

Cleanroom Supervision in Pharmacy Technical Services

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Objective:

Cleanroom supervision is a key area in technical services, QAAPS (Quality Assurance of Aseptic Preparation Services) states this role involves the “control of the aseptic processes”. It has been shown that:

- Operators are expected to have the skills suitable to undertake cleanroom supervision but have not received adequate training to accomplish this.
- Cleanroom Supervisor roles are vital, providing assurance that Good Manufacturing Practice is followed, helping to manage teams and individuals, and are required to interact and communicate well, as well as improving patient safety.
- New roles are being developed and are in place, as stand-alone Cleanroom Supervisors, requiring training and development.
- Career progression and development for technical staff has not been clearly defined.

A need was identified, that formal training was required, to provide the necessary knowledge, skills and competencies for operators to be confident and competent Cleanroom Supervisors.

The development of the new training programme was undertaken by PWDS.

Process:



Desktop Review

- Documentation, papers and literature mentioning cleanroom supervision appraised including:
- EU Good Manufacturing Practice guidelines
- Quality Assurance of Aseptic Preparation Services (QAAPS)



Training Available

- Ascertain if any training already available to ensure no duplication
- New programme to complement existing training and develop advanced skill set



Working Group

- NHS Aseptic Services Accreditation Group (ASAG) vital in steering programme development
- Collaboration with the Technical Services Education and Training group (TSET) and Regional Quality Assurance Group.



Outcomes

- Key Cleanroom Supervision competencies defined
- A unique and brand-new training programme was launched in August 2022 to train new and develop existing Cleanroom Supervisors.
- Training available to licensed and unlicensed units

Trainee Feedback

“It was a good learning experience I feel I came away with a positive attitude on how to become ... a supervisor.”

“(The training) would give confidence to those who are perhaps less experienced in supervisory roles. Empowerment to speak up being a key constituent of that.”

“I really enjoyed the (training) and feel more confident going forward.”

Conclusion

This training programme will:

- ✓ Provide trainees with the skills and knowledge to undertake cleanroom supervision, confidently and competently.
- ✓ Provide a safer working environment ensuring product quality and patient safety.
- ✓ Provide managers with assurance that they have appropriately skilled and competent Cleanroom Supervisors.
- ✓ Provide development opportunities for aseptic services staff to support appropriate and sustainable skill mix.

References & Acknowledgements:

[Quality Assurance of Aseptic Preparation Services](#)

NHS Aseptic Services Accreditations Group

[TSET – Technical Specialist Education and Training group](#)

[Cleanroom Supervision in Pharmacy Technical Services \(CSPTS\)](#)

tset.org.uk

pwds.nhs.uk/prgramme/cspts/

