

GUIDE:

Cultural Excellence



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Preface

Advancing Pharmaceutical Quality (APQ) is a comprehensive program for assessing and improving an organization's quality management maturity. It is an industry-led approach that seeks to advance pharmaceutical quality beyond the submission of data for harmonized, reportable metrics. Organizations can leverage this program to ensure a continuous supply of quality medicines to patients.

The APQ program evolved from the ISPE Quality Metrics Initiative which represents extensive industry engagement, collaboration with academia and other associations, and knowledge sharing with regulatory agencies. The APQ program is harmonized with international regulatory initiatives that promote quality excellence.

APQ is built upon the ICH Q10 Pharmaceutical Quality System (PQS) model [1] that comprises management responsibilities and the following PQS elements:

- Process performance and product quality monitoring system
- Corrective Action and Preventive Action (CAPA) system
- Change management system
- Management review of process performance and product quality

The APQ program further enhances this ICH Q10 model with cultural excellence and operational excellence (continual improvement) principles. Due to the interconnectedness of management responsibilities and management review, these are addressed together for the purposes of the APQ program. The APQ Guide Series focuses on the application of the APQ framework to these PQS topics that are based upon the principles and elements of ICH Q10:

- CAPA system [2]
- Management Responsibilities and Management Review (MRR) [3]
- Change Management (CM) system [4]
- Process Performance and Product Quality Monitoring System (PPQMS) [5]
- Cultural Excellence

The APQ Guide Series provides a practical set of tools and systematic approaches—the Assess, Aspire, Act, and Advance framework—for organizations to advance the maturity and effectiveness of these PQS topics.

This ISPE APQ Guide: Cultural Excellence contains two parts. Part 1 covers the key principles of the APQ program and explains the Assess, Aspire, Act, and Advance framework. This prerequisite information is applicable to all PQS topics. Part 2 covers the practical application of the APQ framework to Cultural Excellence. Tools and examples are provided in the appendices. Additionally, a ZIP file containing the APQ Maturity Assessment Tool (for Cultural Excellence) and the APQ Benchmarking Tool is provided with this Guide at the time of purchase.

Acknowledgements

ISPE wishes to thank all those involved in APQ who have contributed to the program and from whose work this Guide has been created.

APQ Cultural Excellence Guide Team

Maria Amaya	Genentech, A Member of the Roche Group	USA
Erika Ballman (Co-Lead)	Perrigo	USA
Nuala Calnan, PhD (Co-Lead)	BioPharm Excel Ltd.	Ireland
Robert Brian Cutler, Jr.	Johnson & Johnson	USA
Tami Frederick (APQ Advisor)	Perrigo	USA
Apneet Hayer	F. Hoffman-LaRoche	Canada
Harry Jeffreys	Bausch + Lomb Inc.	USA
Christine Teipen Smith	Eli Lilly & Company	USA

APQ Program Core Team

The following individuals contributed to the APQ program's development.

Tami Frederick (Chair)	Perrigo	USA
Maria Amaya	Genentech, A Member of the Roche Group	USA
Erika Ballman	Perrigo	USA
Lori Chelemmedos	Pac-Side LLC	USA
Andrew Denny	Bristol-Myers Squibb	USA
Joseph Famulare	Genentech, A Member of the Roche Group (retired)	USA
Bethany Glyde	Viatris	USA
Marci Goldfinger	Johnson & Johnson	USA
Steven Greer	Genesis Assist and ESI	USA
Michael Grischeau	AbbVie Inc	USA
Harry Jeffreys	Bausch + Lomb	USA
Jennifer Peszek	Pfizer	USA
Christine Teipen Smith	Eli Lilly and Company	USA
Nelson Webb	Procter & Gamble	USA
Christian Wölbeling	Körber Pharma Software	Germany

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Company affiliations are as of the final draft of the Guide.



600 N. Westshore Blvd., Suite 900, Tampa, Florida 33609 USA
Tel: +1-813-960-2105, Fax: +1-813-264-2816

www.ISPE.org

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1 Introduction to the APQ Program and Guide Series

The Advancing Pharmaceutical Quality (APQ) program seeks to advance the current state of pharmaceutical quality by providing a framework for assessing and enhancing the effectiveness of the Pharmaceutical Quality System (PQS).¹ The APQ program recognizes that the ability to advance quality management maturity lies within the industry itself; it has been developed by industry representatives for use by industry. A key driver for this program is to provide a range of sustainable, practical quality management improvement strategies, approaches, and tools for organizations.

The APQ program is built upon the ICH Q10 model [1] and enhances the PQS elements with the aspects of cultural excellence², operational excellence (OPEX), and continual improvement.

As stated in ICH Q10:

“ICH Q10 demonstrates industry and regulatory authorities’ support of an effective pharmaceutical quality system to enhance the quality and availability of medicines around the world in the interest of public health. Implementation of ICH Q10 throughout the product lifecycle should facilitate innovation and continual improvement and strengthen the link between pharmaceutical development and manufacturing activities.” [1]

Pursuit of this desired state has always been central to ISPE’s efforts to advancing the state of pharmaceutical quality within the industry. The APQ Guide Series represents the ongoing commitment towards that journey.

1.1 Objectives

The APQ program is intended to provide a comprehensive approach for assessing and improving an organization’s quality management maturity in order to advance the state of quality within the organization. It is an industry-for-industry program that aims to identify good practices and good behaviors that support the continual improvement of quality management effectiveness within an organization.

The eight overarching goals of the APQ program are to:

- Integrate quality management maturity, cultural, and operational excellence principles, tools, and approaches
- Support and incentivize continual improvement
- Foster industry ownership of quality beyond compliance
- Promote effective and efficient use of resources
- Encourage self-improvement and supplier improvement
- Enable structured benchmarking, knowledge sharing, and learning among organizations
- Increase the reliability of supply for quality products
- Offer routes to delivering sustainable competitive advantage

¹ The Pharmaceutical Quality System (PQS) is also referred to as Quality Management System (QMS) by some organizations. For the purposes of this Guide, the term Pharmaceutical Quality System is used.

² The terms cultural excellence and quality culture are interchangeable. For the purposes of this Guide, the term cultural excellence is used.

The APQ program intends to be relevant to individual organizations and to act as a forum for cooperation in the search for effective and practical solutions to the issues common to all organizations. The detailed discussion for the overarching goals is covered in Section 2.2 and Appendix 1.

The APQ program and APQ Guide Series are designed to incorporate the following aspects:

- Provide an industry-led program that includes a structured framework to assess and advance the effectiveness of pharmaceutical quality management, which organizations can leverage to ensure a continuous supply of high-quality medicines to their patients
- Built upon the principles of the ICH Q10 PQS [1] and further enhanced to include cultural excellence and OPEX tools, approaches, and behaviors which can support the effective management of quality
- Comprised of detailed self-assessments for quality management maturity along with self-improvement tools and Key Performance Indicators (KPIs)/Key Behavior Indicators (KBIs) focused on advancing organizational capabilities across the core elements and principles based on the ICH Q10 PQS: Corrective Action and Preventive Action (CAPA) system, Management Responsibilities and Management Review (MRR), Change Management (CM) system, Process Performance and Product Quality Monitoring System (PPQMS), and Cultural Excellence
- Complement current international regulatory initiatives which promote quality excellence

1.2 Scope

The scope of the APQ Guide Series is aligned with the ICH Q10 PQS model [1] (as explained further in Section 2.1). Therefore, the practices described in the APQ Guides apply to all aspects of the PQS relevant to the manufacturing, packaging, testing, or holding of biological, chemical, advanced therapy medicinal products, combination medicinal drug products, and their associated active pharmaceutical ingredients. The principles described may also apply to medical devices, over the counter products, personal care, and cosmetics products and may be beneficially applied throughout the product lifecycle from research and development, technology transfer, commercialization, and discontinuation.

1.3 Benefits

The benefits of the APQ program are outlined below:

- Benefits for industry:
 - Access to an ICH Q10-based quality management maturity framework that can be utilized in full by an organization to understand the impact to the overall performance of the organization of their maturity assessment, KPI/KBI application, and improvement actions
 - Supports sustained, continual improvement of an organization's PQS
 - Benchmarking against industry peer groups, i.e., by using the St.Gallen APQ Benchmarking Tool or full OPEX benchmarking program
 - Community of practitioners for sharing of best practices to accelerate progress
- Benefits for patients and consumers:
 - Increased reliability of supply of quality product

- Benefits for health agencies:
 - Better insight into industry's focus and current expectations regarding critical quality areas for advancing pharmaceutical quality
 - As industry progresses in quality management maturity, it will become more efficient, agile, and flexible so that it can reliably produce high quality drug products without extensive regulatory oversight.
- Benefits for research:
 - Increased data availability for researching the impact of quality management maturity on pharmaceutical production site performance

1.4 About the ISPE APQ Guide Series

The ISPE APQ Guide Series provide a practical set of tools and systematic approaches—the Assess, Aspire, Act, and Advance framework—for organizations to advance the maturity and effectiveness of their PQS. Each APQ Guide focuses on the application of the framework to the elements and principles set out in ICH Q10 [1]:

- CAPA system [2]
- Management Review and Responsibilities [3]
- CM system [4]
- PPPQMS [5]
- Cultural Excellence

At the core of the APQ Assess, Aspire, Act, and Advance framework is the detailed self-assessment tool to determine the current maturity level of an organization's quality system element (e.g., CAPA system) or culture. These tools integrate objective quantitative and qualitative criteria, enabling organizations to analyze the current state of quality, diagnose gaps, and identify improvement targets—**Assess and Aspire**. Using suggested continual improvement tools and KPIs/KBIs, organizations can then develop an Improvement Action Plan, execute it, and evaluate it for effectiveness—**Act and Advance**.

Additionally, this Guide includes a pre-assessment and post-action benchmarking questionnaire tool that organizations can use in conjunction with the APQ framework. It offers objective evidence of performance improvement to support ongoing investment of an organization's time and resources into implementing the APQ program for each quality system element. This questionnaire was developed by the Institute of Technology Management at the University of St.Gallen (Switzerland) as part of a collaboration with ISPE.

Figure 1.1 provides a high-level overview of the APQ program which comprises the APQ Assess, Aspire, Act, and Advance framework based on a foundation of Cultural Excellence. Figure 1.2 shows the ISPE APQ Guide Series including the application of the APQ framework to the four ICH Q10-based PQS elements, supported by additional ISPE body of knowledge and publications associated with key principles [6, 7, 8] and PQS enablers (knowledge management [9] and quality risk management).

Figure 1.1: Overview of the APQ Program

ISPE Advancing Pharmaceutical Quality Program

Comprehensive industry-led approach for assessing and improving the quality management maturity of Pharmaceutical Quality System elements (based upon ICH Q10)

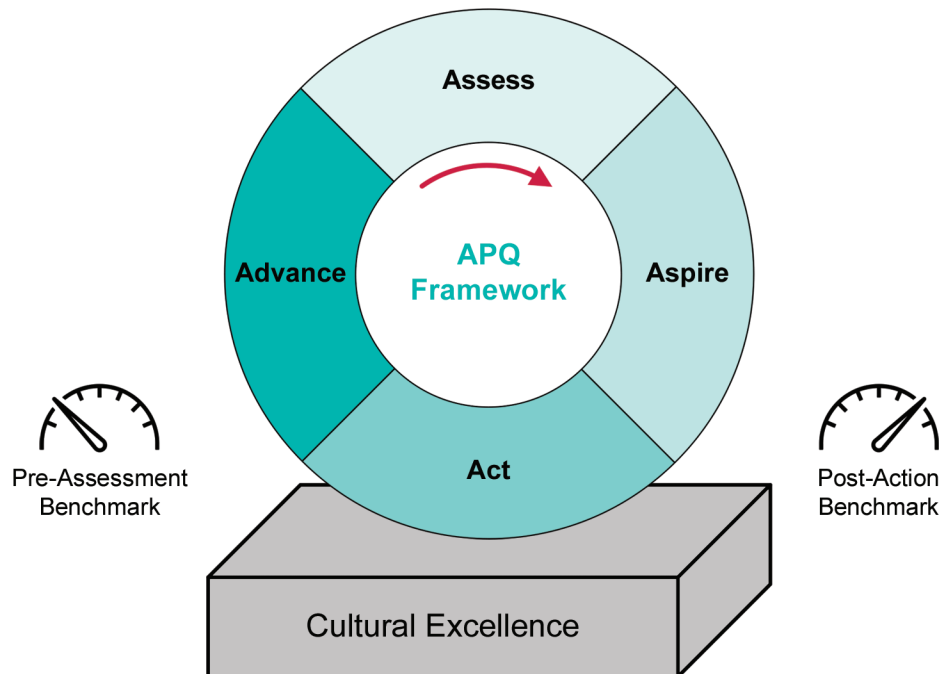
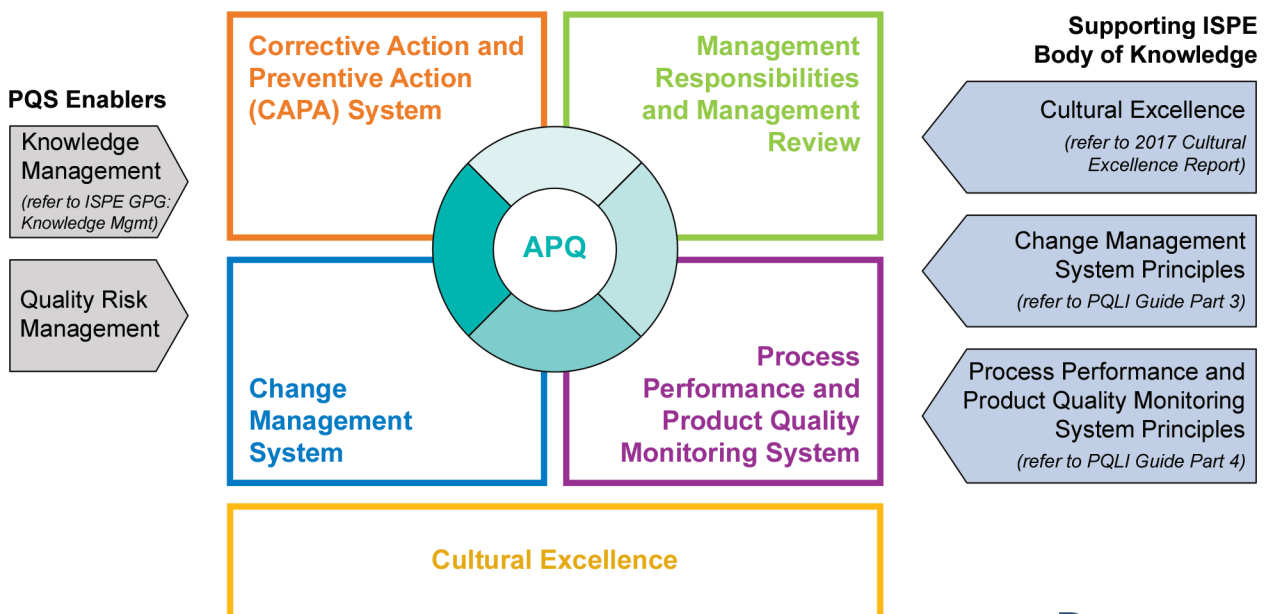


