

Process Filter: Organizations(Internal Audit) Statuses(At Risk, Cancelled, Completed, Need Attention, On Hold, On Track, Rescheduled, Scheduled or Under Review)

Process 22 - 1100.000.4 - IA: Audit QC Procedures - 07Q2

Status:	Need Attention	Planned Start:	06/04/2007
Priority:	Medium	Planned End:	07/13/2007
Type:	Project	Actual Start:	06/11/2007
Template Name:	IA: Audit QC Procedures	Actual End:	-
Risks:	211.22.1.R1 - Obsolete Procedures Documentation 211.22.1.R2 - Unauthorized Procedures in use 211.22.2.R1 - Authorization Failure IA.1100.R1 - Audit Process - Missed Deadline IA.1100.R1 - Audit Process - Missed Deadline IA.1100.R2 - One or more controls failed audit or were noted as deficient.		
Documents:	GENERIX 004 - CFR 211.34.htm		

Control Activity 153 - 211.100.1 - Procedures are written and current for all production and process control.

Priority:	High		
Classifications:	Preventive Operational		
Assertions:	Product Quality and Integrity, Documentation and Records, Policies, Procedures and Specifications		
Mandates:	CFR 211, Quality Control		
COSO Element:	Control Activities		
Risk Level:	Medium		
Description:	Procedures are written and current for all production and process control.		
Frequency:	Unspecified	Required:	No
Control Inception:	-	Locked:	No
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Completed	Due Date:	06/15/2007
Owner:	AI Checkit	Assessment Type:	Self Assessment
Test Owner:	Inspector General	Assessment Grade:	Well Defined
Design Rating:	Control Meets Objective		

Control Activity 154 - 211.22.1 - All QC procedures are documented, approved and followed.

Priority:	High		
Classifications:	Preventive Operational		
Assertions:	Policies, Procedures and Specifications		
Mandates:	CFR 211, Quality Control		
COSO Element:	Control Environment		
Risk Level:	Medium		
Description:	All QC procedures are documented, approved and followed. Routine review and updates occur.		
Frequency:	Unspecified	Required:	No
Control Inception:	-	Locked:	No
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Past Due	Due Date:	06/15/2007
Owner:	AI Checkit	Assessment Type:	None
Test Owner:	Inspector General	Assessment Grade:	Not Graded
Design Rating:	None		

Test 104 - 211.22.1.T1 - Verify that all QC Procedures are documented, approved and followed.

Type:	Interview Users	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Test Steps:	1. Obtain a copy of current Quality Control procedures. 2. Verify that procedures were approved by an authorized person 3. By interviewing QC personnel, verify that QC Procedures are understood and followed.		
Interviewed:	-	Due Date:	-
Actual Sample Size:	-	Test Date:	-
Sample Errors:	-	Test Grade:	Ungraded
Status:	On Track		

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Test 104 - 211.22.1.T1 - Verify that all QC Procedures are documented, approved and followed.

Assigned to: Andy Assessor Assignment Status: Awaiting Response

Control Activity 155 - 211.22.2 - QC responsible for approving or rejecting all procedures and specifications.

Priority: High
 Classifications: Preventive Operational
 Assertions: Product Quality and Integrity, Component Quality and Integrity, Policies, Procedures and Specifications
 Mandates: CFR 211, Quality Control
 COSO Element: Control Environment
 Risk Level: Medium
 Description: QC has responsibility for approving and rejecting all procedures or specifications impacting the identity, strength, quality, and purity of drug products.
 Frequency: Unspecified Required: No
 Control Inception: - Locked: No
 Preparation Required: -
 Audit Procedure: -
 Narrative Reference: -
 Status: Past Due Due Date: 06/15/2007
 Owner: AI Checkit Assessment Type: None
 Test Owner: Inspector General Assessment Grade: Not Graded
 Design Rating: None

Test 105 - 211.22.2.T1 - Verify that QC is responsible for approving and rejecting all procedures and specifications.

