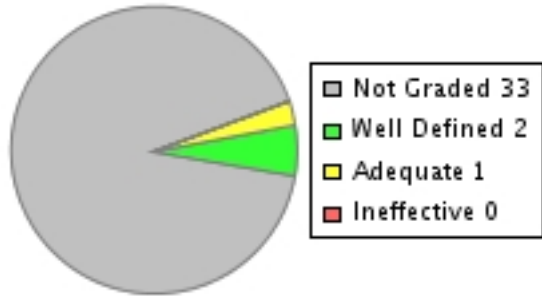
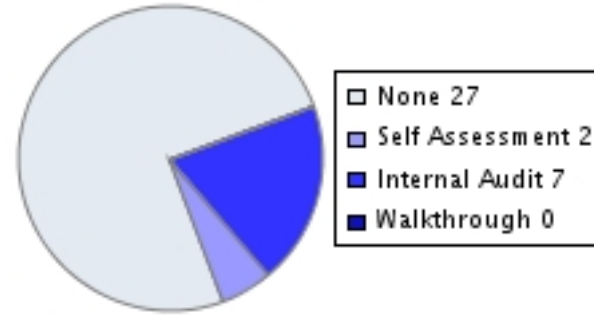


Process Filter: Name Contains(ia:)

Control Activity Grades



Control Assessment Types



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

Ungrouped Controls

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

Control Owner: Al Checkit	Status: Completed	Assessment Type: Self Assessment	Grade: Well Defined	Optional
Assertions: Product Quality and Integrity, Documentation and Records, Policies, Procedures and Specifications			Classifications: Preventive Operational	

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

Control Owner: Al Checkit	Status: Past Due	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Policies, Procedures and Specifications			Classifications: Preventive Operational	

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

Control Owner: Al Checkit	Status: Past Due	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Product Quality and Integrity, Component Quality and Integrity, Policies, Procedures and Specifications			Classifications: Preventive Operational	

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

Control Owner: Al Checkit	Status: Completed	Assessment Type: Self Assessment	Grade: Adequate	Optional
Assertions: Documentation and Records, Reporting and Notification			Classifications: Operational	

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

Ungrouped Controls

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

Control Owner: George Grunt	Status: Past Due	Assessment Type: Internal Audit	Grade: Not Graded	Optional
Assertions: Equipment Calibration, Documentation and Records, Evaluation and Monitoring			Classifications: Preventive Detective Operational System	

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

Control Owner: George Grunt	Status: Completed	Assessment Type: Internal Audit	Grade: Well Defined	Optional
Assertions: Equipment Calibration, Documentation and Records, Signatures and Authorization			Classifications: Operational System	

Process Filter: Name Contains(ia:)

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

Ungrouped Controls

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

Control Owner: George Grunt	Status: Completed	Assessment Type: Internal Audit	Grade: Not Graded	Optional
Assertions: Equipment Calibration, Documentation and Records, Evaluation and Monitoring			Classifications: Preventive Detective Operational System	

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

Control Owner: George Grunt	Status: Completed	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Equipment Calibration, Documentation and Records, Signatures and Authorization			Classifications: Operational System	

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

Ungrouped Controls

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

Control Owner: George Grunt	Status: Past Due	Assessment Type: Internal Audit	Grade: Not Graded	Optional
Assertions: Equipment Calibration, Documentation and Records, Evaluation and Monitoring			Classifications: Preventive Detective Operational System	

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

Control Owner: George Grunt	Status: Past Due	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Equipment Calibration, Documentation and Records, Signatures and Authorization			Classifications: Operational System	

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

Ungrouped Controls

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

Control Owner: George Grunt	Status: Scheduled	Assessment Type: Internal Audit	Grade: Not Graded	Optional
Assertions: Equipment Calibration, Documentation and Records, Evaluation and Monitoring			Classifications: Preventive Detective Operational System	

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

Control Owner: George Grunt	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Equipment Calibration, Documentation and Records, Signatures and Authorization			Classifications: Operational System	

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

Ungrouped Controls

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

Control Owner: George Grunt	Status: Scheduled	Assessment Type: Internal Audit	Grade: Not Graded	Optional
Assertions: Equipment Calibration, Documentation and Records, Evaluation and Monitoring			Classifications: Preventive Detective Operational System	

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

Control Owner: George Grunt	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Equipment Calibration, Documentation and Records, Signatures and Authorization			Classifications: Operational System	

Process 34 - 1100.000.6 - IA: Audit Plasma Refrigeration Monitoring

Ungrouped Controls

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

Control Owner: George Grunt	Status: Completed	Assessment Type: Internal Audit	Grade: Not Graded	Optional
Assertions: Equipment Calibration, Documentation and Records, Evaluation and Monitoring			Classifications: Preventive Detective Operational System	

Process Filter: Name Contains(ia:)

Process 34 - 1100.000.6 - IA: Audit Plasma Refrigeration Monitoring

Ungrouped Controls

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

Control Owner: George Grunt	Status: Past Due	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Equipment Calibration, Documentation and Records, Signatures and Authorization			Classifications: Operational System	