Figure 1.2: Overview of the ISPE APQ Guide Series

ISPE APQ Guide Series

Application of the APQ framework to Pharmaceutical Quality System (PQS) elements based upon ICH Q10



1.5 How to Use This Guide

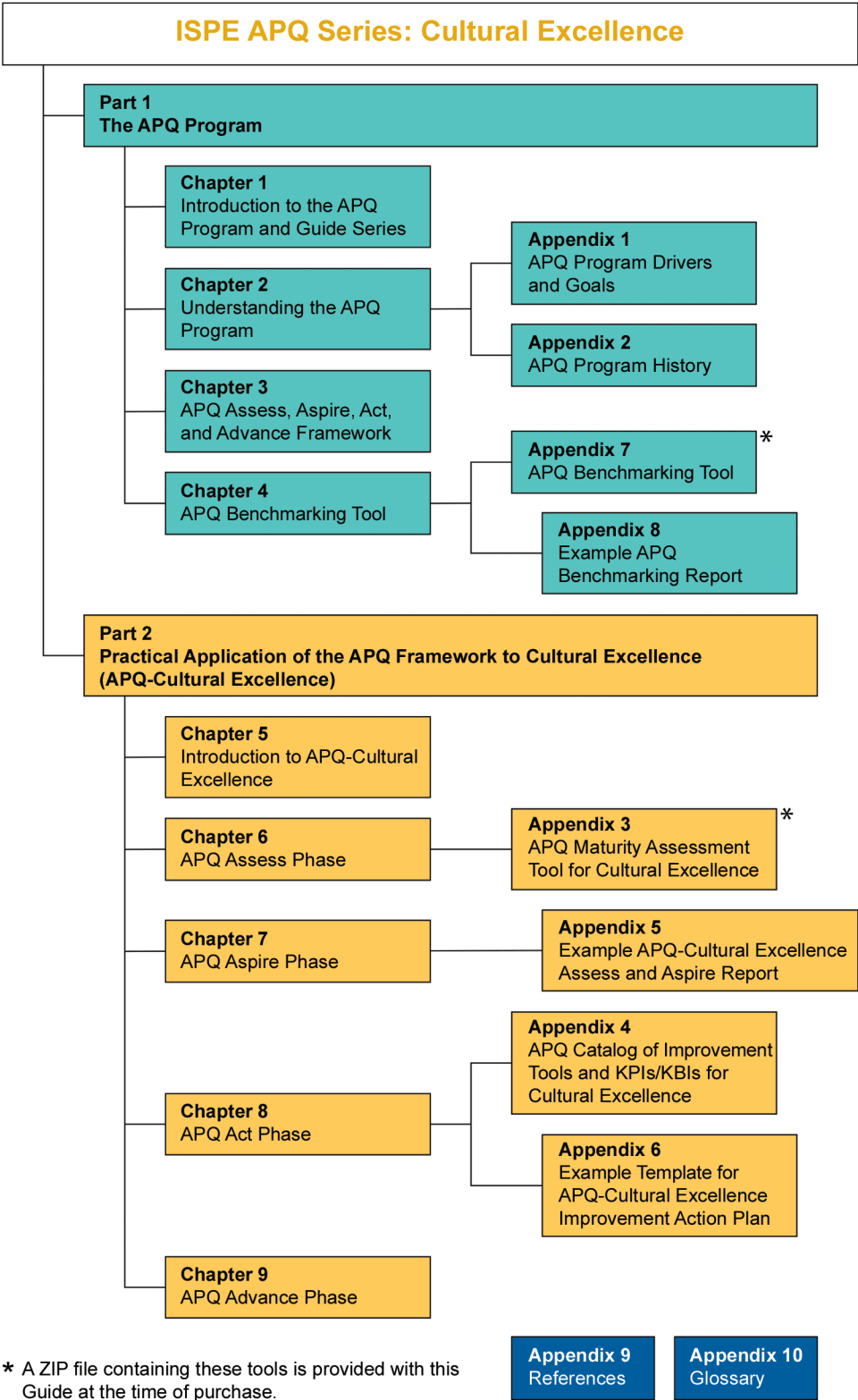
Part 1 covers the key concepts of the APQ program including the link to the ICH Q10 PQS model [1] and the link to cultural and operational excellence. It introduces the Assess, Aspire, Act, and Advance framework and explains how to perform the self-assessment. **This prerequisite information is applicable to assessing Cultural Excellence as well as to the four PQS elements covered in the APQ Guide Series.** Part 1 also covers the pre-assessment and post-action benchmarking questionnaire tool.

Part 2 covers the practical application of the APQ framework to Cultural Excellence (APQ-Cultural Excellence). It guides readers through the four phases of the framework, explaining in detail the comprehensive self-assessment tool for diagnosing the maturity of their organization's culture with respect to quality management. It provides guidance on developing an APQ Improvement Action Plan, with recommendations for KPIs/KBIs and improvement methodologies appropriate for each maturity level.

The appendices include a full explanation of the drivers and overarching goals of the APQ program, a summary of the program's history, and the tools and examples for practical application of the program.

Figure 1.3 provides the chapter organization of this Guide, showing the links between the body chapters and the appendices.

Figure 1.3: Guide Structure



2 Understanding the APQ Program

Robust and well-established quality systems subject to continual improvement are critical to superior performance outcomes. Organizations rely upon the effective implementation of PQS, from early development through to product approval, commercial launch, and routine supply. These aspects of a quality system are generally well considered and detailed in most pharmaceutical organizations; however, in organizations where quality management practices are less mature, there may be an emphasis on meeting compliance requirements and short-term business objectives rather than on achieving quality excellence and continual improvement. Activities that proceed well, according to plans, are usually well cared for; however, failure events or adverse situations leading to a quality defect or an interruption of supply are not always well-anticipated. The ability to predict, detect, and adapt to these events is the signature of a mature quality system.

These concepts are the basis upon which the APQ program has been designed. The APQ program is intended to be comprehensive without being complex. It has been developed to support organizations to **Assess, Aspire, Act, and Advance** the maturity and effectiveness of their quality management. The guiding principles of the APQ program are:

- Simple and practical
- Applicable across all sectors of the pharmaceutical industry
- Valuable and beneficial for industry
- Functional: Using “as is” company data, site definitions, and site procedures as much as possible
- Minimal additional work
- “By industry, for industry”
- Leveraging existing benchmarking, performance management, and OPEX methodologies and principles where relevant

The APQ program proposes that mature quality systems require the integration of excellence in quality with excellence in operations supported by excellence in organizational culture.

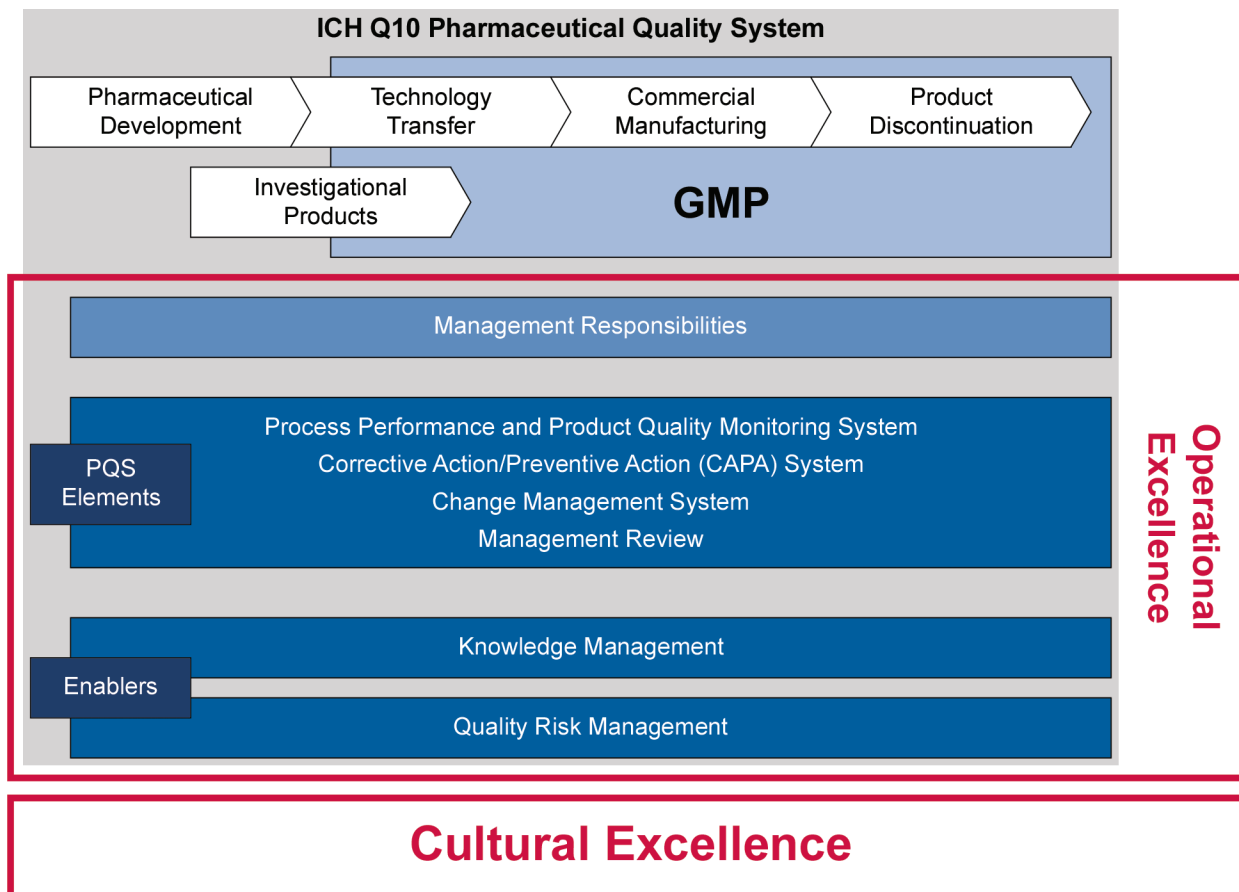
The philosophy behind the APQ program and its overarching goals is detailed in Appendix 1. It is important that readers of this Guide understand the full rationale described in this chapter and in Appendix 1 prior to the implementation of the APQ program.

For background information on how the APQ program evolved from the Quality Metrics program, see Appendix 2.

2.1 Link to the ICH Q10 PQS Model

The fundamental basis of the APQ program is the ICH Q10 PQS model [1]. Figure 2.1 shows the ICH Q10 model with APQ program enhancements (shown in red boxes) to incorporate the additional aspects of cultural excellence and OPEX.

Figure 2.1: APQ Program Link to ICH Q10 PQS Model [1]



Note: Red boxes are the APQ program enhancements to ICH Q10.

ICH Q10 states the following objectives for the implementation of the Q10 model:

- “Achieve product realization”
- “Establish and maintain a state of control”
- “Facilitate continual improvement” [1]

The concept of PQS effectiveness is raised early in the ICH Q10 guideline. Firstly, it emphasizes that the “use of knowledge management and quality risk management enable a company to implement ICH Q10 effectively and successfully.” The guideline then acknowledges that “while some aspects of the pharmaceutical quality system can be company-wide and others site-specific, the effectiveness of the pharmaceutical quality system is normally demonstrated at the site level.” ICH Q10 recommends that “performance indicators . . . should be identified and used to monitor the effectiveness of processes within the pharmaceutical quality system.” [1]

The APQ program has been specifically developed to provide a systematic process that can be used to objectively assess and advance PQS effectiveness at a site or functional unit level through the four elements based on ICH Q10 (CAPA system, MRR, CM system, and PPPQMS) and to evaluate the impact an organization’s culture can have on performance outcomes. The APQ program includes detailed diagnostic tools, based on a 5-Level Maturity Model, for assessing and improving the effectiveness of the PQS. A detailed description of the APQ program and how to apply it is provided in the next chapter (Chapter 3).

2.2 Link to Cultural Excellence and Operational Excellence

As stated earlier in this chapter, an overarching goal of the APQ program is to integrate quality, cultural, and operational excellence principles, tools, and approaches.

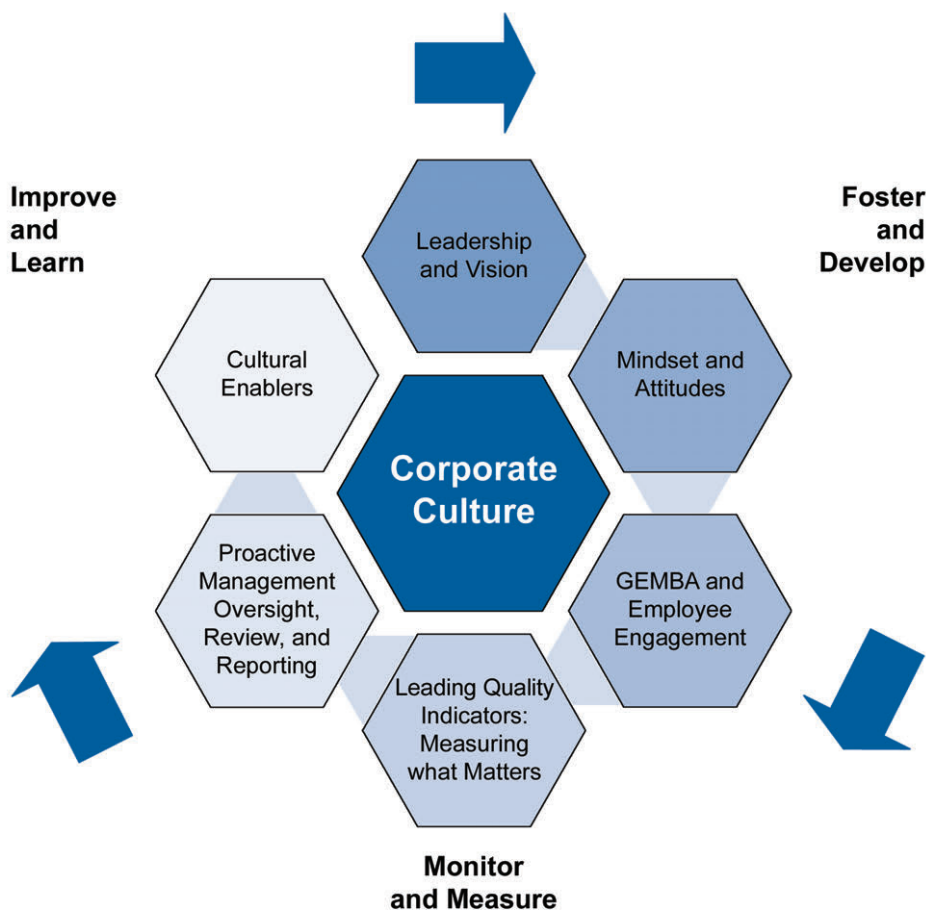
2.2.1 Cultural Excellence

Excellence in quality culture is essential for delivering robust and sustained quality performance, as demonstrated in the analyses from the ISPE Quality Metrics Wave 1 and Wave 2 pilot programs [10, 11]. (Background information on Quality Metrics and the relationship to APQ is covered in Appendix 2.) In Figure 2.1 (from Section 2.1), cultural excellence is depicted as the foundation stone for all other elements in the APQ program.