Type: Observation Frequency: Unspecified
 Test Procedure Reference: -
 Command Media Reference: -
 Test Steps: 1. Verify that company policies and procedures require that QC approve or reject all manufacturing procedures and specifications.
 Interviewed: - Due Date: -
 Actual Sample Size: - Test Date: -
 Sample Errors: - Test Grade: Ungraded
 Status: On Track
 Assigned to: Andy Assessor Assignment Status: Awaiting Response

Test 106 - 211.22.2.T2 - Verify that procedures and specifications have been approved by QC

Type: Sampling Frequency: Unspecified
 Test Procedure Reference: -
 Command Media Reference: -
 Test Steps: 1. Select appropriate samples of manufacturing procedures and specifications.
 2. Verify that procedures were approved by QC prior to implementation.
 3. Verify that approvals are properly documented and have been communicated to appropriate management.
 Interviewed: - Due Date: -
 Actual Sample Size: - Test Date: -
 Sample Errors: - Test Grade: Ungraded
 Status: On Track
 Assigned to: Andy Assessor Assignment Status: Awaiting Response

Test 107 - 211.22.2.T3 - Verify that procedures were rejected by QC

Type: Sampling Frequency: Unspecified
 Test Procedure Reference: -
 Command Media Reference: -
 Test Steps: 1. Select a sample of procedures that have been rejected.
 2. Verify that QC reviewed and rejected procedures.
 3. Verify that rejections are documented, approved and communicated to appropriate management.
 Interviewed: - Due Date: -
 Actual Sample Size: - Test Date: -
 Sample Errors: - Test Grade: Ungraded
 Status: On Track
 Assigned to: Andy Assessor Assignment Status: Awaiting Response

Process Filter: Organizations(Internal Audit) Statuses(At Risk, Cancelled, Completed, Need Attention, On Hold, On Track, Rescheduled, Scheduled or Under Review)

Control Activity 156 - 211.22.3 - All QC approvals and rejections are properly documented, approved and communicated.

Priority:	High	Required:	No
Classifications:	Operational	Locked:	No
Assertions:	Documentation and Records, Reporting and Notification		
Mandates:	CFR 211, Quality Control		
COSO Element:	Control Activities		
Risk Level:	Medium		
Description:	All QC approvals and rejections are properly documented, approved and communicated to appropriate management.		
Frequency:	Unspecified		
Control Inception:	-		
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Completed	Due Date:	06/15/2007
Owner:	AI Checkit	Assessment Type:	Self Assessment
Test Owner:	Inspector General	Assessment Grade:	Adequate
Design Rating:	Compensating Controls Meet Objective		

Test 108 - 211.22.3.T1 - All QC Procedure Changes are properly documented and approved.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Interviewed:	-	Due Date:	-
Actual Sample Size:	-	Test Date:	-
Sample Errors:	-	Test Grade:	Ungraded
Status:	On Track		
Assigned to:	Andy Assessor	Assignment Status:	Awaiting Response

Event 46 - Prepare for Audit

Task 88 - Notify organization / manager of audit

Type:	-	Required:	Yes
Status:	On Track	Due Date:	-
Organization:	-	Completed:	-
Assigned to:	Andy Assessor	Assignment Status:	Awaiting Response

Task 89 - Review related policies and procedures

Type:	-	Required:	Yes
Status:	On Track	Due Date:	-
Organization:	-	Completed:	-
Assigned to:	Andy Assessor	Assignment Status:	Awaiting Response

Event 47 - Conduct Audit

Task 90 - Execute tests based on sampling, observation, interview or replay

Type:	-	Required:	Yes
Status:	On Track	Due Date:	-
Organization:	-	Completed:	-
Assigned to:	Andy Assessor	Assignment Status:	Awaiting Response

Task 91 - Document test results as specified.

Type:	-	Required:	Yes
Status:	On Track	Due Date:	-
Organization:	-	Completed:	-
Assigned to:	Andy Assessor	Assignment Status:	Awaiting Response

Task 92 - Note any exceptions or deficiencies.

Type:	-	Required:	Yes
Status:	On Track	Due Date:	-
Organization:	-	Completed:	-
Assigned to:	Andy Assessor	Assignment Status:	Awaiting Response

Process Filter: Organizations(Internal Audit) Statuses(At Risk, Cancelled, Completed, Need Attention, On Hold, On Track, Rescheduled, Scheduled or Under Review)

Event 48 - Complete Testing Process

Task 93 - Finalize test results and documentation

Type:	-	Required:	Yes
Status:	On Track	Due Date:	-
Organization:	-	Completed:	-
Assigned to:	Andy Assessor	Assignment Status:	Awaiting Response

Task 94 - Notify appropriate persons of any deficiencies noted.