Process 112 - 1100.000.5 - IA: Audit Quality System and Design System Procedures

Ungrouped Controls

Control Activity 386 - 820.20.1 - Quality policy, plans and procedures have been defined and documented

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Product Quality and Integrity, Quality Systems, Review and Approval			Classifications: Preventive Operational System	

Control Activity 387 - 820.20.2 - Quality Plan is in place to govern the design and manufacture of medical devices.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Product Quality and Integrity, Documentation and Records, Policies, Procedures and Specifications			Classifications: Preventive Operational System	

Control Activity 388 - 820.20.3 - Quality Plan defines all quality controls used in the design and manufacturing processes

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Product Quality and Integrity, Component Quality and Integrity, Documentation and Records			Classifications: Preventive Operational System	

Control Activity 389 - 820.20.4 - Quality plan, policies, procedures and controls have been implemented

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Product Quality and Integrity, Component Quality and Integrity, Documentation and Records, Evaluation and Monitoring			Classifications: Detective Operational System	

Control Activity 390 - 820.20.5 - Firm's organizational structure provides for proper responsibilities, authorities and resources.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Segregation of Duties, Skills and Training, Signatures and Authorization, Reporting and Notification, Evaluation and Monitoring			Classifications: Preventive Detective Operational	

Control Activity 391 - 820.20.6 - A management representative is responsible for ensuring the effectiveness of the quality systems.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Signatures and Authorization, Quality Systems, Review and Approval			Classifications: Operational System	

Control Activity 392 - 820.20.7 - Management routinely reviews the suitability and effectiveness of the quality system.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Signatures and Authorization, Quality Systems, Review and Approval			Classifications: Preventive Detective Operational	

Control Activity 393 - 820.20.8 - Quality System is routinely audited and deficiencies are corrected and re-audited.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Verification, Evaluation and Monitoring, Quality Systems, Review and Approval			Classifications: Detective Operational	

Control Activity 394 - 820.30.1 - Firm routinely conducts risk analysis of its Design Control System.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Evaluation and Monitoring, Review and Approval, Risk Assessment and Remediation			Classifications: Preventive Detective Operational System	

Process Filter: Name Contains(ia:)

Process 112 - 1100.000.5 - IA: Audit Quality System and Design System Procedures

Ungrouped Controls

Control Activity 395 - 820.30.2 - All unresolved discrepancies in the design plan validation have been identified and documented.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Documentation and Records, Quality Systems, Risk Assessment and Remediation			Classifications: Detective Operational	

Process 113 - 1100.000.5 - IA: Audit Quality System and Design System Procedures 2008-01-14

Ungrouped Controls

Control Activity 396 - 820.20.1 - Quality policy, plans and procedures have been defined and documented

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Product Quality and Integrity, Quality Systems, Review and Approval			Classifications: Preventive Operational System	

Control Activity 397 - 820.20.2 - Quality Plan is in place to govern the design and manufacture of medical devices.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Product Quality and Integrity, Documentation and Records, Policies, Procedures and Specifications			Classifications: Preventive Operational System	

Control Activity 398 - 820.20.3 - Quality Plan defines all quality controls used in the design and manufacturing processes

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Product Quality and Integrity, Component Quality and Integrity, Documentation and Records			Classifications: Preventive Operational System	

Control Activity 399 - 820.20.4 - Quality plan, policies, procedures and controls have been implemented

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Product Quality and Integrity, Component Quality and Integrity, Documentation and Records, Evaluation and Monitoring			Classifications: Detective Operational System	

Control Activity 400 - 820.20.5 - Firm's organizational structure provides for proper responsibilities, authorities and resources.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Segregation of Duties, Skills and Training, Signatures and Authorization, Reporting and Notification, Evaluation and Monitoring			Classifications: Preventive Detective Operational	

Control Activity 401 - 820.20.6 - A management representative is responsible for ensuring the effectiveness of the quality systems.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Signatures and Authorization, Quality Systems, Review and Approval			Classifications: Operational System	

Control Activity 402 - 820.20.7 - Management routinely reviews the suitability and effectiveness of the quality system.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Signatures and Authorization, Quality Systems, Review and Approval			Classifications: Preventive Detective Operational	

Control Activity 403 - 820.20.8 - Quality System is routinely audited and deficiencies are corrected and re-audited.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Verification, Evaluation and Monitoring, Quality Systems, Review and Approval			Classifications: Detective Operational	

Control Activity 404 - 820.30.1 - Firm routinely conducts risk analysis of its Design Control System.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Evaluation and Monitoring, Review and Approval, Risk Assessment and Remediation			Classifications: Preventive Detective Operational System	

Process Filter: Name Contains(ia:)

Process 113 - 1100.000.5 - IA: Audit Quality System and Design System Procedures 2008-01-14

Ungrouped Controls

Control Activity 405 - 820.30.2 - All unresolved discrepancies in the design plan validation have been identified and documented.

Control Owner: Mary Bloodlett	Status: Scheduled	Assessment Type: None	Grade: Not Graded	Optional
Assertions: Documentation and Records, Quality Systems, Risk Assessment and Remediation			Classifications: Detective Operational	