To address this key cultural excellence aspect, ISPE previously developed the six dimensions of the cultural excellence framework, published in the 2017 Cultural Excellence Report [6], which is comprised of a range of tools and practical approaches for improving the impact of culture on the performance outcomes for an organization. See Figure 2.2 for a diagram of the six dimensions of cultural excellence framework.

Figure 2.2: Six Dimensions of Cultural Excellence

Adapted from ISPE Cultural Excellence Report [6].



There is broad alignment between the mature quality behaviors valued in the APQ assessments and the key behavioral criteria provided in the Cultural Excellence Report. For example, appropriate leadership behaviors include:

- Regular emphasis from management on quality topics and the importance of quality
- When quality issues conflict with business issues, consideration of both aspects by management before taking a decision
- Leaders regularly providing sufficient support and coaching to line workers to help them improve quality
- Leaders always modeling the desired behavior of “doing the right thing” on issues of quality

Another area of core alignment between the APQ program and the recommendations in the Cultural Excellence Report is in the design of meaningful metrics and leading quality indicators; these include:

- Quality goals and objectives routinely established, linked, and aligned with organizational goals
- Management regularly involved in reviewing and assessing product, process, and quality system performance
- Organization’s oversight and reporting capabilities systematically applied to effectively manage external manufacturing performance within the supply chain
- Regular involvement by management of line workers in problem identification, problem solving, troubleshooting, and investigations

For these reasons, the APQ series has been extended to include a detailed maturity assessment of an organization’s culture, mindsets, attitudes, and behaviors in this APQ-Cultural Excellence Guide. For those embarking on a journey to advancing pharmaceutical quality within their organization, it is also recommended that the full Cultural Excellence Report (2017) [6] is read in conjunction with the ISPE APQ Guide Series.

2.2.2 Operational Excellence

Integration of the next key aspect of the APQ program relates to operational excellence (OPEX), which is defined as “a philosophy of the workplace where problem-solving, teamwork, and leadership leads to continual improvement in an organization.” [12] Continual improvement is a key goal of ICH Q10 [1] and should be considered as a critical factor for a comprehensive and sustainable OPEX initiative.

The *ISPE Good Practice Guide: Operations Management* [13] highlights that for many years the pharmaceutical industry has been successfully adopting operational approaches that come under the umbrella term “operational excellence”, including the use of improvement practices, Lean/Six Sigma techniques and tools, and the deployment and monitoring of relevant KPIs across the entire organization. The *ISPE Good Practice Guide: Operations Management* provides a useful knowledge base for promoting operational excellence within pharmaceutical operations management and is also recommended as a companion read to this Guide.

Recent research has shown, however, that quality and OPEX often exist as parallel dedicated functions in a formal pharmaceutical organizational structure, with OPEX activities managed independently of the quality unit. (Friedli, et al. [14]) Integration of these two infrastructures throughout the pharmaceutical organization is advised to more fully realize the positive impact of organization-wide improvement. The APQ Assess, Aspire, Act, and Advance framework has been carefully designed to incorporate cultural excellence behaviors and OPEX principles.

3 APQ Assess, Aspire, Act, and Advance Framework

The APQ program comprises a practical and systematic set of tools and approaches called the APQ Assess, Aspire, Act, and Advance framework that organizations can use to assess the current state of their quality management maturity at either a single site or across all sites within their organization.

The APQ Assess, Aspire, Act, and Advance framework is:

- A guided self-assessment and self-improvement process
- Comprised of four distinct but interconnected phases of Assess, Aspire, Act, and Advance
- Based on a 5-Level Maturity Model that identifies good practices and behaviors which support the advancement of quality management maturity within an organization
- Intended as an iterative, continual improvement process

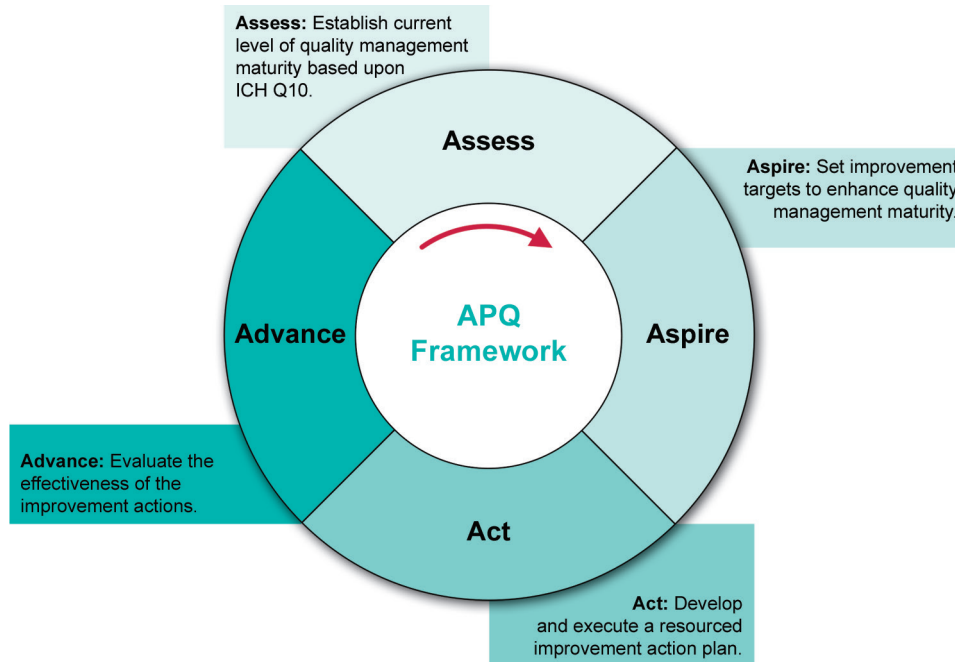
The APQ Assess, Aspire, Act, and Advance framework provides deep diagnostic tools for the PQS elements and principles based on ICH Q10 [1]:

- CAPA system
- MRR
- CM system
- PPPQMS
- Cultural Excellence

These self-assessment tools include detailed quantitative and qualitative criteria to evaluate the current state of quality, diagnose gaps, and identify improvement opportunities.

The APQ framework for assessment and improvement is based on the classic Plan-Do-Check-Act (PDCA) improvement cycle. It involves establishing a baseline and assessing for gaps, developing a set of systematic improvement goals, acting to advance maturity against those goals, monitoring the outcomes periodically for effectiveness, and prioritizing the next improvement opportunities. Furthermore, the program is iterative, as shown by the cycle in Figure 3.1. Ideally, continual improvement of the maturity of the PQS should remain a key focus for organizations.

Figure 3.1: APQ Assess, Aspire, Act, and Advance Framework



3.1 APQ Framework Process

This section provides a high-level overview of the four phases in the APQ framework process. Part 2 of this Guide (starting with Chapter 5) covers the practical application of the APQ framework to Cultural Excellence, explaining the four phases in more detail.

1. Assess Phase

In the Assess phase, an APQ self-assessment team performs a deep evaluation of the current state of maturity of the organization's PQS with respect to the PQS elements (CAPA system, MRR, CM system, and PPPQMS) as well as the organization's culture.

The evaluation may include one or more of these PQS elements or culture, depending on the improvement focus or business need. The APQ Benchmarking Tool described in Chapter 4 can be used to inform the prioritization of where the organization should start. The individual detailed self-assessment chosen is further divided into a number of sub-elements to enable a deeper level of enquiry.

The APQ Maturity Assessment Tool is a deep diagnostic tool that comprises quantitative and qualitative criteria against which the PQS maturity can be evaluated. Using the assessment tool, the team evaluates the current state of maturity, establishes objective evidence of organizational capability, and assigns an appropriate maturity rating for each sub-element. This assessment forms the basis for setting objective, measurable improvement goals.

2. Aspire Phase

In the Aspire phase, the self-assessment team analyzes the results of the assessment process to review the improvement opportunities identified and to determine where and by how much the organization aspires to improve. This analysis involves confirming the overall maturity rating for the PQS aspect under consideration and prioritizing the specific improvement opportunities based on current performance or business needs. An APQ Assess and Aspire Report should be prepared to summarize and present the findings from the self-assessment team. The report should be presented to management, the functional leader, and the business process owner(s) to ensure the analysis is endorsed and appropriately resourced. A formal summary report should also be presented to the executive sponsors. The output of the Aspire phase forms the basis for the Improvement Action Plan developed in the next phase.

3. Act Phase

In the Act phase, an APQ improvement team develops and executes an Improvement Action Plan for the prioritized gaps and improvements that were determined in the Assess and Aspire phases by the APQ self-assessment team. The APQ Improvement Action Plan should meet the SMART criteria—Specific, Measurable, Attainable, Relevant, and Time-bound.

To support the production of the Improvement Action Plan in the Act phase, the APQ Catalog of Improvement Tools and KPIs is a resource that action owners can leverage. It provides a listing of recommended good practices and useful KPIs specific to the PQS aspect undergoing the APQ framework process.

4. Advance Phase

In the Advance phase, an evaluation of the Improvement Action Plan effectiveness criteria is performed to demonstrate the achievement of the improvement goals. If the results are shown to be fully effective, reproducible, and sustainable, then the improvement team may recommend the next PQS aspect to be prioritized for improvement, thus commencing the next cycle of the APQ framework as an iterative process for continual improvement.

After confirmation of effectiveness has been completed in the Advance phase, a post-action benchmark may be triggered at an appropriate time point to demonstrate the impact of the improvements on the relevant company performance outcomes and KPIs.

3.2 APQ Self-Assessment Tool

3.2.1 *The 5-Level Maturity Model for Quality Management Maturity*

The APQ self-assessment tool incorporates quantitative scoring against a 5-Level Maturity Model, where **Level 1 Undefined** represents the lowest level of maturity and **Level 5 Optimized** represents the highest level of maturity.

The qualitative criteria contained within each maturity level are specific to each of the individual PQS aspects, e.g., the APQ self-assessment tool for the CAPA system contains specific qualitative criteria that are distinct from the criteria for assessing maturity of the change management system.

Figure 3.2 provides descriptions for each of the five levels in the maturity model. These five levels are applicable to all PQS elements.

Figure 3.2: APQ 5-Level Maturity Model

Level 1: Undefined	Compliance Risk	Undefined	Uncontrolled	Not Monitored	No Evidence
Level 2: Defined	Partially meets ICH Q10 Requirements	Partially Defined	Not Formally Controlled	Not Formally Monitored	Person Dependent
Level 3: Managed	Fully Meets ICH Q10 Requirements	Defined Policy and Processes	Meets Requirements for Application	Process Monitoring and Controls in Place	
Level 4: Improved	Demonstrates Improved/Optimized Execution	Defined Policy and Processes	Routine Application	Routine Monitoring, Advancing Improvements	
Level 5: Optimized	World Class/ Industry Leader	Proactive	Continual Improvement	Predictive	

To determine which maturity rating should be assigned, the APQ self-assessment tool incorporates specific qualitative criteria to each of the five levels in the maturity model. The cross-functional assessment team should review evidence of maturity against the qualitative criteria and then assign the appropriate maturity rating for that PQS element.

The typical attributes of the five levels in the APQ 5-Level Maturity Model are described below:

Level 1 Undefined

An assigned maturity assessment rating of 1 indicates that the element under review is poorly or not defined, reactive, and operates on an ad hoc basis or not done at all. There are no formal controls in place and no monitoring or oversight of results/outcomes is undertaken. There is no consideration given to supply chain risk. This level of maturity represents a compliance risk.

Level 2 Defined

An assigned maturity assessment rating of 2 indicates that the element under review has been partially defined but is not formally controlled or managed by a well-defined business process. The level of understanding is limited, and the process is applied inconsistently. The operation of the process is reactive. This level of maturity is likely to arise where processes are person dependent and rely on an individual or small number of individuals to function. There is little consideration given to supply chain risk with potential for supply chain disruption. This level of maturity may be considered to partially meet ICH Q10 requirements.

Level 3 Managed

An assigned maturity assessment rating of 3 indicates that the element under review has defined policies and procedures. While this level of maturity is considered to meet the minimum ICH Q10 requirements, it may be inefficient. For example, it may have a relatively high number of CAPAs, some repetition or recurrence of events, high levels of pharmaceutical process troubleshooting, and a costly supply chain supported by high stock levels with potential for supply disruption. Improvement projects identified from CAPA processes are more likely to be focused on corrective actions. Risks to the supply chain are identified with reactive actions to resolve disruptions. Continual improvement projects are largely reactive with some traces of proactive activity. This level of maturity represents the application of the minimum acceptable standard.

Level 4 Improved

An assigned maturity assessment rating of 4 indicates that the element under review demonstrates improved execution and enhanced performance. There are well-defined policies and procedures that are routinely and effectively applied. The management review and oversight processes are routinely deployed, and improvements are identified and acted upon. The process operates on both a reactive (corrective) and proactive (preventive) basis. Risks to the supply chain are identified, understood, and proactively managed. This level of maturity fully meets ICH Q10 requirements.

