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Nationally Recognised Competency Framework for Pharmacists and Pharmacy Technicians:

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

NHS ASEPTIC SERVICES ACCREDITATIONS GROUP

TABLE OF CONTENTS

CHAPTER 1 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 and Human Medicines Regulations 2012, 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". 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 (the publication that made amendments to the relevant sections of the 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 Specialist Pharmacy Service: https://www.sps.nhs.uk/articles/guidance-on-definition-of-supervision-under-section-10-aseptic-preparation-activities-3rd-edition-sep-2019-yellow-cover/

DISCLAIMER

The Product Approval National Framework is the intellectual property of NHS Aseptic Service Accreditations Group (NHS ASAG). Whilst NHS ASAG accepts the use of this framework in the development of new programmes, any content used should be acknowledged accordingly.

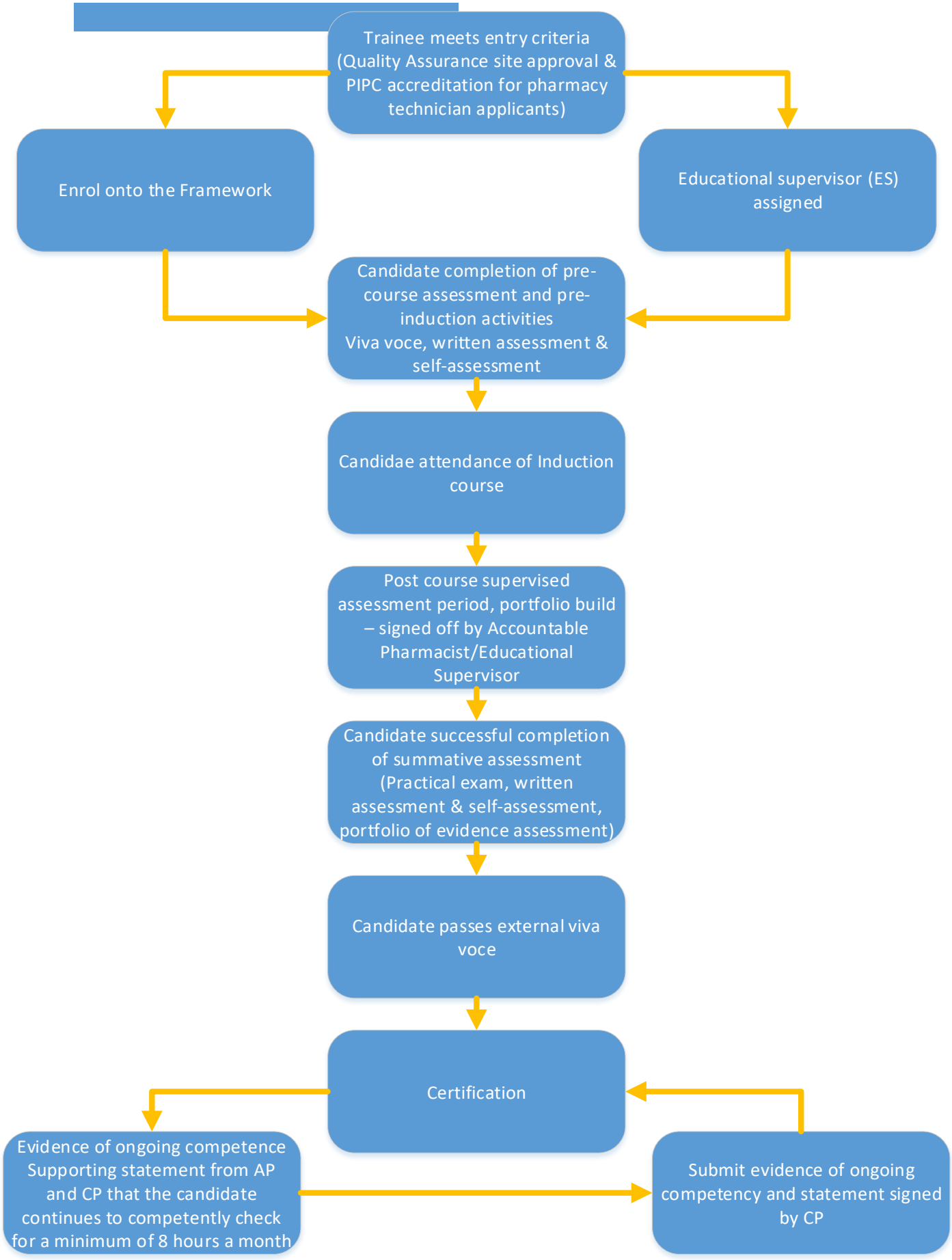
No responsibility is accepted for the content of documents derived from this original publication. Training providers remain responsible for the training, assessment, accreditation and reaccreditation of individual trainees.

