees have been involved in inspecting products for approval, all the information regarding the products that the trainee has inspected should be collated and documented on a Daily Summary of Products Inspected form. The overall daily summary of product approval activity must be submitted within the portfolio.

An example of a Daily Summary of Products Inspected Form is provided within this document (Appendix 10).

Please note: If a trainee is allocated 8 weeks to complete at least 50 CIVAS, 50 CYTOs or 25 PN inspections, this would equate to approximately **6 - 7 product inspections a week**. Trainees and Accountable Pharmacists should plan time accordingly to accommodate this workload**.**

Errors

If a trainee identifies any errors or problems with the products they are inspecting they must record the details of the error(s) on an Error Record Form and describe the action taken to resolve it.

An example of an Error Record Form is provided within this document (Appendix 7).

Procedure for when errors are missed

Any medicines-related errors that could potentially reach the patient represent a risk to patient safety and therefore consistent accuracy must be demonstrated. As a result, there is **no scope** for missing errors within the evidence collection for this programme. **It is therefore imperative that trainees have completed all the necessary training prior to commencing the assessment period.**

If an error/problem with a product is missed by the trainee, they are required to reflect on this error and the reasons why it happened, as well as what they will need to do differently in order to avoid the error being missed again. Trainees must document this reflection by completing an Error Analysis Report for EVERY error missed.

An example of an Error Analysis Record is provided within this document (Appendix 8).

If an error is missed within the required 50 CIVAs, 50 CYTOs products or 25 PN products, trainees must re-start the collection of their evidence (within that product type) after a review with the Accountable Pharmacist.

Trainees must ensure that any Error Analysis Reports that they complete are attached to the associated Error Record Forms and kept within their portfolio as evidence.

Accountable Pharmacists must be made aware of any errors missed and should review the trainee's reflection and discuss with them the circumstances and possible implications of the error.

No trainee will be allowed more than three attempts at completing the evidence collection stage of the assessment process without re-entering the scheme.

Using Professional Judgement

There may be occasions when although the trainee has not missed an error or problem with a product, there is a difference in opinion with the authorised pharmacist about the suitability for release. Under these circumstances the following action should be taken:

Scenario 1:

The trainee identifies errors or problems with a product and recommends that the product should be rejected; the authorised pharmacist decides that the product could be released on that occasion based on their experience and enhanced knowledge of suitable alternative steps that could be taken.

Action: This would not be deemed as an error, however the trainee should complete a Reflective Diary Log to demonstrate what they have learned from that situation, and what action they would take if they came across this situation again in the future.

An example of a Reflective Diary Log is provided within this document (Appendix 9).

Scenario 2:

The trainee identifies errors or problems with a product and recommends that the product should be released; the authorised pharmacist decides that based on the errors found, the product should be rejected.

Action: This situation should be referred to the Accountable Pharmacist for a decision on the appropriate outcome.

If the Accountable Pharmacist agrees that the product should be rejected, this would be classified as a trainee error and the usual procedure for when errors are missed should be followed. An Error Analysis Report must be completed.

If the Accountable Pharmacist decides that the product can be released based on the trainees rationale for doing so, this would not be classified as an error.

Competency Based Assessments

During the training and assessment period trainees should start to develop in their role as a product approver. Having a robust checking method is vital but trainees should also be thinking about other aspects of the role such as their understanding of the validation processes and environmental monitoring. They will also need to be aware of the training that takes place for all members of aseptic staff as well as any changes and deviations to process. .

The **first 5 products** and the **last 5 products** that a trainee inspects (within each product type) must include a competency based assessment *carried out by the Accountable Pharmacist*. The Competency Based Assessment included within this document (Appendix 11) provides all the criteria that a trainee must fulfil to ensure that they have developed a robust product approval technique. Training Providers developing a Product Approval Accreditation Programme must ensure that all of these criteria are assessed in order to meet the national framework standards.

The Accountable Pharmacist is required to complete the Competency Based Assessment Log for **EACH** assessment undertaken and circle the assessment number at the top of each log. The 10 documented assessments should then be included in the trainee's portfolio. After each assessment constructive feedback must be provided and documented by the Accountable Pharmacist.