Level 5 Optimized

An assigned maturity assessment rating of 5 indicates best in class. The element under review is optimized and continual improvement processes are routinely embedded in the workflow. The process is proactive, agile, and can respond quickly to the business needs. It reacts effectively with minimal resources to emerging issues and routinely operates on a proactive, preventive, and predictive basis. Oversight and review processes are optimized to drive accountability and ownership, and there is a formal responsive process for escalation. The supply chain is effective and agile with risks identified and minimized, and efficiency is optimized to its highest level. This level of maturity is best in class and is optimized to deliver maximum benefit to the business.

3.2.2 Quantitative and Qualitative Aspects

Detailed and specific qualitative criteria associated with the five maturity levels are included in the tool to guide the assessment team in accurately evaluating the current state of capabilities, competencies, and associated behaviors and to reflect those findings in the assigned maturity ratings.

Figure 3.3 illustrates the relationship between the quantitative (Maturity Rating) and qualitative (Maturity Criteria) aspects for the APQ self-assessment tool.

Figure 3.3: APQ Self-Assessment Tool – Relationship between the Maturity Rating and Maturity Criteria

Maturity Rating

Maturity Criteria

Level 1 Undefined	Compliance risk	<ul style="list-style-type: none"> • Undefined • Uncontrolled • Not monitored • No evidence 	☐ No SOPs. ☐ No formal process for documenting CAPA. ☐ No monitoring or traceability oversight.
Level 2 Defined	Partially meets ICH Q10 requirements	<ul style="list-style-type: none"> • Partially defined • Not formally controlled • Not formally monitored • Person dependent 	☐ SOP provides high-level overview and expectations (lacks details for defined responsibilities, process, and expectations). ☐ Formal process to document CAPA exists. ☐ CAPAs are monitored, however the process is not defined in an SOP.
Level 3 Managed	Fully meets ICH Q10 requirements	<ul style="list-style-type: none"> • Defined policy and processes • Meets requirements for application • Process monitoring and controls in place 	☐ SOP defines process, expectations, and responsibilities across individual site or functions. ☐ Process for documenting CAPA is applied, however may have inconsistencies in execution from record to record. ☐ Monitoring process is defined in an SOP.
Level 4 Improved	Demonstrates improved/ optimized execution	<ul style="list-style-type: none"> • Defined policy and processes • Routine application • Routine monitoring, advancing improvements 	☐ SOP defines process, expectations, and responsibilities across the organization's entire network. ☐ Process for documenting CAPA is executed consistently from record to record, across the PQS (Pharmaceutical Quality System). ☐ Robust and defined monitoring ensuring successful KPI performance for the CAPA quality system.
Level 5 Optimized	World class/industry leader	<ul style="list-style-type: none"> • Proactive • Continual improvement • Predictive 	☐ CAPA documentation process is periodically reviewed and proactively enhanced. ☐ Process for documenting CAPA includes full integration with PQS processes, seamless network collaboration, and proactive actions to drive continual improvement. ☐ CAPA Key Performance Indicators and Key Behavioral Indicators are engrained within the CAPA quality system. ☐ Monitoring process is proactive and assesses real time data. May include evaluating stress points and forecasting of upcoming CAPA; further granularity of CAPA for trending (category or effectiveness) is included within the documented process.

The APQ self-assessment tool provides space to contemporaneously record observations, evidence, and outcomes that may be later leveraged to develop the formal assessment report. This APQ Assess and Aspire Report, prepared in the organization's preferred format, details the findings of the assessment and the recommendations for next steps. The report should be presented to management, the functional leader, and the business process owner(s). A formal summary report should also be submitted to the executive sponsors. Each Guide in the APQ Guide Series Practical Module includes an example APQ Assess and Aspire Report.

3.3 Cross-Functional Team Approach

3.3.1 Self-Assessment Team (*Assess and Aspire*)

An APQ self-assessment team should be formed to perform the Assess and Aspire phases of the APQ framework process. The APQ program is not intended as an audit process but as an overall self-improvement process undertaken in the development of an organization. Effective self-assessment emerges from a culture of honest dialogue and critical thinking. It is best approached as a learning opportunity for a cross-functional self-assessment team made up of technical experts drawn from relevant fields such as:

- Quality Assurance
- OPEX
- Learning and development professionals
- Process owners and/or process users from independent sites in the organization

A small cross-functional team that has strong executive sponsorship is essential to ensuring an effective assessment is conducted. Potential improvements that are identified may be more difficult to implement if executive sponsorship is not secured at the outset.

This self-assessment team should actively engage with both the business process owner(s) and functional leadership of the element under assessment. This is essential to ensuring that the improvement recommendations and prioritization are agreed by all stakeholders. If this is not the case, a meeting between the sponsors, the self-assessment team, and the functional/process owner may be necessary to negotiate the next steps. The self-assessment team should have excellent interpersonal and communication skills and be committed to completing the tasks on time with a consistent approach to all criteria.

The cross-functional team approach should help to neutralize the challenges of team bias and ensure that there is an appropriate knowledge of detail within the team necessary to perform a thorough assessment. During the assessment, evidence of the following factors should be reviewed by the team to document the baseline “as found” practices, and serve as a basis for prioritizing the improvement and the post-action comparison:

- Process inputs (e.g., SOPs, process documentation/workflows, and training records)
- Execution-related documents (e.g., completed or in-process records, and related documentation)
- Demonstrated process outcomes (e.g., results, efficacy analysis, and trend analysis)
- Demonstrated behaviors such as leader standard work

It is strongly recommended that the cross-functional assessment team practice the Gemba method of “Go, Look, Ask, Coach” as part of the inquiry and assessment process. This approach ensures a full understanding of the current situation, identification of potential improvement opportunities and issues, and opportunity to provide constructive feedback to the department or function under review. The location of the Gemba walks should include observing front line activities including engagement with a cross-section of process users (e.g., attendance at CAPA meetings run by the CAPA system owner) and participation in the relevant oversight and review meetings conducted by the process and/or functional owners. For additional recommendations on how to conduct an effective Gemba activity refer to the ISPE Cultural Excellence Report [6].

Ideally, the assessment activities should be carried out by an independent self-assessment team not directly responsible for the activities under review. This team is also responsible for preparing the Aspire Report which identifies and prioritizes the improvement opportunities.

3.3.2 Improvement Team (Act and Advance)

In the Act phase, the design of the Improvement Action Plan should include engagement with key stakeholders, process owners, and process users. When the Improvement Action Plan is fully developed, ownership of the APQ framework process transitions from the self-assessment team to an APQ improvement team.

This APQ improvement team is responsible for the execution and evaluation of the APQ Improvement Action Plan during the Act and Advance phases. This team should be led by the functional owner and/or business owner of the PQS aspect under review. The team should consist of the necessary cross-functional resources applicable to the improvement area(s). Oversight of the progress of this team's improvement actions should be the responsibility of the site leadership team, actively supported and sponsored by the global leadership.

4 APQ Benchmarking

The APQ program incorporates a pre-assessment and post-action benchmarking questionnaire tool developed by the St.Gallen OPEX Benchmarking team specifically for use with the APQ program.³ It provides standardized support to initially baseline the level of quality performance and allows organizations to prioritize which of the four ICH Q10 elements to embark upon first with the APQ framework. Used in conjunction with the APQ self-assessment and self-improvement tools, the pre- and post-benchmarking activities offer objective evidence of performance improvement to support ongoing investment of time and resources. The effectiveness and impact of the improvements from the APQ program can be evaluated and quantified, and priorities for next improvement opportunities can be derived.

4.1 Benchmarking Questionnaire

The St.Gallen APQ benchmarking questionnaire (provided in Appendix 7) can be used by organizations for either:

- Internal self-evaluation (no peer comparison possible), or
- External benchmarking against a tailored industry peer group (selected from the St.Gallen OPEX database of hundreds of pharmaceutical production sites).⁴

The benefits of opting to engage in the external benchmarking process include:

- Support from the St.Gallen team in terms of accurate data collection and completion, as part of data validation procedures applied to all datasets entering the benchmarking process
- A personalized APQ Benchmarking Report (example provided in Appendix 8) as an output of the process – this report will allow organizations to:
 - Understand individual strengths and weaknesses
 - Gain meaningful comparisons of its position as compared to a tailored peer group of comparable organizations/sites (based on the contextual factors queried in the questionnaire)

This APQ benchmarking questionnaire is a subset of the scientifically derived legacy St.Gallen OPEX benchmarking performance indicators and selected enablers that have been proven as meaningful surrogates for overall system stability and performance [12].

The APQ Benchmarking Tool is simple to use and user friendly, but still comprehensive enough to deliver a solid and balanced overview of operational performance and quality management maturity. The benchmarking tool includes:

- 13 KPIs in four dimensions (maintenance, quality, delivery, and people)
- 18 maturity questions in three categories (organization enablers, social and employee enablers, and technical and tool enablers)
- Contextual factors (such as site type and size, production technology platforms and size, and days of inventory on hand)

³ ISPE is in a partnership with the Institute of Technology Management at the University of St.Gallen (Switzerland) to collaborate on tools designed to advance the state of pharmaceutical quality.

⁴ For information about participating in the external benchmarking study, contact the St.Gallen OPEX Benchmarking team at benchmarking@unisg.ch. St.Gallen may collect a fee for the benchmarking service.

- High-level ICH Q10 maturity evaluation that contains questions scored on a Likert scale:
 - 71 maturity questions evaluating management responsibilities, knowledge management, CAPA system, quality risk management, process performance and product quality monitoring system, change management system, and management review
 - 8 dedicated maturity questions on Environment, Health, and Safety to complement the overall picture of maturity

This tool is intended to assist in the determination of where initial improvement efforts can be best invested.

Additionally, the St.Gallen team offers participating APQ sites that are engaged in broader business performance improvement programs an opportunity to seek synergies and upgrade the APQ Benchmarking to a full St.Gallen OPEX & QC Lab Benchmarking, which provides a more granular and comprehensive set of benchmarking results and insights.

The metrics and enablers included in the APQ Benchmarking Tool are summarized in Table 4.1.

Table 4.1: High-Level Performance Evaluation using the St.Gallen APQ Benchmarking Tool

St.Gallen APQ Benchmarking Tool			
Maintenance	Quality	Delivery	People
1. Share of Unplanned Maintenance 2. Maintenance FTE / Total FTE	3. Rejected Batches 4. Recurring Deviation 5. Quality FTE / Total FTE 6. IOOS rate (Lab) 7. Deviation Closure Time	8. Service Level – Delivery (OTIF) 9. Service Level – Supplier (OTIF) 10. Customer Complaint Rate 11. Adherence to standard lead time	12. Safety level 13. Sick leave
Enabler		Contextual Factors	
<ul style="list-style-type: none">• Organization enablers• Social and employee enablers• Technical and tool enablers		<ul style="list-style-type: none">• Site type and size• Production technology platforms and size• Days on Hand (DOH)	
ICH Q10 Maturity Assessment			
<ul style="list-style-type: none">• Management Responsibilities• Knowledge Management• CAPA System• Quality Risk Management		<ul style="list-style-type: none">• Process Performance and Product Quality Monitoring System• Change Management System• Management Review	

Refer to Appendix 7 for the APQ Benchmarking Tool and to Appendix 8 for an example APQ Benchmarking Report.

4.2 APQ Pre-Assessment Benchmarking

At the outset of the APQ framework process, it is useful to establish a baseline of current performance by formally documenting selected KPIs and organizational enablers. The goal of the pre-assessment benchmark is to set a quantitative baseline and to identify potential improvement opportunities. The APQ Benchmarking Tool can also inform the prioritization of which PQS element an organization should focus its resources to apply the deeper diagnostic APQ self-assessment tool as part of the first Assess phase. Ultimately, the results from this pre-assessment benchmark can act as an important comparator or baseline against which future advancement results can be evaluated using the post-action benchmark.

4.3 APQ Post-Action Benchmarking

At an appropriate duration after implementation of the APQ framework process (generally within an 18- to 24-month timeframe), it is recommended that post-action benchmarking is performed using the APQ Benchmarking Tool. This post-action benchmarking is intended to evaluate the impact of the improvements on the overall company performance.

The results of the post-action benchmark can be compared to the pre-assessment baseline to provide evidence of value to the business and return on investment.

As part of the iterative continual improvement process, if the overall performance goals have not yet been met, a return to the Aspire phase may be needed to identify further improvement activities or to review the effectiveness criteria. If the overall performance goals are confirmed, the next improvement opportunity may be prioritized to commence another cycle of the APQ Assess, Aspire, Act, and Advance process on any one of the four PQS elements as required.

5 Introduction to APQ-Cultural Excellence

Part 2 of this Guide covers the practical application of the APQ framework to support and guide an organization's journey towards cultural excellence.

The concept of cultural excellence was first introduced in the 2017 ISPE Cultural Excellence Report [6]. This report was published in response to a growing acceptance of the influence that organizational culture has on the behaviors and actions that give rise to quality, data integrity, and safety outcomes that matter to the patient and the business. A culture of excellence is defined as follows:

"[A culture of excellence is one] that fosters cross-functional ownership of quality. It treats quality not as a hindrance for success, but as a necessity that allows the company to make decisions that best benefit patients." [6]

The report highlights that within the pharmaceutical sector, culture is expressed and implied in the ways that an organization operates. Culture affects quality performance and supply chain excellence and ensures that a patient focus is maintained at all times. Culture determines quality outcomes because it affects the organization's ability to identify and act upon near-miss shortages, ensures the integrity of its data, assures transparent problem escalation, and strives for OPEX.

Cultural excellence is driven by leadership example. It requires management ownership and accountability, performance metrics that promote continual improvement, and a strong risk management framework. All are key to the proactive identification and prevention of poor-quality outcomes.

Patient focus is another key term used throughout this Guide to describe a quality management approach that is focused on performance and outcomes that affect the patient, enabling the organization to make decisions that best benefit their patients.

The ISPE Cultural Excellence Report [6], which offers a range of practical tools and approaches to advancing cultural maturity, is a valuable companion to this Guide.

This APQ-Cultural Excellence Guide provides guidance on how to use the APQ framework to:

- **Assess:** Evaluate the current maturity level of cultural excellence using a Maturity Assessment Tool (Chapter 6)
- **Aspire:** Set improvement targets to enhance and improve cultural excellence (Chapter 7)
- **Act:** Develop and execute a targeted Improvement Action Plan (Chapter 8)
- **Advance:** Evaluate the effectiveness of the improvement actions (Chapter 9)

In Chapters 6 to 9, **APQ Framework Universal Topics** are noted. These sections represent information that is universally applicable to advancing the maturity of all PQS elements, though content may be provided in the context of cultural excellence for ease of understanding.

