Plan for the Session

1. *Short “refresher” summarising the legislative changes*

1. *Slido questions*

1. *Panel –led discussion of the questions and responses on “Slido”*

Legislative & Guidance Changes Timeline

MHRA Guidance for Specials Manufacturer's

2021

2022

GMP Annex 1

Dispensing Errors (Hospital & other Pharmacy Services) Order

GPhC Standards for Chief Pharmacists

NHSE Aseptics Assurance Guidance

2023

2025

Human Medicines (Authorisation by Pharmacists & Supervision by Pharmacy Technicians) Order

10th Dec

“Consequential Amendments”

The “Supervision Order” affects other legal instruments. The consequential amendments are listed in the Order itself and include:

- Regulation 37 Clinical Trials
- HMRs 2012
- Misuse of Drugs Regulations 2001

The Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2025

…..at this link there is also a very helpful Explanatory Memorandum

What is “supervision”?

“Supervision” is not defined in legislation and there is conflicting case law”.

*‘**authorisation’** is not being defined in legislation, there is a risk a similar issue could occur with this term too.*

Pharmacy regulators and professional bodies have been asked to define what professional good practice means in-terms of authorisation and supervision

Existing guidance and **relevant “models”** can we use to inform our best practice?

- GMP - MHRA “Guidance for Specials Manufacturers”
  - Primary guidance is GMP, safe preparation of medicines is paramount
- GPhC
  - Legislation on pharmacy supervision: FAQs | General Pharmaceutical Council

www.sps.nhs.uk

How is “supervision” applied in Unlicensed Aseptic Services?

Level	Includes…	Relevant Role...
Organisational	Governance, risk justification, service level, clinical service consideration, capacity	Chief Pharmacist
Departmental	CCS, SOPs, staffing, EM, investigations, staff competency, PQS,	“Accountable Person” appointed and authorised by the Chief Pharmacist
Session	Documented control of each aseptic session	“Authorised Person “
Operational	Aseptic technique oversight, Operator behaviour and contamination control	“Clean Room Supervisor"
Product	Delegated release of prepared doses including: • Product has been prepared correctly and according to GMP. • Accuracy check to ensure dispensed product matches the clinically approved prescription	Authorised Person OR Product Specific Releasing Person

Job Titles subject to change

Supervision legislation changes - Panel discussion

Accountability and Governance: Product Approval & Putting it into Practice

Chair: Anne Black

Panel Members: Linda Hardy; Scott Hillery; Phil Jones

Putting the change into practice:

Considering the change to allow supervision by a pharmacist or pharmacy technician:

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Do you think your organisation will adopt updated oversight processes and personnel following the regulatory change?

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Putting the change into practice:

Considering the change to allow supervision by a pharmacist or pharmacy technician:

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What do you think will be the biggest benefit in implementing the legislative change in your organisation?

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What do you think will be the biggest risks associated with in implementing the legislative change in your organisation?

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The role of the Chief Pharmacist

Considering the Chief Pharmacists role and overarching governance:

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Regulation and Guidance are clear about the Chief Pharmacists overarching responsibility for aseptic services. Do they understand their role?

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What training and support do the Chief Pharmacists need to fulfil role in a meaningful way?

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Delegation and Accountability

Considering the product release process:

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Should product approval and release remain primarily pharmacist and pharmacy technician-led, or can we safely develop a broader releasing workforce within an appropriate governance framework?

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If the releasing person was a non-GPhC registrant operating under delegated authority who would be accountable if an error occurred?

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