

QC 21 Non Conformance Report

Date	22.10.2020
Issue id unique identifier	201668
BSI Ref (if applicable) unique identifier	1970716-202010-N2
Responsibility Person Overall responsible	Derek Lamb
Non-Conformance statement of the problem	<p>The statement of the problem:</p> <p>The internal audit process isn't fully effective as no evidence was provided for the internal auditor to have been trained to the ISO 13485 version 2016.</p>
Investigation By: Person responsible	Derek Lamb / Helen Lamb
Investigation Issue id (if applicable) Root Cause Analysis	<p>201674</p> <p>In the training records, there is no specific training for auditing of ISO 13483:2016. Audit training is present but not specific to 13485:2016.</p> <p>Root Cause Analysis</p> <p>When the auditor completed audit training in the past, there was not enough detailed added to the training record. So no details as to what version of the ISO standard training has been carried out.</p>
Corrective Action By: Person responsible	Derek Lamb
Corrective Action Issue ID (if applicable): Relevant and Proportionate Corrective Action	#201708 Rolling Task 316
Time Scale for Corrective Action Time for completion of all identified actions	Immediate Action and Corrective Action to be carried out by 22 nd November 2020
Corrective Action:	<p>Immediate Action</p> <p>To update the training manager with details of the training carried out in house. Including more details of what has been trained / covered in the training. Specifically the standard and</p>

	<p>version of the standard that was trained on.</p> <p>Corrective Action</p> <p>To make sure more details are added to the training as it is entered in to the Training Manager. This will be done at the time of signing off. The rolling task will be updated to remind that this needs to be checked.</p>
Follow-up future issue id (Effectiveness verification)	#201708
Effectiveness verification	To be able to look at the training carried out and be able to see specifics of what has been done and what areas or versions covered.
Closed By:	
Closed on	