Type:	-	Required:	Yes
Status:	On Track	Due Date:	-
Organization:	-	Completed:	-
Assigned to:	Andy Assessor	Assignment Status:	Awaiting Response

Task 95 - Submit final testing results

Type:	-	Required:	Yes
Status:	On Track	Due Date:	-
Organization:	-	Completed:	-
Assigned to:	Andy Assessor	Assignment Status:	Awaiting Response

Process 24 - 1100.000.2 - IA: Audit Quarterly Summary Process - 07Q2

Status:	Need Attention	Planned Start:	04/02/2007
Priority:	Medium	Planned End:	07/13/2007
Type:	Routine	Actual Start:	04/02/2007
Template Name:	IA: Audit Quarterly Summary Process	Actual End:	-
Risks:	QC.2310.R1 - QC Process - Missed Deadline		
Documents:	- Copy of CAPA Competitive Analysis Sentinel updates.xls		

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

Status:	At Risk	Planned Start:	07/16/2007
Priority:	High	Planned End:	07/06/2007
Type:	Project	Actual Start:	12/04/2007
Template Name:	IA: Audit Equipment Calibration	Actual End:	-
Risks:	- Audit Process - Missed Deadline		
	211.101.7.R1 - Equipment Calibration Error		
	211.101.7.R2 - Equipment Malfunction		

Control Activity 165 - 211.101.7 - All production equipment shall be routinely calibrated according to procedures and specifications.

Priority:	High	Required:	No
Classifications:	Preventive Detective Operational System	Locked:	No
Assertions:	Equipment Calibration, Documentation and Records, Evaluation and Monitoring		
Mandates:	CFR 211, CFR 820		
COSO Element:	Control Activities		
Risk Level:	Medium		
Frequency:	Unspecified		
Control Inception:	-		
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Past Due	Due Date:	07/19/2007
Owner:	George Grunt	Assessment Type:	Internal Audit
Test Owner:	Audrey Auditor	Assessment Grade:	Not Graded
Design Rating:	Control Meets Objective		

Test 117 - 211.101.7.T2 - Verify that production equipment has been calibrated according to policies and procedures.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Test Steps:	1. Obtain calibration policies and procedures for production equipment.		
	2. Obtain copies of production calibration reports.		

Process Filter: Organizations(Internal Audit) Statuses(At Risk, Cancelled, Completed, Need Attention, On Hold, On Track, Rescheduled, Scheduled or Under Review)

Test 117 - 211.101.7.T2 - Verify that production equipment has been calibrated according to policies and procedures.

- 3. Verify that calibrations were conducted in accordance with policies and procedures.
- 4. Verify that tests and changes were properly recorded and signed.

Interviewed:	-	Due Date:	07/19/2007
Actual Sample Size:	-	Test Date:	-
Sample Errors:	-	Test Grade:	Ungraded
Status:	Past Due	Assignment Status:	Awaiting Response
Assigned to:	Audrey Auditor		

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

Priority:	High	Required:	No
Classifications:	Operational System	Locked:	No
Assertions:	Equipment Calibration, Documentation and Records, Signatures and Authorization		
Mandates:	CFR 211, CFR 820		
COSO Element:	Control Activities		
Risk Level:	Medium		
Description:	Equipment calibration tests and changes shall be properly recorded and signed. All modifications shall be made by one person and verified by a second person.		
Frequency:	Unspecified		
Control Inception:	-		
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Completed	Due Date:	07/19/2007
Owner:	George Grunt	Assessment Type:	Internal Audit
Test Owner:	Audrey Auditor	Assessment Grade:	Well Defined
Design Rating:	None		

Test 118 - 211.101.8.T1 - Verify that equipment calibration tests and changes are recorded and signed.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Interviewed:	-	Due Date:	07/19/2007
Actual Sample Size:	-	Test Date:	-
Sample Errors:	-	Test Grade:	Ungraded
Status:	Past Due	Assignment Status:	Awaiting Response
Assigned to:	Audrey Auditor		

Punchlist 6 - Absence of calibration signoff

Status:	On Track	Priority:	High
Control Activity:	Equipment calibration tests and changes shall be properly recorded and signed.	Due Date:	-
Assigned To:	George Grunt		
Description:	Calibration reports are not all properly signed.		