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 trainees.

CHAPTER 2 SUGGESTED PAAP FRAMEWORK



CHAPTER 3 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 services within an 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

CHIEF PHARMACIST (CP)

Generally responsible for the strategic development and management of medicines use and pharmacy services within an organisation. This encompasses patient safety, effective medicine use, medicines optimisation, safe and secure handling of medicines, procurement and medicines quality.

CLINICAL GOVERNANCE

The system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care.

CLINICAL PHARMACY VERIFICATION

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

EDUCATIONAL SUPERVISOR (ES)

A suitably experienced pharmacy technician or pharmacist responsible for support of the trainee and facilitation of their training. Responsible for overall supervision and management of a specified trainee's educational progress during the programme.

FINAL ACCURACY CHECK

Checking all details of the product and production process against the worksheet. Note this is carried out prior to final approval of the product.

ONGOING COMPETENCE

Recognition of revalidation of practice, to demonstrate that required standards of competence continue to be met.

PHARMACIST

A person who holds an appropriate university degree and is qualified and licensed to prepare and dispense medicines and who is registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society Northern Ireland (PSNI).

PHARMACY TECHNICIAN

A person who is registered with the General Pharmaceutical Council (GPhC) as a Pharmacy Technician or who holds the appropriate and recognised Pharmacy Technician qualifications in Northern Ireland (where registration is not currently a requirement).

PRACTICE-BASED

Learning based in actual situations related to professional practice.

PRODUCT APPROVAL

Approval of the product as being suitable for issue to and administration to the patient. This must take place by an accredited product approver against all relevant documentation and the prescription and must include a visual and physical examination of the product.

REFLECTIVE PRACTICE

The process of critically analysing a specific task, day-to-day practice, learning or an error or incident, identifying successes and weaknesses of personal practice, and planning and taking action to address areas for development and improvement.

REVALIDATION

Revalidation is the process of providing evidence to your governing body of how you to keep your professional skills and knowledge up to date, how you provide the safe and effective care patients and the public expect, as set out in the standards for pharmacy professionals. For the purposes of this framework revalidation is applicable to Pharmacy Technicians and Pharmacists.

ROOT CAUSE ANALYSIS (RCA)

Root cause analysis (RCA) is a systematic process for identifying the "root causes" of errors and incidents and identifying an approach for responding to them and finding a way to prevent them from re-occurring.

SENIOR PHARMACY MANAGER (SPM)

See Chief Pharmacist definition.

STANDARD OPERATING PROCEDURES (SOPS)

Standard operating procedures are detailed written documents formally approved by the Accountable Pharmacist. They describe the operations to be carried out, the precautions to be taken and the measures to be applied that are directly or indirectly related to the preparation and supply of the product. They give directions for performing certain operations, e.g. cleaning, changing, environmental monitoring and equipment operation, to ensure that they are performed to a consistent standard.

SUPERVISED PRACTICE PERIOD

A period of training under the direct supervision of a person deemed suitably trained/qualified by the Accountable Pharmacist.

TRAINEE

The person undertaking the training and assessment programme.

TRAINING PROVIDER

An organisation responsible for delivery of the training programme, assessment and accreditation process and quality assurance of training materials.

