

Organization 14 - 1100.100 - Internal Audit

Process 29 - 1100.000.6 - IA: Audit Equipment Calibration 2007-07-16

Punchlist 6 - Absence of calibration signoff

Control Activity 166 - 211.101.8 - Equipment calibration tests and changes shall be properly recorded and signed.

Exception: - Control Deficiency Due Date: -
 Reference: - Status: On Track
 Assigned To: George Grunt - Awaiting Response
 Description: Calibration reports are not all properly signed.

Punchlist 10 - Preparation for Chemical Labeling Audit

Exception: - Due Date: -
 Reference: - Status: On Track
 Assigned To: George Grunt - Awaiting Response
 Description: Manager prepares for audit by collecting and having ready all documentation and logs associated with Label audit.

Process 30 - 1100.000.6 - IA: Audit Equipment Calibration 2007-07-23

Punchlist 7 - Autonomic Software

Control Activity 167 - 211.101.7 - All production equipment shall be routinely calibrated according to procedures and specifications.

Exception: - Control Deficiency Due Date: -
 Reference: - Status: On Track
 Assigned To: Audrey Auditor - Awaiting Response
 Description: ;ldf'asdlf';alsdf';lasd

Organization 16 - 2420.200 - Manufacturing - Packaging

Process 84 - 2410.000.1 - MF: Equipment Calibration Testing 2007-09-17

Punchlist 9 - 211.101.7 - Equipment not checked on schedule

Control Activity 334 - 211.101.7 - All production equipment shall be routinely calibrated according to procedures and specifications.

Exception: - Due Date: -
 Reference: - Status: On Track
 Assigned To: Boyd Tech - Awaiting Response
 Description: Equipment not checked on schedule

Organization 34 - 2320.000 - Regulatory Affairs

Process 67 - 2310.400.2 - QC: Revise Existing SOP

Punchlist 3 - VIVUS REM 001 - SOP Draft Approval

Exception: - Document Deficiency Due Date: 07/20/2007
 Reference: - Status: Past Due
 Assigned To: Quentin Adams - Awaiting Response
 David Gould - Awaiting Response
 Description: We are behind schedule on drafting the new manufacturing SOP
 Resolution Plan: Please provide a plan for remediation.

Organization 35 - 2310.310 - System Validation Project Team

Process 74 - 2310.400.0 - Master IQ Protocol

Punchlist 8 - 001 - Punchlist

Exception: - Document Deficiency Due Date: -
 Reference: - Status: On Track
 Description: as'd;las'd;la'sld;

Process 75 - 2310.400.1 - Develop New Installation Qualification Protocol

Punchlist 4 - CTR -- 001 - Remediate date and time stamping

Control Activity 308 - 11.10.4 - System maintains a date and time-stamped audit trail of record creation and modification.

Exception: - Control Deficiency Due Date: 07/27/2007
 Reference: - Status: Completed
 Assigned To: Sam DeMarco - Completed
 Valerie Verifier - Completed
 Description: We are not consistently creating an audit trail for activities

Organization 40 - 2100.000 - CTI Client Services

Process 98 - CTI.001 - Generix CMMS SRS Writing

Punchlist 5 - CTI PFIZER REMEDIATION - Follow-up actions of Pfizer Account Report

Exception:	-	Due Date:	09/14/2007
Reference:	-	Status:	Past Due
Assigned To:	Inna Telvin - Accepted		
Description:	We need to address the issues raised in your report		
Resolution Plan:	Inna: Please let me know how you will resolve these issues.		
Resolution:	Sam, Im going to look into this.		