



The QEHS Guide to Operational Excellence

Executive Summary

As companies grow, efficiency and consistent execution of operations often become the defining factor in sustaining growth and profitability. Modeling other market leaders, many companies implement operational excellence programs designed to uncover inefficiencies for improved performance.

One problem commonly revealed is the negative impact of managing quality and environmental health and safety (EHS) in separate “silos.”

Duplicate and siloed processes increase costs, errors and risk, with multiple software systems and underlying IT infrastructure representing a huge financial burden. And while companies may have long-term safety, quality and sustainability goals, disparate systems block visibility into how to attain them.

This white paper will investigate why integrating quality and EHS is key to achieving operational excellence. We'll look at practical tips for using technology to promote operational excellence objectives, plus a proven process for using an integrated Quality and Environmental Health and Safety (QEHS) System to support operational excellence.

What is Operational Excellence?

Operational excellence has many definitions and methodologies. Some industries focus more on product quality, while high-risk industries like oil and gas tend to focus on safety and sustainability. However, common elements exist across all methodologies, including:

- Standardization of systems to increase reliability.
- Closed-loop processes that enable continuous improvement.
- Proactive risk management that goes beyond compliance.
- Generating actionable data from key performance indicators (KPIs).
- Collaboration among cross-functional teams.

Business Benefits of Operational Excellence

Minimizing waste and improving reliability can deliver big results in terms of lowering costs and boosting profits. Motorola—the pioneer of Six Sigma—has credited the system with delivering \$16 billion in savings over 12 years.¹ General Electric (GE) has also attributed more than \$12 billion in savings achieved within 5 years of Six Sigma adoption.²

In fact, more than half of Fortune 500 companies have deployed some form of Six Sigma, saving an estimated \$427 billion over 20 years.² Table 1 shows the top 10 global drug and biotech companies according to Forbes, all of which have some form of operational excellence program.^{3,4}

Table 1. Forbes list of Top 10 Global Drug and Biotech Companies

Rank	Company	Profits (\$B)	Market Value (\$B)	OpEx Program
1	Johnson & Johnson	16.3	275.7	Yes
2	Pfizer	9.1	211.7	Yes
3	Novartis	10.1	272.6	Yes
4	Merck & Co.	11.9	162.3	Yes
5	Roche Holding	10.2	240.4	Yes
6	Sanofi	5.8	136	Yes
7	Bayer	4.5	126.4	Yes
8	GlaxoSmithKline	4.5	114.1	Yes
9	Amgen	5.2	117.7	Yes
10	McKesson	1.7	52.3	Yes

Oil and gas leaders like Chevron and ExxonMobil also leverage operational excellence for better performance, with well-developed programs aimed at minimizing injuries, safety risks and environmental impacts. One Bain & Company report showed operational excellence management systems cut primary containment incidents by as much as half, also reducing emergency work by up to 90 percent.⁵

For global companies, operational excellence is a critical strategy for managing the inherent complexity of operating multiple divisions, locations and business units. It also enables faster improvement and the agility to respond to market changes. The fact that so many Fortune 500 companies have operational excellence programs sends a clear signal about what it takes to break into these upper echelons of market leadership.

The Link Between Operational Excellence, Quality and EHS Management

Operational excellence is closely tied to quality and EHS performance. Employees can't produce quality goods while working unsafely for extended periods, and companies with quality issues are also likely to have safety gaps. Conversely, improved EHS performance can increase overall equipment effectiveness (OEE)—a measure closely related to operational excellence—by up to 20 percent.⁶

The connection between safety and quality is represented in the overlap among requirements for ISO 9001 for Quality Management, ISO 14001 for Environmental Management and OSHAS 18001 for Occupational Health and Safety. Companies certified to ISO 9001 have already done roughly 60% of the work for ISO 14001,⁷ which is why so many companies adopt integrated systems that address multiple standards.

But while these standards manage specific quality, safety and environmental outcomes, operational excellence is an integrative concept that improves performance across all areas of operations. This unity of purpose supports eliminating duplicate systems and the overhead required to run them, which we'll look at in the next section.



The Role of Integration in Operational Excellence Programs

Many companies use an assortment of point solutions and manual systems to manage various quality and EHS management processes, creating redundancies, errors and excess costs. Integrating these disconnected point solutions delivers measurable savings in terms of lower maintenance costs and increased productivity.

However, cost savings are just one reason why many operational excellence consultants advocate integrated QEHS Systems. They also provide a unified framework for tracking related processes, providing the visibility and control required for operational excellence.

Let's look at 10 areas where an integrated QEHS System enables operational excellence, focusing on the vital elements of risk management and reporting.

1. Document Control

Effective documentation is the foundation of operational excellence, yet one of the most common mistakes companies make is not having a Document Control system.

Specification management, for instance, is a huge problem for organizations struggling with multiple spreadsheets, document versions or shared network drives. Similarly, having numerous iterations of job instructions floating around can lead to safety and quality issues. No matter how you share documents in a manual system, there's a fundamental lack of visibility that inevitably creates errors and waste.