CHAPTER 4 LEARNING OUTCOMES AND 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
	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

CHAPTER 5 ENTRY CRITERIA AND REGISTRATION ON THE FRAMEWORK

ENTRY 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 documented 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:
  - i. All relevant SOPs are in place and all worksheets approved by the Accountable Pharmacist
  - ii. Risk management arrangements are satisfactory, including robust change control processes
  - iii. Suitable staff training programmes and resources are available
  - iv. Clinical verification of the prescription is carried out by suitably trained pharmacists in line with organisational procedures
  - v. Technical verification is carried out by authorised pharmacists or through a fully validated electronic worksheet and label system in accordance with the Supervision YCD
  - vi. 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. There must be data to support the baseline error rate.
  - vii. Sites must report to the National Error Reporting Scheme
  - viii. Robust Quality Management Systems including deviations and untoward events reporting and investigation are in place
  - ix. The management structure is compliant with the nationally agreed definition of supervision.

ENTRY 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 24 months of 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.

SCOPE OF THE FRAMEWORK

This guidance document applies to section 10 aseptic services final product approval, including cytotoxics, biopharmaceuticals, parenteral nutrition and CIVAs products

Intrathecal products can be included as long as the final product approver is trained, competent and named on the intrathecal register for this task.

With suitable additional training this can be extended to cover final product approval of Clinical Trials under Paragraph 37 of the Clinical Trials

Regulations where the medicines used are licensed products (but not for novel IMPs).

Subject to suitable training and understanding of the status and requirements to the release of outsourced named-patient ready-to-administer products.

Products made in anticipation of a prescription cannot be released until matched with a verified prescription

EXCLUSIONS FROM THE PROCESS

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

- Radiopharmaceuticals
- Products made under Manufacturing and Importation Authorisation (MIA), Manufactured Specials (MS) or MIA (Investigational Medicinal Products (IMP)) licences
- One off products made without a fully approved worksheet
- Advanced Therapy Medicinal Products

CHAPTER 6 ROLES AND RESPONSIBILITES

MANAGEMENT OF THE PROGRAMME 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.

ROLE OF EMPLOYER (THE 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.

ROLE OF ACCOUNTABLE PHARMACIST

The Accountable must ensure that:

- All local policies and procedures regarding technical services processes are in place and up to date.

- Establish clear departmental guidelines/written 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 programme are fully informed of the process
- Identify the appropriate product types for which the trainee will accredit
- Identify an appropriate Educational Supervisor (if not undertaking the role themselves) to support the trainee through the training and assessment period

ROLE OF THE 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 learning 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.

The Educational Supervisor is required to offer support, guidance and feedback to the trainee whilst they undertake the practice activity, and to facilitate the local implementation of this Framework.

The educational supervisor is responsible for controlling the issue of assessment documentation. In accordance with MHRA 'GXP' Data Integrity requirements (Medicines & Healthcare products 'GXP' Data Integrity Guidance and Definitions, 2018) The Educational Supervisor should complete the trainee's performance reviews and the Summary of Achievements. This may be based on feedback from other colleagues who have worked closely with the trainee during the practice activity. The final assessment panel will review this information, as appropriate.

All documentation must be submitted to the training provider or an appropriate quality assured process be in place for final assessment.

Where appropriate, the Educational Supervisors must plan the trainee's probationary period in line with the training provider's requirements.

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.

DUTIES OF THE EDUCATIONAL SUPERVISOR

- Ensuring that a learning agreement is read, agreed and signed by the Chief Pharmacist, Accountable 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' - 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 training programme
- 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.

THE ROLE OF THE TRAINEE

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 educational supervisor/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 training programme
- Read and comply with the 'Standards on Conduct, Ethics and Performance3' (or equivalent) produced by their professional regulatory body
- Complete all the necessary pre-course work prior to attending the 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 teaching sessions or courses as required by the training provider 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 programme within the agreed timescales as set by the training provider

- Be aware of the training provider's appeals procedure.

CHAPTER 7 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. 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.

The pre-course work is divided into 5 areas:

- Pre-course Assessment
- Defining the Scope of Role and completion of the Learning Agreement
- Essential and Recommended Reading
- Knowledge of Policies and Procedures
- Pre-course Tasks

PRE-COURSE ASSESSMENT

PRE-COURSE 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.

DEFINING THE SCOPE OF ROLE, COMPLETION OF THE LEARNING AGREEMENT AND LEARNING PLAN

DEFINING THE SCOPE OF ROLE

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.