The following resources are provided in the APQ-Cultural Excellence Appendices:

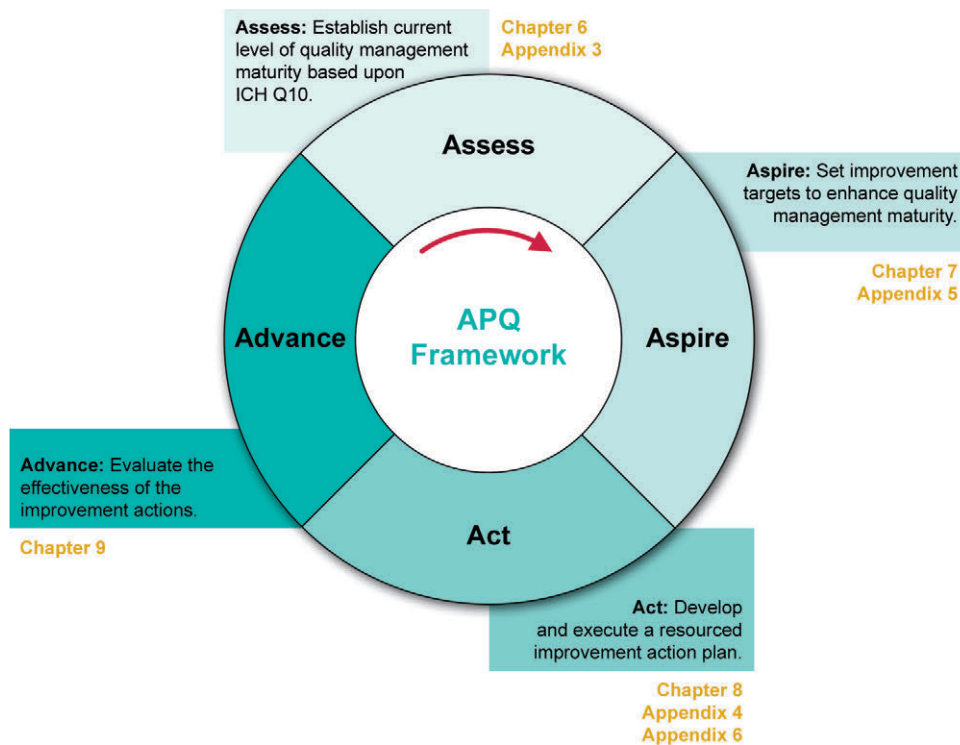
- APQ Maturity Assessment Tool for Cultural Excellence (Appendix 3)
- APQ Catalog of Improvement Tools and KPIs/KBIs for Cultural Excellence (Appendix 4)

- Case studies:
 - Example APQ-Cultural Excellence Assess and Aspire Report (Appendix 5)
 - Example Template for APQ-Cultural Excellence Improvement Action Plan (Appendix 6)

Note: The information presented in Part 2 of this Guide builds on the prerequisite explanation of the APQ framework in Chapter 3.

Figure 5.1 provides a roadmap of the application of the APQ framework to cultural excellence, with chapter references for each phase of the framework.

Figure 5.1: Practical Application of the APQ Framework to Cultural Excellence – Roadmap

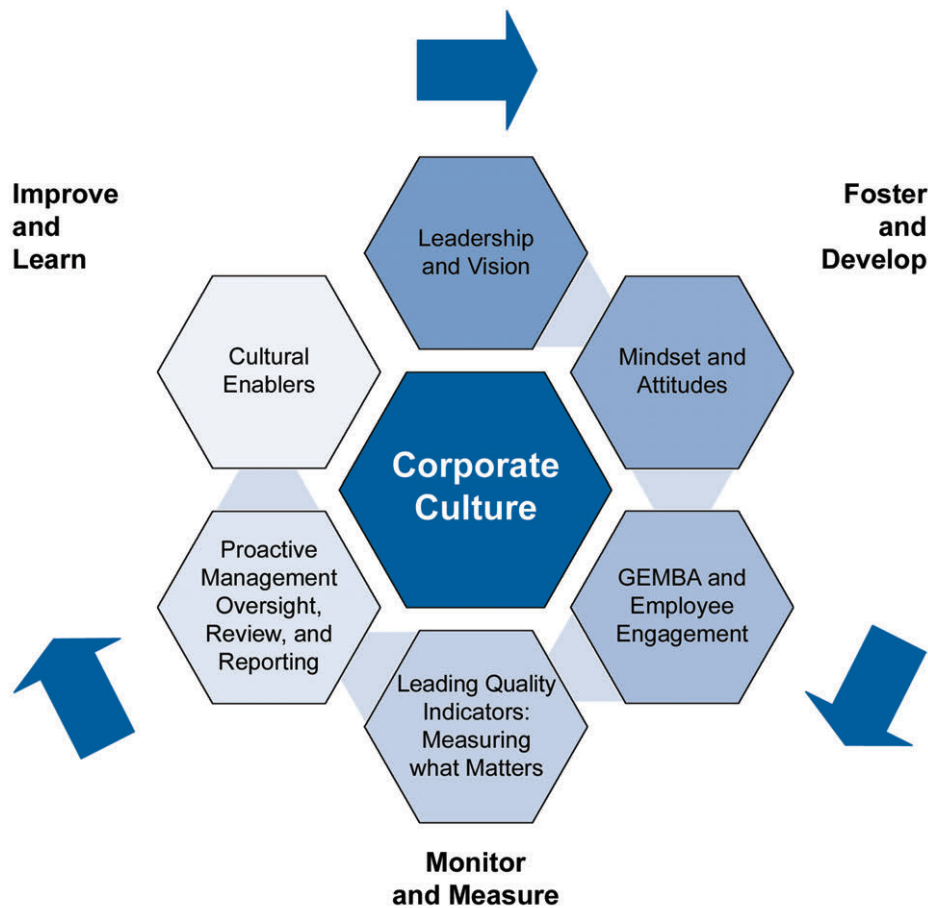


5.1 Key Concepts

Cultural excellence acts as the foundation for all elements in the APQ program. This premise is based on the belief that excellence in culture is fundamental to the delivery of sustained quality and performance improvement. The APQ Assess, Aspire, Act, and Advance framework has been designed to incorporate the essential cultural excellence behaviors and key OPEX principles within each of the PQS maturity assessments presented in the APQ Guide series. See Figure 2.1 in Part 1 of this Guide to review the APQ program enhancements to the traditional ICH Q10 PQS model [1].

The ISPE six dimensions of cultural excellence framework (shown in Figure 5.2) was first introduced in the ISPE Cultural Excellence Report [6] and has been further developed in this APQ-Cultural Excellence Guide to identify the routine practices and behaviors required to foster, develop, monitor, measure, learn, and ultimately improve an organization's culture. Detailed assessment criteria have been developed for each of these six dimensions to assist organizations in evaluating the current cultural excellence maturity level and to identify practical actions and approaches to advancing maturity.

Figure 5.2: Six Dimensions of Cultural Excellence
Adapted from ISPE Cultural Excellence Report [6].



Continual improvement is a key goal of ICH Q10 model [1] and should be considered as a critical success factor for a sustainable journey towards excellence. For many organizations, continual improvement is delivered through the application of standard OPEX principles, approaches, and tools, where OPEX is defined as:

“A philosophy of the workplace where problem-solving, teamwork, and leadership leads to [continual] improvement in an organization.” [12]

These OPEX approaches include the use of structured problem-solving and improvement practices, application of Lean principles, Six Sigma techniques and tools, and the deployment of a proactive, tiered performance management process which is cascaded throughout the entire organization. Such approaches form the continual improvement toolbox for many organizations, empowering employees to develop and practice skills that deliver the quality and performance targets required. For readers less familiar with some of the standard OPEX terminology, a glossary of key terms is included in Appendix 10.

To better understand how the APQ program integrates quality, cultural, and operational excellence, it is highly recommended to review the eight overarching goals of the APQ program described in Appendix 1 of this Guide. Understanding these goals is essential for the correct application of the APQ program.

Additional key concepts that support the advancement of cultural excellence within an organization are discussed in Sections 5.1.1 through 5.1.9.

5.1.1 Driving Quality Beyond Compliance

The ISPE Cultural Excellence Report [6] was an early advocate on the need for organizations to transform from the traditional “culture of compliance” towards a “culture of excellence”, stating:

“This signals a shift from reliance solely on regulatory compliance to an emphasis on continuous improvement in which there is deep understanding throughout an organization of the elements critical to product quality.”

Cultural excellence recognizes quality not as an operational burden or compliance requirement, but as a necessity that allows companies to make decisions that best benefit the patient. It focuses on practicing desired behaviors as a means to delivering enhanced quality outcomes and advancing quality management maturity.

The 2019 FDA Drug Shortage report provides the following definition:

“Quality management maturity starts with a foundational [Quality Management System] that conforms to CGMPs and builds in a performance and patient focus that utilizes technology, statistical process control, and planning activities such as risk-management and [continual] improvement plans.” [15]

The ISPE APQ program recognizes that advanced levels of quality management maturity offer benefits to the patient by securing the supply of high-quality medicines but can also deliver real value to the business. The FDA Drug Shortages Task Force found that manufacturers with a proven track record of prompt and regular delivery of product apply a more mature quality management approach that is focused on performance and outcomes that affect the patient. These organizations routinely practice proactive prevention to significantly reduce their overall cost of quality. In short, it is less expensive to do something right the first time rather than to pay for rework, rejects, recurring deviations or recalls, proving that what is good for the patient is good for the business. [15]

A company that advances quality management maturity beyond compliance preempts and detects manufacturing problems more readily, enabling the company to act promptly and continually improve product quality while also improving overall business performance.

5.1.2 The Benefits of Establishing a Cultural Excellence Program to Advance Maturity

Organizations that aspire to drive quality beyond compliance towards a strategy of patient-focused excellence must view quality as everyone’s responsibility. In the ISPE Cultural Excellence Report [6] that describes the six dimensions of the cultural excellence framework, the importance of **leadership and vision** (dimension 1) and **attitudes and mindsets** (dimension 2) are emphasized. These dimensions establish the right environment for excellence by defining what “good” looks like for the organization. Changing culture and embedding new behavioral norms is hard work. It takes time and vigilance coupled with a structured approach to develop individual competencies and advance organizational capabilities. To deliver on this aspiration, it is recommended that a structured approach to guide this change is considered with the establishment of a cultural excellence program.

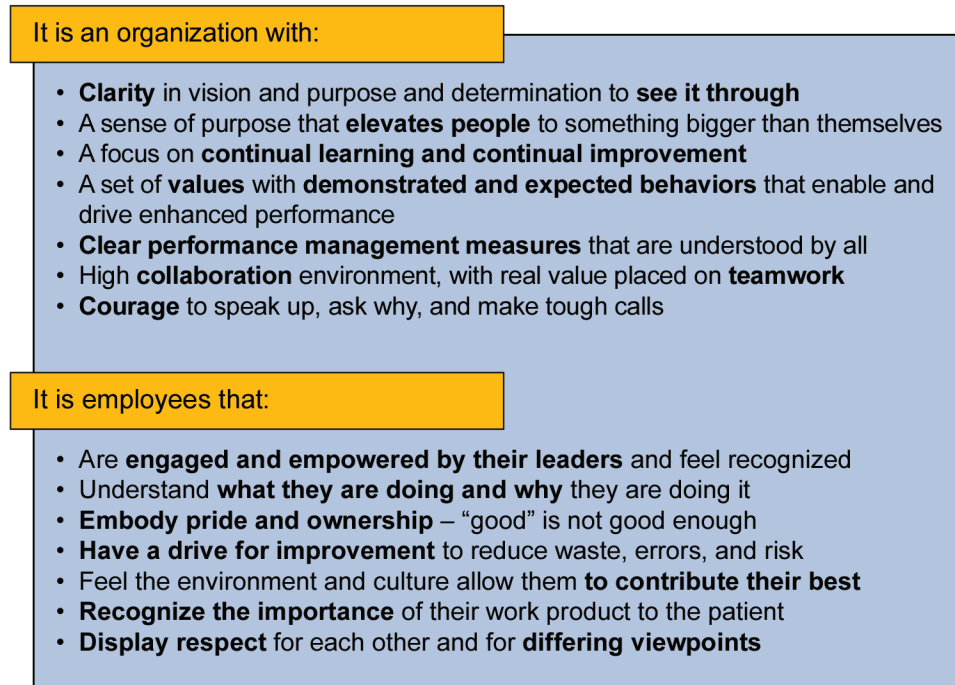
Adopting a programmatic approach to advancing cultural excellence ensures that leadership clearly communicates the organization’s vision and values and demonstrates its commitment to actively sponsor the journey. The level of ambition for the program is less important than a determination to start. For those commencing on this journey, a useful motto to adopt is: “Start, start small... but start!”

What is the main purpose of a cultural excellence program?

A formal cultural excellence program seeks to enhance organizational capability and performance outcomes through increased employee engagement, the use of systematic improvement processes, and rigorous proactive performance management practices.

In the “Shaping Excellence” research undertaken by the ISPE Cultural Excellence Team [16], a range of organizational and employee traits associated with a culture of excellence was identified. This useful information has been adapted and provided in Figure 5.3.

Figure 5.3: What Does Cultural Excellence Mean?



Top-level management have the ultimate responsibility to create and clearly communicate a vision that fosters a culture of excellence for everyone in the organization. Their active sponsorship of a formal cultural excellence program is a critical factor for success.

5.1.3 The Role of Management and Leaders in Building a Culture of Excellence – A Key Distinction

To build a robust culture of patient-focused excellence, an organization requires all levels of management from top line to front line to act as leaders. These managers have formal responsibilities to create the vision, espouse the values, model the desired behaviors, motivate others to follow by example, and implement and uphold the systematic improvement processes that deliver the quality and performance outcomes sought.

Perhaps more importantly, to sustain a robust culture of patient-focused excellence, an organization needs to have engaged employees at all levels within the business who act as leaders. These employees proactively identify risks and opportunities for improvement, speak up openly, and motivate their peers to do what is right by demonstrating the desired behaviors through their actions.

In the context of this Guide, the term **management** pertains to the people who are administratively responsible for directing others in an organization. Managers are formally responsible for human resources and performance management by providing direction for the work on a day-to-day basis.