An integrated Document Control system serves as a central repository for managing specifications, policies and procedures in quality and EHS, reducing risk by:

- Preventing conflicted versions that cause mistakes.
- Enabling automated employee training updates for new or revised documents.

- Minimizing delays with automatic routing through draft, review, approval and release.
- Allowing control over who's responsible, what they can edit and the timeframe for completion.

Housing quality and EHS documents in a single automated system eliminates redundancy while improving efficiency, both central goals of operational excellence.

2. Employee Training

Operational excellence requires employee training that addresses both quality and EHS. An integrated QEHS System simplifies the process, allowing companies to capture all of the quality and safety requirements of each job role.

For example, chemical plant workers need training on how to ensure safety as well as product quality. By tracking employee training in a unified QEHS System, companies can easily:

- Pull human resources (HR) data to determine requirements.
- Organize scheduling priorities with risk-based assessments.
- Uncover training gaps contributing to both quality and safety issues.
- Gauge effectiveness of courses by reporting on assessment results.

A QEHS System allows seamless employee training management, ensuring reliability and effectiveness to drive improved safety and quality.

3. Audits

Audits are essential to the continuous improvement process. Centralizing audit activities in a single QEHS System promotes operational excellence by allowing you to:

- **Consolidate audit plans:** With separate EHS and quality management solutions, companies must perform individual audits for systems like Document Control. A combined system lets you performing a single audit covering all requirements, saving time and reducing costs.
- **Spot underlying issues:** An integrated QEHS System lets companies view results holistically, allowing you to pinpoint common causes of safety and quality issues. For instance, you may notice EHS and quality noncompliances around a certain operation indicating a need for more training or even a process change.
- **Prioritize follow-up work:** Audits generate numerous findings, with some issues more critical than others. For those items that can't be fixed on the spot, the quantitative Risk Assessment tools of an integrated system let you prioritize corrective and preventive actions (CAPAs) based on risk.

Leading QEHS Systems streamline the audit process with automated scheduling, checklist repositories for common standards and even mobile audit capabilities. This increases audit efficiency, reducing administrative burden while improving results.

4. Change Management

Effective change management is a central tenet of operational excellence. With process changes potentially impacting both quality and safety, a unified QEHS System delivers big-picture visibility so you can make change with minimal risk.

In fact, using risk to inform change management is one of the hallmarks of a mature operational excellence culture. Making the right decision requires quantifying the risks and costs associated with various alternatives, and separate quality and EHS systems only tell part of the story.

Benefits of integrated change management include:

- Risk Assessment tools like risk matrices and decision trees to standardize decision-making.
- On-screen reporting to monitor change management initiatives in real-time.
- Automatic updates for all affected documents, projects and action plans.
- Analysis of past projects to see how long it took versus how long it should have, plus where problems occurred so you can avoid them in the future.

These benefits result in reduced cycle time for engineering changes, lower costs and increased productivity, all of which promote operational excellence.

5. Regulatory Compliance

Integrating compliance tracking in a QEHS System supports operational excellence by allowing you to institute a single automated process for all the requirements that apply to your company.

Companies with well-established operational excellence programs typically use the following process to ensure regulatory compliance:

1. List all applicable requirements in the QEHS System.
2. Link requirements to existing controls within the organization.
3. Identify gaps for regulations without controls, or where controls are insufficient.
4. Apply quantitative Risk Assessment to each compliance gap to determine where to focus on adding controls first.

By centralizing requirements in a single QEHS System, you can better see how compliance issues in quality affect safety, and vice versa. Making these larger connections among processes is crucial to operational excellence.

6. Process Safety and Quality

Companies often monitor process safety and quality data independently. In reality, a change in either can indicate larger problems threatening either quality or safety.

For example, viscosity changes in the oil refining process may signal a process deviation that could impact safety. One study showed that incorporating quality data in process safety monitoring systems allowed researchers to identify more near-miss events, enabling more robust risk calculations and better detection of threshold events.⁸

An integrated QEHS System has dashboards to centralize quality and safety data, including real-time alerts for when parameters approach or exceed specific thresholds. Since quality problems may precede equipment malfunctions—a leading cause of workplace injuries—monitoring EHS and quality data from a single location can help prevent accidents.

7. Incident Management

Process deficiencies typically surface as either safety or quality events. A single-platform QEHS System centralizes tracking of both to better identify and eliminate systemic risk, a main goal of operational excellence.

Things like safety incidents, customer complaints and quality issues document gaps in controls that warrant deeper analysis. QEHS integration streamlines the process with:

- Incident filtering by risk level so you can see where to focus your efforts.
- Automated CAPA routing so problems don't fall through the cracks.
- Risk-based verification to ensure corrective action sufficiently reduces risk.

Risk management is also critical to preventing incidents. Some pharmaceutical companies are borrowing approaches from the energy and aviation industries to mitigate the risk of high-impact events with the bowtie model. Used for visualizing complex risk environments, the bowtie model identifies causes and consequences of major events, as well as preventive and recovery controls on either side.