THE LEARNINNG AGREEMENT

The Learning Agreement is essential in ensuring that each stakeholder understands their role within the training programme and have considered the training needs of the trainee.

The Learning Agreement also provides a declaration that each stakeholder's commitment to the trainee's training will be upheld.

The trainee, Accountable Pharmacist and Chief Pharmacist must read and agree to the conditions outlined in the learning agreement.

THE LEARNING PLAN

The educational supervisor and accountable pharmacist should spend time with their trainee formulating a plan for how/when the training and assessment period will take place.

The 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

The documented learning plan should be included as part of the portfolio of evidence.

ESSENTIAL AND RECOMMENDED READING

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

ESSENTIAL READING

It is essential that all trainees read:

1. The 'Standards for Pharmacy Professionals' provided by the GPhC (or equivalent)
2. Chapter 4, 5, 8 and 14 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.

Trainees should complete a written reflection for each of the above publications to acknowledge that these have been read and understood.

The written reflection should then be included in the portfolio of evidence.

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.

Written reflections 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:

- Bateman R. Determining the rates and types of errors in pharmacy-managed aseptic preparation units. Hosp Pharm 2003; 10:496–8.
- 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
- Dixon R, Forsey P, Morrison L. NHS technical specialists—strengthening the career path. Hosp Pharm 2007; 14:337.
- Royal Pharmaceutical Society Professional Standards for Hospital Pharmacy

ADDITIONAL READING/REFERENCES

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

KNOWLEDGE OF POLICIES AND PROCEDURES

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

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

- The 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
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.
3. 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.

   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.

PRE-COURSE TASKS

The pre-course tasks are designed to prepare the trainee for the product approver role. As a result, the trainee 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 programme.

TASK 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.

The trainee should reflect on:

- what the product approver looks for when checking the product
- what factors are they considering when determining if the product is appropriate and fit for human use

TASK 2

Discuss with other accredited or experienced product approvers, their approach to checking.

The trainee should reflect on:

- what was learned from these discussions
- how might this learning affect the trainees practice as an accredited product approver
-

TASK 3

The trainee is required to examine a variety of local preparation or checking error/incident reports and discuss the following with their Accountable Pharmacist and provide written reflection.

- what was the impact of the errors on the patient and how they may or may not have led to a change in practice and why

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

CHAPTER 8 THE INDUCTION COURSE

After completing all areas of the pre-course work, trainees must attend and complete a training programme induction.

The induction 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

CHAPTER 9 POST-INDUCTION COURSE SUPERVISED EVIDENCE COLLECTION

During the first week of the post- induction 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

EVIDENCE COLLECTION

In order to demonstrate evidence of ongoing competence, the trainee will compile a log of products that have been inspected for approval.

The products inspected 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 product inspections must be performed for all product types (i.e. CIVAS, Cytotoxics, Biopharmaceuticals) with the exception of Parenteral Nutrition (PN), where 25 product inspections must be performed.

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

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 or accredited product approver has approved (or rejected) the product for its intended use.

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

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.

Please note: Evidence should be collected over a number of weeks during the evidence collection period.

This evidence should reflect the trainee carrying out the process during quiet and busy periods. Time should be planned 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.

PROCEDURE FOR WHEN ERRORS ARE MISSED BY THE TRAINEE

Any medicines-related errors that could potentially reach the patient represent a risk to patient safety and therefore consistent accuracy from the trainees 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 root cause of why it happened, as well as preventative actions in order to avoid the error being missed again.

Trainees must document this reflection by completing an Error Analysis Report for EVERY error missed.

If an error is missed within the required 50 CIVAs, 50 Cytotoxic, 50 Biopharmaceuticals 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 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 programme.

PROCEDURE FOR WHEN ERRORS ARE IDENTIFIED BY THE TRAINEE

If the trainee identifies any errors or problems with the products that they are inspecting a record the details of the error identified as well as the action taken to resolve it must be recorded on an Error Record Form.

The Error Record Form must also be completed by the Accountable Pharmacists with comments agreeing or disagreeing with the trainee's decision.

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 or Accredited Product Approver 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 or Accredited Product Approver 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.