Please note: Trainees are also required to record the details of any products inspected on the Recommend for Approval Log Form (Appendix 6) and details of any errors found or missed on the Error Record Form (Appendix 7) during the 10 competency based assessments.

Practical Examination

During the post-induction course assessment period, each trainee must complete a practical examination.

The examination involves simulated inspection of aseptically prepared products against test prescriptions, worksheets and labels. The examination is intended to test the trainee's checking process and their ability to identify errors in a stressful environment. The trainee will check an agreed number of products over a range of prescriptions within 60 minutes. The product types used in the exam should reflect those selected for the portfolio of evidence collection. The pass mark is 100%, there are no errors/mistakes allowed.

The training provider will arrange, coordinate and mark the examination which will be facilitated locally. As soon as it is agreed that the trainee is ready to sit the exam they should apply by contacting the training provider.

If a trainee is unsuccessful on their first attempt at the exam, they are permitted to sit a new practical examination on one further occasion. If unsuccessful on the second occasion the trainee will be required to re-enter the training and assessment programme.

Assessment of knowledge and self-assessment

Prior to attending the summative viva voce each trainee will be asked to repeat the self-assessment questionnaire and complete a further written assessment of knowledge. These should be submitted in the trainee's portfolio of evidence and will help the Accountable Pharmacist and viva voce panel establish the trainee's knowledge, skills and attitudes upon completing the programme.

Upon receipt of the application to attend the summative viva voce, the training provider should issue the required post-course documentation for the trainee to the Accountable Pharmacist.

Summative Review of Performance

Upon satisfactory completion of the work based assessment period, the Accountable Pharmacist will conclude the programme by performing a final review of the trainee's performance during the training and assessment period. The review should be documented on a Summative Review of Performance form. An example of a Summative Review of Performance Form is provided within this document (Appendix 12).

The Accountable Pharmacist should consider and discuss the following questions with the trainee:

- How well has the trainee progressed through the programme?
- What has gone well for the trainee?
- What have been the challenges and how were these overcome?
- Are there any weaknesses where the trainee still needs support?
- Is the trainee confident when feeding back errors to individuals?
- Is the trainee confident with their product approval inspection process?
- How has the trainee performed in quieter sessions?
- How has the trainee performed in busier sessions?

Once the Accountable Pharmacist has concluded the summative review, they must provide an overall written assessment of the trainee's performance and competence as a product approver. This will provide the feedback in support of the trainee's progression to the summative viva voce and provide assurance to the viva voce panel that the trainee has demonstrated competence in the work place.

Summary of Achievements

The Summary of Achievements gives the trainee, their Accountable Pharmacist, the Chief Pharmacist and the course board, a summary of all the learning and assessments that have taken place over the training period. The form can be completed by ticking the boxes, providing a summary of what has been included as evidence or simply by signing in the boxes once a task has been completed. This form must be signed at the end of the training period by the trainee, the Accountable Pharmacist, a member of the training provider team/course board and the Chief Pharmacist.

The Summary of Achievements form provides the authorisation that, upon the satisfactory completion of all stages of the assessment process, including the portfolio assessment and outcome of the summative viva voce, the Accountable Pharmacist is confident that the trainee has demonstrated competency and therefore the training provider can proceed with certification.

An example of a Summary of Achievements form is provided within this document (Appendix 13).

Portfolio Review

The portfolio must be submitted to the training provider for assessment in advance of the summative viva voce and must contain:

- Learning agreement and learning plan
- Confirmation of completion of underpinning knowledge and pre-course work requirements
- Information about the candidate e.g. Job description/summary of role
- Satisfactory evidence of a minimum of 50 CYTO products, 50 CIVAs products or 25 PN products accurately inspected for approval
- Details of all checking errors *detected* and *missed* and associated reflection
- 10 competency based assessments carried out by the Accountable Pharmacist *for each product type*
- Confirmation of satisfactory assessment of practical examination
- Summative self-assessment and written answers to knowledge questions
- Summative Review of Performance and Summary of Achievements

Assessment Criteria for Portfolio

Trainees must not make any errors in the product assessments.

Trainees must meet the criteria (within permitted error rate) set for the portfolio.

