VST

Internal Audit Check list

Design

Created:	17/May 1995	Audit No 03	VM3/COP16 & 09 VOP 17
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Audit Date	15-7-15	Auditor H LAMB	ISO 7.2 7.3

QUESTION:	RESPONSE:	Y/N
Check that the final design responsibility is a Sole Authority.	Top management	Y
Check that all products are C.E. marked and Viamed products have a C.E. file.	Intrastats	Y
Verify that EMC testing has been identified where required.	CE Files	N/A
Are the latest BS ISO MDD, CMDCAS requirements are available	Library, Paperport	Y
Check that product classification is done to MDD, CMDCAS principles.	CE Files Intrastats	Y
Verify that each design was initiated from a job description & specification	Intrastats or QC22	Y
Has each design has received a job number and a job progress form	Intrastats or QC25	Y
Verify the existence of a design documentation checklist.	Intrastats or QC29	Y
Check that estimated times have been noted. Electronic timing being introdced		Y
Have final testing requirements, and test criteria, been identified	VM Caps	Y
Have concession notes have been raised on non-approved suppliers	Not normal	NA
Check that current status is identified on a regular basis.	Intrastat meetings	Y
Verify that design reviews are undertaken and that records are retained	Intrastat meetings	Y
Check that any amendments to design are logged	Intrastats or QC24	Y
Check that design output records are verified against design input		Y #1
Does design verification comply with COP 16 - 7.7.1 - .4		Y
Check that clinical trials have been carried out and relevant records retained	CE Files	Y #1
Verify that design validation has been carried out as required by form QC30	CE Files	Y #1
Check that any design changes have been identified, recorded and approved	CE Files	Y
Have risk analysis has been carried out and recorded at all relevant stages	CE Files	Y
Check that CE files are complete, correct and maintained	Intrastats, Library	Y
Check and list current design files: Technical Library. Intrastats a) Red Plastic Holder b) Red Binder &/or Red CE mark Binder all in Intrastats c) Hardware R & D or Archives No active		
Do all the files contain the master layout	Intrastats CE	Y
Are the sections in the master layout being filled in correctly		Y
Are the designated people filling in ~~log sheets~~ Intrastats		Y
Is information from the logs being copied to master files . N/A	Intrastats CE	N/A
Are design components kept separate from stock and adequately stored	all barcoded	Y
Are design component stocks labelled		Y
Check the existence of design compliance forms Issue to SSL # 60912		
Have risk analyses been carried out and recorded	CE Files	Y
Check that these files are maintained	Intrastats CE	Y
Verify that they are complete and correct	Intrastats CE	Y
If more space is required for answers use the reverse of this form		

#1 None in progress