SCENARIO 2:

The trainee identifies errors or problems with a product and recommends that the product should be released; the Authorised Pharmacist or Accredited Product Approver 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 (for each product type) must include a competency based assessment carried out by the Accountable Pharmacist.

The Competency Based Assessment should include the following criteria; the trainee must meet these criteria to ensure that they have developed a robust product approval technique.

- Carry out a visual inspection of the product
- Ensure the worksheet complies with a current prescription
- Ensure the product complies with the worksheet and prescription
- Ensure all labelling complies with the worksheet / prescription / product
- Ensure you are aware of recent retrospective-testing results for products
- Ensure all necessary checks prior to the final check have been completed
- Ensure all documentation has all relevant signatures and ready for release
- Complete records according to SOPs including environmental records
- Communicate any outcomes of the assessment or any errors found to relevant people
- Refer any issues outside personal limitations
- Follow security/safety procedures

The trainee must also ensure that:

- The product has been produced in accordance with SOP's
- You are aware of recent microbiological and environmental results for the facilities
- The daily monitoring records for the unit are satisfactory, e.g. pressure differentials, cleaning

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 and details of any errors found or missed on the Error Record Form during the 10 competency based assessments.

CHAPTER 10 POST EVIDENCE COLLECTION

PRACTICAL EXAMINATION

Once the evidence collection is complete, each trainee must pass 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 inspection process and their ability to identify errors in a stressful environment.

The trainee will inspect 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. 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 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.

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 assessment and approval 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.

PORTFOLIO REVIEW

The portfolio of evidence 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
- The trainees Job description/scope of practice (this should include mention of the Product Approval Role)
- Satisfactory evidence of a minimum of 50 CYTO products and/or 50 CIVAs products and/or 50 Biopharmaceuticals and/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 – including meaningful feedback on each occasion
- 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 inspections.

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

Once 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 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, ascertain their risk management skills and general knowledge of the role they will be undertaking 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 trainees 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
- Regional Quality Assurance/Quality Control
- 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.

PROBATIONARY PERIOD AND CERTIFICATE OF ACCREDITATION

Upon successful completion of all stages of assessment, the trainee should be notified confirming that they have successfully met all requirements and completed the programme.

The trainee should then commence a probationary period.

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.

CERTIFICATE OF ACCREDITATION

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 of the trainee's successful completion of the programme for entry into departmental records.

CHAPTER 11 APPEALS PROCESS

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 Training Programme Director (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 training provider within 10 working days of the trainee having given notice of their intention to appeal.

On receipt of an appeal, the training provider 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.

CHAPTER 12 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 programme 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, 50 Biopharmaceuticals or 25 PN).

Evidence should be collected following the Product Approval programme format and using approved documentation.

Once complete this should be forwarded to the training provider and an updated certificate issued including the new product type and the date at which it was added as a competency.

Upon completion, individuals and departments should maintain their own records of the evidence for this activity and demonstration of their competence.

CHAPTER 13 REFERENCES

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CHAPTER 14 ACKNOWLEDGMENTS

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Role	Named Individual	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 of PWDS	Ellen Williams	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
Current Members of NHS ASAG		
Regional Quality Assurance	Mark Santillo	South West region
Accountable Pharmacist	Oonagh McGrath	University Hospitals Bristol and Weston NHS Foundation Trust
Director or Pharmacy Workforce Development South	Ellen Williams	Pharmacy Workforce Development South (PWDS)
Pharmacy Workforce Development South, Training Programme Director	Jennifer Gilliam	Pharmacy Workforce Development South (PWDS)
Project Manager, Education and Training Lead, Technical Services	Catherine Talbot	Cardiff and Vale University Health Board
Regional QA Specialist Pharmacist	Linda Hardy	Yorkshire & The Humber
Training Manager Technical Services	Kate Preston	Royal Free Hospital, London
Pharmacy Aseptic Service and Specialist Product Manager	Scott Hillery	Kettering General Hospital, East Midlands
Pharmacy Workforce Development South - Training Programme Director and Senior Pharmacy Technician Education & Training - Bristol Oncology and Haematology Centre	Phil Jones	Pharmacy Workforce Development South (PWDS) and University Hospitals Bristol and Weston NHS Foundation Trust