



INTERNAL AUDIT PLAN

Issued by: QA

Eff. Date: 00-00-00

Revision: A

QF-82-02-1

Audit Cycle

Start: *Mar 1, 2005*End: *Feb 28, 2006*

Quality Management System Process (ref. QM 4.1.1)	Auditor	Audit Date	Additional Date
1 Product Info., Quotations and Orders	<i>QA Manager</i>	<i>Apr 2006</i>	
2 Product Design	<i>QA Manager</i>	<i>Apr 2006</i>	<i>Oct 2006</i>
3 Production and Quality Planning			
4 Purchasing and Receiving			
5 Production			
6 Labeling, Packaging, Shipping and Distribution			
7 Monitoring and Measurement of Products			
8 Monitoring/Measurement of QMS (Internal Audits)			
9 Monitoring Customer Feedback and Satisfaction			
10 Management Policies, Planning and Commitments			
11 Management Review			
12 Human Resources (Training and Awareness)			
13 Plant, Facility and Equipment			
14 Information Resources (Document Control)			
15 Measuring/Monitoring Devices			
16 Corrective/Preventive Action & Cont. Improvement			

Coordinate the list of quality management system processes with the Quality System Process Map diagram and the Quality System Process Matrix documented in the Quality Manual Section 4, Quality Management System, Clause 4.1.1, Process Approach.

Assign auditors that don't have a conflict of interest with respect to the audited area or activity (e.g., are not responsible for the area or activity being audited).

Schedule dates for an additional audit of some critical or poorly performing processes.



AUDIT NONCONFORMITY REPORT

Issued by: QA

Date: 00-00-00

Revision: A

QF-82-02-2

Department: *identify the audited department, area, operation and the responsible manager/supervisor*Audit Ref.: *date or number/letter code*

Area/Operation:

Mngr/Supervisor:

Procedure/Work Instr./Standard: *reference the document/requirement against which this nonconformity is noted*

Auditor:

ISO 13485 Clause:

Date:

NONCONFORMITY

Finding No.:

Auditor use this block to describe the nonconforming condition

Auditor:

Resp. Mngr/Supervisor:

Date:

CORRECTIVE ACTION

Due Date:

Responsible manager/supervisor use this block to propose a corrective action

Auditor:

Resp. Mngr/Supervisor:

Due Date:

FOLLOW-UP AND CLOSEOUT

New Due Date:

Approved

 Yes No Extension

Approved

 Yes No Extension

Document or reference what objective evidence was reviewed for closeout

Use this block only when the nonconformity could not be closed out on the first follow-up visit

Auditor (sign &date):

Auditor (sign &date):