It's essential for any organization that takes product and service quality seriously to harmonize their Quality Management System (QMS) to ensure consistency of process, KPI achievement and end product quality via a common technology platform. Regardless of physical location or operational area, a standard process is needed for both quality and compliance while maintaining local control over business processes.

When data is disjointed or kept in information siloes, you have limited visibility and can miss critical issues that might be obvious if you had a complete picture. For example, a Corrective Action (CAPA) that should apply to all areas of an organization might only be seen by one workgroup while others that need to apply it never see it.

**What is Harmonization?**

Harmonization provides a consistent approach to your organization's quality environment across the entire company. This allows everyone in the organization to have a single version of the truth and operate on a common platform to ensure process consistency and uniformly high quality.

It's especially important in large organizations with multiple work sites. While you want local operators to manage their operations, you have overriding quality goals that must be met regardless of where processes are employed or what products are being produced.
Harmonization is often the answer when an organization encounters one or more of the following:

- Acquisition or mergers
- Rapid growth
- Distributed development and production facilities
- Local compliance needs
- Trends or patterns of nonconformities
- Inconsistent quality across internal departments or organizations

It may also be needed to improve operational performance and create economies of scale.

Harmonization does not insist on absolutely adherence to the same standards globally – rather it provides a framework for global consistency while acknowledging local requirements. For example, it allows you to define a global policy that can be tailored based on local conditions.

**The Benefits of Harmonizing Your QMS**

The workflow in most organizations is evolving constantly. Your QMS provides a way to manage the speed and consistency that’s necessary for today’s rapid development cycles. When you can bring together all your management systems into a harmonious whole and apply it across an organization, you can realize significant benefits, including:

**Process Consistency**

The end product must meet customer expectations regardless of where it’s created. Harmonization brings standardization across an organization that ensures consistency in the products being developed. At the same time, it creates repeatable processes that ensure quality and can help lower overall unit costs by producing fewer nonconformances.

**Surfacing Inconsistencies**

Not all operations are identical. They may have slightly different technical resources or skill levels in personnel. Harmonization can identify inconsistencies or unrecognized problems across an organization and identify areas for new training and process improvement.

**Flexible for Localization**

Local operators still need the flexibility to apply harmonized quality standards and adapt them to processes in their particular environment. For example, you may have locations creating vastly different products that have unique compliance needs, but you still want the same big-picture quality standards and data reporting.

**Auditing**

When your systems are harmonized, auditing is much easier. Using QMS software and consistency throughout your organization creates a complete audit trail to monitor and improve processes.
An Eight-Step Approach to QMS Harmonization

Bringing together multiple or fragmented systems creates standardization that drives the benefits of a harmonized QMS. To get started, here is an eight-step approach to QMS harmonization.

1. Identify inconsistencies
2. Develop quality goals
3. Create quality metrics
4. Develop best practices
5. Align QMS software
6. Deployment
7. Analysis of KPIs
8. Continuous Optimization

1. Identify Inconsistencies

If you're approaching the harmonization process, you've likely uncovered areas that need better alignment. The first step is identifying the problem areas, including variations in process.

Process maps and gap assessments are important tools at this stage.

Process Mapping
Business process mapping helps you visually represent workflows and break down processes into the steps, machinery, and people involved at each stage. It helps you better understand even the smallest steps that can impact quality, assess vulnerabilities, and increase standardization.

Gap Analysis
A gap analysis takes current conditions and outcomes and compares them to desired outcomes. The delta between the two steps identifies the gap that needs to be closed to improve performance to meet the overall objective.

2. Develop Quality Goals

You'll also need to reach agreement on quality goals across an organization — especially if you are managing multiple locations or have different product lines. This requires working with key stakeholders across the organization to ensure alignment.
3. Create Quality Metrics

It's difficult to manage things you can't measure. After agreement on quality goals, you need to define the key performance indicators (KPIs) to measure that will track whether you're meeting those goals and where you're falling short.

Real-time information tracking of the entire production pathway from purchase order to product delivery is necessary for effective quality control. Develop the KPIs necessary at each stage of the production pathway to meet your quality goals.

4. Develop Best Practices

To meet your quality goals, you will also need to develop a series of best practices that can meet your quality standards across an organization. While many of these may already be in place, examining processes in detail can help refine your practices.

These best practices are what will drive the process to minimize your inconsistencies and improve overall quality. Product-specific best practices will need to be developed in line with your quality goals.

5. Align QMS Software

It's only after the first four steps are completed that you can create alignment within your QMS software. By creating common goals, measurements and best practices, you can bring a consistent approach to your manufacturing processes.

This will be difficult to manage if you're still relying on manual processes or spreadsheets. You need QMS software that creates higher visibility in your organization to harmonize your data. It must encompass document management, reporting, inspection and audit to track product lifecycles in a meaningful — and consistent — way.

6. Deployment

Deploying your best practices, processes and measurements across an organization will require educating your workforce. Make sure you provide adequate training and explain the value proposition of harmonization. Don't minimize this step — make sure you have identified all impacted individuals and have set them up for success in this harmonized environment.
7. Analysis of KPIs

With your goals, best practices and metrics aligned, there should be a careful analysis of the KPIs on an ongoing basis to look for flaws in design and processes. When goals aren’t being met or nonconformances are discovered, a CAPA program can be used to identify root causes and find solutions. Harmonization allows you to apply the solutions organization-wide.

8. Continuous Optimization

The best organizations are never satisfied. They are constantly identifying areas that can be improved and optimized. Many organizations are employing formal optimization programs, such as Kaizen.

**Kaizen**

Kaizen is a philosophy developed by Japanese manufacturers and means “change for the better” or “continuous improvement.”[*iii*] It involves employees across divisions and hierarchy to focus on gradual improvements to make the workplace more efficient. The idea is that by constantly reviewing what you’re doing, you can make small improvements that lead to significant results over time.

Harmonization provides the standardization you need to implement Kaizen effectively. It keeps you focused on the overall quality goals while also continuously identifying areas for improvement.

**Value Stream Mapping**

While process mapping helped diagram the workflow to identify process roadblocks, value stream mapping (VSM) takes a more focused look at eliminating waste in the process.[iv] Even if the current process delivers on your quality goals, VSM tries to find ways to make it ever more efficient.

Value stream mapping is one facet of the Six Sigma philosophy to apply lean principles.[v]

Whether you adopt Kaizen, Six Sigma or another method for improving performance, the goal is the same: continuous improvement.

**Harmonizing your Quality Management System**

Harmonizing your Quality Management System creates consistent and repeatable quality across your organization while allowing flexibility necessary for a local approach. It helps identify areas of concern, create better processes and workflow, standardize quality and begin a cycle of continuous improvement.

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