Punchlist 10 - Preparation for Chemical Labeling Audit

Status:	On Track	Priority:	Low
Control Activity:	None	Due Date:	-
Assigned To:	George Grunt		
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

Status:	At Risk	Planned Start:	12/03/2007
Priority:	High	Planned End:	12/07/2007
Type:	Project	Actual Start:	12/03/2007
Template Name:	IA: Audit Equipment Calibration	Actual End:	-
Risks:	<ul style="list-style-type: none"> - Audit Process - Missed Deadline 211.101.7.R1 - Equipment Calibration Error 211.101.7.R2 - Equipment Malfunction 		

Process Filter: Organizations(Internal Audit) Statuses(At Risk, Cancelled, Completed, Need Attention, On Hold, On Track, Rescheduled, Scheduled or Under Review)

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

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

Priority:	High		
Classifications:	Preventive Detective Operational System		
Assertions:	Equipment Calibration, Documentation and Records, Evaluation and Monitoring		
Mandates:	CFR 211, CFR 820		
COSO Element:	Control Activities		
Risk Level:	Medium		
Frequency:	Unspecified	Required:	No
Control Inception:	-	Locked:	No
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Completed	Due Date:	-
Owner:	George Grunt	Assessment Type:	Internal Audit
Test Owner:	Audrey Auditor	Assessment Grade:	Not Graded
Design Rating:	Control Meets Objective		

Test 119 - 211.101.7.T2 - Verify that production equipment has been calibrated according to policies and procedures.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Test Steps:	<ol style="list-style-type: none"> 1. Obtain calibration policies and procedures for production equipment. 2. Obtain copies of production calibration reports. 3. Verify that calibrations were conducted in accordance with policies and procedures. 4. Verify that tests and changes were properly recorded and signed. 		
Interviewed:	-	Due Date:	07/26/2007
Actual Sample Size:	-	Test Date:	-
Sample Errors:	-	Test Grade:	Ungraded
Status:	Past Due		
Assigned to:	Audrey Auditor	Assignment Status:	Awaiting Response

Control Activity 168 - 211.101.8 - Equipment calibration tests and changes shall be properly recorded and signed.

Priority:	High		
Classifications:	Operational System		
Assertions:	Equipment Calibration, Documentation and Records, Signatures and Authorization		
Mandates:	CFR 211, CFR 820		
COSO Element:	Control Activities		
Risk Level:	Medium		
Description:	Equipment calibration tests and changes shall be properly recorded and signed. All modifications shall be made by one person and verified by a second person.		
Frequency:	Unspecified	Required:	No
Control Inception:	-	Locked:	No
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Completed	Due Date:	07/26/2007
Owner:	George Grunt	Assessment Type:	None
Test Owner:	Audrey Auditor	Assessment Grade:	Not Graded
Design Rating:	None		

Test 120 - 211.101.8.T1 - Verify that equipment calibration tests and changes are recorded and signed.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Interviewed:	-	Due Date:	07/26/2007
Actual Sample Size:	-	Test Date:	-
Sample Errors:	-	Test Grade:	Ungraded
Status:	Past Due		
Assigned to:	Audrey Auditor	Assignment Status:	Awaiting Response

Process Filter: Organizations(Internal Audit) Statuses(At Risk, Cancelled, Completed, Need Attention, On Hold, On Track, Rescheduled, Scheduled or Under Review)

Test 120 - 211.101.8.T1 - Verify that equipment calibration tests and changes are recorded and signed.

Punchlist 7 - Autonomic Software

Status:	On Track	Priority:	High
Control Activity:	All production equipment shall be routinely calibrated according to procedures and specifications.	Due Date:	-
Assigned To:	Audrey Auditor		
Description:	;ldf'asdlf';alsdf';lasd		

Process 31 - 1100.000.6 - IA: Audit Equipment Calibration 2007-07-30

Status:	At Risk	Planned Start:	07/30/2007
Priority:	High	Planned End:	08/04/2007
Type:	Project	Actual Start:	-
Template Name:	IA: Audit Equipment Calibration	Actual End:	-
Risks:	- Audit Process - Missed Deadline 211.101.7.R1 - Equipment Calibration Error 211.101.7.R2 - Equipment Malfunction		

Control Activity 169 - 211.101.7 - All production equipment shall be routinely calibrated according to procedures and specifications.

