IMPLEMENTATION PHASES: An accelerated approach...clients usually extend phase durations to 8 weeks

- **Phase 1: 4-5 Weeks**
  - Document the Quality Management System (QMS); Quality Manual, Procedures, Work Instructions and Forms
  - Conduct employee Quality Management System orientation
  - Create training records of orientations and officially launch the QMS

- **Phase 2: 4-5 Weeks**
  - Train internal auditors
  - Conduct internal audits to confirm good behaviors
  - Conduct a full Management Review Meeting (MRM) to verify the effectiveness of the QMS
  - **NOTE:** The Registrar’s Pre-Assessment (document review) Audit comes at the end of this period

- **Phase 3: 4-5 Weeks**
  - Systematically correct any Pre-Assessment non-conformances
  - Continue to create quality records
  - Audit for conforming behavior prior to the Registration Audit

**PHASE 1 DOCUMENTATION SEQUENCE:** Use the LeanISO.com Visio 5.0 Flowchart Models for Gap Analysis Focus Groups

**Section 5 - Management Responsibility**
- Quality Manual
- P51 - Management Responsibility (text)
- P55 - Quality Objectives
- P56 - Internal Communications
- P566 - Control of Documents
- P567 - Control of Records

**Section 6 - Resource Management**
- P6 - Resource Management
- P601 - QMS Awareness
- W601 - Training Effectiveness Reporting Instruction
- P602 - Supplier Training, if applicable

**Section 7 - Product Realization**
- P71 - Product Realization
- P72 - Customer Requirements
- P73 - Design and Development, if applicable
- P74 - Purchasing
- P75 - Production Operations
- P752 - Identification and Traceability, if applicable
- P753 - Customer Property, if applicable
- P754 - Preservation of Product, if applicable
- P755 - Validation of Process, if applicable
- P76 - Control of Measuring and Monitoring Devices, if appl

This documentation model has 25 procedures and 31 quality records, all applicable sections are needed. Compare to self documented systems with 200 procedures and 300 records.

**SENIOR MANAGEMENT ROLES AND RESPONSIBILITIES:**

1. Review the Project Plan weekly for evidence of steady progress.
2. Have managers report on the status of procedure training in staff meetings.
3. Confirm there is an internal audit schedule and your managers are releasing auditors to test for QMS effectiveness.
4. Lead a Management Review Meeting (MRM) at the end of each audit round to confirm effectiveness of the Quality Management System. Provide resources to correct and prevent the known QMS problems.
5. Review the Corrective Action Log monthly for a bias to close known non-conformances. Target a Closure Rate at 75% or greater, in days, not weeks or months. This shows the Registrar you have committed resources for achieving quality assurance.
7. Confirm the organization's trend charts have a goal line that has a slope. These goal lines are used to measure and report on the required continual improvement. When performance is not at goal, enter a corrective action on the Corrective Action Log so a team gets involved.