The trainee is permitted three attempts at the evidence collection stage of the assessment process. If unsuccessful on the final occasion, the trainee is required to re-enter the training and assessment programme. All documentation relating to any unsuccessful attempts should be included in the portfolio.

Summative Viva Voce

The Accountable Pharmacist confirms that a trainee has successfully completed all of the practice-based evidence collection and assessments by signing the Summary of Achievements form. The trainee can then proceed to their summative viva voce. The summative viva voce is designed to assess the trainee's ability to accept responsibility as a product approver by an independent panel.

Please note: There may be a period of time between the trainee successfully completing all aspects of the work-based assessments and the summative viva voce. It is recommended that the trainee maintains their skills during this time period by undertaking regular product approval activity which must be second checked by an authorised pharmacist.

The summative viva-voce will provide a summative assessment of the trainee's achievements during the training period and will review:

- The portfolio and evidence collection
- Any errors that the trainee has identified and any errors missed
- The assessments made by the local Accountable Pharmacist
- The practical exam results
- The trainee's written self-assessments
- The trainee's professional attitude to the role

The panel will consist of 3 members each representing one of the following specialities:

- The training provider team
- QA/QC
- Accountable Pharmacists

A panel assessment is included within the programme to provide an independent opinion of the trainee's suitability to take on the responsibility of carrying out the product approver role. The trainee must meet the criteria set for the interview and portfolio review.

The trainee is allowed two attempts at the summative viva voce. If unsuccessful on the second occasion the trainee will be required to re-enter the training and assessment programme.

Certificate of Accreditation

Upon successful completion of all stages of assessment, the trainee should be notified confirming that they have successfully completed the programme and have met the scheme requirements. The trainee should then commence a probationary period. The trainee should be entered onto the regional register of accredited Product Approvers, and issued with a certificate of accreditation. The Accountable Pharmacist and the Chief Pharmacist should be notified for entry into departmental records.

The Probationary Period

The probationary period is the final component of the training and assessment programme. The duration of the probationary period should be agreed between the Accountable Pharmacist and the trainee.

The requirement for a probationary period recognises that up to its commencement, all of the product inspections carried out by the trainee will have been subject to a further check by an authorised pharmacist or an experienced accredited product approver.

At the commencement of the probationary period, products inspected by the trainee will be second checked for approval over the agreed period of time. The extent of the re-checking should rapidly decline so that the trainee assumes full responsibility for the product approval and release of designated products.

All errors that are missed during the probationary period will be treated according to departmental SOPs for error reporting. The Accountable Pharmacist should review the error with the trainee and any action taken should be in line with local error reporting procedures.

Appeals

There should be a system in place to allow trainees to appeal against any decision or conduct of any Product Approval assessment process associated with this framework. Below is an example of such an appeals procedure.

Any trainee who is dissatisfied with the conduct or adequacy of an assessment must give notice of their dissatisfaction and of their intention to forward an appeal to the Appeals Officer (Contact your training provider for details).

The notification must be given within 5 working days of their assessment or 5 working days of their receipt of the results.

The formal appeals procedure must then be followed:

- All appeals against the conduct, adequacy or outcome of a Product Approval Programme assessment must be forwarded in writing to the Appeals Officer within 10 working days of the trainee having given notice of their intention to appeal.
- On receipt of an appeal, the Appeals Officer will:
    - Acknowledge receipt in writing and set a date for the appeal within 10 working days
    - Decide how and who will hear the appeal.
- The appeal panel will meet within 20 working days of the Appeals Officer receiving written notification of the appeal.
- The trainee will be offered the opportunity to be accompanied by any person of their choice to help with the presentation of evidence.
- The appeal panel will reach a decision on the day of hearing.
- All involved parties will receive verbal notification of the decision on the day of the hearing and written notification within 3 working days.

The appeals panel's decision is final.

Evidence of Ongoing Competence

Guidance regarding reaccreditation and post course development must be available for all accredited product approvers.

It is the professional responsibility of each accredited individual to keep a personal record of their ongoing competence. This evidence should be recorded at least every 2 years after the certificate is issued.

It is important to note that practising outside of a current certificate will result in the individual being in breach of their job description and professional responsibilities.

