ISO 9001:2015 QMS Implementation Plan

INITIAL ASSESSMENT PHASE
Why is the company seeking Quality Management System (QMS) certification?
Has a timeframe for QMS completion and registration been established?
Is there an existing QMS and what is its status?
Is there Quality System documentation in place (Quality Manual, Procedures, etc.)? Note: a Quality Manual is no longer required by ISO-9001:2015.
What is the scope of the QMS (design, development, manufacture, assembly, installation, service, repair)?
What are the company products, services and SIC codes? Obtain advertising information, including web-based.
Does the company develop software or use embedded software?
Are there existing quality-related systems in place, e.g. JIT, Lean, Six Sigma, SPC?
Are there production control systems in place, e.g. MRP, ERP?
What are the risks to public and the company of potential product/service quality failures? Has a risk analysis been done?
Where is the corporate HQ and address? What is its relationship with the company?
Have there been any recent changes in products/services, management or ownership (mergers, etc.)?
Are there company off-site activities or facilities involved with the QMS, or need to be involved?
Are there out-sourced processes?
Who are the key customers and what are their quality expectations?
Have the key suppliers been identified and qualified? Have appropriate supplier requirements been identified?
Have applicable statutory and regulatory requirements been identified, e.g. CPSC, FDA, REACH, RoHS, etc.?
Have applicable industrial standards been identified, e.g. UL, IPC, ASME, etc.?
Who are the key management members (organizational chart)?

What are the number of employees involved in:

- Production
- Design and Development
- Quality Control / Assurance
- Service / Repair
- Administration?

Have the key personnel responsible for the planning and implementation of the QMS been identified?

Have any members of management or any employees had any QMS training or experience?

Have any registrar or customer Quality System audits been performed and what are their status?

Have resources for implementation been identified and considered (personnel, training, IT systems, production equipment, calibration, documentation, etc.)?

Is a confidentiality agreement or NDA required?

PLANNING PHASE

Identify key processes and organizations. Walk-through tour of the facility.

Identify interruptions that may delay implementation of QMS (new product lines, new projects, new IT system, re-organizations, mergers, trade shows, pending legislation, etc.).

Confirm scope of QMS.

Determine "exclusions" to the QMS Standard. Note: ISO 9001:2015 does not refer to "exclusions" in relation to the applicability of its requirements. However, an organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters. E.g. if you do design activities, design requirements are applicable. See 4.3.

Establish document and records control systems.

A matrix of QMS requirements and where addressed in the company's processes may be useful.

Identify training needed for QMS standard implementation, including industry standards, regulations, new technology, etc. (An ongoing effort.)

Establish management responsibilities: establish Quality Policy, Scope and measurable Quality Objectives. Provide overall planning for QMS implementation, resources and leadership. Assign process ownership. Communicate the purpose and importance of the QMS company wide. Emphasize risk-based thinking and

continual improvement approach, as well as the importance of meeting safety, regulatory and customer requirements. Emphasize error prevention rather that error detection.

Begin management reviews to focus on planning and implementation of the QMS. All company functions/departments need to be represented by persons who have control of resources for implementation.

Develop high-level implementation plan (major tasks, training, responsibilities, resources and target dates). Identify gaps for tracking.

Contact potential QMS registrars and issue RFQs.

Note: these items will typically continue during the Development and Implementation Phase below.

DEVELOPMENT and IMPLEMENTATION PHASE

Provide training and orientations for the QMS development processes (Quality Standard requirements, flow charting, document control etc.). Recommend resources (books, ASQ, web sites).

Continue and expand management reviews to address all QMS management review inputs and outputs.

Develop detailed plans for each department/area (tasks, responsibilities, resources and target dates.)

Document QMS in the "as-is" condition (use flow charts when possible). Identify existing process inputs and outputs, tools for process control (procedures, training, software, forms, recorded data, etc.), responsibilities and quality checks.

Review and revise QMS to the "as-needed" condition. Address gaps with QMS requirements, as well as applicable regulations, standards, customer requirements. Identify risks, opportunities for improvement, additional quality checks and additional training needed.

Provide additional training.

Identify and train internal auditors, from across company functions, preferably with subject matter expertise.

Begin internal audits and report to management reviews.

Monitor and report progress to management (use management reviews when possible).

Prepare QA Manual (may be a series of documents, flow charts, etc.).

Select and schedule QMS registrar pre-assessment (optional but recommended) and certification assessment.

CONCLUDING PHASE

Document QMS in Quality Manual and obtain management approval. Send copy to registrar.

Finalize registrar audit date; disallow vacations and other absences of key personnel.

Complete company-wide training, internal audits, processes and documentation, etc.

PRE-ASSESSMENT PHASE

Registrar pre-assessments are optional, but recommended.

Prepare all employees with "dress rehearsals." Clean facility. Three rules for everyone to follow.

Do we know our weak areas and, as appropriate, are they identified for improvement?

Perform pre-assessment.

Respond to findings and address gaps. May need to re-submit Quality Manual and/or procedures.

REGISTRAR AUDIT and REGISTRATION PHASE

Registrar audit performed.

Respond to findings with corrective actions taken or planned. If required, re-submit Quality Manual and/or procedures.

Registrar recommends, or does not recommend, certification.

Receive certificate of QMS registration.

Celebrate!

POST REGISTRATION PHASE

Maintain and improve QMS (internal audits, management reviews, continual improvement, risk assessments, etc.)

Notify registrar of major changes to QMS (Quality Manual, procedures, policy, scope of registration, new products, mergers or new ownership).

Schedule registrar surveillance audits (annual or semi-annual).