Priority:	High		
Classifications:	Preventive Detective Operational System		
Assertions:	Equipment Calibration, Documentation and Records, Evaluation and Monitoring		
Mandates:	CFR 211, CFR 820		
COSO Element:	Control Activities		
Risk Level:	Medium		
Frequency:	Unspecified	Required:	No
Control Inception:	-	Locked:	No
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Past Due	Due Date:	08/02/2007
Owner:	George Grunt	Assessment Type:	Internal Audit
Test Owner:	Audrey Auditor	Assessment Grade:	Not Graded
Design Rating:	Control Meets Objective		

Test 121 - 211.101.7.T2 - Verify that production equipment has been calibrated according to policies and procedures.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Test Steps:	1. Obtain calibration policies and procedures for production equipment. 2. Obtain copies of production calibration reports. 3. Verify that calibrations were conducted in accordance with policies and procedures. 4. Verify that tests and changes were properly recorded and signed.		
Interviewed:	-	Due Date:	08/02/2007
Actual Sample Size:	-	Test Date:	-
Sample Errors:	-	Test Grade:	Ungraded
Status:	Past Due		
Assigned to:	Audrey Auditor	Assignment Status:	Awaiting Response

Control Activity 170 - 211.101.8 - Equipment calibration tests and changes shall be properly recorded and signed.

Priority:	High		
Classifications:	Operational System		
Assertions:	Equipment Calibration, Documentation and Records, Signatures and Authorization		
Mandates:	CFR 211, CFR 820		
COSO Element:	Control Activities		
Risk Level:	Medium		
Description:	Equipment calibration tests and changes shall be properly recorded and signed. All modifications shall be made by one person and verified by a second person.		

Process Filter: Organizations(Internal Audit) Statuses(At Risk, Cancelled, Completed, Need Attention, On Hold, On Track, Rescheduled, Scheduled or Under Review)

Control Activity 170 - 211.101.8 - Equipment calibration tests and changes shall be properly recorded and signed.

Frequency:	Unspecified	Required:	No
Control Inception:	-	Locked:	No
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Past Due	Due Date:	08/02/2007
Owner:	George Grunt	Assessment Type:	None
Test Owner:	Audrey Auditor	Assessment Grade:	Not Graded
Design Rating:	None		

Test 122 - 211.101.8.T1 - Verify that equipment calibration tests and changes are recorded and signed.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Interviewed:	-	Due Date:	08/02/2007
Actual Sample Size:	-	Test Date:	-
Sample Errors:	-	Test Grade:	Ungraded
Status:	Past Due		
Assigned to:	Audrey Auditor	Assignment Status:	Awaiting Response

Process 32 - 1100.000.6 - IA: Audit Equipment Calibration 2007-08-06

Status:	Cancelled	Planned Start:	08/06/2007
Priority:	High	Planned End:	08/11/2007
Type:	Project	Actual Start:	-
Template Name:	IA: Audit Equipment Calibration	Actual End:	-
Risks:	- Audit Process - Missed Deadline 211.101.7.R1 - Equipment Calibration Error 211.101.7.R2 - Equipment Malfunction		

Control Activity 171 - 211.101.7 - All production equipment shall be routinely calibrated according to procedures and specifications.

Priority:	High		
Classifications:	Preventive Detective Operational System		
Assertions:	Equipment Calibration, Documentation and Records, Evaluation and Monitoring		
Mandates:	CFR 211, CFR 820		
COSO Element:	Control Activities		
Risk Level:	Medium		
Frequency:	Unspecified	Required:	No
Control Inception:	-	Locked:	No
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Scheduled	Due Date:	08/09/2007
Owner:	George Grunt	Assessment Type:	Internal Audit
Test Owner:	Audrey Auditor	Assessment Grade:	Not Graded
Design Rating:	Control Meets Objective		

