Starting A Quality System From Scratch

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Most of us work within the quality systems and departments already in place in our companies. Much of our work is determined by the structure and form of the established quality policies, procedures, processes and systems that we have inherited. These systems grew as our businesses did, evolving from an initial inspection focus to systems using statistical process controls, and they now comply with international quality system standards.

But what of the new enterprise, or a new department or new process? What if you were asked, "How would you implement a brand new quality system where none had existed before, starting from scratch, with a clean slate?" I was recently asked exactly that question, and here is my response.

You must first determine what is to be the organization's commitment to quality. Is this quality thing just a formality to get product approved to ship? Is it to make sure you don't make any bad products? Is it to please your potential customers? Or is it to ensure that your processes are capable and producing to their best capability?

The organization's commitment to quality will be the foundation for the systems and implementation to follow. The selection of the proper tools, personnel and processes will all be determined on the basis of your organizational quality vision.

Identify the quality systems that you are most likely to certify to as your business needs mature.

There is an old saying that without a plan, you'll get exactly wherever you end up. If your business has a broad or general focus, a registration to ISO 9001:2000 is probably in your future. If automotive is your market, TS16949 might be your choice. Other choices could include TL9000 (telecommunications), AS9100 (aerospace), FDA Good Manufacturing Practices Standard, and so on.

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Map your business processes.

Do this for not just production, but also administrative, planning, engineering and customer service processes. Look at these processes in light of advanced product quality planning, failure mode effects analysis and product realization to determine areas where failures can occur, and address making them more robust.

Qualify your tools and processes.

Capability studies and process potential studies are crucial to establishing confidence in your processes as able to meet requirements. Efforts to improve the capability of processes, eliminate operator tasks, and make processes mistake-proof will pay the highest dividends in terms of preventing production of nonconforming products.

AIAG's statistical process control and measurement systems analysis manuals have the system tools you will need to document the efficacy of your processes and the gaging systems that you employ. Preventing the production of nonconforming products by establishing robust, consistent processes is the foundation principle for my vision of a new quality system.

Document your process.

Now that you know what to do, it is time to document what you do so that your system does not "creep" out of compliance over time. Documenting procedures assures a common understanding and provides standard work instructions and references. It also provides a means of both process control and audit traceability. Document what you do, do what you documented, and audit what you do to what you documented – this is the PDCA cycle applied to quality assurance.

Train and review.

Developed procedures are now available for training operators and all employees. These standard instructions are the keys to consistent quality. Procedures sitting in a book have no value in and of themselves. Their value is realized when they are employed to standardize the methods used by all employees.

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Quality System continued

Audit now that you have a system in place.

Internal, external and customer satisfaction reports should be used to further improve the methods and processes employed. Review of customer feedback against control plans and work instructions will identify opportunities for further improvements. Assign follow-ups and corrective actions to appropriate personnel to ensure that the issues identified are reduced or eliminated.

Monitor performance and schedule registration to your chosen quality system standard.

The experience and data from your efforts to date now provide you with the evidence to show an outside registrar that your quality system meets that system's requirements. Perhaps reformatting documents to meet the auditors' requirements will be needed. Perhaps some new procedures will be required to cover an area that was overlooked. The registration of your quality system provides an important assurance to your customers and potential customers about your standards of care and execution in your business.

Continuous improvement.

In today's world, "100 percent on-time and zero defects" are considered the minimum expected of an "ordinary supplier." Improving process capability and gaging methods, and eliminating non-value-added steps are never-ending tasks.

Milestones of a quality system startup

- Determine quality commitment.
- Identify and assign quality personnel.
- Agree on organizational quality culture (simplicity, automation, high CPKs*, de minimus documentation**).
- Identify preliminary goals for the quality system to be followed (QS, ISO, AS).
- Purchase AIAG manuals as resources for SPC, measurement systems analysis, and so on.
- Identify quality requirements to be controlled on products.
- Map processes from quoting, through contract review, first piece, production, final validation, shipment, and finally, customer acceptance.
- Think who, what, how.
- Determine gaging to be used for process control for those requirements.
- Perform gage studies, and create process control and gage plans.
- Document process instructions.
- Document inspection procedures.
- Train employees and record that training.
- Audit what you have implemented.
- Compare to the quality system you are aiming for and organizational quality culture.
- Hold communication meetings with all employees.
- Integrate work-to-date into the documentation system to the selected quality system.
- Monitor performance and schedule registration.
- Pre-audit internally to the quality system.
- Conduct an outside registrar audit.
- Receive quality system registration/certification.
- Strive for continuous improvement.

* CPKs means relying on process capability, rather than relying on inspection.

** De minimus documentation means that you document just the bare minimum required by your selected standard (for example, just the "shall" statements, not the "should" statements, and nothing extra). Nonconformances are most easily found in bulky systems that contain more than the standard requirements. De minimus means the bare minimum required. Anything more is waste.

Selecting Quality Personnel

The person assigned to manage the quality function is going to be making critical decisions every hour of every day. Your selection of this person should be weighted toward:

- The quality of the candidate's decision-making, as well as the relative comfort level in making high-dollar-value decisions. This is not a position for "politicians" or the weak at heart.
- The shared philosophy and values to the organization's quality commitment. If your focus is prevention and the candidate's is inspection, your quality program will not go forward.
- The candidate's understanding of quality issues. Hands-on is good, but don't eliminate a strong candidate by comparing to someone with great technician skills but no management/decision-making insight. Ultimately, as your business grows, you will hire the technician skill sets you need. First, you need a decision-maker who understands quality issues and can implement them.
- The person's computer skills and the quality of his or her writing/documentation.
- The candidate's ability to handle statistics. Ask for examples of work he or she has completed. The work should show how the person started with raw data and used statistics or "did the math" to find the root cause or ultimate conclusion about a process or problem.