8. Supplier and Contractor Management

Effective supplier management is a fundamental tenet of operational excellence, as third parties have a direct impact on safety and quality. A combined QEHS System gives a high-level view of supplier quality and safety issues, allowing you to:

- Improve efficiency around supplier communication. A QEHS System eliminates the chaos of overlapping or conflicting email chains.
- Systematize how you manage supplier incidents. Automated CAPA routing and granting suppliers limited access to the QEHS System help resolve problems faster.
- Assign a level of risk to suppliers (and even their suppliers). This shows where you need to spend your time to improve supplier management.
- Track supplier costs. Reducing supplier costs is crucial to operational excellence. Just look at Apple, whose supply chain practices helped reduce the cost of goods sold by 10% in a decade where share price jumped by over \$100.⁹

Companies can also involve third parties like contract manufacturers in product design, using risk-based tools like Failure Modes and Effects Analysis (FMEA) to resolve issues before production begins. This is far more efficient than, for example, sending out a representative to investigate a medical device problem after you've already manufactured thousands of units.

9. Sustainability

Metrics around waste, emissions and resource use directly reflect the process efficiency, product quality and OEE that are fundamental to operational excellence. For instance, a high rate of product defects results in increased scrap and rework, diminished efficiency and overall higher raw material use and costs.

Unfortunately, many companies make the mistake of focusing environmental activities on basic compliance rather than taking a proactive approach to tracking sustainability metrics. Integrating to a single QEHS System lets companies see where quality problems impact sustainability, also helping quantify the environmental risk associated with various processes, conditions and hazards.

10. Stakeholder Engagement

Engaging stakeholders like employees, government regulators and customers is something you'll find in most operational excellence programs. An integrated QEHS System improves stakeholder engagement in several ways:

- Involving employees in the quality and EHS process.
- Streamlining complaint handling, surveys and post-market feedback.
- Consolidating data so management can make decisions based on the bigger picture.

Reporting reveals insights to drive process improvement, for example if you observe an uptick in product complaints in a category that didn't appear in your risk model. Comparing predictions against reality is only possible with this end-to-end visibility.

The Operational Excellence Journey: A Proven Approach

This section details a framework for implementing an integrated QEHS System to support operational excellence. Based on the proven Plan-Do-Check-Act strategy, this approach provides a continuous feedback loop for refining your efforts and results over time.

Phase 1: Plan

Thorough planning is necessary to ensure implementation success of any new software system. Important questions include:

- Which processes and systems require integration? You'll likely need to integrate not just functions within EHS and quality management, but also other systems like ERP or manufacturing operations management (MOM).
- Where are your biggest risks? Identifying potential challenges up front like user adoption and implementation costs can help you make a stronger plan.
- Which system best meets your needs? Any software must be flexible enough to adapt to your processes and undergo continuous improvement, since this is the foundation of operational excellence.

Once you've selected and implemented a QEHS System, planning shifts to formal documentation of your operational excellence processes with Document Control tools. Your processes will be unique to your company and the methodology you adopt.

Phase 2: Do

After standardizing procedures, it's now time to do what you've documented. For that to happen, employees need training on the updated policies and procedures. This involves:

- Linking new employee training requirements with individual documents.
- Pulling HR profiles to assign training to individual roles or departments.
- Automating scheduling and notifications to ensure training is completed.

Phase 3: Check

This phase is aimed at validating your processes, documents and training. Steps include:

- Tracking training effectiveness with post-assessment results.
- Conducting internal audits to pinpoint areas that need improvement.
- Quantifying risk of identified noncompliances to prioritize follow-up.

It's important that staff know they won't be punished for noncompliances. Operational excellence centers on improvement, which you can't do if people hide problems.

Phase 4: Act

Here's where you'll make adjustments based on audit findings, focusing on:

- Creating CAPAs for noncompliances within the QEHS System.
- Identifying process deficiencies requiring larger change management initiatives.
- Performing a final risk assessment to quantify residual risk and determine which issues need to be fed back into the top of the continuous improvement loop.

Closing Thoughts

There's no doubt pursuing operational excellence is both a challenge and a commitment. But for companies willing to take it on, the result is improved performance across a range of outcomes, including product quality, safety, and ultimately, financial performance.

It's important to remember operational excellence is a journey, not a destination. It's also an iterative, cross-functional process by nature, involving multiple departments, processes and stakeholders. Siloing quality and EHS management creates roadblocks to achieving operational excellence, while an integrated QEHS System streamlines the path forward.

About EtQ

EtQ is the leading Quality, EHS, Operational Risk and Compliance management software provider for identifying, mitigating and preventing high-risk events through integration, automation and collaboration. At the core of EtQ's framework is a compliance management platform that enables organizations to implement best in class compliance processes configured to meet their existing processes, create new compliance processes and automate and control their compliance ecosystem. EtQ's product lineup includes traqpath™ for individual compliance users, VERSE Solutions™ for small to medium sized businesses and Reliance™ for enterprise organizations. EtQ was founded in 1992 and has main offices located in the U.S. and Europe. To learn more about EtQ and its various product offerings, visit www.etq.com or blog.etq.com.

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www.etq.com

800.354.4476

info@etq.com

516.293.0949