For individuals to remain "current" they must keep an ongoing log of any product approval errors made and document these according to their department error recording policy. Any error must be reflected upon and recorded using the CPD cycle. These logs must be reviewed and discussed periodically with Accountable Pharmacist.

Due to the robust external auditing processes applied in technical services units, the need for a formal and external reaccreditation process may not be necessary; it is acceptable for this process to be carried out under local arrangements at the discretion of the Accountable Pharmacist. Training providers should however produce a reaccreditation process and associated documentation for use if required.

The process of reaccreditation:

- Individuals should liaise with their Accountable Pharmacist to ensure they complete the reaccreditation process.
- Individuals should include in their records a supporting statement from the Accountable Pharmacist that they are maintaining their competence by carrying out the product approval role for a minimum of 8 hours per month.
- It is recommended that all staff undertake regular performance management reviews. Any serious error or series of minor errors should require a review of the suitability of the individual to continue the role without further training.
- Reaccreditation records should be maintained by the department and the individual and be available to unit auditors upon request.

Breaks in Checking Activity

An accredited product approver may sometimes experience a break in product approval activity. Individuals may rotate through departments for example, or may have returned from maternity leave, a period of travel or possibly transferred between organisations.

It is the responsibility of each individual as a registered professional to maintain their competency. If breaks in practice occur, appropriate measures should be taken to ensure skills and knowledge are updated and renewed and that competency is demonstrated to the satisfaction of the Accountable Pharmacist. This provides evidence of their CPD.

Transfer of Accreditation

Successful completion of all aspects of assessment for an approved Product Approval Accreditation Programme provides a transferrable accreditation. As a result, accredited product approvers who move to a new organisation would not be required to complete the scheme again.

Accountable Pharmacists are responsible for ensuring that accredited product approvers who are new to their unit undertake an introductory period which should include:

- The orientation and familiarisation with the departmental SOPs
- A reasonable probationary period where inspected products are second checked by an authorised pharmacist
- An agreed timescale for the demonstration of competency within their scope of practice

Extending the Scope of Product Types

Following successful accreditation, individuals may wish to extend the scope of products for which they have demonstrated their competency to approve for release, in agreement with their Accountable Pharmacist. In order to add a new product type to their scope of practice, individuals must accurately inspect and appropriately recommend for approval the required number of products for that speciality (50 CIVAS, 50 CYTOS or 25 PN). Evidence should be collected following the Product Approval scheme format and using approved documentation. Upon completion, individuals and departments should maintain their own records of the evidence for this activity and demonstration of their competence.

How to get a Product Approval training programme approved

Any training provider wishing to develop and deliver a Product Approval training and assessment programme can apply to have their programmes mapped against the standards of the national framework and be approved nationally under the authority of the NHS Aseptic Services Accreditations Group. The approval panel members are occupational experts who have been designated by NHS ASAG.

Before a programme is submitted for approval, the programme lead must have assessed whether the programme fulfils the criteria of the framework. The submitted programme will then be assessed against criteria based on learning outcomes, resources and training delivery, and methods of assessment.

For more information on the programme approval process, please refer to the Approval Application Pack, available to download at www.nhspedc.nhs.uk.

Successful Approval of a Training Scheme

Where a programme is approved against the standards of the national framework, trainees who have completed the assessment process for that programme can be awarded a nationally recognised accreditation.

Programmes will be granted approval for a period of three years, at which time a further review of the approved programme will be required. Training providers will be contacted as the expiry of their approval period approaches with details of the review process.

A further review of the approved programme will also be required should significant changes be made to that programme or to the national framework before the three year approval period expires.

Where a programme is not approved because it does not meet the standards, it may be resubmitted for approval following the implementation of the recommendations made by the approval panel.

For more information on the resubmission process, please refer to the Approval Application Pack available at www.nhspedc.nhs.uk.