Test 123 - 211.101.7.T2 - Verify that production equipment has been calibrated according to policies and procedures.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Test Steps:	1. Obtain calibration policies and procedures for production equipment. 2. Obtain copies of production calibration reports. 3. Verify that calibrations were conducted in accordance with policies and procedures. 4. Verify that tests and changes were properly recorded and signed.		
Interviewed:	-	Due Date:	08/09/2007
Actual Sample Size:	-	Test Date:	-
Sample Errors:	-	Test Grade:	Ungraded
Status:	On Track		
Assigned to:	Audrey Auditor	Assignment Status:	Awaiting Response

Process Filter: Organizations(Internal Audit) Statuses(At Risk, Cancelled, Completed, Need Attention, On Hold, On Track, Rescheduled, Scheduled or Under Review)

Test 123 - 211.101.7.T2 - Verify that production equipment has been calibrated according to policies and procedures.

Control Activity 172 - 211.101.8 - Equipment calibration tests and changes shall be properly recorded and signed.

Priority:	High	Required:	No
Classifications:	Operational System	Locked:	No
Assertions:	Equipment Calibration, Documentation and Records, Signatures and Authorization		
Mandates:	CFR 211, CFR 820		
COSO Element:	Control Activities		
Risk Level:	Medium		
Description:	Equipment calibration tests and changes shall be properly recorded and signed. All modifications shall be made by one person and verified by a second person.		
Frequency:	Unspecified	Required:	No
Control Inception:	-	Locked:	No
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Scheduled	Due Date:	08/09/2007
Owner:	George Grunt	Assessment Type:	None
Test Owner:	Audrey Auditor	Assessment Grade:	Not Graded
Design Rating:	None		

Test 124 - 211.101.8.T1 - Verify that equipment calibration tests and changes are recorded and signed.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Interviewed:	-		
Actual Sample Size:	-		
Sample Errors:	-		
Status:	On Track	Due Date:	08/09/2007
Assigned to:	Audrey Auditor	Test Date:	-
		Test Grade:	Ungraded
		Assignment Status:	Awaiting Response

Process 33 - 1100.000.6 - IA: Audit Equipment Calibration 2007-08-13

Status:	Completed	Planned Start:	08/13/2007
Priority:	High	Planned End:	08/18/2007
Type:	Project	Actual Start:	08/13/2007
Template Name:	IA: Audit Equipment Calibration	Actual End:	10/18/2007
Risks:	- Audit Process - Missed Deadline 211.101.7.R1 - Equipment Calibration Error 211.101.7.R2 - Equipment Malfunction		

Control Activity 173 - 211.101.7 - All production equipment shall be routinely calibrated according to procedures and specifications.

Priority:	High	Required:	No
Classifications:	Preventive Detective Operational System	Locked:	No
Assertions:	Equipment Calibration, Documentation and Records, Evaluation and Monitoring		
Mandates:	CFR 211, CFR 820		
COSO Element:	Control Activities		
Risk Level:	Medium		
Frequency:	Unspecified	Required:	No
Control Inception:	-	Locked:	No
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Scheduled	Due Date:	08/16/2007
Owner:	George Grunt	Assessment Type:	Internal Audit
Test Owner:	Audrey Auditor	Assessment Grade:	Not Graded
Design Rating:	Control Meets Objective		

Process Filter: Organizations(Internal Audit) Statuses(At Risk, Cancelled, Completed, Need Attention, On Hold, On Track, Rescheduled, Scheduled or Under Review)

Test 125 - 211.101.7.T2 - Verify that production equipment has been calibrated according to policies and procedures.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Test Steps:	1. Obtain calibration policies and procedures for production equipment. 2. Obtain copies of production calibration reports. 3. Verify that calibrations were conducted in accordance with policies and procedures. 4. Verify that tests and changes were properly recorded and signed.		
Interviewed:	-	Due Date:	08/16/2007
Actual Sample Size:	-	Test Date:	10/16/2007
Sample Errors:	-	Test Grade:	Ungraded
Status:	Past Due		
Assigned to:	David Potts	Assignment Status:	Awaiting Response

Control Activity 174 - 211.101.8 - Equipment calibration tests and changes shall be properly recorded and signed.