In the context of this Guide, the term **leadership** refers to a behavior that any employee can demonstrate. Leaders take responsibility for the situation, team, or objective, and they help others to achieve the goal. Leaders may be a member of the management team, but they may also be individual contributors that view part of their role as helping to achieve results in collaboration with their peers and colleagues.

It is crucial that both management and individual leaders purposefully direct the influence they have within the organization to derive positive outcomes for the patient and the business. Equally, they must also be cognizant of the potential for their short-term actions, behaviors, and decisions to have long-term negative impacts for either the patient or the business. The ISPE Cultural Excellence Report [6] provides a practical model to help management and leaders use their influence wisely. This 5V model of leader influence is shown in Figure 5.4

Figure 5.4: 5V Model of Leader Influence
Adapted from ISPE Cultural Excellence Report [6].



For each of these 5 categories (Vision, Values, Voice, Visibility, and Vigilance), there are many opportunities for management and leaders to use their influence to advance the maturity of quality management and cultural excellence within their organization. These practical influential levers are outlined in Table 5.1.

Table 5.1: Opportunities for Management and Leaders to Use the 5V Model to Positively Influence Culture

5V Model	Opportunities for Management and Leaders to Influence
Vision	<ul style="list-style-type: none"> • Create a clear vision for the organization. • Seek ways to share the vision often within the organization; the right message cannot be overcommunicated. • Commit to consistently act in alignment with that vision. • Cascade the mission, operational strategy, and unifying goals in-line with the vision. • Motivate and lead the organization to achieve the required operational milestones towards that vision. • Celebrate gains and work through the setbacks.
Values	<ul style="list-style-type: none"> • Put the patient first in the hierarchy of organizational values, ensuring decisions that best benefit the patient are prioritized. • Emphasize the values of transparency and openness to protect the patient and the business. There is no place for fear of blame or consequences in organizations that value honesty and integrity. • Practice humility, empathy, and the willingness to listen. These are all values connected to higher levels of employee engagement that enable a culture of excellence. • Value courage. It takes courage to innovate, push continual improvement efforts, challenge the status quo, and break old paradigms.

Table 5.1: Opportunities for Management and Leaders to Use the 5V Model to Positively Influence Culture
(continued)

5V Model	Opportunities for Management and Leaders to Influence
Values <i>(continued)</i>	<ul style="list-style-type: none"> Encourage curiosity, another key component of innovation and change, in employees. Encourage employees to ask why by facilitating forums where process improvements and knowledge sharing can take place. Commit to model the company values in all of their own actions and behaviors. Link the organization's values to the company reward and recognition program to regularly recognize colleagues who demonstrate the values in their daily efforts.
Voice	<ul style="list-style-type: none"> Use their voice to routinely articulate the vision and values, strategy, and goals. Recognize the power of using their voice to inspire and motivate others and to lead by example by their own actions and behaviors. Speak authentically with passion and credibility to influence desired behavior most effectively. Be aware of the power of nonverbal cues by ensuring alignment of their tone, body language, and actions with their message. This is an important aspect for leaders to be viewed as trustworthy. Use every opportunity, whether during operational meetings, during Gemba walks, or directly on the shopfloor, to use their voice as a positive influence and to coach for enhanced performance outcomes. Be open-minded and keep open channels for honest dialogue. These are key aspects of coaching. Ask questions to understand current status, encourage diversity of opinion, and listen actively to the responses, by adopting a motto of "ask, don't tell".
Visibility	<ul style="list-style-type: none"> Participate in Gemba walks as a key aspect for employee engagement and creating a "listening post" between employees and management. Gemba walks enhance visibility and enable real-time evaluation of a site or function's fit-for-purpose status. Participate regularly in site walk-throughs which provide important opportunities to engage employees, frontline supervisors, and area leaders. Use opportunities for visibility that can be formal (town halls, standing management review meetings, or corporate quality updates) or informal (employee-management round tables, one-on-one or skip level meetings with leaders, or Gemba walks). <ul style="list-style-type: none"> A structured approach to scheduling both formal and informal engagements is recommended. Both types of engagements give management an opportunity to talk about performance and allow employees to ask questions and provide direct feedback. These sessions also allow management to listen to quality concerns, issues, and ideas from within the organization and for them to take time to recognize individual and team efforts.
Vigilance	<ul style="list-style-type: none"> Be vigilant in staying the course and enduring the ups and downs of a quality and performance improvement/culture change journey. Ensure actions continue to be aligned with the vision and values. Ensure that they are measuring what matters and holding themselves and the rest of the organization accountable to the performance and continual improvement targets. Understand the importance of designing proactive, leading behavioral indicators to drive quality and performance improvement. Consider including leading behavioral indicators for measures of organizational learning, such as number of employees actively engaged in improvement teams and structured problem-solving, or measures for on-the-job experiential learning related to improvement project implementation. Be vigilant in periodically assessing the state of the cultural excellence within the organization and developing actionable plans to improve it.

Section 6.1 of this Guide provides the further detailed maturity criteria for advancing the maturity of the leadership practices that are central to the success of a cultural excellence program. An index of additional improvement resources from the ISPE Cultural Excellence Report [6] is provided in Appendix 4 of this Guide.

5.1.4 Building Organizational Capability and the Learning Organization

Building organizational capabilities in the core disciplines that support cultural excellence is not simply a matter of creating company training programs in continual improvement, structured problem-solving, performance management or project execution. Similarly, setting targets for the numbers of individual employees who have successfully completed formal Six Sigma competency certifications does not ensure that these key improvement skills are actually put to good use every day in pursuit of patient-focused excellence.

To enhance and sustain quality and performance improvement, organizations need to purposefully use what they know to inform what they do. This requires a determination to expand “what is known” by encouraging curiosity and dialogue to better understand the root causes of failures or near misses and a commitment to learn from mistakes. Once new knowledge is created and successfully utilized to implement an effective process improvement, the next step is to share this new best practice across the organization. This is a core trait of a learning organization.

A learning organization is one where employees act as “*proactive problem solvers*” and “*perpetual learners*” (Schein [17]) and where the process of learning is made part of the culture, not just the solution to a given problem. Senge [18] defines a learning organization where:

“People continually expand their capacity to create the results they truly desire, where new and expansive patterns of thinking are nurtured, where collective aspiration is set free, and where people are continually learning to see the whole together.”

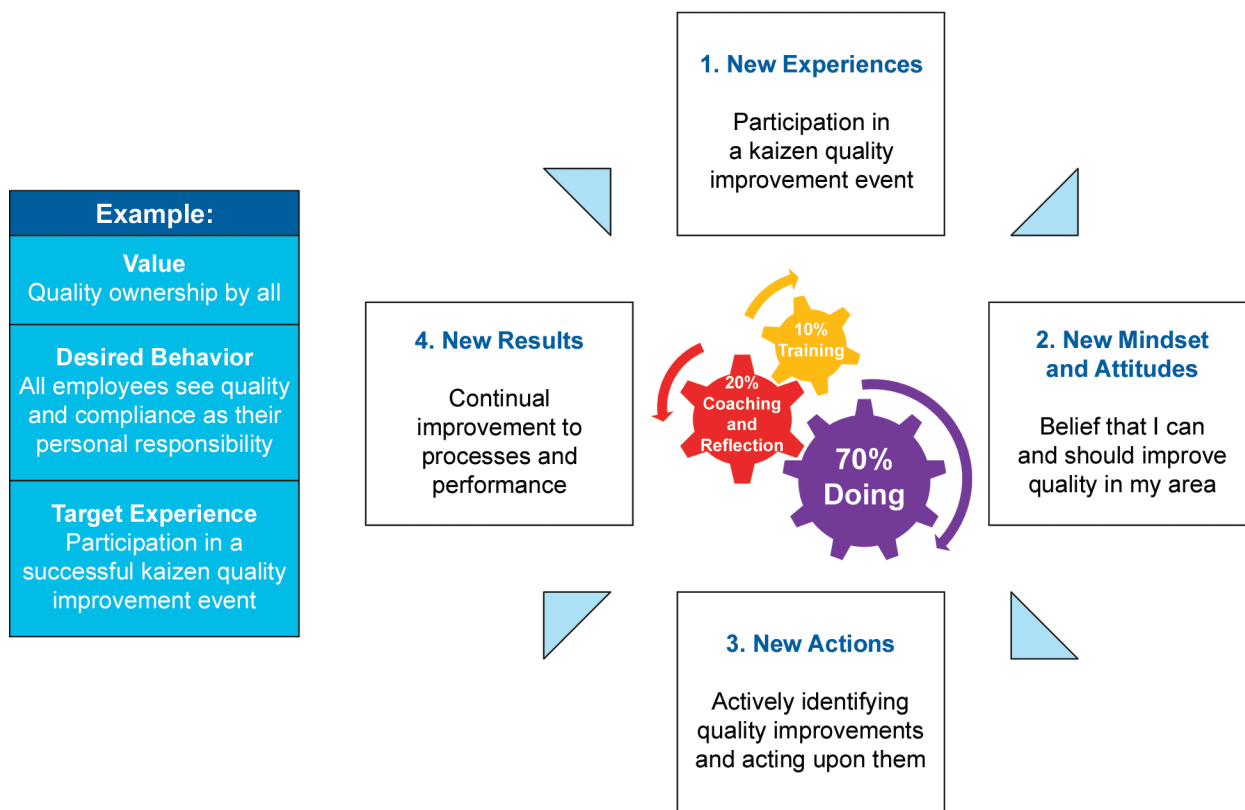
Building the organizational capability to learn requires leaders who value and invest in the power of learning. It requires leaders who personally demonstrate an ability to learn by acknowledging their own lack of wisdom and personal expertise, while demonstrating flexibility in response to change. These “learning leaders” must take the initiative by creating a vision for building a learning organization as well as acting to create the time and space within which “learning teams” can explore, experiment, and experience learning through participation in improvement activities, events, or projects. Such activities could be something as simple as completing an area 5S⁵ checklist for their workplace or conducting a focused kaizen⁶ improvement event on a process or operation they have responsibility for. It could also involve team participation in a larger scale, multi-disciplinary business process improvement project. These learning or improvement teams are the fundamental learning unit in modern organizations. Unless teams can learn, the organization cannot learn.

The ISPE Cultural Excellence Report [6] identified that employee mindsets and attitudes can be shaped using experience-based learning. New learning experiences generate new positive mindsets and attitudes that lead to new actions, generating new results, which continues the virtuous cycle of creating new learning experiences. Figure 5.5 shows this concept of a virtuous experiential learning cycle. This example depicts how a successful kaizen quality improvement event can positively change the mindset and attitudes of the individuals that experience the event directly. Involving teams in these targeted learning experiences are transformational levers to shift mindsets and attitudes from non-quality thinking to a culture of continual improvement and excellence.

⁵ **5S:** A lean manufacturing tool for creating and maintaining workplace efficiency. Each “s” is a Japanese word: *seiri* (tidiness), *seiton* (orderliness), *seiso* (cleanliness), *seiketsu* (standardization), and *shitsuke* (discipline). [6]

⁶ **Kaizen (change for better):** The practice of continual improvement; industrial or business techniques for implementing continual improvement. “kaizen events” are short-duration projects with a specific aim for improvement. [6]

Figure 5.5: A Virtuous Experiential Learning Cycle
Adapted from ISPE Cultural Excellence Report [6].



Based on internationally recognized Lessons of Experience research in adult learning conducted by the Center for Creative Leadership, Figure 5.5 applies the 70-20-10 framework⁷ to experiential learning. In order to shift employee mindsets and attitudes, it is important to be aware that this research finds that only 10% of their learning will stem from the formal training completed as part of a training or development plan, e.g., delivered as classroom-based training or by participation in online learning. The bulk of their learning, 70%, is generated by actually practicing these skills in an on-the-job situation, e.g., learning by doing through participation in a learning or improvement team. A critical final step to ensure these new skills are embedded and sustained requires that the remaining 20% of their learning is supported by coaching and reflection activities that are routinely conducted before, during, and after each learning event with other team members. This coaching and reflection process should be guided by “learning leaders” such as process improvement champions, local process owners, or area management. This virtuous experiential learning cycle represents a learning organization in action.

Sections 6.2 and 6.6 of this Guide provide practical approaches for advancing the maturity of employee mindsets and attitudes and the cultural enablers that underpin the cultural excellence program.

⁷ **70-20-10 Framework:** 70% of learning comes from challenging experiences and assignments, 20% of learning comes from developmental relationships (e.g., team reflection and coaching), and 10% of learning comes from coursework and training. [29]

5.1.5 *The Importance of Standard Work and Systematic Improvement Processes to Engage Employees*

Effective implementation of systematic improvement processes⁸ based on standard work⁹ practices that are used routinely by employees engaged across the organization form the foundation of any successful cultural excellence program. These continual improvement practices represent another example of the key role that an organization's OPEX program plays in the delivery of its cultural excellence goals.

Within the pharmaceutical industry, implementation of standard work should not be confused with the need to have Standard Operating Procedures (SOPs) which is a regulatory compliance requirement. The two concepts are distinct and have very different purposes and goals.

The concept of standard work is a core OPEX philosophy that establishes and documents a standard for the best arrangement of people, materials, and methods within a work area to successfully execute a task, reduce error, eliminate waste, and ensure the safety of those conducting the work. A standard work practice may include details related to the sequence of specific micro-tasks, expected cycle time, provide a checklist of the minimum inventory of components or materials needed to prepare for the activity and often includes visual representations of critical aspects of the task. Tasks that benefit from having standard work practices applied are typically those that require an advanced level of skill and attention to detail or those that have a track record of recurring human errors or repeated safety events.

Other examples of improvement activities that are typically governed by standard work practices include the effective use and deployment of standardized continual improvement tools (e.g., how to run a Kaizen event, how to complete an A3 improvement report¹⁰, how to apply a DMAIC¹¹ process improvement approach) or structured problem-solving tools (e.g., how to use root cause analysis tools such as fishbone diagrams or a control chart).

Improvement requires two integral efforts that go hand in hand. Developing standard work practices that set out how specific individual tasks consistently get done is only one part of the improvement effort. For these practices to be effective, the active sponsorship by management for the systematic implementation of continual improvement processes company-wide is required. Such a commitment cannot be achieved with ad hoc drives for "post-mortem" style (after the event) improvements following a failure event. Instead, to enable proactive "pre-mortem" style prevention and risk reduction requires the systematic deployment of improvement processes that actively engage employees. Such systematic improvement processes might include, but are not limited to:

- A formal process for identification of improvement opportunities by eliciting suggestions and feedback from employees through a formal "good catch" system, with employee engagement metrics and targets to encourage adoption.

