

**INSPECTION OF UNLICENSED ASEPTIC PREPARATION
SUMMARY OF RESULTS**

Region: North East **Hospital Trust:** Durham and Darlington **Hospital Site:** Darlington Memorial

In accordance with EL(97)52 the aseptic unit at the site named below was audited against the Quality Assurance of Aseptic Preparation Services Standards (NHS QA Committee 2016). The findings are summarised below.

Date of Audit	: 16/11/2018
Date of Previous Audit	: 05/09/2017
Date of Proposed Re-audit	: May 2020

**Overall Risk
Assessment
to Patient Safety:**

Low

Deficiencies	Action
Critical	Critical deficiencies that require immediate action (within 24 hours)
Major	Major deficiencies that require action within three months
Other / Minor	Other / Minor deficiencies that need to be addressed within twelve months
Satisfactory	Complies with standards

Category	Audit Result	Summary of Comments / Action Required (see full report for details)
Minimising Risk with Injectable Medicines	Other / Minor	Local review against the High Risk Injectable Medicines List as defined by UKMI/PASG IS REQUIRED
Prescription Verification	Other / Minor	Multidisciplinary roles and responsibilities should be defined for Parenteral Nutrition.
Management	Other / Minor	Key Performance Indicators related to quality are recommended
Formulation, Stability & Shelf-Life	Other / Minor	Local assessment procedures are required
Facilities	Major	Robust systems for monitoring contactors are required
Pharmaceutical Quality Systems	Major	Sustained emphasis and resource required to ensure the quality management culture is embedded
Personnel, Training & Competency Assessment	Other / Minor	Minor updates required
Aseptic Processing	Other / Minor	Needles should be separated prior to entering the preparation room
Monitoring	Other / Minor	Trending and actions taken as a result of microbiological deviations require strengthening
Cleaning & Sanitisation	Other / Minor	An SOP for disinfection requires review
Starting Materials, Components & Consumables	Satisfactory	
Product Approval	Other / Minor	A daily summary of the unit's status is recommended to facilitate approval
Storage & Distribution	Other / Minor	Transport validation between sites is required.
Internal & External Audit	Other / Minor	The internal audit programme should be integral to the quality system

Overall Comments:

Since the last audit a significant improvement has been seen. The team are to be commended on this and with sustained resource and commitment it is envisaged that improvements will continue and quality systems will be embedded.

Auditor: Anne Black

Affiliation: Regional QA Specialist

Signature:



Date: 4 December 2018