Priority:	High		
Classifications:	Operational System		
Assertions:	Equipment Calibration, Documentation and Records, Signatures and Authorization		
Mandates:	CFR 211, CFR 820		
COSO Element:	Control Activities		
Risk Level:	Medium		
Description:	Equipment calibration tests and changes shall be properly recorded and signed. All modifications shall be made by one person and verified by a second person.		
Frequency:	Unspecified	Required:	No
Control Inception:	-	Locked:	No
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Scheduled	Due Date:	08/16/2007
Owner:	George Grunt	Assessment Type:	None
Test Owner:	Audrey Auditor	Assessment Grade:	Not Graded
Design Rating:	None		

Test 126 - 211.101.8.T1 - Verify that equipment calibration tests and changes are recorded and signed.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Interviewed:	-	Due Date:	08/16/2007
Actual Sample Size:	-	Test Date:	-
Sample Errors:	-	Test Grade:	Ungraded
Status:	On Track		
Assigned to:	David Potts	Assignment Status:	Awaiting Response

Process 34 - 1100.000.6 - IA: Audit Plasma Refrigeration Monitoring

Status:	At Risk	Planned Start:	08/20/2007
Priority:	High	Planned End:	08/25/2007
Type:	Project	Actual Start:	-
Template Name:	IA: Audit Equipment Calibration	Actual End:	-
Audit Process:	Plasma Monitoring - Weekly 06-25-2007		
Risks:	- Audit Process - Missed Deadline 211.101.7.R1 - Equipment Calibration Error 211.101.7.R2 - Equipment Malfunction		

Control Activity 175 - 211.101.7 - All production equipment shall be routinely calibrated according to procedures and specifications.

Priority:	High		
Classifications:	Preventive Detective Operational System		
Assertions:	Equipment Calibration, Documentation and Records, Evaluation and Monitoring		
Mandates:	CFR 211, CFR 820		
COSO Element:	Control Activities		

Process Filter: Organizations(Internal Audit) Statuses(At Risk, Cancelled, Completed, Need Attention, On Hold, On Track, Rescheduled, Scheduled or Under Review)

Control Activity 175 - 211.101.7 - All production equipment shall be routinely calibrated according to procedures and specifications.

Risk Level:	Medium	Required:	No
Frequency:	Unspecified	Locked:	No
Control Inception:	-		
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Completed	Due Date:	08/23/2007
Owner:	George Grunt	Assessment Type:	Internal Audit
Test Owner:	Audrey Auditor	Assessment Grade:	Not Graded
Design Rating:	Control Meets Objective		

Test 127 - 211.101.7.T2 - Verify that production equipment has been calibrated according to policies and procedures.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Test Steps:	<ol style="list-style-type: none"> 1. Obtain calibration policies and procedures for production equipment. 2. Obtain copies of production calibration reports. 3. Verify that calibrations were conducted in accordance with policies and procedures. 4. Verify that tests and changes were properly recorded and signed. 		
Interviewed:	-	Due Date:	08/23/2007
Actual Sample Size:	-	Test Date:	-
Sample Errors:	-	Test Grade:	Ungraded
Status:	Past Due		
Assigned to:	David Potts	Assignment Status:	Awaiting Response

Control Activity 176 - 211.101.8 - Equipment calibration tests and changes shall be properly recorded and signed.

Priority:	High		
Classifications:	Operational System		
Assertions:	Equipment Calibration, Documentation and Records, Signatures and Authorization		
Mandates:	CFR 211, CFR 820		
COSO Element:	Control Activities		
Risk Level:	Medium		
Description:	Equipment calibration tests and changes shall be properly recorded and signed. All modifications shall be made by one person and verified by a second person.		
Frequency:	Unspecified	Required:	No
Control Inception:	-	Locked:	No
Preparation Required:	-		
Audit Procedure:	-		
Narrative Reference:	-		
Status:	Past Due	Due Date:	08/23/2007
Owner:	George Grunt	Assessment Type:	None
Test Owner:	Audrey Auditor	Assessment Grade:	Not Graded
Design Rating:	None		

Test 128 - 211.101.8.T1 - Verify that equipment calibration tests and changes are recorded and signed.

Type:	Sampling	Frequency:	Unspecified
Test Procedure Reference:	-		
Command Media Reference:	-		
Interviewed:	-	Due Date:	08/23/2007
Actual Sample Size:	-	Test Date:	-
Sample Errors:	-	Test Grade:	Ungraded
Status:	Past Due		
Assigned to:	David Potts	Assignment Status:	Awaiting Response