⁸ **Systematic Improvement Practices:** The application of standardized operational excellence or continual improvement practices, tools, and approaches to evaluate and execute improvement activities coordinated through a formal operational excellence/continual improvement program.

⁹ **Standard or Standardized Work:** Establishing precise procedures for each operator's work in a production process. The benefits of standardized work include documentation of the current process for all shifts, reductions in variability, easier training of new operators, reductions in injuries and strain, and a baseline for improvement activities. [30]

¹⁰ **A3 Report:** A Toyota-pioneered practice of getting the problem, the analysis, the corrective actions, and the action plan down on a single sheet of large (A3) paper, often with the use of graphics. [31]

¹¹ **DMAIC (Define, Measure, Analyze, Improve, Control) Cycle:** A data-driven improvement cycle for improving, optimizing, and stabilizing business processes and designs; the core tool used to drive Lean Six Sigma projects.

- A tiered accountability¹² and visual performance management¹³ system that reports on routine operational performance, manages key decision and actions, and charts progress on improvement projects within an area (e.g., local tier or shift huddle boards). This tiered accountability process must also have a clear escalation and review cycle with area supervisors and local cross-functional management involvement, reporting up through site leadership for more complex issues and decisions. Above-site review may also be included on a weekly or periodic basis, as appropriate.
- A formal significant investigation process involving rapid response teams who are skilled in the effective use of structure problem-solving methods, data analysis, and critical thinking and knowledge sharing. This process should apply a standardized approach to conducting and completing event investigations and to designing effective CAPAs to reduce the risk of recurrence.
- A standardized Gemba¹⁴ process that sets out the where, when, who, what, and how required to ensure adequate and frequent engagement by leaders with the frontline activities and enables active engagement by employees with their leaders to facilitate knowledge sharing and speak-up opportunities. A range of practical Gemba tools are indexed in Appendix 4 (Section 13.3) of this Guide.
- A proactive performance management system carefully designed using leading indicators that measure what matters to enable the early identification of performance issues, swift action to course correct when necessary, and set meaningful improvement targets that are visible to all.
- A robust reward and recognition program firmly linked to the company values which enables recognition of the desired behaviors and celebration of quality and performance improvements at both individual and team levels.
- Holistic Learning and Development (L&D) programs that are not just based on job-specific technical skills and qualifications but focus on individual competency development and on creating experiential learning opportunities which support critical thinking, knowledge sharing, best practice replication, and other organizational capability building goals.

Standard work, coupled with L&D plans designed for individual competency development, improve the ability of individuals and teams to execute tasks consistently. The design and implementation of systematic improvement processes build organizational capability to control and improve these task effectively. Both are needed to advance quality management maturity and drive cultural excellence.

Sections 6.3 and 6.6 of this Guide provide practical approaches for advancing the maturity of the systematic improvement processes related to employee engagement, Gemba, and the cultural enablers underpinning the cultural excellence program.

¹² **Tiered Accountability Meetings or Huddles:** Meetings at progress or project tracking boards among improvement teams doing status reports on value-stream performance or progress toward value-stream improvement goals and action plans. The meetings identify where expected outcomes are not being achieved and who needs to investigate possible causes and experiment with potential countermeasures. The meetings are usually brief and done standing up. [32]

¹³ **Visual Management:** A key component of Lean and lean management systems, which offers tools and practices that support adherence to standards, quick identification of abnormalities, daily problem solving, organizational alignment, and (when integrated with leader standardized work) the daily routine of lean leaders. [33]

¹⁴ **Gemba:** Well-defined element of Lean concepts and an accepted operational excellence tool in industries that have adopted lean principles. Gemba walks demonstrate visible commitment from the leadership to all members of the organization. [6]

5.1.6 Enabling Proactive Performance Management by Measuring what Matters

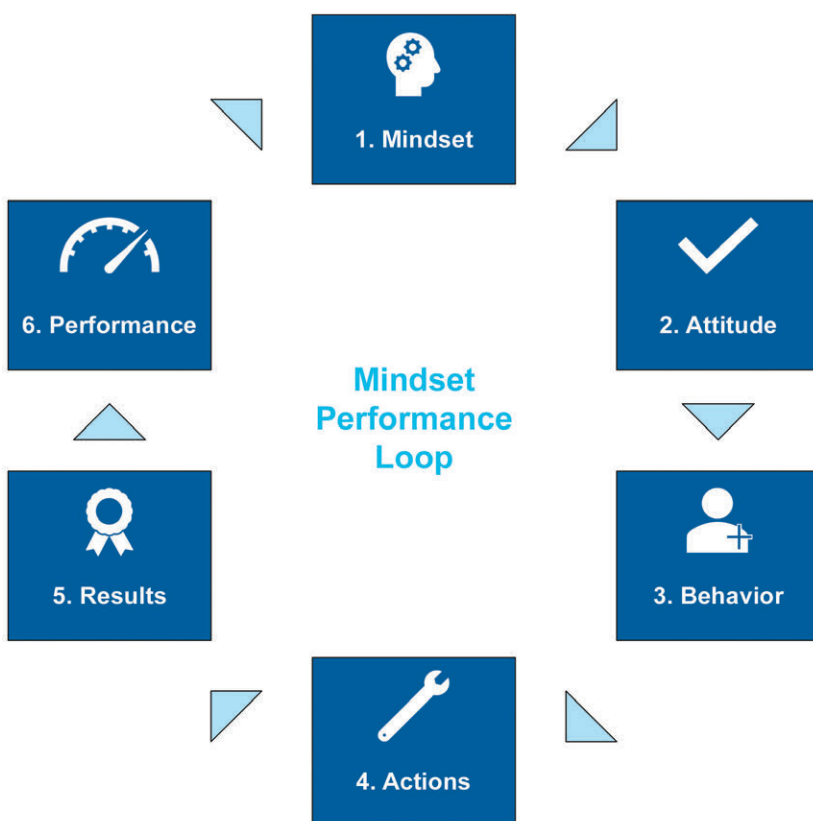
Key Learning: To deliver long-term change in organizational culture, focus on changing the everyday behaviors. It is the daily practice of the new “desired” behaviors that changes the culture.

To transform organizational culture and to shift the prevailing mindsets, it is necessary to first identify and select the “desired” behaviors most critical for the success of the organization. The challenge then becomes a matter of modeling and embedding these new behaviors into the daily work practices, so they become hardwired into new habits and employees themselves become champions of the transformation effort [19].

This concept of how influential prevailing mindsets and behaviors are in terms of performance outcomes was illustrated in the ISPE Cultural Excellence Report [6] as the mindset performance loop and is shown in Figure 5.6.

Figure 5.6: The Mindset Performance Loop

Source: Adapted with permission from leadership and high performance advisor, Shane Cradock © 2022, www.shanecradock.com.



A company's ability to monitor and shape the prevailing mindset and attitudes can greatly increase results and performance. Figure 5.6 shows the process by which mindset influences attitudes, which directly influence the acceptable behaviors, which influence the actions taken (or not taken), which influence the results and the overall performance outcomes. This means that if we are not purposeful about managing the mindset, we may achieve the results we deserve rather than the results we desire. When the impact of mindset on performance is well understood by management and leaders, this becomes a continual improvement loop where new results and performance positively shape the organizational and individual mindset.

To pursue a patient-focused culture of excellence, there needs to be a shift away from reactive, “detect and correct” mindsets and the associated compliance-led behaviors towards a more proactive, preventive approach championed by enlightened leaders and practiced by engaged employees. Employees need to become passionate about eliminating mistakes by learning to think critically and apply their knowledge and skills to make decisions in complex situations, while reflecting more deeply about the potential risks and consequences of their day-to-day actions. This requires a more process-focused approach to quality, examining what is known about the process through knowledge sharing, process trending to observe areas of near or potential failure, and identifying opportunities and overcoming barriers for process improvement.

Teams should be provided with practical opportunities to engage in proactive prevention by encouraging and rewarding them to raise their concerns about potential risks or issues before they result in a failure or safety event. This could be facilitated by routinely asking direct questions about any risks or concerns at the local operations or at shift handover meetings, capturing employee suggestions in a “good catch” system, and having local managers recognize these preventive efforts during their Gemba walks. Another way to shift the attention from correction to prevention is to periodically run team brainstorming events on a given process to identify ways to reduce risks, waste, or inefficiencies. Once opportunities are identified, teams can actively engage in improvement projects based on greatest need or operational priorities.

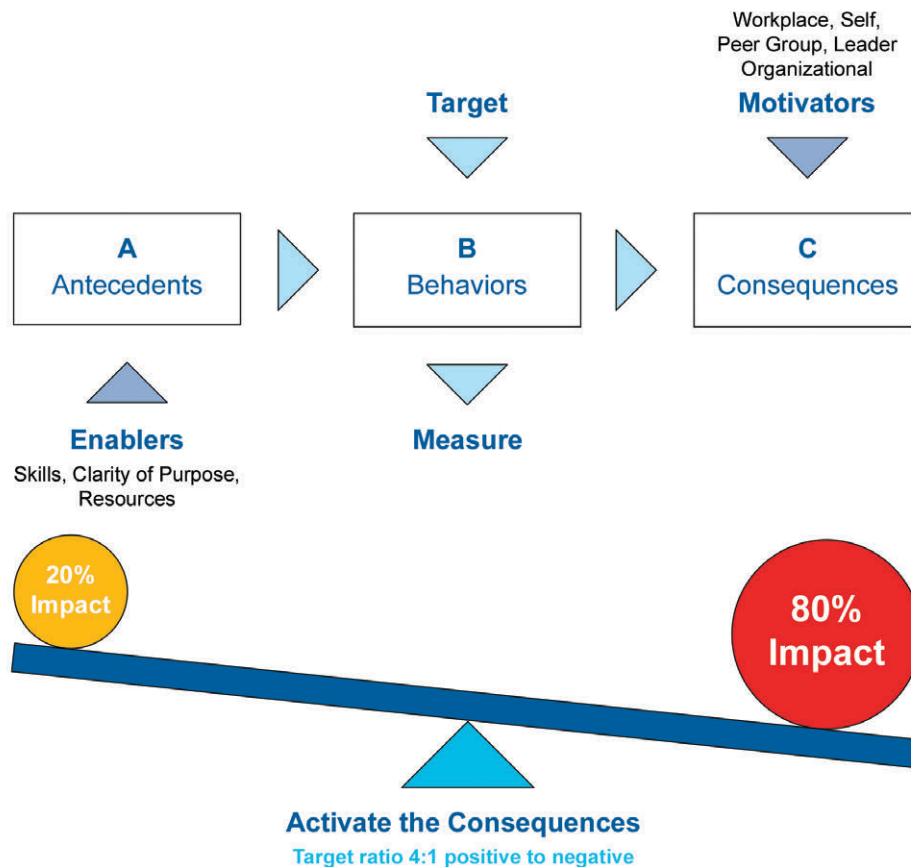
If the route to improvement is through behavior, it now becomes obvious that behaviors must be incorporated into the performance management process.

Within the pharmaceutical industry, traditional performance management metrics or quality dashboards can rely too heavily on KPIs which are primarily focused on lagging (historical) compliance-based metrics, with fewer oriented toward proactive, leading indicators of quality.

Leading indicators typically measure behaviors and can be early predictors of outcomes. Lagging indicators, on the other hand, tend to be historical measurements of past results.

The ISPE Cultural Excellence Report [6] introduced practical concepts that can be useful in designing behavior-based leading performance indicators. Figure 5.7 shows the ABCs of behavioral science based on the work of Braksick [20] and Morse [21]. This concept indicates how Antecedents lead to Behaviors, which lead to Consequences.

Figure 5.7: The ABCs of Behavioral Science – Activating the Consequences [6]



Antecedents are events that precede behaviors; they trigger what people say and do. They enable behaviors but they do not motivate behaviors. Examples of antecedents include: hiring suitably qualified candidates, training them on the organizational procedures and processes, and setting up a formal job description outlining their duties. Behavioral science research shows that antecedents only exert approximately 20% of the influence on our behaviors [20]. Yet this is where the greater proportion of management time and resources are spent in the selection and development of our workforces.

Consequences motivate behaviors by either reinforcing how the desired behavior delivered the required performance outcome or discouraging unsuccessful behaviors as a result of failed outcomes. Consequences determine if behaviors will recur and exert 80% of the influence on our behaviors. Yet research shows that there is an overreliance on antecedents to foster new behaviors and when they fail to deliver, management piles on more antecedents (e.g., issue more memos, pep talks, training and retraining events, restate expectations of what needs to get done) [20]. Unfortunately, to a large extent, management leaves consequences unmanaged. Examples of consequences that could better positively reinforce behaviors and increase employee engagement include: leader recognition by personally thanking employees who speak up, celebrating the identification of a near miss, rewarding successful root cause analysis activities completed when failures do arise, rewarding teams engaged in improvement projects, promoting employee suggestion/improvement project of the month awards, sharing employee stories of learning from mistakes, encouraging teams/individuals to host a lunch-and-learn session to share lessons learned, and offering opportunities for teams and individuals to get involved in internal and external networks to learn and share best practices with their peers.

Ultimately, the balance required is to focus on selecting the right antecedents that are backed up by activating the appropriate consequences. This strategy will produce the greatest effect on changes in behavior by designing change programs that not only outline the goals but seek to motivate the desirable behaviors necessary to achieve those goals.