References

1. Medicines Act (1968) http://www.legislation.gov.uk/ukpga/1968/67/contents
2. The Human Medicines Regulations 2012 http://www.legislation.gov.uk/uksi/2012/1916/pdfs/uksi_20121916_en.pdf
3. Quality Assurance of Aseptic Preparation Services, Ed A.M. Beaney Pharmaceutical Press (London)
4. The Health Act 2006, http://www.legislation.gov.uk/ukpga/2006/28/pdfs/ukpga_20060028_en.pdf
5. HSC 1999/065. (March 1999) Health Service Circular. Clinical Governance: Quality in the new NHS
6. http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012043.pdf
7. Jubraj, B, Fleming, G, Wright, E, et al. Say goodbye to clinical tutors: standardising the terminology in education. Pharmaceutical Journal 2010; 285:21-28
8. General Pharmaceutical Council. GPhC Standards of Conduct, Ethics and Performance. *http://www.pharmacyregulation.org*

Acknowledgments

With thanks to the members of the South West Product Approval steering group and the National Aseptic Services Accreditations Working Group (ASAG) for their help and support with the development of the framework.

Role	Named Individual(s)	Role Description
Chief Pharmacist / Senior Pharmacy Manager	Paul Foster	Direction and interface with Senior Pharmacy Manger group and Chair of Technical Services and Quality Assurance Managers Group (SW)
Director or SWMIT	Trevor Beswick	Chair of project group
Regional Quality Assurance	Mark Santillo	Project support for QA input
Regional Quality Assurance	Tim Sizer	Project support for QA input
Local Quality Assurance	Sarah Hepburn	Project support for QA input
Accountable Pharmacist	Oonagh McGrath	Project support - technical services managers
Accountable Pharmacist	Yvonne Palmer	Project support – technical services managers
Accountable Pharmacist	Paul Spark	Project support – technical services managers
Lecturer in Pharmacy Practice	Lynette James	Project support - educational specialist
Pharmacy Technician	Sarah Griffiths	Project support - pharmacy technician
Pharmacy Technician	Rachael Whiteley	Project support - pharmacy technician
Education and development Pharmacy Technician (project manager)	Sally Kemp (up to 09/11) Ellen Williams (from 09/11)	Project manager
Members of NHS ASAG		
Regional QA Specialist	Alison Beaney	North East & North Cumbria
Regional QA Specialist	Richard Bateman	East and South East England Specialist Pharmacy Services
Regional Quality Assurance	Mark Santillo	South West region
Accountable Pharmacist	Paul Spark	Cardiff
Accountable Pharmacist	Oonagh McGrath	University Hospitals Bristol NHS Foundation Trust
Regional Specialist Pharmacist, Education and Training	Helen Fawcett	North East & North Cumbria
Operations Manager	Gill Robson	Newcastle Specials & Pharmacy Production, Royal Victoria Infirmary Newcastle upon Tyne
Education and development Pharmacy Technician	Sally Kemp (up to 09/11) Ellen Williams (from 09/11)	South West Medicines Information & Training (SWMIT)
Director or SWMIT	Trevor Beswick	South West Medicines Information & Training (SWMIT)

NHS Aseptic Services Accreditations Working Group

Nationally Recognised Competency Framework for Pharmacists and Pharmacy Technicians:

The Assessment of Product Approval (Release) in Aseptic Services under Section 10 exemption

Sample Assessment Documentation

The following pages provide some examples of assessment documentation that compliments and can be used in conjunction with the assessment framework.

Learning Agreement (Appendix 1)

Chief Pharmacist- Accountable Pharmacist - Trainee

The Product Approval Accreditation Programme will require a degree of commitment from participating organisations and their trainees. This agreement clarifies what is expected of the employing organisations, the Accountable Pharmacist and the trainee in order that the training and assessment will be carried out to its full potential.

The Chief Pharmacist……..supports that:

- The programme will be carried out by members of the pharmacy department under the supervision of a pharmacist and in line with the project guidance
- In conjunction with the Accountable Pharmacist, approval to be part of the programme is given to appropriate trainees

The Accountable Pharmacist……...will ensure that:

- Approved and current SOPs are in place and that the trainee is familiar with and will work competently within these
- Support mechanisms are in place for trainees
- They meet regularly with the trainee to review progress
- They regularly review evidence presented to them within agreed timescales
- They provide honest and constructive feedback on a regular basis both formally and informally
- They feed back any problems regarding trainees to the training provider as they arise

The trainee……will:

- Become familiar with the requirements of the Product Approval Accreditation Programme
- Fulfil all responsibilities outlined in the handbook and comply with all organisational and departmental policies and procedures
- Attend the training sessions and assessment interviews as required
- Ensure that the competency evidence is completed within agreed deadlines
- Act upon feedback received from the Accountable Pharmacist and course board to improve learning
- Meet regularly with their Accountable Pharmacist and record progress
- Take responsibility for their own learning and actively seek new learning opportunities
- Undertake study activities in their own time in addition to any study time allocated to them within the workplace
- Ensure that all work submitted is entirely their own work
- Discuss any problems regarding the training with their Accountable Pharmacist or the training provider as soon as they arise
- Be expected to show continuous and consistent progress throughout their training period

The above points have been discussed and agreed between:

Trainee……..

Signature……..Date……

Accountable Pharmacist ……..

Signature……..Date…….

Chief Pharmacist……

Signature ……..Date……..

Reading Log (Appendix 2)

Trainee name:	Accountable Pharmacist:	Date:

Title of publication:
What aspects of the article were relevant to product approval?
What did you learn from the article?
Has the article prompted further reading, if so what?
The trainee has demonstrated learning and understanding. Trainee signature: …….. Date:……..…… Accountable Pharmacist signature: …… Date:……..

Pre-Course Work Reflective Log (Appendix 3)

Pre-course task undertaken (please state):
What did you learn from this? How is this relevant to the role of a product approver?
Feedback/comments from Accountable Pharmacist:

Trainee signature:…….. Date:……

Accountable Pharmacist signature:…….. Date:……

Working Knowledge of Procedure Log (Appendix 4)

Title of Procedure	Aspects of the product approval procedures ✔ / ✘	Questions answered correctly ✔ / ✘			Comments
		1	2	3	

Comments:

Trainee signature:…… Date:……

Accountable Pharmacist signature:…… Date:……

Learning Plan (Appendix 5)

Trainee Name:	**Accountable Pharmacist:**	**Date:**	
Discussion Points		**Signature Trainee:**	**Signature AP:**
i. Date to start training period			
ii. Date to end training period			
iii. SOPs read and understood			
iv. Learning points discussed from Viva Voce, MCQs and self-assessment			
v. Products group (s) to be included in the training period			
vi. Products that will be excluded from the programme			
vii. Numbers of products to be inspected			
viii. Discuss the 5 first/last competency based assessments			
ix. Date set for next discussion			

Discussion Notes	
Trainee Signature: Accountable Pharmacist Signature: Date:	

Recommend for Approval Log Form (Appendix 6)

Trainee Name:	Accountable Pharmacist:

	Date	Type of Product CIVAS/ CYTOS/PN	Product Name	Batch No. / ID	Error Found? Y/N If Yes, please complete error log form	Recom-mend for approval? Y/N	Trainee Signature	Product Approved? Y/N	Authorised pharmacist Signature	Error missed? Y/N If Yes, please complete error log form
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

Sheet ..... of .....

Authorised Pharmacist Initials.....

Error Record Form (Appendix 7)

Trainee Name:	Accountable Pharmacist:	Product Type: CIVAS / CYTO / PN

Date:	Product Name:	BN/ID:

Errors Found & Description of Action Taken:				
Recommended for Approval:	**Yes**	**No**	**Trainee Signature:**	**Date:**
Authorised pharmacist Comments:				
Product Approved:	**Yes**	**No**	**Authorised pharmacist Signature:**	**Date:**

Error Analysis Report (Appendix 8)

Trainee Name:	**Accountable Pharmacist:**
Date:	**Batch Number:**
Associated Error Record Form (Appendix 7) page number:	
Brief description of error:	
Corrective actions taken:	
Potential impact of the error:	
Root cause of trainee's error:	

Preventative Actions / Learning Objectives:
Root Cause of initial error:
Potential of actual outcome (Accountable Pharmacist assessment): None / Minor / Major / Critical **Comments**:
Assessment of next steps / ability of the candidate to continue with assessment programme / restart the programme:

Trainee signature:…….

Accountable Pharmacist:……

Reflective Diary Log (Appendix 9)

To be completed when an Authorised pharmacist has decided to approve a product that you recommended should be rejected.

