

Typical Schedule to QMS Registration

(Pro-rate dates in Milestone and Schedule columns to match your project timeline)

| Milestone | Description | Schedule |
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| Management Commitment and Responsibility – Start 6-16-09 | <ol style="list-style-type: none"> Define and document policy for quality Ensure policy is usable / understandable | <ol style="list-style-type: none"> 6-16-09 <input type="checkbox"/> 7-15-09 <input type="checkbox"/> |
| Establish and Train Management Representative 6-16 to 7-22 | <ol style="list-style-type: none"> Ensure quality policy is established, implemented and maintained at all levels Report performance (policy only) Liaison to external parties (A/R) Authority across departments | <ol style="list-style-type: none"> 8-22-09 <input type="checkbox"/> 8-22-09 <input type="checkbox"/> 8-22-09 <input type="checkbox"/> 8-22-09 <input type="checkbox"/> |
| Internal Audits In addition, focus on highly visible work functions: Calibration (unmarked, out-of-date) Configuration (docs available, multiple revisions) Purchasing (matl's with no identification, expired) | <ol style="list-style-type: none"> Conduct initial internal audits Identify areas for upgrade and improvement Provide and assign qualified resources for management, performance of work and verification of activities | <ol style="list-style-type: none"> 7-22-09 <input type="checkbox"/> (100% gap) 8-22-09 <input type="checkbox"/> 8-22-09 <input type="checkbox"/> |
| Initial Documentation Efforts | <ol style="list-style-type: none"> Create first draft of quality manual Identify applicable regulatory authorities Establish external audits with applicable regulatory authorities (A/R) Analyze work processes Create and revise QMS procedures and QMS inspection instructions Implement procedures and production work instructions Continue internal audits and corrective actions (internal-audit-progress-report.xls) | <ol style="list-style-type: none"> 7-22-09 <input type="checkbox"/> 8-22-09 <input type="checkbox"/> 8-22-09 <input type="checkbox"/> 8-22-09 <input type="checkbox"/> 8-22-09 <input type="checkbox"/> 8-22-09 <input type="checkbox"/> 8-22-09 <input type="checkbox"/> |
| Practices Documented and Implemented Begin Training Sessions | <ol style="list-style-type: none"> Continue internal audits and corrective actions – begin QMS procedure training (training-matrix-for-qms-procedures.doc) (training-program-progress-report.xls) Review, revise and approve quality manual Continue external audits with applicable regulatory authorities (A/R) Management: performance and status review of QMS | <ol style="list-style-type: none"> 8-16-09 <input type="checkbox"/> 8-22-09 <input type="checkbox"/> 8-2-09 <input type="checkbox"/> 8-23-09 <input type="checkbox"/> |
| Complete QMS Assessment Form and Close Findings | <ol style="list-style-type: none"> Identify and correct system and process deficiencies Management: complete Management Review form | <ol style="list-style-type: none"> 9-6-09 <input type="checkbox"/> 9-20-09 <input type="checkbox"/> |
| Choose Registrar | <ol style="list-style-type: none"> Initial visit Establish configuration management of QMS and production work instructions | <ol style="list-style-type: none"> 10-21-09 <input type="checkbox"/> 10-21-09 <input type="checkbox"/> |
| Registrar Pre-Assessment | <ol style="list-style-type: none"> Correct internal system and process deficiencies Correct external system and process deficiencies for compliance to applicable regulatory authorities (A/R) | <ol style="list-style-type: none"> 10-28-09 <input type="checkbox"/> 10-28-09 <input type="checkbox"/> |
| Registration Assessment 12-15-09 | <ol style="list-style-type: none"> Document continuous improvement opportunities discovered since registration of QMS Continue internal audits and corrective actions – partial audits are Ok Continue external audits with applicable regulatory authorities and corrective actions (A/R) Management: schedule next Management Review meeting | <ol style="list-style-type: none"> 1-6-10 <input type="checkbox"/> 3-6-10 <input type="checkbox"/> 3-6-10 <input type="checkbox"/> 3-14-10 <input type="checkbox"/> |