A typical example of “if we measure the wrong things, then the wrong things get done” found in many pharmaceutical companies is related to the KPI which measures the number of CAPAs closed within 30 days. While acknowledging the compliance driver to ensure timely closure of actions to address a known failure, the design of the metric can also drive the wrong behaviors and consequently the wrong outcomes for the patient and the business. This “30 day closure” criteria can end up being reduced to a productivity measure for how busy the Quality Assurance (QA) department was on day 29 or day 30 of closing CAPAs within the PQS, rather than a driver for local operations departments to identify, eliminate, and prevent known causes of failure, or worse, recurring failures. A much more effective way of ensuring an organization’s ability to manage their deviation and CAPA processes would be to incorporate leading quality indicators such as:

- **Recurring deviations rate (as a percentage of all deviations):** Identify the current recurrence rates, then build awareness of the impact of recurring deviations for the patient and the business, and promote the importance of learning from mistakes. Set small but achievable operational targets for local departments to reduce their recurrence rate through targeted improvement projects and celebrate the wins. To ensure this driver does not lead to unintended consequences of under reporting, report progress on the area recurring deviation rate as well as the employee engagement rate (the number of employees involved in improvement projects in the area).
- **Number of significant investigations or CAPAs commenced within 2 days of the failure event:** Best practice confirms that responding quickly to a failure event yields the best chance of providing an effective solution to the problem. This involves setting the expectation for the investigation team or lead (those with specialist structured problem-solving skills) to go directly to the place of the event and talk to the people involved to gain understanding at the earliest available opportunity (within the first few days) while the details and evidence are still fresh in people’s minds. Setting a target for the investigation to start rather than focusing the KPI on the end date promotes more timely and accurate solutions.
- **Rate of preventive actions to corrective actions recorded in the CAPA system:** Measuring the ratio of preventive to corrective actions implemented encourages teams to focus their efforts on prevention rather than cure. Setting local targets for preventive actions can seed improvement suggestions from the team to surface potential issues and risks. It offers an opportunity to then engage those employees in the improvement actions, before the failure event. This encourages a proactive rather than reactive mindset within the team.
- **Proportion of CAPAs that include retraining due to human error:** In the hierarchy of effective risk control mechanisms, operator retraining is well recognized as the least effective control of future failures categorized as human errors. Retraining ranks just below rewriting the procedures in the risk control effectiveness hierarchy. More robust controls to reduce the opportunity for human errors to arise include re-engineering/automating the process, which can include setting process alerts utilizing process capability data or other proactive process alerts to trigger preventive actions based on threshold indicator values. The most effective risk controls involve replacing or removing the risk by eliminating the necessity for human intervention. Setting targets to reduce the number of CAPAs that include retraining as the primary control mechanism encourages teams to explore more effective, longer-term solutions to issues.

Reducing the overall number of failure events is the primary focus of an effective PQS. Reducing the potential risk of future failure events arising is a secondary driver. Integrating thoughtfully designed leading indicators of quality will help to ensure that organizations are measuring what matters.

5.1.7 Using Leading Behavioral Indicators to Measure what Matters

The use of Leading Behavioral Indicators (LBIs) is a practical way to bring this “measuring what matters” concept closer to the frontline teams, i.e., those with the greatest influence on actual performance outcomes. Involving these local teams in designing measurable leading indicators that are directly related to their behaviors and actions enables the teams to purposefully focus on the behaviors and actions that can and will improve outcomes. The ISPE Cultural Excellence Report [6] introduced a tool for deriving LBIs from existing management KPIs as a means of reinforcing positive behaviors that contribute to desired quality and performance outcomes. The LBI-IMPACT tool comprises the following steps:[6]

- Assemble a local improvement team and get them to **Identify** the desired quality or performance improvement goal (the top-level goal)
- Establish the existing **Measure** (KPI) used to confirm and report achievement of the goal
- Get the team to **Pinpoint** the “desired” behaviors necessary to deliver the goal (brainstorm the behaviors that contribute to successes and failures)
- **Activate** the **Consequences** to motivate the delivery of the goal (target a ratio of 4:1 positive to negative actionable consequences to motivate the team towards achievement of the goal)
- **Transfer** the knowledge across the organization to sustain the performance improvement (share best practices and lessons learned with other teams)

Table 5.2 provides an example of the LBI-IMPACT tool with a focus on implementing local team-based LBIs as part of the continual improvement and cultural excellence program. In this example, the team was seeking to promote Right First Time (RFT) behaviors within a typical pharmaceutical manufacturing setting.

Table 5.2: Example of How the LBI-IMPACT Tool Can Be Used to Design LBIs for Local Teams to Champion Behavioral Change

Adapted from ISPE Cultural Excellence Report [6].

I Identify Goal	Consistent delivery of high-quality medicinal products.
M Select the Measure To Deliver Goal	Increase the number of RFT batches to X%.
P Pinpoint the Behaviors	<ol style="list-style-type: none"> 1. Promote and coach for enhanced attention to detail where “quality is everyone’s job” through leadership and vision, as well as routine Gemba walks. 2. Encourage a speak-up culture where concerns, issues, or suggestions are shared in a timely manner in a neutral, constructive forum. 3. Run a series of local workshops with the team to identify behaviors that contributed to successful outcomes and to establish ways to measure these behaviors for every batch on the local visual management board. Begin proactive daily multidisciplinary interim batch issue review for early detection and resolution. Measure attendance at these meetings and number of good catches identified.
AC Activate the Consequences	<ol style="list-style-type: none"> 1. Organize team briefings on the consequences of rejected or delayed batch approvals for the business and the patient. 2. Review outcomes from recent rejected or delayed batches or relevant customer complaints with the team. 3. Senior leadership and local management celebrate/acknowledge each RFT batch during Gemba walks. 4. Use local visual management boards for motivation on progress toward KBI and KPI goals. 5. Acknowledge and recognize improvement efforts by team members in team/public areas/newsletters. 6. Motivate the team through team awards, e.g., movie tickets, team lunches.
T Transfer Knowledge and Skills to Sustain Change	<ol style="list-style-type: none"> 1. Create learning teams use root cause analysis (RCA) tools to proactively identify and document solutions to issues raised. 2. Lessons learned are documented and shared with wider workforce. 3. Lunch-and-learn sessions are arranged to facilitate Q&A between different improvement teams. 4. Create improvement case studies in a shared area on intranet.
Leading Quality Indicators/ Leading Behavioral Indicators	<p>Leading</p> <ol style="list-style-type: none"> 1. Measure and report attendance at the multidisciplinary daily meetings. 2. Number of employee/team RFT improvement suggestions implemented (by period). 3. Number of good catches identified at interim batch reviews (by batch). 4. Number of successful RCA exercises completed (by period). <p>Trended Lagging</p> <ol style="list-style-type: none"> 1. % RFT batch approvals/investigation free lots. 2. % RFT batch records (paperwork completions).

In this example shared in Table 5.2:

- The high-level goal identified (I) for the local team was to improve their ability to consistently deliver high-quality products.
- The existing KPI measure (M) selected to report progress towards this goal was to achieve X% RFT batch approvals, i.e., the total percentage of “started” batches to be successfully “completed and approved” and which are investigation or deviation-free. (Note: all “started” batches need to be included in this measure so that any aborted or rejected batches are not hidden from the results.)

- To establish this target, a baseline figure for the past year was calculated and an achievable improvement of +10% on that baseline was agreed upon with the local teams.

This is the point at which many traditional performance management systems stop. They identify the goal and select a KPI, leaving the consequences unmanaged. They report progress on a monthly basis and wonder why improvement is not achieved or sustained in the long term.

- Using the LBI-IMPACT tool, the next step is to get the team to brainstorm and pinpoint (P) the desired behaviors that can contribute to enhanced RFT outcomes. In this example, the team was coached on the importance of enhanced attention to detail and the need to prepare, focus, and support each other on critical tasks. A pareto analysis of recent causes of failures was undertaken and the top three causes were targeted for improvement/enhanced focus by the team. Concerns and issues were then proactively surfaced through speak-up sessions at local daily tier meetings/shift huddles. Multi-disciplinary interim, on-the-shopfloor, reviews of batch related paperwork were incorporated as part of the daily checks to detect and avoid any issues arising and to maintain focus on RFT behaviors and actions. Progress on the improvement projects were reported by the teams involved.
- In terms of activating the consequences (AC), a range of measures were taken. Firstly, increased awareness of the impacts of delayed or rejected batches was shared with the local teams. Acknowledgement of improvement efforts by leaders during Gemba walks was undertaken, and local team recognition and rewards were linked to successful process improvements and near misses/good catches.
- Finally, team members were offered the opportunity to share their improvement experience with their peers. The new knowledge gained and lessons learned were transferred (T) as best practice or as part of after-action reviews with other teams in the organization.

Using the LBI-IMPACT tool to derive locally relevant LBIs offered this team an ability to monitor leading behavior-based quality indicators on their local visual management boards. This included levels of engagement at the daily multi-disciplinary meetings, numbers of RFT improvement suggestions successfully implemented, numbers of near miss events avoided, and number of root cause analysis events for non-RFT errors completed by the team (capturing the learning from mistakes). In addition to trending the existing (lagging) KPI of % RFT batches actually achieved, an additional KPI related to % RFT batch paperwork completed was also reported on (i.e., paperwork errors that contributed to a non-RFT batch approval delay).

The takeaway message here is that there is no single “silver bullet” (simple solution) to target and measure behavioral change. The intention of the LBI-IMPACT tool is to empower local teams to identify a range of small, meaningful changes in their patterns of behavior that together can contribute to improved quality and performance outcomes. Promoting ownership and accountability for quality and performance outcomes using LBIs designed and actioned by local teams can and will sustain real improvements in results that matter to the patient and the business.

Sections 6.4 and 6.5 of this Guide provide practical approaches for advancing the maturity of designing proactive performance management processes to ensure that organizations are measuring what matters.

5.1.8 Active Reward and Recognition Programs Linked to Organizational Values

Reward and recognition programs can have a significant influence on changing mindsets and attitudes within the organization. They are a crucial, yet often overlooked, cultural enabler to support the successful deployment of the cultural excellence program. It is most important that the reward and recognition programs are directly linked to the values and desired behaviors defined for the organization.

Employees respond to appreciation expressed through **recognition**. It confirms that their behavior or results are valued by others and when valued, job satisfaction and productivity rise. Employees become motivated to maintain or improve their work and on-the-job performance. Moreover, positive behaviors that are recognized are more likely to be repeated. Being recognized provides a feeling of job mastery and of being a good fit for the role and the company.

Acknowledgement can enhance both company and leader loyalty and promote greater levels of collaboration. Employee recognition in the workplace is the foundation of cultivating an attitude of gratitude and encourages a culture of learning.

When one expresses authentic gratitude to another person, the sentiment creates a multiplier effect. This is known as “the recognition effect”, where a simple action of acknowledging an ideal behavior can trigger additional positive outcomes. The recognition cycle can work to the mutual benefit of both employee and employer through positive feelings, increased satisfaction, productivity, and business results. Figure 5.8 shows the potential impact of this effect.

Figure 5.8: The Recognition Effect



Not all recognition is equal though, and care should be taken in the way recognition is shared so that it does not lead to undesirable result or unintended consequences contrary to the intention of motivating teams to succeed. Table 5.3 provides key points for ensure recognition practices have the desired impact.

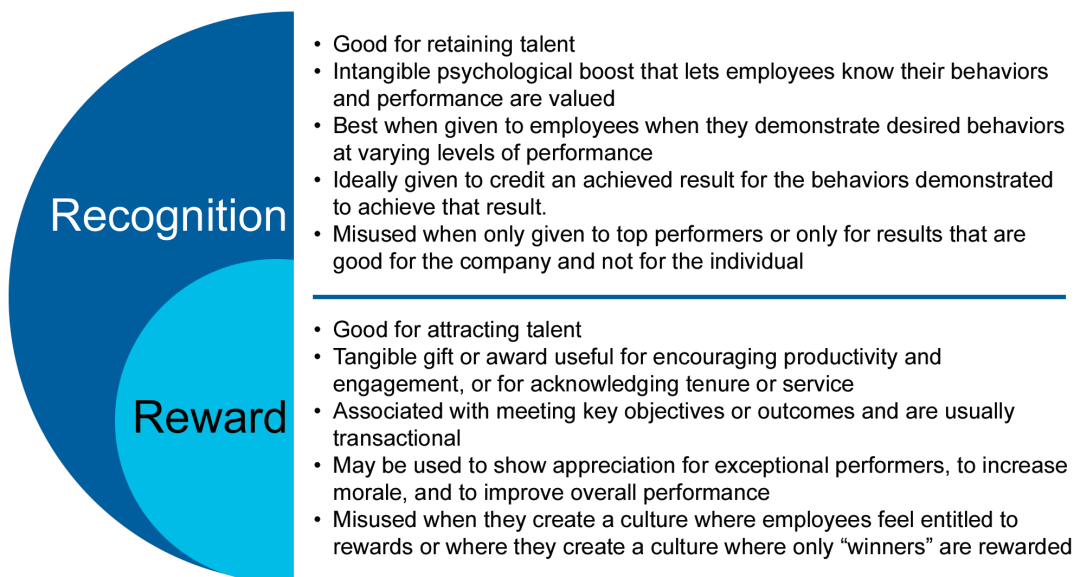
Table 5.3: Effective Employee Recognition Practices

Recognition is done well if it is...	Recognition should be improved if it is...
Timely	Late
Sincere/Personal	Generic
Given for demonstrating desired behaviors	Focused only on hard goals
Givers and receivers are at all levels	Given only from top executive level
Given formally and informally	Given only formally
Visible and transparent	Non-apparently at a program level
Inherently practiced by leaders	“Flavor of the Day”, short-term initiative

Providing a psychological boost through recognition lets employees know that their behaviors and performance meet or exceed expectations and are valued. Team recognition is also important in driving participation by team players across the organization in working collaboratively toward common quality and performance improvements goals. Recognition is a very effective practice for retaining talent.

On the other hand, **rewards** provide a different motivational lever and can be used for attracting talent, encouraging productivity and engagement, or for acknowledging tenure or service. Rewards are typically associated with meeting organizational goals and objectives or performance outcomes and are usually tangible and transactional. They may be used to show appreciation for exceptional performers to increase morale (e.g., annual excellence awards) or to improve overall performance. However, rewards can be misused when they create a culture where employees feel entitled to rewards or a culture where only “winners” are rewarded. Figure 5.9 outlines the distinctions between recognition and reward practices and how they should be targeted to have the desired impact.

Figure 5.9: Distinction between Rewards and Recognition Practices



Sections 6.2 and 6.6 provide practical approaches for advancing the maturity of the mindsets and attitudes and the cultural enablers through effective use of rewards and recognition practices that support the cultural excellence program.

5.1.9 Leveraging Diversity, Equity, and Inclusion Programs to Support the Cultural Excellence Program

There has been a growing emphasis and recent proliferation of diversity, equity, and inclusion (DEI) programs across the corporate world. These programs are intended to enhance empathy, address inherent inequities, and create inclusive and open environments where every employee feels safe and has the opportunity to contribute. The goals, practices, and behaviors that are at the heart of these DEI programs are fully aligned with creating a culture of excellence and offer a key partnership opportunity on the journey to ensure all voices are heard in a quest to “crowdsource” excellence.

A leading inclusion strategist and author, Ruchika Tulshyan, points to the need for organizations to turn empathy into action and offers practical advice on cultivating an inclusion mindset at work. [22] She has coined a useful acronym of BRIDGE, outlining some key behaviors to consider when seeking diverse opinions and perspectives:

- **Be** OK with being uncomfortable