Trainee Name:		**Date:**	
Product:		**BN/ID:**	
Please describe what you learnt from this experience?			
Trainee Signature:			
Authorised pharmacist Signature:			

Daily Summary of Products Inspected (Appendix 10)

Date	Number of Cytotoxic products	Number of CIVAS products	Number of PN products	Errors found? Please indicate Batch No. / ID of product (s)	Errors missed? Please indicate Batch No. / ID of product (s)	Daily Total	Cumulative Total

Competency Based Assessment (Appendix 11)

Trainee Name:	Accountable Pharmacist:	Date: Assessment number (please circle): 1/2/3/4/5 6/7/8/9/10

Product Name:	BN/ID:	
You must always:		✓ or X
I.	Carry out a visual inspection of the product	
II.	Ensure the worksheet complies with a current prescription	
III.	Ensure the product complies with the worksheet and prescription	
IV.	Ensure all labelling complies with the worksheet / prescription / product	
V.	Ensure you are aware of recent retrospective-testing results for products	
VI.	Ensure all necessary checks prior to the final check have been completed	
VII.	Ensure all documentation has all relevant signatures and ready for release	
VIII.	Complete records according to SOPs including environmental records	
IX.	Communicate any outcomes of the assessment or any errors found to relevant people	
X.	Refer any issues outside personal limitations	
XI.	Follow security/safety procedures	
You must ensure that:		
XII.	The product has been produced in accordance with SOP's	
XIII.	You are aware of recent microbiological and environmental results for the facilities	
XIV.	The daily monitoring records for the unit are satisfactory, e.g. pressure differentials, cleaning	

Assessment Feedback:	
Trainee Signature:	
Accountable Pharmacist Signature:	

Summative Review of Performance (Appendix 12)

Trainee Name:	Accountable Pharmacist:	Date:

Discussion Points:	✓ or X
I. How well has the trainee progressed through the programme?	
II. What has gone well for the trainee?	
III. What have been the challenges and how were these overcome?	
IV. Are there any weaknesses where the trainee still needs support?	
V. Is the trainee confident when feeding back errors to individuals?	
VI. Is the trainee confident with their product approval inspection process?	
VII. How has the trainee performed in quieter sessions?	
VIII. How has the trainee performed in busier sessions?	
IX. Are there any other comments that you feel may be relevant?	

Accountable Pharmacist Overall Feedback on Performance: (must be completed)	
Trainee Signature:	
Accountable Pharmacist Signature:	

Summary of Achievements (Appendix 13)

Trainee Name:	Accountable Pharmacist:	Date:

Stage	Log	Evidence of completion	
Pre-course Viva Voce	*Feedback form*		
Pre-course assessment	*Self-Assessment log* *Completion and submission of written assessment of knowledge*		
Pre-course work	*Essential Reading Inc. SOP's*		
Pre-course work	*Working knowledge of procedures Inc. Product Approval SOP and pre-course tasks*		
Course programme completed/any additional tutorials – dates completed:			
Products Inspected		**Numbers of Inspections**	
TPN* CIVAS* Cytotoxic*			
Competency based assessments completed		**X5**	**X5**
PN* CIVAS* Cytotoxic*			
Post course interview	*Summative review of performance by Accountable Pharmacist*		
Practical Exam	*Training Provider Marking Scheme - must have achieved a 100% pass rate*		
Post course assessment	*Self-Assessment log* *Completion of MCQ's*		
Post course Viva Voce	*Feedback form*		

Trainee: I have completed the pre course work, competency based assessments and post course work in accordance with the Product Approval Accreditation Programme criteria.	**Name of the Trainee:** Date: Registration No: Signature of the Trainee:
Accountable Pharmacist: I am satisfied that this trainee has met all of the programme criteria and recommend that they proceed to the summative assessment viva voce.	**Name of the Accountable Pharmacist:** Date: Registration No: Signature of the Accountable Pharmacist:
Chief Pharmacist: I am satisfied that this trainee can be certificated as competent for accreditation when all aspects of assessment criteria met.	**Name of the Chief Pharmacist:** Date: Registration No: Signature of the Chief Pharmacist:
Training Provider: All aspects of programme assessment criteria have been met and the trainee approved as competent.	**Name:** Date: Registration No: Signature of the Training Provider: