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BSR/PDA Standard 006-202x, Assessment of Quality Culture
Guidance Documents, Models, and Tools

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Committee Draft

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BSR/PDA Standard 006-202x, Quality Culture Assessment of Quality Culture Guidance Documents, Models, and Tools

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1. Introduction

Global Health Authorities are increasingly emphasizing the importance of quality culture within organizations which produce medicinal products for the healthcare industry. Pharmaceutical and medical device companies have been developing an understanding of how they can respond to health authority expectations and what criteria and metrics are important in the assessment of quality culture maturity. However, there is currently no agreed-upon standard designed specifically for this industry. The goal of this standard is to provide detailed comparisons of how each model addresses the key factors in pharmaceutical quality culture so that an organization can choose what is most effective for their needs, not to provide general pros and cons.

The purpose of this standard is to identify key focus topics with attributes, characteristics, and measurements that should be considered to effectively establish, measure, and maintain a mature quality culture as an important fundamental element of a robust quality management system.

This standard also reviews several available quality culture assessment resources and what approach each takes in addressing the recommended key focus topics to allow an organization to determine whether one of these programs may be a best fit for their needs.

There were many contributors including Joseph Juran, Walter Shewart, and W. Edwards Deming, in the history of quality management that led to the development of quality culture across multiple industries which are foundational to the current discussion in the context of pharmaceutical manufacturing within the scope of this standard [36]. Quality Culture refers to an organizational culture that intends to enhance a quality mind-set which is characterized by two distinct elements. The first is a cultural/psychological element of shared values, beliefs, expectations, and commitment towards quality. The second is a structural/managerial element with defined processes that enhance quality and drive for continuous improvement at all levels of the organization.

The United States Food and Drug Administration (US FDA) initially focused on the use of quality metrics to modernize pharmaceutical quality systems and advance innovation. They conducted pilot programs to refine their risk-based inspection model, optimize their evaluation of drug manufacturing, control operations, and to identify situations in which there may be a risk for drug supply disruption. Over time, it became clear that both a robust quality system containing metrics and a mature quality culture are fundamental to achieving continuous improvement and thereby reducing risk to product quality and ensuring patient safety.

Many basic elements inherent to a quality system that conforms with global CGMP are facilitated by a strong quality culture. For example, CGMP requires personnel competencies, data integrity, quality risk management, CAPA, change management, process performance and quality monitoring, systems for error and defect prevention, timely actions, accountable senior management, continual improvement, operations that reflect current technological capabilities, and a continuing state of control.

The concept of quality culture has evolved as an auditable focus area for regulators. Since 2015, the U.S. FDA, Medicines and Healthcare Products Regulatory Agency (MHRA), Pharmaceutical Inspection Scheme (PIC/S), and the World Health Organization (WHO) have all issued guidance on data integrity [31-34]. These guidance documents advise companies to address quality culture as a means to foster transparent communication from management to all levels as a foundation for pharmaceutical quality systems. This standard includes key source documents that span the topic of quality culture as a foundational element of a strong quality management system.

In 2022, FDA sponsored a virtual workshop on a quality management maturity model that included assessment of both metrics and quality culture along with other factors. In 2023 they published a White Paper titled: *CDER's Quality Management Maturity (QMM) Program: Practice Areas and Prototype Assessment Protocol Development*. This paper discussed the assessment approach planned to be used at establishments participating in their QMM program [30].

The ISO 9000 and 10000 document series have been adopted as global standards to describe many aspects of quality management systems. ISO 9000:2015, 2.2.1, states that "an organization focused on quality promotes a culture that results in the behavior, attitudes, activities and processes that deliver value through fulfilling the needs and expectations of customers and other relevant interested parties" [1]. ISO 10018:2020(E) identifies a

167 "strong, positive quality culture, where people agree upon and care deeply about organizational values, can
168 improve organization performance, motivate people and coordinate their behavior towards a vision and specific
169 performance goals" [2]. ISO 10010:2022 *Quality Management – Guidance to understand, evaluate and*
170 *improve organizational quality culture to drive sustained success* [3] describes the importance of assessing
171 quality culture and calls on the organization to "determine the appropriate tools and techniques to obtain
172 meaningful data which will contribute towards an understanding of the organization's quality culture."

173 There are models that have demonstrated the business benefits of a strong quality culture in other industries,
174 such as the Corporate Executive Board (CEB) and PricewaterhouseCoopers (PwC) [15-16]. However, they are
175 not adapted specifically for current Good Manufacture Practice (CGMP) environments and are not reviewed
176 in this standard. The FDA guidance 'Fostering Medical Device Improvement: FDA Activities and
177 Engagement with the Voluntary Improvement Program' was not considered as the FDA and the Medical
178 Device Innovation Consortium (MDIC) program activities and operations are transitioning into a permanent
179 program, titled the Case for Quality Voluntary Improvement Program (CfQVIP). The guidance issued to date
180 is in draft and the complimentary policy for engaging with CfQVIP is not yet finalized.
181
182 This standard is intended to guide organizations to determine which tools or techniques are most appropriate
183 for assessment of quality culture maturity given their specific circumstances. In addition, it includes common
184 vocabulary to describe the various terms and concepts that are applicable to quality culture.
185
186

2. Scope

188 This proposed American National Standard (ANS) evaluates various guidance documents, models, and tools to
189 measure and provide a better understanding of quality culture for the pharmaceutical/medical device industry.
190 The standard identifies 5 key focus topics with attributes, characteristics, and measurements that should be
191 considered to effectively establish, measure, and maintain a mature quality culture as an important fundamental
192 element of a robust quality management system. The 5 key focus topics were selected from the PDA Quality
193 Culture Assessment Tool for their comprehensiveness. See section 4 titled **Terms and Definitions** for the
194 meaning of each.

195 The key focus topics selected were:
196
197 • Leadership Commitment
198 • Communication and Collaboration
199 • Employee Ownership and Engagement
200 • Continuous Improvement
201 • Technical Excellence
202
203 This standard supports the assessment of an existing quality culture and the establishment of a mature quality
204 culture that is compatible with Health Authority and industry regulatory expectations in the context of the
205 current GxP landscape for the pharmaceutical/medical device industry. It provides a thorough review of the
206 references and summarizes best practices by highlighting the key characteristics that each provides for an
207 organization to review.
208
209 A quality culture assessment that conforms to this standard will:
210
211 a) Collect verifiable data to assess culture at all levels of the organization.
212 b) Identify opportunities to facilitate and sustain positive changes and continuous improvement within
213 their organization.
214 c) Determine at what level a quality mindset and behaviors are embedded into the daily work of the
215 individuals.
216 d) Involve employees at all levels to ensure a broad overview across the organization.
217
218

3. Relevant References

220 The following quality culture resources were chosen to represent a cross section of currently existing models,
221 tools, and guidance documents that could be considered for use by pharmaceutical manufacturing
222 establishments. Each of them was evaluated within the five key focus topics so that users of this standard have
223 direction about which resource is the most applicable for their own specific situations.

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3.1. ISO10018:2020 Quality management — Guidance for people engagement [2]

226 The *ISO10018:2020 Quality management — Guidance for people engagement* document gives guidelines for
227 engaging people in an organization's quality management system and guidance on enhancing their
228 involvement and competence within it.
229 This document is applicable to any organization, regardless of its size, type or activity.
230 The standard describes the importance of establishing a quality culture and the need for leadership and
231 management "to establish a unity of purpose and shared values." In general, this standard lays out concepts
232 for quality culture and considerations for its implementation including potential actions steps. It also discusses
233 how the concepts are linked to and supportive of other ISO quality management standards. This document
234 generally serves as a framework to identify any large gaps in an existing quality culture program as well as a
235 reference to other quality related ISO standards and is a starting point for a high-level overview of quality
236 culture concepts.

237 **Figure 1: ISO10018:2020 Quality Management Framework**
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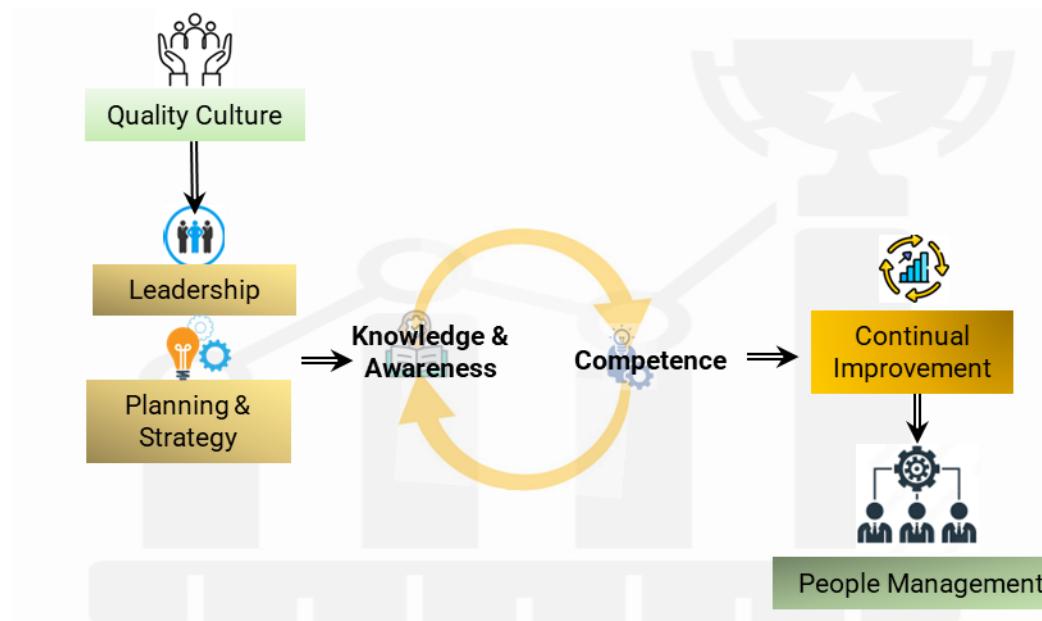
240 (Member adapted)

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3.2. ICHQ10 Pharmaceutical Quality System [4]

243 The International Conference on Harmonisation's (ICH) quality guidelines Q8, Q9, Q10 and Q11 identify
244 important key focus areas for a pharmaceutical quality system [4-7].

245 Of these, ICH Q10 is the most relevant for quality culture because it describes a comprehensive model for an
246 effective pharmaceutical quality management system. It is based on International Organization for
247 Standardization (ISO) quality concepts, including applicable good manufacturing practice (GMP) regulations,
248 and integrates with ICH Q8 Pharmaceutical Development and ICH Q9 Quality Risk Management.

249 The ICH Q10 guidance provides the following parameters: Management Responsibilities and Review;
250 Knowledge Management, Corrective and Preventive Action, Change Management, Quality Risk
251 Management, Process Performance and Product Quality Monitoring.

252 ICH Q10 is a model for a pharmaceutical quality system that can be implemented throughout the different
253 stages of a product lifecycle. Much of the content of ICH Q10 applicable to manufacturing sites is currently
254 specified by regional GMP requirements. ICH Q10 is not intended to create any new expectations beyond
255 current regulatory requirements. Certain elements of ICH Q10 may not be explicit requirements, depending on
256 regional requirements. For instance, GMP also does not typically encompass the earliest product development
257 phase in which a dosage form is being selected but does kick in when product formulation and packaging is
258 chosen and when batch experimentation begins for purposes of process development. GMP also does not
259 specify a requirement for ICH Q10 elements such as quality manual, a DOE-based design space, enhanced
260 approaches using PAT, or changes in business environment and objectives.   ICH Q10 demonstrates industry
261 and regulatory authorities' support of an effective pharmaceutical quality system to enhance the quality and
262 availability of medicines around the world in the interest of public health. Implementation of ICH Q10
263 throughout the product lifecycle should facilitate innovation and continual improvement and strengthen the
264 link between pharmaceutical development and manufacturing activities.

265 This guideline applies to the systems supporting the development and manufacture of pharmaceutical drug
266 substances and drug products, including biotechnology and biological products, throughout the product
267 lifecycle. Although not explicitly stated, ICH Q10 aligns with the foundational elements/concepts in this
268 proposed standard that are critical for a successful quality culture (2).
269
270 **Figure 2: ICHQ10 Pharmaceutical Quality System Framework**
271

272
273   https://www.simplerqms.com/ich-q10-pharmaceutical-quality-system/
274   Quality System Model ICH Q10 - ppt video online download https://search.app.goo.gl/4UhdUpT

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277 **3.3. European Foundation for Quality Management (EFQM) Excellence Model [8]**

278 The EFQM is a not-for-profit organization founded in Brussels in 1989 that partners with more than 50 thousand
279 organizations across the globe to provide the skills to develop a culture of continuous improvement. The EFQM

280 Model "is a globally recognized management framework that supports organizations in managing change and
281 improving performance." It is a model, essentially developed within the European environment and taking into
282 account regulations in the EU market. The Model structure is based on the 3 key sections labeled Direction,
283 Execution, and Results.

284 The purpose of the model is to help organizations achieve success by measuring where they are on the path to
285 create sustainable value. It helps understand the gaps and possible solutions available, empowerment to
286 progress and significantly improve an organization's performance.

287 Each key section (Direction, Execution and Results) can be assessed with a scoring matrix chart. The assessment
288 follows a RADAR (Results, Approaches, Deploy, Assess, Refine) logic. The maximum number for each sub-
289 category, which is divided across the seven criteria as shown in the image below, varies between 100 and 200,
290 adding up to a maximum of 1000 points. Therefore, success is measured using a multi-dimensional and holistic
291 approach.

292 **Figure 3: European Foundation for Quality Management (EFQM) Excellence Model Framework**

294 https://efqm.org/the-efqm-model/

296 **3.4. Malcolm Baldrige Excellence Framework [9]**

297 The Baldrige Performance Excellence Program is designed around a set of core values and concepts which are
298 embedded in systematic processes leading to measurable performance results in the following categories:
299 Leadership and Governance, Financial, Market and Strategy, Product and Process, Workforce, and Customer.
300 Although the concepts remain aligned, the evaluation criteria are customized for application in three sectors:
301 Education, Healthcare and Industry. The Excellence Framework provides definitions and evaluation criteria
302 for the following core concepts:

    a) Systems Perspective

    b) Visionary Leadership

    c) Customer- (or Patient-, or Student-) Focused Excellence

    d) Valuing People

    e) Organizational Learning and Agility

308   f)   Focus on Success

309   g)   Managing for Innovation

310   h)   Management by Fact

311   i)   Societal Contributions

312   j)   Ethics and Transparency

313   k)   Delivering Value and Results

314
315   The below diagram from the Malcom Baldridge framework illustrates interdependency of the core concepts
316   just discussed.
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319   **Figure 4: Malcom Baldridge Framework**
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321
322   (This figure (or figure used on slide) is used with permission of the Baldrige Performance Excellence Program. 2023. *2023–2024*
323   *Baldrige Excellence Framework: Proven Leadership and Management Practices for High Performance.* Gaithersburg, MD: U.S.
324   Department of Commerce, National Institute of Standards and Technology. Purchase a copy of the Baldrige Excellence
325   FrameworK®.)
326

327   ## 3.5. Shingo Model [10]

328   Dr. Shigeo Shingo was an early pioneer developing the concepts of LEAN, Total Quality Management, and
329   Just in Time manufacturing working with Toyota in Japan. His approach to quality centered on the belief that
330   long-term success depends on a relentless quest to improve.   Sustainable results require a culture in which
331   every person is engaged every day in making improvements to systems and tools and having that culture
332   aligned to specific guiding principles.   The Shingo Model has been developed and refined based on research
333   by the Shingo Institute established in his memory at the University of Utah in the United States. The ten
334   Shingo Guiding Principles are divided into three dimensions: Culture Enablers which addresses the people of
335   the organization; Continuous Improvement which focuses on ensuring the processes maximize value; and
336   Enterprise Alignment which emphasizes a common focus on the systematic thinking and primary purpose of
337   an organization to create value for the customer. Within each of these dimensions the guiding principles are
338   further elaborated, and the model describes enablers that can be used to ensure the culture is aligned and
339   makes best use of the systems and tools to deliver the desired results.
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346 **Figure 5: Shingo Guiding Principles**

The Shingo Model ™

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348 https://shingo.org/shingo-model/

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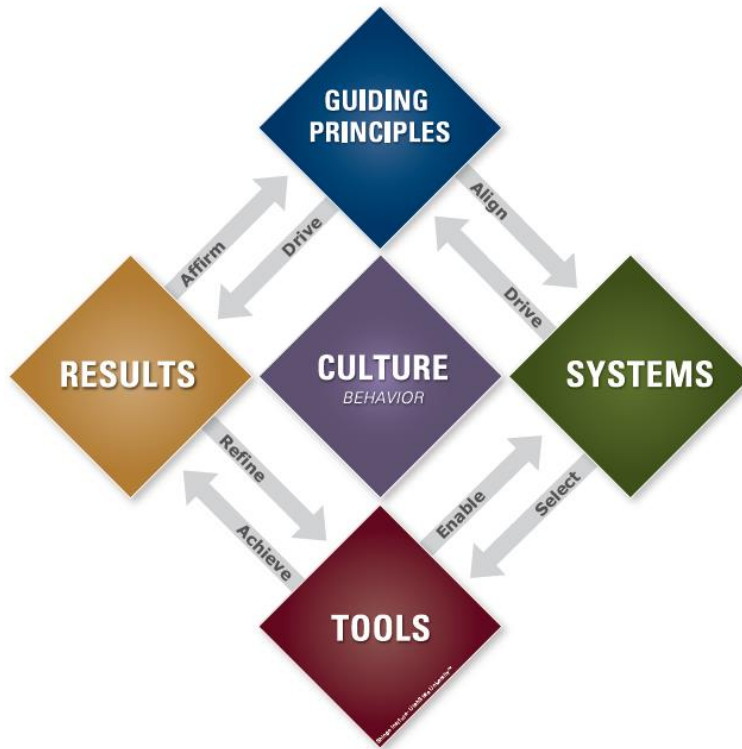
3.6. SIQ Model for Performance Excellence [11]

353 Swedish Institute for Quality (SIQ) is an excellence model designed to address the 5th wave of Quality (Q5)
354 which is described as focused on societal satisfaction and how global technological development has erased
355 borders. SIQ calls out "the inefficiency arising from uncommitted employees" as a key weakness in Q5. To
356 address this, the model focuses on doing the "right things" in the "right way". The most recent update of the
357 SIQ model includes a focus on sustainability principles to achieve societal satisfaction which is unique to the
358 other models addressed by this standard. This model is one of the best suited to support sustainability
359 assessments and should be considered if sustainability is a focus area for a company.

360 The three cornerstones of the SIQ model are culture, structure, and systematics (a way of asking questions that
361 leads to insights and motivations) (see to **Figure 6).** Similar to PDA's approach, the SIQ model is backed by
362 research [12] and built around a focus on working methods and the idea that in order to improve results we have
363 to change the way we work. For the purposes of this standard, we will focus on the culture portion of the SIQ
364 model which includes five success factors: creating value with customers and stakeholder; leading for
365 sustainability; involving motivated co-workers; develop value-creating processes and improve operations and
366 innovate (see **Figure 7).**

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372 **Figure 6: SIQ Management Model**
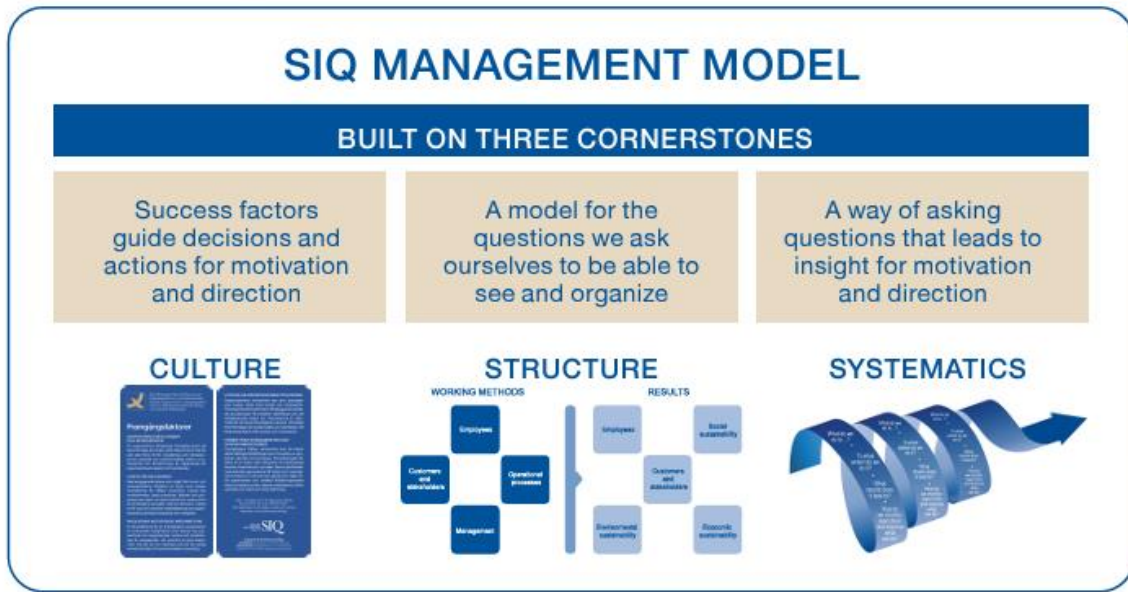
374 SIQ_Management_Model_manual1.pdf

375

376 **Figure 7: SIQ Model Success Factors**

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380 https://en.siq.se/in-english/siq-management-model/

3.7. ISPE Advancing Pharmaceutical Quality (APQ), Cultural Excellence Guide [13]

The International Society for Pharmaceutical Engineering (ISPE) has written a guide that shares insights on quality culture improvement across six dimensions and outlines a series of assessments, approaches, practices, measures, and improvement tools to support implementation of a cultural excellence framework at all levels within an organization. The APQ program provides a framework for assessing and enhancing the effectiveness of the Pharmaceutical Quality System (PQS) as described in ICH Q10.

The program recognizes that the ability to advance quality management maturity is the responsibility of the pharmaceutical industry and builds upon the ICH Q10 model by enhancing the traditional elements of a PQS with the aspects of cultural excellence, operational excellence (OPEX), knowledge management, and continual improvement. It provides a comprehensive approach for assessing and improving an organization's quality management maturity to advance the state of quality within the organization.

The APQ program focuses on eight overarching aspects:

    a) Integrate quality management maturity, cultural, and operational excellence principles, tools, and approaches

    b) Support and incentivize continual improvement

    c) Foster industry ownership of quality beyond "compliance" *

    d) Promote effective and efficient use of resources

    e) Encourage self-improvement and supplier improvement

    f) Enable structured benchmarking, knowledge sharing, and learning among organizations

    g) Increase the reliability of supply for quality products

    h) Offer routes to delivering sustainable competitive advantage

    *Note: Compliance is sometimes inappropriately interpreted as differing from quality assurance. True CGMP compliance cannot be measured or achieved through checkbox approach or regulatory citation avoidance, but it is instead underpinned by preventive practices and quality assurance and is driven by the quality culture principles in this standard.

At the core of the APQ Program is the Assess, Aspire, Act and Advance framework which provides a set of tools, resources, and systematic approaches for organizations to advance the maturity and effectiveness of their quality culture.

ISPE APQ Cultural Excellence Guide shares insights on quality culture improvement across six key dimensions and outlines practical approaches, practices, and tools to support implementation of the cultural excellence framework. It is based upon the *2017 ISPE Cultural Excellence* report with enhanced features supporting key behaviour assessment at employee and management levels, a robust recognition and reward program, and third-party contract evaluation. As shown in the diagram below, it provides a quality management framework for assessing and advancing corporate culture maturity by evaluating the following elements:

- Leadership and Vision
- Mindsets and Attitudes
- Gemba and Employee Engagement
- Leading Quality Indicators with Metrics that Matter
- Proactive Management Oversight, Review and Reporting
- Cultural Enablers

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426 **Figure 8: ISPE Framework**

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428 (Member adapted)

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430 **3.8. PDA Quality Culture Assessment Tool [14]**

431 The PDA has designed a comprehensive *Quality Culture Assessment Tool and Training* [14] to guide
432 companies to a better understanding of quality culture, how to assess it, and what actions to take to improve it.
433 The tool helps a company effectively collect verifiable data that will help them to assess their culture at all
434 levels of their organization by identifying 21 elements of Quality Culture over five categories that can be
435 objectively assessed. The tool defines criteria for five levels of maturity enabling a site to compute a maturity
436 score by element and category.   The individual site scores are collected by PDA who produce an industry
437 benchmarking report which sites can use to find their relative strengths and weaknesses as compared to
438 overall industry results. The PDA Tool has been developed based on research demonstrating a positive
439 correlation between culture behaviors and quality system elements and refined through industry testing and
440 user feedback. The research demonstrated that the presence of specific quality system elements can be a
441 surrogate for more positive culture and behaviors within a pharmaceutical manufacturing environment. The
442 model is based on ICH Q10 principles as well as incorporating mature quality system elements that go beyond
443 GMP requirements such as process ownership, safety culture, rewards and recognition, and level of
444 technology implementation.
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456 **Figure 9: PDA Tool Attributes**
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459 http://www.pda.org/docs/default-source/website-document-library/chapters/presentations/australia/data-integrity---focus-on-
460 quality-culture.pdf?sfvrsn=d89b6381_4
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4. Terms and Definitions

American National Standard Institute (ANSI)	The American National Standards Institute (ANSI) is a private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. Founded in 1918, the Institute works in close collaboration with stakeholders from industry and government to identify and develop standards- and conformance-based solutions to national and global priorities [18].
Communication and Collaboration	For the purposes of this standard, communication and collaboration are combined as a key focus area and are further described in section 7.0. They are essential for establishing a mature quality culture.
Continuous Improvement (CI)	Continuous Improvement is a key focus area and is further described in section 9.0. In the context of quality culture, continuous improvement is the ongoing enhancement of products, services, or processes through incremental and breakthrough improvements. This includes evaluating current processes, suggesting ideas, and implementing solutions to improve operational performance. Generally, Continual improvement (CI) is based on the idea that small, ongoing, and well-calculated changes can lead to major improvements over time [11].
Corrective Action /Preventive Action (CAPA)	(Corrective)Action to eliminate the cause of a detected non-conformity or other undesirable situation. (Preventive)Action to eliminate the cause of a potential non-conformity or other undesirable potential situation. NOTE: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence [1]. A subsystem used to collect and analyze information, identify, and investigate product and quality problems, and take appropriate and effective measures to prevent recurrence of the identified problem [2,23].
Cultural Excellence	Cultural excellence is the expressed and implied ways in which an organization operates and fosters cross-functional ownership of quality at all levels. It is essential for delivering robust and sustained quality performance and ensuring patient-focused outcomes.
Employee Ownership and Engagement	In the context of this standard, Employee Ownership and Engagement are combined as a key focus area and are further described in section 8.0.
GEMBA	Gemba (also written as genba) is a Japanese word meaning "the actual place." In lean practices, the gemba refers to "the place where value is created," such as the shop floor in manufacturing. A popular approach in companies who implement lean principles is called "Gemba walks," which denote the action of going to see the actual process, understand the work, ask questions, and learning from those who do the work (showing respect to them). The broader aim is to foster a culture of continuous improvement and quality mindset. [15]. Its initial purpose is to allow managers

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	and leaders to observe the actual work process, engage with employees, gain knowledge about the work process, and explore opportunities for continuous improvement [35].
Innovation	The way in which an organization updates, changes, and improves its internal processes, manufacturing techniques, and management methods. Innovations must meet certain criteria to be successful, including meeting customer needs, satisfying expense and return on investment requirements, improving employee satisfaction, and product quality. Innovations help introduce new concepts, knowledge, products, services, and processes into organizations and the outside marketplace [25].
International Organization for Standardization	The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies from more than 160 countries, one from each member country. ISO is a non-governmental organization established in 1947 and based in Geneva. Its mission is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological, and economic activity. ISO's work results in international agreements which are published as International Standards and other types of ISO deliverables [16].
Leadership	The role of leaders is to provide guidance within the company to define and enable beliefs and behaviors that promote operational excellence and product quality. Leadership applies to all levels of the organization in the context of quality culture and is imperative to the success of the organization. Leadership is a key focus area and is further described in section 6.0.
Leadership Commitment	Leadership commitment in a company culture is demonstrated by the engagement of management in offering employees opportunities to participate in and recommend changes to improve the organization's performance. The level of engagement, commitment and leadership qualities are consistently demonstrated by senior management, both strategically and operationally.
Operational Excellence	Operational Excellence is a philosophy that directs an organization towards continuous improvement and that comprises structural and behavioral changes to optimally support necessary activities [27].
Quality	A high degree and level to which a set of inherent characteristics of a product, system or process to fulfill a set of requirements [1].
Quality Culture	Quality Culture is the overriding attitude, both expressed and implied, of an organization towards quality. It is characterized by two distinct elements: a cultural/psychological element of shared values, beliefs, expectations, and commitment towards quality and, a structural/managerial element with defined processes that enhance quality and aim at coordinating individual efforts (from introduction). A mature quality culture, in many cases, requires changing from a minimal approach focused on compliance to an excellence-led approach, and requires a transformational change to be implemented. Culture drives people's behavior, innovation, and customer service.

Quality Management	Person(s) who direct and control a company or site at the highest levels with the authority and responsibility to mobilize resources within the company or site [1, 4, 17]. Quality management includes establishing quality policies and quality objectives and processes to achieve these quality objectives through quality planning, quality assurance, quality control, and quality improvement [11]. Note- The word management sometimes refers to people i.e a person or group of people with authority and responsibility for the conduct and control of an organization [11].
Quality Management Maturity	Quality management maturity (QMM) is the state attained when drug manufacturers have consistent, reliable, and robust business processes to achieve quality objectives and promote continuous improvement [30]. The consistent, reliable, state attained by having consistent, reliable, and robust business processes to achieve quality objectives and robust business and promote continual improvement [30].
Quality Management System	A quality management system (QMS) is a set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organization (i.e., areas that can impact the organization's ability to meet customer requirements) [11].
Quality Metrics	Quality metrics are a key component of an effective quality management plan and are the measurements used throughout the pharmaceutical industry to monitor manufacturing and quality control systems and processes. They are used to drive continuous improvement to deliver key stakeholder expectations into acceptable performance measures. Quality metrics are one element of companies' commitment to quality culture.
Senior Management	Person(s) who direct and control a company or site at the highest levels with the authority and responsibility to mobilize resources within the company or site. Senior management has the ultimate responsibility to ensure an effective pharmaceutical quality system is in place to achieve the quality objectives, and that roles, responsibilities, and authorities are defined, communicated, and implemented throughout the company [2].
Technical Excellence	Technical excellence is the ability to foresee and eliminate issues that may affect patient safety, schedule, budget, quality, and employee ownership and is achieved by implementing innovative technological advancements with talented resources, resulting in the best quality product. In the context of this standard, Technical Excellence as a key focus area and is further described in section 10.0.

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477 **5. Acronyms**

ANSI	American National Standards Institute
CAPA	Corrective Action / Preventative Action
CI	Continuous Improvement
ISO	International Organization for Standardization
PQS	Pharmaceutical Quality System
QI	Quality Improvement
QMM	Quality management maturity
QMS	Quality Management System

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482 **BSR/PDA Standard 06-201x, Quality Culture Assessment of Quality Culture Guidance**
483 **Documents, Models, and Tools**

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485 **6. Leadership Commitment**

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487 **6.1. Introduction to Leadership**

488 Leadership is required to promote an effective and sustainable quality culture at all levels of an organization.
489 The role of leaders is to provide guidance within the company to define and enable beliefs and behaviors that
490 promote operational excellence and product quality. Quality culture starts with leadership that understands
491 their quality management system and knows the necessity of successfully serving customers. The result of that
492 understanding is a culture where a positive internal environment and the creation of satisfied customers go
493 together. It is a culture that naturally emphasizes continuous improvement of processes and one that results in
494 a healthy workplace, satisfied customers, and a growing, profitable company.

495 Behaviors are driven from individual's beliefs, which are influenced by the values promoted by the
496 organization. It is the responsibility of leadership to demonstrate the behaviors that will influence the
497 employees' perceptions to align with the organization values. Since culture is often implied and felt rather
498 than directly stated, leadership has the responsibility to define the values important to the organization as well
499 as the expected behaviors. Leaders must then consistently and transparently demonstrate the behaviors that
500 align with the organization's values. This brings clarity to the workforce on how to embody the values. When
501 people care deeply about the organization's values, and they are behaving as expected, people can improve
502 performance and they are motivated to work toward the company vision.

503 Positive leadership behavior is a set of actions, taken by individuals in a position of authority and influence, to
504 motivate and cultivate others through mechanisms of empowerment, engagement, and collaborative
505 assignment to meaningful work. Positive leadership behavior promotes happiness, well-being, and
506 mindfulness as goals for organizations that are as important as profit, achievement, and winning in
507 competitive situations, like markets and contract awards.

508 An effective Leadership framework sustains the commitment towards interpersonal effectiveness,
509 management skills and change resiliency. In an organization with a culture of quality, product quality and
510 operational excellence are owned by all employees. It is not just managers that should drive quality culture
511 within an organization. Ideally Quality Improvement (QI) should be inherently built into the cyclical
512 performance management plans for all employees so that it is embedded across all levels of the organization.
513 This should also include provision of ongoing training opportunities, granting authority to make decisions,
514 and eliminating fear of consequence or blame culture.

515 Senior management should lead the process for transformational change, dedicate financial and human
516 resources to QI, communicate progress, hold staff accountable, address resistance to change, and exhibit
517 visible support for QI. Middle managers and supervisors should ensure that all employees have the direct
518 support needed and are being held accountable to QI values and behaviors.

519 **6.2. Resource Review of Current Guidance, Models and Tools**

520 In this section, the available resources that provide further direction on effective leadership commitment for
521 cultural excellence are reviewed. The resources are guidance documents that describe leadership commitment,
522 as well as models or tools that can be implemented to measure and improve leadership commitment.
523 Organizations looking to evaluate leadership commitment can refer to the table for resources that discuss the
524 topic as well as provide measurements, criteria for success, and suggestions for improvement. For this
525 Leadership section, there were four criteria applied as part of the review:

526
527 • Leadership Commitment in Quality Culture
528 • Measurements of Leadership Commitment
529 • Criteria for Success of Leadership Commitment

18

530   • Suggestions for Improvement in Leadership Commitment

531

532 Using **Table 1**, the organization can decide which reference document(s) may be more pertinent for them to use
533 as part of their Quality Culture journey. An "X" in one of the columns below denotes that the resource document
534 contains additional information on this aspect of leadership. Readers are directed to consult the source document
535 for details.

536
537 **Table 1: Current Guidance, Models and Tools for Leadership**
538

Resources	Type: G=Guidance M=Model T=Tool	Leadership Commitment in Quality Culture	Measurements of Leadership Commitment	Criteria for Success of Leadership Commitment	Suggestions for Improvement in Leadership Commitment
ISO10018:2020 Quality management Guidance	G	X			X
ICHQ10 Pharmaceutical Quality System	G	X			
EFQM Excellence Model	M	X		X	
Malcolm Baldrige Excellence Framework	M	X	X	X	
Shingo Model	M	X	X		
SIQ Model for Performance Excellence	M	X	X	X	
ISPE APQ Cultural Excellence Guide	T	X	X		X
PDA Quality Culture Guided Assessment Tool	T		X		X

539
540

541 **6.2.1. ISO10018:2020 Quality Management Guidance**

542 ISO 10018 provides guidance on Leadership by describing what leaders do and what is the process of
543 Leadership. Management is included as referenced in ISO 9000:2015, whereby leadership is linked to ISO
544 9001 and other QMS systems and standards through the description of effective leadership with regards to
545 three behaviors for top management.

546   • Accountability

547   • Integration

548   • Support

549 ISO 10018 includes possible action steps that can be taken to ensure effective leadership by (1) listing typical
550 components of leadership with examples and (2) by describing the typical attributes of effective leaders which
551 should be considered. The standard also lists the potential benefits of effective leadership.

552
553

554 **6.2.2. ICHQ10 Pharmaceutical Quality System**

555 As described by ICH Q10, leadership is essential to establish and maintain a company-wide commitment to
556 quality and for the performance of the pharmaceutical quality system (PQS), and senior management is
557 defined as "person(s) who direct and control a company or site at the highest level with the authority and
558 responsibility to mobilize resources within the company or site." The document then describes the
559 management commitment requirements to maintain an effective PQS as:
560

561 a) Senior management has the ultimate responsibility to ensure an effective pharmaceutical quality
562 system is in place to achieve the quality objectives, and that roles, responsibilities, and authorities are
563 defined, communicated, and implemented throughout the company.

564 b) Management should:

565 • participate in the design, implementation, communication, monitoring, and maintenance of an
566 effective PQS.

567 • demonstrate strong and visible support for the PQS and ensure its implementation throughout
568 their organization.

569 • ensure a timely and effective communication and escalation process exists to raise quality
570 issues to the appropriate levels of management.

571 • define individual and collective roles, responsibilities, authorities, and inter-relationships of
572 all organizational units related to the PQS and ensure that these interactions are
573 communicated and understood at all levels of the organization.

574 • provide governance and establishment of an independent quality unit/structure with authority
575 to fulfil certain PQS responsibilities as required by regional regulations.

576 • determine and provide adequate and appropriate resources (human, financial, materials,
577 facilities, and equipment) to implement and maintain the pharmaceutical quality system and
578 continually improve its effectiveness.

579 • ensure appropriate communication processes are established and implemented within the
580 organization.

581 • conduct governance management reviews of process performance, product quality, and of the
582 PQS to ensure its continuing suitability and effectiveness.

583 • advocate continual improvement.

584 • commit appropriate resources.

585 • assess the conclusions of periodic reviews of process performance and product quality and of
586 the pharmaceutical quality system.

587
588 **6.2.3. EFQM Excellence Model**

589 The EFQM model uses a criterion entitled "Organizational Culture and Leadership' under Direction which
590 describes the aspiration required for a company. The fundamental concept of leadership within EFQM is
591 'leading with vision, inspiration and integrity' and "Excellent organizations have leaders who shape the future
592 and make it happen, acting as role models for its values and ethics"[8] .
593 Organizational Leadership applies to all employee levels rather than the traditional top-down management
594 style. When the organization is described as outstanding it is due to Leadership behaviors being evident across
595 all levels. The so called 'model leadership behavior' steers organizational culture by inspiring others to adopt
596 the values required. An organization achieves success by following the concepts below:

597 a) Steer the Organization's Culture & Nurture Values.

598 b) Create the Conditions for Realizing Change.

599 c) Enable Creativity & Innovation.

600 d) Unite Behind & Engage in Purpose, Vision & Strategy.

6.2.4. Malcolm Baldrige Excellence Framework

The Baldridge Excellence Framework uses a systems approach with leadership as one of the seven criteria categories - (1) Leadership; (2) Strategy; (3) Customers; (4) Measurement, Analysis, and Knowledge Management; (5) Workforce; (6) Operations; and (7) Results. There are eleven core values and concepts which are embedded in the systematic processes including Leadership. The systematic processes yield performance results, of which 'Leadership and Governance Results' is one. Leadership commitment is referenced across the 11 core values as listed in the introduction above (section 3.4).

From the Baldrige foundation there has been a set of leadership behaviors developed to reinforce these core values in high-performing organizations. These behaviors typify role-model leaders and can form the basis for leadership development and design of senior leadership teams. It is expected that senior leaders utilize their strengths in these behaviors and make sure that their leadership team includes others who complement their strengths or who possess strengths in behavior other leaders do not. The leadership behaviors are aligned with the 11 Baldrige core values and concepts, respectively. To be an effective leader Baldridge expects senior leaders to possess and personally exhibit the executive behaviors associated with visionary leadership, systems perspective', 'ethics and transparency', and 'delivering value and results.'

6.2.5. Shingo Model

The Shingo Model is based on ten guiding principles divided into four dimensions. See **Figure 10** below. The first dimension, 'Cultural Enablers', includes 'Lead with Humility'. When leaders utilize intellectual humility, they have a level of vulnerability that helps them discard preconceived ideas that prevent the exploration of unlikely solutions. Use of the Shingo model encourages leadership at every level by all employees who feel empowered to find solutions and work on process improvement.

Figure 10: Concept of Cultural Enablers

https://www.xcelliumconsulting.com/_files/ugd/5f29c4_0c926ca80e214874b81078ea329025aa.pdf?index=true

6.2.6. SIQ Model for Performance Excellence

The model was designed based on the characteristics of Swedish culture and principles of leadership which focus on the following:
- Decentralization
- Employee participation and co-determination
- Employee mandate for decision-making
- Equality, diversity, and a sense of security and safety
- Short decision-making processes
- Transparency
- Trust, sustainability, and innovation

Where these principles exist, it is a sign of excellence and success in an organization.
Of the three cornerstones (Culture, Structure, and Systematics) it is in Culture where there is a focus on leadership with 'Lead for Sustainability' being seen as a success factor. There are five main criteria with Management being number two and including reference to Leadership. This criterion consists of sub-criteria with points that ask for information about the working methods chosen by the organization and the extent to which these are applied. Refer to **Figures 6 and 7**.
Information is requested about the way in which the organization evaluates and improves its chosen working methods within each sub-criterion. It deals with working methods used to plan and lead the organization based on the needs, requirements, wishes and expectations of customers and stakeholders. There is a clear link to the criteria for customers and stakeholders. It describes how managers on all levels practice committed leadership

652 that creates the conditions for all employees to take part in the development of the organization and how the
653 organization leads and develops its business processes in general. In criterion four, Results, there is reference
654 to leading and improving processes.
655

6.2.7.ISPE Advancing Pharmaceutical Quality, Cultural Excellence Guide

657 The ISPE, APQ Cultural Excellence Guide, places a strong emphasis on the importance of Leadership in
658 Quality Culture. Leadership and Vision are combined as one of the six dimensions of a quality excellence
659 framework. Leaders establish and promote the vision for the organization to establish and maintain a culture
660 of operational excellence. Therefore, Leadership and Vision are key in establishing the culture at all levels via
661 use of a Leader 5-V model.
662 The Leadership and Vision 5-V model consists of a five-level maturity assessment of: Leadership and Vision
663 through:

664   a) Vision

665   b) Vigilance

666   c) Values

667   d) Visibility

668   e) Voice

669 Within the tool, this section identifies desired states and possible improvement actions such as:
670 • Create a quality vision.
671 • Share the quality vision throughout the organization.
672 • Model the desired behaviors in support of the quality vision.
673

6.2.8.PDA Quality Culture Guided Assessment Tool

675 The PDA Quality Culture Assessment Tool defines Leadership with the attributes of **Commitment to Quality**
676 and **Enabling Resources**. These are separated into the four metrics of:

677   a) **Accountability and Quality Planning** – measures the level of commitment to establishing a robust
678   Quality Manual, formally documented quality improvement projects and accountability for quality
679   extended across the company including quality goals for all staff.

680   b) **Safety Program** – measures the maturity of the Environmental Health & Safety (EH&S) formal
681   program including ergonomic and health related issues with the expectation that safety prevention is
682   embedded in everyone's goals and being actively measured and communicated.

683   c) **Rewards & Recognition** (R&R) – measures the focus of the R&R programs for the prevention of
684   quality issues.

685   d) **Feedback & Staff Development** - where Leadership is mentioned, the tool identifies where
686   improvements in roles and communication are required with the emphasis on visibility of staff
687   engagement and recognition linked to quality improvement.

688
689

6.3. Role of Leadership and Management at All Levels

6.3.1. Top Leadership

692 Leaders establish unity of purpose and the direction of the organization. They should create and maintain the
693 internal environment in which people can become fully involved in achieving the organization's objectives.
694 Leadership provides a clear focus for people throughout an organization and enables them to follow a path to
695 achievement of the organizational objectives. They should also promote continuous improvement and
696 supporting other relevant management roles to demonstrate their leadership as it applies to their area of
697 responsibility.

698 Through effective leadership, top management is held accountable for ensuring the overall effectiveness of the
699 quality management system by keeping the quality policy and quality objectives in alignment with the strategic

700 direction of the organization, by integrating the quality management system requirements into the organization's
701 processes, and by supporting other members of the management team in their respective areas of responsibility.

6.3.2. Managers

703 Leaders define objectives and designate resources, and they act in a more strategic role. Managers organize
704 resources to achieve a result by engaging the people in the organization, and they act in a more tactical role.
705 Managers coordinate activities to direct and control an organization. However, managers are still accountable
706 for the effective quality culture in the ecosystem they manage.

6.3.3. All Colleagues

708 A successful organization values its workforce members and the other people who have a stake in the
709 organization, including customers, community members, suppliers and partners, and other people affected by
710 its actions.

711 All colleagues should lead and contribute to a strong, effective quality culture and have sufficient understanding
712 and awareness of quality policies, quality objectives, benefits of improved performance and consequences of
713 nonconformance.

6.4. Role of Management (Sphere of Control)

715 1) **Senior Management**
716   Senior Management establishes unity of purpose and the direction of the organization. They should create
717   and maintain the internal environment in which people can become fully involved in achieving the
718   organization's objectives. They provide a clear focus for people throughout an organization and enable
719   them to follow a path to achievement of the organizational objectives. They should also promote continuous
720   improvement and provide a strongly positive influence on other relevant Senior management peers to
721   demonstrate their leadership as it applies to their area of responsibility.
722
723   Through effective leadership, top management is held accountable for ensuring the overall effectiveness of
724   the quality management system by keeping the quality policy and quality objectives in alignment with the
725   strategic direction of the organization.
726   A strong quality culture is achieved by integrating the quality management system requirements into the
727   organization's processes, championing the behaviors and framework for a strong culture and by supporting
728   other members of the Senior management team in their respective areas of responsibility.

729 2) **Middle Management**
730   Senior Management define objectives and designates resources, and they act in a more strategic role.
731   Middle management are leaders of individual contributors and supervisors who organize resources to
732   achieve a result by engaging the people in the organization, and they act in a blended role combining
733   strategic objectives implementation with an oversight of tactical operations. Managers coordinate activities
734   to direct an organization to meet performance and quality objectives and are accountable for the effective
735   quality culture in the ecosystem they manage.

736 3) **Supervisors**
737   Supervisors could include various roles in the organization such as Production Supervisors, Lab
738   Supervisors, Administrative, Team Leaders, etc. and report to Middle Management. Their role is highly
739   tactical in nature, and they manage the day-to-day operations. They are expected to provide solid examples
740   of expected behavior and can emote and promote the foundation for a strong quality culture.
741

6.5. Leadership Attributes

743 Leadership Attributes are the inner or personal qualities that constitute effective leadership. These are relatively
744 stable and coherent integrations of personal characteristics that foster a consistent pattern of leadership
745 performance across a variety of group and organizational situations. These characteristics reflect a range of
746 stable individual differences, including personality, temperament, motives, cognitive abilities, and expertise.
747 World class leaders must create a positive environment to nurture talented employees and recognize their

748 polarized needs, ambitions, and values. They must possess the ability to create a sustainable organizational
749 capacity while making efficient use of resources. Below, key attributes are discussed in more detail.

750 **a) Visionary**

751 - Vision is the ability to concentrate on the most important aspects of business, such as what the
752 organization aims to achieve. Vision embodies the desired optimal state of an organization to achieve
753 world class quality culture based on a core set of values. The vision of leadership permeates the
754 workplace and is manifested in the actions, beliefs, behaviors, and goals of the organization. This
755 requires a vision that is clearly articulated, energetically shared, and passionately owned ensuring others
756 will follow and share the vision and enables success by providing the necessary resources, removing
757 barriers, and promoting collaboration.
758 - Transparency involves gaining the trust of others by openly sharing information. Sharing visibility
759 with the team will promote the vision in achieving the goal.
760 - Creativity is being open to new ideas, possibilities, and perspectives, and understanding that there's no
761 "right" way to do things. The creative leader can listen, observe, and be willing to change course when
762 necessary. Innovation distinguishes between a leader and a follower.
763

764 **b) Strategic Thinking**

765 - Strategic thinking, applied to quality culture, is an intentional and rational thought process focused on
766 the analysis of critical factors and variables that will influence the long-term vision and success for a
767 business to achieve their desired state. Leaders need to embrace and facilitate strategic conversations,
768 which help them solve their key quality challenges.
769 - With communication, strong leaders know the importance of and how to communicate with people at
770 all levels of their organization. Communicating should feel genuine to others and leaders should
771 demonstrate empathy, engage in active listening, and build meaningful working relationships with
772 others in the team. In successful communication, messages are understandable, and the team is clear on
773 what is expected and are motivated to achieve the vision.
774 - Decisiveness is the ability of leaders to make timely decisions based on available information. People
775 will often look to their leaders, not for perfection, but for someone able to make quick, considered, and
776 well discerned decisions to allow them to focus on deployment within an agreed set of priorities.
777 Leaders possess the ability to make the right decision at the right time with strong forethought. Once
778 the decision is made, a good leader stands by the decision. When new information is introduced and
779 warrants a change in strategy, it is clearly communicated.
780 - Leading Change is a key behavior for strategic thinking. Leadership involves the knowledge that
781 success comes with a willingness to change how things are done and to bring in new talent to inspire
782 innovative and creative ideas to achieve maturity of the quality culture. Effective leaders know that they
783 do not exist alone and need other people to help them achieve the organizational vision. Strong
784 leadership can identify change agents in the organization that can be mentored and coached to help
785 drive the desired changes.
786

787 **c) Effective Enabler**

788 - Enablers bring visibility to all the work necessary to support efficient development and delivery of
789 future business requirements to create the desired quality culture. They identify and initiate
790 opportunities for key improvements, continuously challenge and find ways to improve systems,
791 processes, and practices to ensure long term success. Additional considerations include:
792   i. Motivation through Empowerment is demonstrated by delegating authority and allocating more
793   autonomy and responsibilities to people in a team, by enhancing the meaningfulness of work,
794   fostering participation in decision making, and by expressing confidence in other people's
795   decisions.
796   ii. Delegation is critical to a leader's success because it allows them time to focus on more strategic
797   planning to accomplish the vision of the organization. Delegation also allows the team members
798   to grow and demonstrate their leadership capabilities.
799   iii. Passionate leaders are successful because they believe that their work is important. Sharing
800   that enthusiasm is motivating for all people involved and is a way to leverage greater success.
801   iv. Empathy is when supportive leaders take into consideration other people's points of view.
802   v. Authenticity is demonstrated by consistency and transparency in values, beliefs, and actions;
803   integrating values and principles to create a purposeful vision and to contribute to the growth

804 of others. Authentic leaders are self-aware enough to understand their strengths and weaknesses
805 and how these translate to the workplace. Authenticity in leadership includes the capacity of a
806 leader to be open, honest, and forthright and factual with their team.

807   vi. Team building is important in an organization. Collaborative leaders understand that the
808 organization achieves more when its people work together. Working across roles and functions
809 brings energy, ideas, and new solutions to any task. Leadership welcomes the opinions of others
810 in the team to support decision making which encourages a participative open culture.
811 Discussions are open and frank, which leads to innovative new ideas being utilized to promote
812 the quality culture. When managers act in a collaborative fashion, all staff come together to
813 work as a team where information is shared organically, and all involved take responsibility.

814

d) Ensures Accountability

816 - Accountability occurs when individuals reliably deliver on their commitments, showing others they can
817 be trusted to do what they say they'll do. Leaders further demonstrate accountability by taking
818 responsibility for the outcomes of their actions and decisions and successfully transforming effort into
819 results.

820 - Confidence in an effective leader is demonstrated when they ensure that others follow their plans.
821 Assertiveness and confidence enable the leader to gain the respect of their followers/team.

822 - Learning from failure is an excellent tool of knowledge building and understanding of self. It allows for
823 survival, renewal, and reinvention of oneself and the organization. How a leader manages and learns
824 from failure often defines one's character as a leader.

825

6.6. Leadership Values

827 Leadership values are the core principles that guide us in our personal and professional lives. They are closely
828 connected to both personal and company core values. Values are the basic beliefs concerning what is right,
829 correct, good, desirable, and moral. People behave according to their values, and, in an organization, people
830 behave in ways that are consistent with the quality culture. The core values are set by Senior Leadership and
831 middle management. However, everyone in the organization is responsible for upholding the core values and
832 leading by example.

833 The trustworthiness of a leader can be gauged by their personal characteristics of competence, compassion, and
834 work ethic in terms of core values such as courage, empathy, equity, excellence, integrity, joy, respect for others
835 and trust. Some of the Core Values that contribute to a strong quality culture are described below:

a) Trust

837 In a leadership context, trust means that employees expect their leaders to treat them with equity and
838 respect and, consequently, are comfortable being open with their leaders. Trust in leadership takes time
839 and starts with observing, being familiar and having belief in other people's competences and
840 capabilities. Trust is a two-way interaction, and it can develop to a stage where informal interactions
841 and body language are intuitively understood, and positive actions and reactions contribute to a strong
842 quality culture. While an authoritarian style of leadership can be effective in given situations, it is now
843 being recognized that high performing organizations can benefit greatly by following a more dispersed
844 model of responsibility focused on employee trust.

b) Integrity

846 Integrity is a leader that displays honorable, truthful, and straightforward behavior. An organization
847 with integrity at its core believes in a high-trust environment, honoring commitments, teamwork, and
848 an open exchange of ideas.

c) Excellence

850 Excellence within an organization can encompass employees, product quality, and customers. Strong
851 leadership ensures employees own product quality and promote excellence in their organization which
852 benefits customers. Leadership Excellence means being on a path towards what is better and more
853 successful. This requires the leader to be committed to development and improvement.

854   **d) Respect for People**

855   Respect for people is foundational and central to effective leadership. This requires leaders to be
856   truthful, open, thoughtful, and have the courage to do the right thing. Regardless of the size of the
857   business, people are critical to an organization's success and should be viewed as important resources
858   for management investment. Organizations with a strong quality culture invest heavily in all their assets,
859   including their people, by upgrading the skills and knowledge of people. Leaders institutionalize ways
860   in which to recognize and reward positive behaviors they want to reinforce. In turn, employees in a
861   positive quality environment become more engaged, productive, receptive to change and motivated to
862   succeed.

863   **e) Joy**

864   Organizations with a strong quality culture understand it is essential to assess the workplace
865   environments and how it impacts on people's experiences. To promote joy in the workplace leaders
866   positively engage with employees and managers to consider the following factors and how they impact
867   the work environment.

868   • Workload
869   • Workload Efficiency
870   • Flexibility at work
871   • Work life integration
872   • Meaning in work

873   **f) Equity**

874   Across a diverse workforce, employes receives fair treatment, regardless of gender, race, ethnicity, or
875   any other social or economic differentiator. Leaders should ensure there is transparency in decisions
876   and all staff know what to expect with regards to consequences and rewards. When equity exists, the
877   ideal scenario is that people have equal and fair access to opportunities within the organization as it
878   aligns with the individual's role, responsibilities, and capabilities.

879   **g) Courage**

880   Courage is when leaders and people do the right thing in the face of opposition. Everyone in the
881   organization should have the opportunity and responsibility to speak up and to do the right thing. A
882   courageous organization engenders trust with both employees and customers.

883   **h) Humility**

884   Humble leaders have a team first mindset and understand their role in the success of the team. Humility
885   is demonstrated by a sense of humbleness, dignity, and an awareness of one's own limitations whilst
886   being open to other people's perspectives which may be different. Humble leaders take accountability
887   for the failures and successful outcomes of the team. They ensure that lessons are learned and embraced
888   to provide improvement to the quality culture.

889

890 **6.7. Leadership Behaviors**

891 Leaders must be willing to accept that a quality culture is critical to their survival. They must step forward to
892 demonstrate their commitment to that quality. All employees must nurture that environment and share
893 ownership of the culture of quality. Leadership behaviors are the actions that make an individual effective as a
894 leader. This behavior is the process by which a person can guide, direct, and influence the work of others to
895 meet specific goals. These actions and strategies can be learned to increase the effectiveness of those around
896 them.

897 While culture is not easy to capture in written statements, leaders should communicate the behaviors that they
898 expect within the organization. Stated behaviors such as "speak-up when issues are observed" or "be solution-
899 oriented" help the employees understand what is expected and motivate the organization to align with the
900 behavior. It is crucial that the leadership engage with employees, discuss the behaviors so that they are visible

and known, serve as role models, use recognition to reinforce desired behaviors, and hold employees accountable for undesired behaviors. To change the behavior of employees, the context in which they work within processes, organizational structures, performance metrics, incentive systems, or the distribution of roles and tasks may also need to change. Leaders who define the expected behaviors and adjust the way work is done help the organization adopt and demonstrate the behaviors required to support the vision and values and achieve a robust quality culture.

In addition to communicating expected behaviors to the organization, the leader must reflect on their behaviors to ensure that they are fostering an environment for cultural excellence. Below are key leadership behaviors that should be demonstrated in an organization to support quality culture.

a) Driving Innovation

Leaders who progress innovation demonstrate to others that they are forward-looking in how they manage technology, set strategy, and do business. This promotes looking for new ways to do daily work that are efficient and effective.

b) Influence and Credibility

Leaders must have credibility in their organization to appropriately influence others to model the behaviors and practices required for positive culture. Leaders gain credibility by consistently aligning their words and their actions and leading by example. Credibility is also gained by understanding the work that the organization performs, and this includes the challenges that the team face in their daily work. Authoritarian, direct and indirect influence should be applied in a situational leadership manner.

c) Sharing the vision

Leaders must develop the strategic plan of the company and find ways to help their organization see the broader view of the business. The leader must share a vision of where the team fits into the strategic plan and empowers them to achieve the objectives to progress the vision.

d) Teacher

Leaders that teach others and invest in training and skill-building create an organization of knowledgeable people who are valued for their expertise that they have gained in their career experience. People appreciate learning the technical skills that help them develop in their career, and the soft skills that help them in the workplace and in their personal lives.

e) Master Delegator/Empower Others

Successful leaders learn to delegate by considering their development, empowerment, and autonomy of their team. Leaders are open minded, prepared, and make allowance for failure as others learn the task. This empowers the team to make decisions and take actions that are appropriate and creates an organization with strong and capable individuals.

f) Acting with Integrity

Leaders achieve results through people. It is important for the leader to believe in the good intentions of others and have strong moral principles. They must give credit where credit is due and recognize the efforts of the team. A leader's integrity is critical during stressful situations, and they must be honest and trustworthy to do the right thing.

g) Accountability

Leaders must hold themselves and others accountable for results and actions. Recognition and rewards should be used as positive reinforcement, encouraging the desired behaviors. Timely corrective actions may be needed to adjust undesirable behaviors when members of the organization are not meeting the expectations. Leaders must be objective and fair by holding everyone, including themselves, to the appropriate standard.

945 **h) Servant Leadership**

946 The concept of servant leadership considers the needs of others first and supports employee
947 development to achieve shared objectives. Servant leadership focuses on inclusiveness, welcoming
948 diverse ideas, and openly listening to all perspectives.

949 **i) Operating with a strong results orientation**

950 Leaders must set objectives, monitor performance, and seek strong results. Leaders with this behavior
951 set a clear example of pursuing excellence, while promoting a healthy work life balance.

952 **j) Supporting others**

953 Leaders create an organization of inspired, engaged, and capable people by supporting them. This
954 supportive style demonstrates to employees that they can trust in their leader, seek guidance when
955 needed, and feel empowered to perform optimally for the company.

956 ## 6.8. Summary

957 This Leadership section described the critical elements of leadership that are required to promote an effective
958 and sustainable quality culture at all levels of an organization. Using **Table 1** readers can review existing quality
959 culture references and determine which is relevant to their organization and quality culture journey.

960 Quality culture excellence begins with leaders, whether in formal management roles or seen as expert role
961 models. Leaders must set the expectations of the culture by defining the common organizational values,
962 leveraging inherent leadership attributes, and defining and modelling the behaviors that will achieve business
963 results in a way that also supports employees, customers, and other key stakeholders. Adopting a practice of
964 evaluating and continuously improving leadership practices will create a culture of quality where employees
965 will seek self-improvement, and where product quality and operational excellence are owned by employees.

966

967 # 7. Communication and Collaboration

968 ## 7.1. Introduction

969 Regardless of which tool or approach one takes to begin a journey towards greater maturity of quality systems
970 and quality culture, the ability to communicate and collaborate is central to the effort. A leader must be able to
971 communicate a vision for the end goals and collaborate with peers to develop a shared set of objectives. A fully
972 mature quality culture relies on employees at all levels having the ability and empowerment to speak up and
973 share both their concerns regarding quality risks as well as their ideas for improvement. Effective
974 communication and collaboration extend beyond periodic updates from leadership and to include the day-to-
975 day operational activities, which furthers the relationship between all employees in achieving the vision of the
976 company and facilitates the ability of all involved to make appropriate decisions.

977 ## 7.2. Role of Communication and Collaboration in Quality Culture

978 Successful communication is essential to the success of an organization in the promotion of a quality culture
979 and enables openness and trust at all levels. Communication is critical in ensuring that everyone involved in
980 the process is aware of goals, expectations, and requirements. It can also help with identifying and resolving
981 issues before they become major problems, increasing customer satisfaction, and establishing a mature quality
982 culture.

983 Collaboration is fundamental to achieving and maintaining a shared vision; transformational leadership;
984 constructive and productive communication; and demonstrated competency with key stakeholders. It ensures
985 high standards of quality and performance using openness and trust; respect for others with an equity platform
986 that embodies constructive feedback; learning and continuous improvements to achieve organizational
987 objectives aligned with partner organizations; and a shared quality culture vision.

988 Effective communication and collaboration in quality culture leads to improved efficiency, reduced costs,
989 enhanced reputation (i.e., regulatory, public, investors, etc.) and employee, customer, and stakeholder
990 satisfaction.

991 **7.3. Resource Review of Current Guidance, Models and Tools**

992 In this section, the available resources that provide further direction on Communication and Collaboration for
993 quality cultural excellence were reviewed. Organizations looking to evaluate this focus area can refer to the
994 table for resources that discuss the topic as well as provide measurements, criteria for success, and suggestions
995 for improvement. For this section, there were four criteria applied as part of the review:
996

997 • Communication and Collaboration in Quality Culture.
998 • Measurements of Communication and Collaboration.
999 • Criteria for Success of Communication and Collaboration.
1000 • Suggestions for Improvement in Communication and Collaboration.
1001

1002 Using **Table 2 below**, the organization can decide which reference document(s) may be more pertinent to use
1003 as part of their quality culture journey. An "X" in one of the columns below denotes that the resource document
1004 contains additional information on this aspect of Communication and Collaboration. Readers are directed to
1005 consult the source document for details.

1006 **Table 2: Current Guidance, Models and Tools for Communication and Collaboration**

Resources	Type: G=Guidance M=Model T=Tool	Communication and Collaboration in Quality Culture	Measurements of Communication and Collaboration	Criteria for Success in Communication and Collaboration	Suggestions for Improvement in Communication and Collaboration
ISO10018:2020 Quality management Guidance	G	X			X
ICHQ10 Pharmaceutical Quality System	G	X			X
EFQM Excellence Model	M	X	X	X	X
Malcolm Baldrige Excellence Framework	M	X	X	X	X
Shingo Model	M	X			X
SIQ Model for Performance Excellence	M	X	X		
ISPE APQ Cultural Excellence Guide	T	X	X	X	X
PDA Quality Culture Guided Assessment Tool	T	X	X	X	X

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7.4. ISO10018:2020 Quality management — Guidance for people engagement

There are many ISO standards that address quality, however, 10018:2020 is uniquely focused on the engagement of people within the context of their "cultures, work values, perceptions and practices". An important feature of this standard defines employee engagement as the "emotional commitment that people have to the organization and its goals".

Communication and Collaboration are woven into all six aspects of quality culture that are defined within this standard. For example, one of the action steps to establish a quality culture is having effective systems for "communicating the intent of the quality culture." Under the Leadership section, Communication is identified as one of the typical attributes of competent leaders, and effective communication should be accessible to people at all levels of the organization and contain consistent and understandable information. The section on Planning and Strategy emphasizes the need to engage people at operational levels to provide relevance to the requirements of the quality management system.

7.5. ICHQ10 Pharmaceutical Quality System

The ICH Q10 document has a specific section around internal communication and states that management should ensure communication processes are established and implemented within the organization, and that the flow of information occurs between all levels of the company with timely escalation of product quality and pharmaceutical quality system issues.

7.6. EFQM Excellence Model

In the EFQM Excellence Model the need for communication and collaboration is dispersed throughout the document. Example includes:

- Leadership and Constancy of Purpose: Excellent organizations have leaders who set and communicate a clear direction for their organization. In doing so they unite and motivate other leaders to inspire their people.
- Management by Process and Facts: Excellent organizations have an effective management system based upon, and designed to deliver, the needs and expectations of all stakeholders. The systematic implementation of the policies, strategies, objectives, and plans of the organization are enabled and assured through a clear and integrated set of processes. These processes are effectively deployed, managed and improved on a day-to-day basis. Decisions are based on factually reliable information relating to current and projected performance, process and systems capability, stakeholder needs, expectations and experiences, and the performance of other organizations, including, where appropriate, that of competitors
- Partnership Development: Excellent organizations recognize that in the constantly changing and increasingly demanding world of today success may depend on the partnerships they develop. They seek out, and develop, partnerships with other organizations. These partnerships enable them to deliver enhanced value to their stakeholders through optimizing core competencies. Partners work together to achieve shared goals, supporting one another with expertise, resources and knowledge and build a sustainable relationship based on mutual trust, respect, and openness.

7.7. Malcolm Baldrige Excellence Framework

The Malcolm Baldrige Excellence Framework deals with communication and collaboration in their leadership section. A portion of the leadership section of the Baldrige framework specifically probes whether senior leaders encourage frank, two-way communication across the entire workforce. Baldrige has a measurement, analysis and Knowledge Management component which includes "how do you track data and information on daily operations?". Also, in this section the Baldrige model assesses how to review the organization's performance and capabilities.

Collaboration and shared learning are essential to the Baldrige approach as demonstrated by a requirement that all Baldrige award winners present at the next annual Baldrige Quality Conference to share with others who are pursuing similar improvements. Both the conference and the awards are divided into focused

1057 disciplines so those with similar organization types (Education, Healthcare, and Business) can learn from each
1058 other.

7.8. Shingo Model

1060 The Shingo model does not directly refer to communication and collaboration; however, *Communication* is
1061 mentioned in the first dimension, *Cultural Enablers,* and in the third dimension, *Enterprise Alignment* which
1062 also has inferences to Collaboration.

7.8.1. Cultural Enablers

1064 Cultural enablers have two key principles focusing on the foundation of an organization:

  a) **Respect every Individual.**
   - "Respect for every individual naturally includes respect for employees, customers, suppliers, the community, and society in general."

  b) **Lead with Humility**
   - "Humility is an enabling principle that precedes learning and improvement."

1072 Information transparency is expected and promoted. Within the principle 'Respect every Individual Shingo
1073 promotes the idea of open communication which will clearly lead to the best collaboration.

7.8.2. Enterprise Alignment

1075 Enterprise Alignment details the following three key principles supporting the purpose of an organization:

  a) **Think Systemically**
   - "By understanding the relationships and interconnectedness of a system, people will make better decisions and improvements that will more naturally align with the desired outcomes of an organization."

  b) **Create Constancy of Purpose**
   - "An unwavering understanding of why the organization exists, where it is going, and how it will get there enables people to align their actions, as well as to innovate, adapt and take risks with greater confidence."

  c) **Create Value for the Customer**
   - "Ultimately, value must be defined through the lens of what a customer wants and is willing to pay for. Organizations that fail to deliver both effectively and efficiently on this most fundamental outcome cannot be sustained long term."

1092 To achieve an effective quality culture, an organization must establish clear and effective communication to
1093 ensure a clear connection between purpose and the work being performed.

7.9. SIQ Model for Performance Excellence

1095 As described above, SIQ calls out "the inefficiency arising from uncommitted employees" as a key weakness
1096 in the 5th wave of Quality (i.e. Q5). To address this, the model focuses on doing the "right things" in the "right
1097 way" with the most recent update including a focus on sustainability principles to achieve societal satisfaction.

1098 The three pillars of the SIQ model are culture, structure, and systematics (a way of asking questions that leads
1099 to insights and motivations). This is backed by research [12] and built around a focus on working methods and
1100 the idea that in order to improve results organizations have to change the way they work. The culture portion of
1101 the SIQ model includes five success factors:

1102 - creating value with customers and stakeholders
1103 - leading for sustainability
1104 - involving motivated co-workers
1105 - develop value-creating processes

1106 • improve operations and innovate
1107

1108 One of the success factors for communication and collaboration in the SIQ model, is the involvement of
1109 motivated coworkers as described by the following language: "A precondition of a successful organization is
1110 motivated co-workers who feel appreciated and respected. Leaders and co-workers are committed to developing
1111 a good working environment. Everyone sees their role in the whole and has a clear mandate to contribute to the
1112 organization's development."

1113 In addition, the SIQ assessment focuses on communication of visions that include measuring co-workers'
1114 creativity and participation.

1115 The concept of collaboration is woven throughout the SIQ Model in how the seven quality levels are described.
1116 The manual describes levels two or three as the most common level with seven as "unattainable." Collaboration
1117 is mentioned in the descriptions of these levels. For example, the lowest level, one, is described as "no
1118 integration of collaboration between the different divisions in the organization" while level two still has
1119 "deficient collaboration." Level four description includes "activities well planned and documented with good
1120 collaboration and integration." Level seven is achieved when organizations have a long term firmly established
1121 quality culture, and results are exceptional, lasting, and competitive.

7.10. ISPE Advancing Pharmaceutical Quality, Cultural Excellence Guide

1123 ISPE has a very detailed assessment, aspire, act, and advance framework with a deep-dive, five-level assessment
1124 process. It highlights the importance of management communicating quality topics and ensuring support is
1125 provided to staff to help improve quality with defined measurements. In addition, the tools highlight the
1126 importance of management engagement with employees, and their empowerment to provide ideas and feedback
1127 for continuous improvement. Also, the tool indicates that management should enable employees at all levels to
1128 identify and communicate risk across the organization. The ISPE APQ Cultural Excellence Guide further
1129 establishes a robust rewards and recognition program distinguishing the difference between the two important
1130 elements and formalizing the program.

1131 The ISPE guide also demonstrates tools to assess and engage with third parties, and provides key case studies
1132 to demonstrate the Assess, Aspire, Act and Advance model. Fundamental to this program is changing culture
1133 by changing behaviors.

7.11. PDA Culture of Quality

1135 In PDA's Model, the category of Communication and Collaboration consists of four attributes:

1136   1) Quality communication.

1137   2) Management review and metrics.

1138   3) Internal stakeholder feedback.

1139   4) Collaboration with assessors (optional).

1140 To be considered a mature organization, the PDA tool looks for consistent and frequent communication
1141 around the importance of quality from Senior Management as well as readily accessible programs to raise
1142 quality related issues available to associates in all areas.

1143 Mature organizations also focus on preventive metrics which are routinely reviewed through the management
1144 review program and visible to all levels of the organization. Maturity is assessed by leaders who are actively
1145 collecting stakeholder feedback through direct interactions on the shop floor as well as periodic internal
1146 surveys.

7.12. Summary

1148 The various resources reviewed for this standard refer to communication and collaboration as key elements in
1149 establishing a mature quality culture. The strategic responsibility to create an environment in which ideas for
1150 improvement can be freely exchanged lies with senior management. Once this environment is established it is
1151 the tactical responsibility of the employee to inform management of inefficiencies in their job functions, offer

1152 solutions, and implement improvements. The level of employee engagement is critical to maintaining a
1153 positive quality culture. The quality culture becomes stronger and more mature when employees at all levels
1154 of an organization feel free to offer suggestions and voice their opinions on various aspects of continuous
1155 improvement.
1156 Effective communication and collaboration must be driven in both directions: from the top down and from the
1157 bottom up.
1158

1159 8. Employee Ownership and Engagement

1160 8.1. Introduction to Employee Ownership and Engagement

1161 Employee ownership and engagement is critical in establishing a robust quality culture, resulting in a significant
1162 investment in an organization by its employees. Essentially, it is where employees have a voice in how the
1163 organization operates for successful outcomes. When staff are empowered, this leads to engagement and there
1164 is an increase in performance and productivity.

1165 8.2. Role of Employee Ownership and Engagement in Quality Culture

1166 When employees are engaged and take ownership the organization benefits because there is a lower risk of
1167 employee turnover, elevated productivity levels, increased company and employee growth, and better
1168 satisfaction at work. Highly engaged employees produce better outcomes, which leads to long-term business
1169 success. The introduction of a focus on quality culture in an organization succeeds when employees feel
1170 involved and engaged at every level. One of the hallmarks of a positive quality culture is shared ownership,
1171 where good leadership promotes engagement with all employees during the decision-making process.
1172 Through active participation of employees and by giving them substantial responsibilities, the employee's
1173 sense of ownership increases and ultimately leads to positive changes and improvement (i.e., ownership by
1174 empowerment).
1175
1176 There are 5 positive outcomes from employee ownership and engagement:
1177 • improves quality culture.
1178 • reduces staff turnover.
1179 • increases productivity and quality.
1180 • builds better work and customer relationships.
1181 • affects profits positively.
1182

1183 In this section, the available resources that provide further direction on Employee Ownership and Engagement
1184 were reviewed. Using **Table 3** below, the organization can decide which reference document(s) may be more
1185 pertinent to use as part of their quality culture journey. An "X" in one of the columns below denotes that the
1186 resource document contains additional information on this aspect of Employee Ownership and Engagement.
1187 Readers are directed to consult the source document for details

1188

1189   **Table 3: Current Guidance, Models and Tools for Employee Ownership and Engagement**

Resources	Type: G=Guidance M=Model T=Tool	Employee Ownership and Engagement in Quality Culture	Measurements of Employee Ownership and Engagement	Criteria for Success of Employee Ownership and Engagement	Suggestions for Improvement in Employee Ownership and Engagement
ISO10018:2020 Quality management Guidance	G	X		X	
ICHQ10 Pharmaceutical Quality System	G	X			
EFQM Excellence Model	M	X	X	X	X
Malcolm Baldrige Excellence Framework	M	X		X	
Shingo Model	M	X			
SIQ Model for Performance Excellence	M	X	X	X	X
ISPE Cultural Excellence Report	T	X	X	X	X
PDA Quality Culture Guided Assessment Tool	T	X	X	X	X

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1191

8.3. ISO10018:2020 Quality management — Guidance for people engagement

1193   In this model, engagement with those at operational levels is key and the leadership must prove how an
1194   employee's role is relevant to the quality system. In an immature quality culture, an employee's perception can
1195   be that the quality management system (QMS) is just a set of interrelated documents stored in an office used by
1196   auditors to identify flaws and inconsistencies in business and operational processes. In a mature quality culture,
1197   employees engage with the QMS and drive positive outcomes. Knowledge and awareness (training and
1198   development) are required for engagement. Improvement in engagement allows resiliency when there are
1199   challenges. Attributes that are important include:

1200   a) Leadership responsibility in employee engagement,

1201   b) Employee engagement requires the employees to connect with the quality management system,

1202   c) Knowledge and awareness (training and development) are required for engagement, and

1203   d) Improvement in engagement allows resiliency when there are challenges.

1204   Successful methodologies to enhance employee ownership include establishing a strategy and set of targets,
1205   involving key stakeholders, clearly defining roles and responsibilities, and improving employee commitment to
1206   align with the strategy. Methodologies to enhance knowledge and understanding include:

1207   • using effective communication based on role and /or situation
1208   • use tools such as coaching and mentoring
1209   • motivate ongoing enhancement of knowledge
1210   • nurture the development and retention of personnel
1211

1212 Methodologies for improving employee engagement include leveraging development, knowledge, skills, and
1213 awareness of the policies, strategies, and actions that drive the business. To improve the culture and enhance
1214 leadership and management processes, personnel at all levels should be engaged when making strategic
1215 improvement in response to internal and external challenges.

8.4. ICHQ10 Pharmaceutical Quality System

1217 Although quality culture is foundational throughout the ICH Q10 guidance document, employee engagement
1218 and ownership are only indirectly addressed. There is an emphasis on Management Responsibilities and Review
1219 that cascades to how an organization manages their personnel, processes, systems, and technologies.

1220 Success is captured/measured by The ICH Q10 set of parameters- it does not include a maturity model, an
1221 assessment process, or tools for improvement of Cultural Excellence (CE). It looks to an organization to use
1222 CE as a foundation for the PQS.

1223 For more information, see the ICH Q10; ISPE Advancing Pharmaceutical Quality Program.

8.5. EFQM Excellence Model

1225 The EFQM Excellence Model states that employees must be given ownership in decision-making and must take
1226 part in creativity and innovation. Excellent organizations (i.e., organizations that rate at the top of the model)
1227 invest in developing the skills of their employees, who are empowered to use their skills to improve and advance
1228 the organization. Additionally, there is clear communication with personnel, and they are recognized through
1229 reward programs. Company goals are achieved when employees share common values and are truly empowered.

1230 Ownership in company success, empowered decision-making, employee development and skills building,
1231 recognition, rewards, and a strong communication system are necessary in establishing a culture that promotes
1232 employee ownership and engagement. Success can be recorded by Employee performance (measured
1233 objectively), absence rate, job satisfaction, and injury rate.

8.6. Malcolm Baldrige Excellence Framework

1235 The Baldridge Excellence Framework uses a systems approach with workforce as one of the six criteria
1236 categories, however, employee ownership and engagement is not explicitly described. Workforce Results
1237 aligns as the performance result from the program. The following core concepts and values would be used to
1238 display some level of employee ownership:

1239   • Valuing People
1240   • Managing for Innovation

1241 From the excellence framework there are 10 recommendations that can be made to improve employee
1242 engagement:

1243   a) **High ethical standards:** People want to work for an ethical organization that has clear values which
1244   are displayed at all levels of an organization.

1245   b) **Vision:** There is better employee engagement when an organization has a clear vision for the future.

1246   c) **Segment your workforce:** All employees will not have the same expectations or desires, by
1247   understanding the needs of different work groups leaders can pay attention to all needs.

1248   d) **Provide learning and development opportunities:** One of the most powerful motivators of
1249   engagement is the opportunity to continue growing through training, coaching, and new opportunities.
1250   It is important to make learning relevant to the person and the organization by showing the employee
1251   they are appreciated.

1252   e) **Encourage career progression:** Look for the ability to promote from within and reward employee
1253   development and loyalty especially during difficult times where career progression is difficult.

1254   f) **Never lose focus on employee health and safety:** When employees are valued their health and safety
1255   is valued above everything else. Employees will disengage if there is a demonstrable lack of concern.

g) **Provide a sense of ownership:** Let employees own their work processes and ensure they understand the link between their work and what is important to the organization, so they have a sense of ownership in the organization's success. Encourage them to fully participate in the organization and to be sources of innovation.

h) **Reward and recognize:** Always find the time and occasions to recognize the contributions of employees. This is especially important in uncertain times.

i) **Draw from diversity:** When an organization has a diverse workforce, this results in diverse ideas, and diverse thought processes showing gains from capitalizing on this diversity. Employees know their opinions are values which ultimately benefit the organization.

j) **Communicate, communicate, communicate**: Leaders need to be visible, especially during a challenging or uncertain time. Communications must be open, honest, and transparent when sharing information on the organization's status and challenges. They also need to be good listeners to gain insights and be responsive to peoples' ideas and needs.

8.7. Shingo Model

Empowered team members are essential to success. This means that employees are engaged in the success of the company and take ownership of their job responsibilities. Enterprise Alignment (interdepartmental) is one of three dimensions of the guiding principles for determining the commitment of employees. Cultural Enablers and Continuous Improvement are the other two dimensions. The following statement taken directly from the Shingo Model demonstrates the importance of employee ownership and engagement: "The results of an organization depend on the way its people behave."

8.8. SIQ Model for Performance Excellence

The SIQ Management Model (Excellence Model) is a tool that can be used to lead to success. It champions employee ownership where knowledgeable, motivated employees step forward and take responsibility for the bigger picture, beyond traditional roles. When there is a culture in place to add value to processes with continuous improvement and visible ease of adaptation the employee engages with the leadership and organization. This culture should also encourage openness, a willingness and courage to innovate, and the engagement of employees leading to improved processes and ultimately better products.

In the culture cornerstone of the five success factors there are two which relate to employees - involving motivated co-workers and improving operations with innovation. For employee engagement, there are sub-criteria with points that ask for information about the working methods chosen by the organization and the extent to which these are applied. Information on how the organization does what it does, and which working methods have been chosen in the area is requested to be successful.

The main criterion describes methods for drafting relevant employee development plans that detail how skills development is carried out based on strategies, objectives, and action plans for the organization's overall competence. Within the Employees criteria there is a sub-criterion that deals with creativity and innovation, with innovation referring to both continuous improvement and radical innovations. There are descriptions of how to deal with issues concerning working methods to promote a good work environment and employee satisfaction. Additional sub-criteria for Employees are provided in the "Results" section.

8.9. ISPE Advancing Pharmaceutical Quality; Cultural Excellence Guide

The ISPE Advancing Pharmaceutical Quality (APQ): Cultural Excellence Guide is a wholistic model based upon six dimensions of cultural excellence, and follows the framework of Assess, Aspire, Act, and Advance. It includes a five-level scale assessment, aspirational plan for improvement, action tracking, and aspirational tools to measure this improvement. The six dimensions of Cultural Excellence include:

- Leadership and Vision

- Mindsets and Attitudes

- GEMBA & Employee Engagement

1302   •   Leading Quality Indicators: Measures that Matter

1303   •   Proactive Management Oversight, Review, and Reporting, and

1304   •   Cultural Enablers

1305 The model assesses behaviors at all levels of the organization, includes systematic improvement processes, and
1306 includes reward and recognition programs. The APQ contains bonus content that aids assessors in evaluation of
1307 third-party relationships.

1308 In the ISPE APQ Cultural Excellence Guide model employee ownership and engagement starts with Leadership
1309 and Vision. Leadership establishes the foundational elements that engage employees to commit to establishing
1310 a mature quality culture.

1311 Behavioral measures are very important to employee ownership and engagement. These measures are included
1312 within the 21-behavior assessment tool in the pre-assessment and the full deep-dive, five-level scale APQ
1313 Cultural Excellence Assessment.

1314 GEMBA is the key dimension that defines the employee ownership and engagement plans. It includes
1315 leadership and employee communications, goals, performance enablers, and monitoring behaviors in a
1316 transparent and visual manner to assess the PQS and the culture of the organization at multiple levels. The
1317 dimension of cultural enablers provides tools needed to track and measure behaviors and resulting cultural and
1318 business performance. Additionally, a key element in GEMBA is a recognition and reward system that
1319 establishes the behaviors and measures actions associated with quality culture excellence. Success is captured
1320 via employee behaviors, and performance aligned to the business strategy and cascading goals and criteria that
1321 show success.

1322 ## 8.10. PDA Culture of Quality

1323 In the PDA Quality Assessment Tool Employee Ownership and Engagement define two attributes:
1324 Understanding Quality Goals and Staff Empowerment and Engagement.

1325 The metrics 'Impact on Product Quality' and 'Patient Impact' are measured under 'Understanding Quality
1326 Goals' and 'Process Ownership and Engagement' and 'QMS Processes' are linked to 'Staff Empowerment
1327 and Engagement.'

1328 The tool allows the organization to assess if process owners are engaged with the processes and products they
1329 work with and if they feel able to make decisions and drive change. If employees have ownership and are
1330 engaged in the success of the organization, they will have the ability to ascertain if processes are clear and
1331 when necessary, they can make changes that result in improvements to the processes.

1332 ## 8.11. Summary

1333 Employee ownership and engagement is inherently linked to Leadership. With strong effective leadership,
1334 employees feel empowered and valued which results in a strong quality culture.

1335 As shown in **Table 3** above, several of the models give criteria for success and detail how success can be
1336 measured when employees have ownership and are engaged within the company. ISPE and SIQ place a detailed
1337 emphasis on employee engagement and are excellent resources.

1338

1339

1340

9. Continuous Improvement (CI)

9.1. Introduction to Continuous Improvement

Continuous/continual improvement is the ongoing advancement of products, services or processes through incremental and breakthrough improvements gained from process knowledge and experience. ISO 9001:2015 Quality management systems [29], describes improvement in general and in relation to nonconformities, corrective actions, and continual improvement. Clause 10 states "The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system" [18].

Continuous improvement not only includes processes, but also the state of striving towards a better and more cohesive quality culture. An effective way to sustain and spread a continuous improvement culture is by focusing on solving real problems inside an organization.

The four components of continuous improvement are as follows [37].

- **Plan**: Identify an opportunity and plan for change.

- **Do:** Implement the change on a small scale.

- **Check:** Use data to analyze the results of the change and determine whether it made a difference.

- **Act:** If the change was successful, implement it on a wider scale.

When the following eight key elements are in place, an organization is demonstrating a culture of continuous improvement:

a) **Customer Focused**
   Making decisions based on the best interest of the client.

b) **Total Employee Involvement**
   Employees are empowered and engaged at every level of the organization.

c) **Process Centered**
   Use of methods, (e.g., PDCA, Lean, etc.) to understand the elements that transform inputs into outputs whilst removing emotion from decision making Integrated System: Understanding how all areas of an organization function together and fostering a culture of cohesion and communication.

d) **Strategic Approach**
   Use of organizational and departmental plans to describe the vision and how to implement changes.

e) **Continual Improvement**
   Foster an understanding that improvement is constant and encourages improvements in processes and systems.

f) **Fact-Based Decision Making**
   Gather the data on how a process looks to understand how it can be improved.

g) **Communication**
   Open communication removes the fear of failure and in turn sparks creativity whilst engaging employees at every level of the organization.

9.2. Role of Continuous Improvement in Quality Culture

Continuous improvement can be perceived in two distinct ways. The first is to view continuous improvement as the outcome, a state of an organization. The second is to view it as an enabler or integral part of a larger goal. This logic also applies to continuous improvement and quality culture. While higher levels of quality culture will achieve the continuous improvement of products, processes, and systems, striving for continuous improvement is fundamental to a quality- and patient-focused culture. The former refers to continuous improvement when it is reflected in key performance indicators that improve over time. The latter refers to

1387 continuous improvement when it is further broken down into practices that will lead to improved results (e.g.,
1388 Shingo Model).
1389 Subsequent subsections outline how each guide, model, and tool views the role of Continuous Improvement in
1390 Quality Culture. Organizations looking to evaluate continuous improvement can refer to **Table 4** below for
1391 resources that discuss the topic's attributes as well as provide some measurements, criteria for success, and
1392 suggestions for improvement. An "X" in one of the columns below denotes that the resource document
1393 contains additional information on this aspect of Continuous Improvement. Readers are directed to consult
1394 the source document for details

1395

1396 **Table 4: Current Guidance, Models and Tools for Continuous Improvement**

Resources	Type: G=Guidance M=Model T=Tool	Continuous Improvement in Quality Culture	Measurements of Continuous Improvement	Criteria for Success of Continuous improvement	Suggestions for Improvement in Continuous Improvement
ISO10018:2020 Quality management Guidance	G	X	X	X	X
ICHQ10 Pharmaceutical Quality System	G	X	X	X	X
EFQM Excellence Model	M	X	X	X	X
Malcolm Baldrige Excellence Framework	M		X	X	X
Shingo Model	M	X	X	X	X
SIQ Model for Performance Excellence	M	X	X	X	X
ISPE Advancing Pharmaceutical Quality, Cultural Excellence Guide	T	X	X	X	X
PDA Quality Culture Guided Assessment Tool	T	X	X	X	X

1397

9.3. ISO 10018:2020 Quality management — Guidance for people engagement

1399 ISO 10018:2020 states, "Improvement should be routinely celebrated as a proactive strategy to support broader
1400 organizational development and outcomes. The organization can support improvement by training, knowledge,
1401 and awareness to improve the effectiveness of its people engagement strategies, policies, and activities."

1402 The standard links to ISO 9001:2015 *Quality management systems* [29] regarding continual improvement of the
1403 quality management system whilst suggesting possible action steps and potential benefits.

9.4. ICH Q10 Pharmaceutical Quality System

1405 ICH Q10 has an objective to identify and implement appropriate product quality improvements, process
1406 improvements, variability reduction, innovations, and pharmaceutical quality system enhancements, thereby
1407 increasing the ability to fulfil quality needs consistently. The model aims to promote a lifecycle approach to
1408 product quality by enhancing four specific pharmaceutical quality elements, driving continuous improvement.

1409 Quality risk management can be useful for identifying and prioritizing areas for continual improvement.
1410 Ultimately, management review guides the continuous improvement of the pharmaceutical quality system.

9.5. EFQM Excellence Model

1412 The EFQM Excellence Model recommends challenging the status quo and effecting change by utilizing learning
1413 to create innovation and improvement opportunities. A key driver to measuring change is the use of
1414 benchmarking while maintaining a future focus. The EFQM standard defines performance (results) in two sub-
1415 dimensions: Stakeholder Perceptions, and Strategic & Operational Performance. A second category is the
1416 "Direction", which comprises Purpose, Vision, and Strategy as well as Organizational Culture and Leadership
1417 as sub-categories. Culture in the understanding of the EFQM is *"the specific collection of values and norms*
1418 *that are shared by people and groups within an organization that influence, over time, the way they behave with*
1419 *each other and with Key Stakeholders outside the organization"* [3]. An important perspective here is, that the
1420 external link to stakeholders outside the organization is explicitly mentioned. The Execution category highlights
1421 the sub-categories of Engaging Stakeholders, Creating Sustainable Value and Driving Performance &
1422 Transformation. Continuous Improvement is reflected in the Driving Transformation part within the latter sub-
1423 category. The need to transform, and thus to improve, is driven by both internal and external changes that the
1424 organization needs to adapt to remain successful [3].

1425 The inherent logic of the EQFM excellence model is that the entire "Direction" category, which in turn includes
1426 the culture, should guide the "Execution" category, incorporating transformation or continuous improvement,
1427 which will eventually drive performance "Results". Leaders are a key factor in steering the organizational
1428 culture. Based on that, the organization can prepare for the future, which is driving transformation or
1429 continuously improving performance.

9.6. Malcolm Baldrige Excellence Framework

1431 The Baldrige Excellence Framework includes criteria for performance excellence along with a set of values and
1432 concepts designed to help an organization carry out their mission and improve results. Self-assessment using
1433 the scoring system identifies opportunities for improvement and increased productivity while also measuring
1434 the progress of organizational goals.

1435 Baldrige scoring is strongly weighted towards results. Organizations focused on continuous improvement and
1436 measuring results often have a competitive edge. In healthcare, results often have the patient as the focus.
1437 Results can include patient outcomes, customer engagement, workforce engagement, financial performance,
1438 and leadership communication with patients and the workforce.

1439 Culture is an important attribute that guides ethical behavior, contributes to company values, and increases
1440 resiliency. This in turn creates a patient-focused environment that can adapt to changing circumstances.

9.7. Shingo Model

1442 Continuous Improvement is 1 of 3 dimensions of the guiding principles in the Shingo Model, and guiding
1443 principles drive results. Every element of work is done right the first time. If a defect occurs, it must be detected
1444 and corrected at the time it is created. There is a large focus on process understanding and continuous
1445 improvement. For any organization to be successful, it must be engaged in a relentless quest to make things
1446 better. Therefore, continuous improvement is a key in the Shingo model.

1447 According to Shingo "Improvement means the elimination of waste, and the most essential precondition for
1448 improvement is the proper pursuit of goals." Additionally, the four goals of improvement are to make things
1449 easier, better, faster, and cheaper.
1450
1451 In a culture of continuous improvement, the organization incorporates aspects of value such as innovation,
1452 quality, cost, flexibility, quick delivery, and a comprehensive view of environment, health, and safety.
1453 According to the Shingo model, continuous improvement focuses on principles, Supporting Concepts,
1454 Behavior indicators, and Subsystems as indicated in **Figure 11** below:

1455 **Figure 11: Continuous Improvement in the Shigo Model**
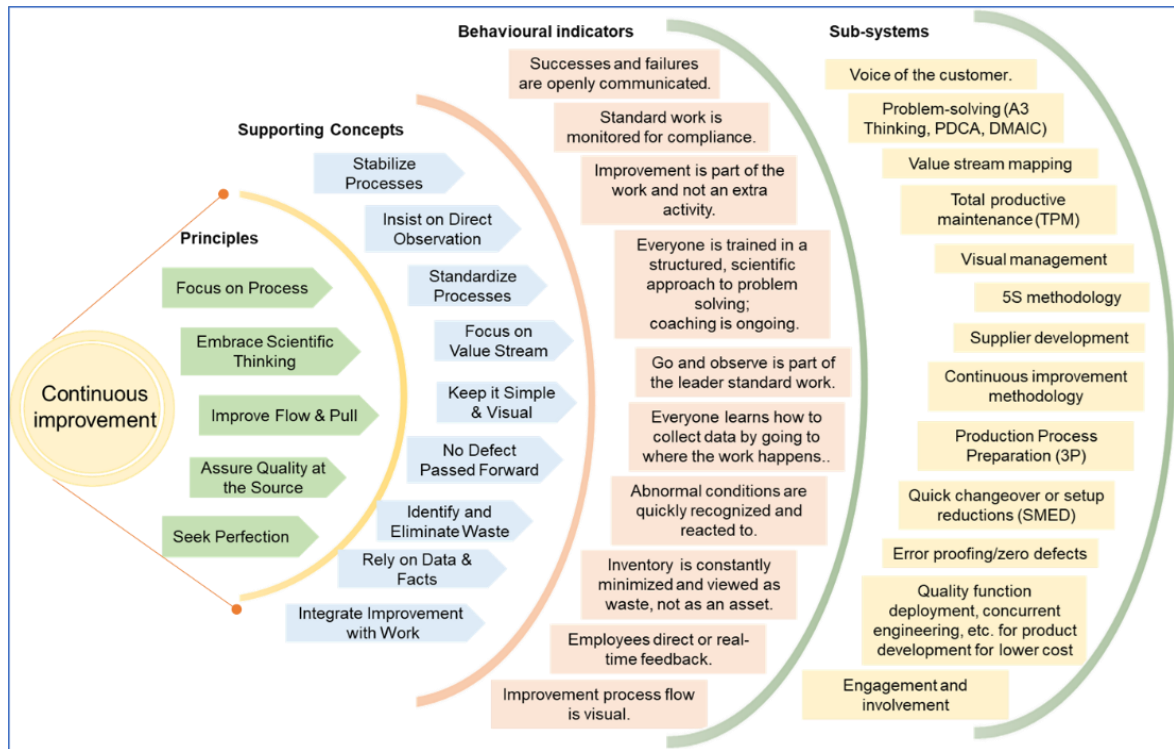
1456

1457 (Member adapted)

9.8. SIQ Model for Continuous Improvement

1459 The SIQ model defines Continuous Improvement as "The constant improvement of processes that helps the
1460 organization reach ever-higher results through gradual change." Part of the culture in the model is to improve
1461 the organization and create innovations which can be achieved in the Systematics section based on Deming's
1462 PDSA wheel—Plan, Do, Study, Act. It is believed that continuous improvement is achieved by asking a series
1463 of systematic questions:

1464 • What do we do to...?

1465 • To what extent do we do it?

1466 • What are the results?

1467 • How do we monitor, learn from, and improve what we do?

1468 This provides insight into the working of the organization, by increasing awareness and prioritizing what needs
1469 to be improved.

9.9. ISPE Advancing Pharmaceutical Quality; Cultural Excellence Guide

1471 The ISPE APQ Cultural Excellence Guide seeks to enhance organizational capability and performance
1472 outcomes through increased employee engagement, the use of systematic improvement processes and rigorous
1473 proactive performance management practices.

1474 The ISPE model shows that Cultural Excellence is driven by leadership example, requires management
1475 ownership and accountability, performance metrics that promote continual improvement, and a strong risk-
1476 management framework. All are key to the proactive identification and prevention of poor-quality outcomes.

1477 The ISPE guide demonstrates that engaged employees proactively identify risks, communicate opportunities for
1478 improvement, speak up openly, motivate their peers to do what is right and demonstrate the desired behaviors
1479 through their actions.

1480 Another aspect of continual improvement addressed by the ISPE APQ program is using Gemba to identify
1481 continuous improvement opportunities, where it is critical to record commitments and agreed actions. The APQ
1482 program provides performance and behavioral measures and continual improvement tools at five maturity levels
1483 for each of the five guides in the series.

9.10. PDA Culture of Quality

1485 Continuous Improvement is one of the five categories of the PDA Culture of Quality tool. This is further
1486 detailed with a focus on clear quality objectives and targets as well as the elements of root cause, s and human
1487 error. Each of these elements in the model has a five-level scale to allow a site to assess and measure their
1488 maturity. When the culture needs improvement a more formal corrective action plan is required to achieve a
1489 higher level of quality culture that relies on routine improvements. Attributes that are important include
1490 functional quality culture with preventative measures and continuous improvement integrated into the fabric of
1491 the organization. The use of a metric scale to identify where an organization is on the continuum is important.

9.11. Summary

1493 Continuous improvement is an integral part of any quality system and is necessary to establish an effective
1494 quality culture. At the same time, an effective quality culture guides an organization towards continuous
1495 improvement.

1496 Most published standards show that continuous improvement is supported by management commitment.
1497 Inherent in the quality culture is the idea that continuous improvement is driven by good metrics that assess the
1498 overall health of the organization.

1499 The best practices for continuous improvement include a proactive strategy, self-assessment, strong leadership,
1500 and a lifecycle approach to quality culture. Continuous improvement vision is established by management, and
1501 the plan is implemented by all levels of the organization. Continuous improvement is viewed as a progressive
1502 process which is focused on increasing the effectiveness and/or efficiency of an organization to fulfil its policy
1503 and objectives with respect to internal, customer focused, and external regulatory requirements.

1504

10. Technical Excellence

10.1. Introduction to Technical Excellence

1507 Technical excellence is the ability to foresee and eliminate issues that may affect patient safety, schedule,
1508 budget, quality, and employee ownership. Technical excellence is foundational to quality culture because a lack
1509 of focus on technical excellence can result in facilities or processes which do not ensure product quality and
1510 patient safety. In the context of quality culture Technical Excellence is achieved by implementing innovative
1511 technological advancements with talented resources, resulting in the best quality product. Technical excellence
1512 includes elements related to agility, competence, maturity of systems, organizational learning, and use of
1513 technology. A foundational requirement is the ability to manage people successfully by hiring and retaining
1514 skilled personnel, providing relevant training, and effective knowledge management tools to achieve the highest
1515 level of competency. Management's guidance, direction, and sense of urgency are integral in achieving a high
1516 level of technological success aligned with the organization's vision and mission. While technical excellence
1517 was not a well-developed concept within many of the quality culture tools and models as such, The PDA Model
1518 and Malcolm Baldrige were the exception.

10.2. The Role of Technical Excellence in Quality Culture

1520 Technical excellence includes the ability to be innovative, to implement new tools and techniques, and
1521 having knowledgeable and experienced employees with the ability to streamline processes and enhance
1522 outcomes within an organization. An organization with a strong quality culture will look proactively at
1523 technical excellence and ensure it is prioritized alongside maintaining day to day operations. For the purposes
1524 of this standard, five key elements have been identified that are critical to technical excellence in the context
1525 of quality culture.

a) **Agility** is the capacity for rapid change and flexibility in operations enabled by a foundation of performance excellence. It is the ability to identify and respond quickly in an efficient and effective manner to both opportunities and issues. Agility influences effective continuous improvement including, for example, implementation of corrective and preventive actions in a timely manner to reduce recurring deviations for improved performance.

b) **Competence** is the combination of practical and theoretical knowledge, skills, behaviors, and values. It is a state of being suitably qualified where a person has the ability to apply knowledge, skills, and experience to improve performance. A focus on competence enhances quality culture through increased employee engagement and sense of fulfillment.

c) **Maturity of Systems** is the state of having reached a stage of full or advanced development of relevant elements supporting the Pharmaceutical Quality System (PQS). For example, training and development, quality risk management, knowledge management, business integrity and compliance. Maintaining excellence in this area also includes evolving the elements internally to stay current with industry and regulatory expectations.

d) **Organizational Learning** is the ability to increase and retain knowledge in the organization to enhance the organization's capacity for performance and to upskill the organization for the future. This includes both continuous improvement of existing approaches (e.g., GEMBA, Lean, Six Sigma etc.), as well coaching and development across all staff on new regulatory expectations, data governance and analytics tools, and advanced manufacturing approaches. It is driven by opportunities to bring about significant, meaningful change utilizing innovative practices, processes, and procedures.

e) **Use of technology** is the degree of the utilization of advanced systems and automation in operations. Mature organizations will proactively identify new technology and set aside resources in advance to ensure processes and systems are evolving to meet regulatory expectations and deliver high quality products. Technology also functions as a change assistant in the use and adaptation of best-in-class knowledge sharing processes, so that the organization can improve its use of critical data.

10.3. Technical Excellence Measurement

Technical excellence can be measured by the maturity level of each element, by using the key performance indicators listed below:

Agility:
- Response times to adapt more effective technology
- Cycle time
- Problem solving time (e.g., root cause identification, investigations on time, CAPA actions executed on time)
- Recurring errors (e.g., effectiveness checks)

Competence:
- Training plan completion linked to job description
- Training compliance and comprehension
- Training effectiveness
- Human-related errors

Maturity of Systems:
- Right first time
- Proactive goals and objectives
- Sustainable supply without interruption Significant Compliance observations (internal, third party, regulatory authorities)

Organizational Learning:
- Workforce cross-training rates
- Workforce turnover

1575	•	Waste reduction

Use of technology:

1576		**Use of technology:**
1577	•	Existing technologies meet or exceed regulatory requirements and industry standards
1578	•	Proactive investments for implementation of new technologies
1579	•	Budgeting for continual improvement

1580 Although the models, guidance and tools reviewed for this standard provide limited direct reference to
1581 technical excellence; they do discuss many aspects important to achieving technical excellence and infer its
1582 importance on quality culture. This standard provides two assessments for Organizations looking to evaluate
1583 technical excellence. **Table 5** indicates the presence of key elements listed above and **Table 6** as shown in the
1584 format of other sections of this standard indicating which models, guidance or tools cover the element of
1585 technical excellence, measurement, criteria for success and opportunity for improvement.
1586
1587
1588 **Table 5: Key Elements of Technical Excellence**
1589

Resources	Type: G=Guidance M=Model T=Tool	Agility (capacity for rapid change)	Competence/ Expertise in place	Organizational Learning	Maturity of systems e.g., Quality Risk Management Knowledge Management	Use of technology (Innovation)
ISO10018:2020 Quality management Guidance	G		X	X		
ICHQ10 Pharmaceutical Quality System	G	X			X	
EFQM Excellence Model	M	X	X	X	X	X
Malcolm Baldrige Excellence Framework	M	X	X	X	X	X
Shingo Model	M			X		
SIQ Model for Performance Excellence	M	X	X	X	X	X
ISPE Advancing Pharmaceutical Quality, Cultural Excellence Guide	T			X		
PDA Quality Culture Guided Assessment Tool	T		X	X	X	X

10.3.1. Overview of Current Models and Tools for Technical Excellence

In addition to comparing the culture models against the elements of technical excellence above, Table 6 also indicates how each guide, model, and tool views the role of Technical Excellence in quality culture. Organizations looking to evaluate this can refer to **Table 6** for resources that discuss the topic's attributes as well as provide some measurements, criteria for success, and suggestions for improvement.

An "X" in one of the columns below denotes that the resource document contains additional information on this aspect of Technical Excellence. Readers are directed to consult the source document for details.

Table 6: Current Guidance, Models and Tools for Technical Excellence

Resources	Type: G=Guidance M=Model T=Tool	Technical Excellence in Quality Culture	Measurements of Technical Excellence	Criteria for Success of Technical Excellence	Suggestions for Improvement in Technical Excellence
ISO10018:2020 Quality management Guidance	G			X	X
ICHQ10 Pharmaceutical Quality System	G		X	X	X
EFQM Excellence Model	M	X	X	X	X
Malcolm Baldrige Excellence Framework	M	X	X	X	X
Shingo Model	M			X	
SIQ Model for Performance Excellence	M	X	X	X	
ISPE Advancing Pharmaceutical Quality, Cultural Excellence Guide	T	X	X	X	X
PDA Quality Culture Guided Assessment Tool	T	X	X	X	X

10.4. ISO10018:2020 Quality management — Guidance for people engagement

There are no specific references to technical excellence in ISO10018:2020 *Quality management — Guidance for people engagement.* However, the guidance does include some relevant commentary on how competence and organizational learning impact performance and cultural excellence. ISO 9000:2015 *Quality management systems* [11] defines competence as the ability to apply knowledge and skills to achieve intended results. Training and development create value for the organization and its customers while increasing employee engagement. The result is improved operational performance. A learning organization focuses on increasing and retaining its knowledge to enhance the organization's capacity for improvement.

1609 10.5. ICHQ10 Pharmaceutical Quality System

1610 Related to technical excellence, ICH Q10 discusses management's responsibility for ensuring there are
1611 appropriate processes, resources, and oversight of outsourced suppliers and service providers. Competence
1612 within management and the assigned resources are needed to successfully provide oversight for third party
1613 services related to manufacturing operations. Proposed changes should be evaluated by a cross functional team
1614 contributing the expertise and knowledge from relevant areas (e.g., Pharmaceutical Development,
1615 Manufacturing, Quality, Regulatory Affairs, and Medical) to ensure the change is technically justified and meets
1616 regulatory requirements.

1617 ICH Q10 defines both knowledge management and quality risk management as enablers to achieve the
1618 following key objectives in pharmaceutical operations: Achieve product realization, Establish and maintain
1619 state of control, and Facilitate continual improvement.

1620 These enablers are also important to achieving technical excellence in the context of quality culture and
1621 providing the means for science-based and risk-based decisions related to product quality throughout the
1622 product lifecycle.

1623 10.6. EFQM Excellence Model

1624 Technical Excellence is considered within the EFQM Excellence model mainly in the Execution section
1625 which includes **Criterion 5: Driving Performance & Transformation** and the Results section which
1626 includes **Criterion 6: Stakeholder Perceptions**.

1627 **Criterion 5**: Driving Performance & Transformation contains five elements associated with driving
1628 performance and managing risks, transforming the future organization, while continuing to deliver results
1629 using current resources. Additional elements also include the innovative use of technology; converting data
1630 into information and knowledge and managing assets and resources to achieve operational excellence.

1631 Agility is embedded in driving transformation; it is linked to a company's need to ensure readiness for the
1632 future. This brings both internal and external challenges, that need to be addressed efficiently and in a timely
1633 manner, to ensure successful outcomes. In the competence space, "Leverage Knowledge" is a major element
1634 linked to outstanding performance related to an organization's ability to prepare for transformation.

1635 **Criterion 6:** Stakeholder Perceptions criteria of the EFQM model bridges with Organizational Learning and
1636 Agility when it recommends the use of past and current performance perceptions to predict future
1637 performance. Intentional search for feedback and inputs, obtained from various sources provides increased
1638 visibility into areas for improvement. As well as being an assessment tool, the model offers a framework and
1639 methodology to help individuals and organizations to measure their current state and to understand the
1640 existing gaps related to performance.

1641 This influences the organization's pathway allowing for predictive measures for the future and ensuring rapid
1642 response to eventual future opportunities and threats.

1643 10.7. Malcolm Baldrige Excellence Framework

1644 Elements within the Baldrige model that are linked to Technical Excellence as defined by this standard are:
1645 Agility, Competence/Expertise, Organizational Learning, Maturity of Systems, and Innovation.

1646 Agility is widely cited in the Baldrige framework and is a critical factor for success. It is interconnected with
1647 "resilience", when considering the required ability to anticipate, prepare for, and recover from disasters,
1648 emergencies, and other disruptions. When these occur, it is necessary to protect and enhance workforce and
1649 customer engagement, supply network and financial performance, organizational productivity, and community
1650 well-being.

1651 Competence is another key element within the Baldrige framework and is closely linked to Organizational
1652 Learning. Building core competencies and preparing the workforce for future challenges is essential to reach
1653 the required expertise leading to technical excellence. Competence and expertise are closely connected with
1654 Workforce capability, which can include the ability to build and sustain relationships with customers and the
1655 business community, to innovate and transition to emerging technologies, to develop new services and work
1656 processes and to meet challenging market and regulatory demands.

Organizational Learning is an essential attribute of high-performing organizations, and it connects with other elements of Technical Excellence (e.g., Competence, Knowledge Management, Innovation and Agility). Effective, well-deployed learning can help an organization improve from early stages of reacting to problems to the highest levels of organization-wide improvements, refinement, and innovation. It includes continuous improvement of existing approaches; the adoption of best practices; rapid response to change leading to new goals, approaches, and system optimization.

Organizational Learning is achieved through research and development, evaluation and improvement cycles, ideas and input from the workforce and stakeholders, the sharing of best practices, and benchmarking. Workforce learning is embedded through education, training, and developmental opportunities that further individual growth. To be effective, both kinds of learning should be embedded in the way organizations operate, contributing to a competitive advantage and ongoing success for the organization.

Maturity of Systems is mainly covered by the Knowledge Management element. It is important in building and managing the knowledge assets of an organization and integrating with the other core values and concepts. It defines knowledge assets as the organization's accumulated intellectual resources; the knowledge possessed by the organization and its workforce in the form of information, ideas, learning, understanding, memory, insights, cognitive and technical skills, and capabilities. Knowledge assets are the know-how that organizations have available to use, invest, and grow. Managing organizational knowledge is a vital asset and a key component of creating value to stakeholders and sustaining competitive advantage.

Use of Technologies highlights the importance of considering the need for innovation, including emerging technologies, into the organization's strategic plan, preparing staff for changes and incorporating new company processes. It also emphasizes the use of digital and web-based technologies in internal processes, the need for agility when disruptive technologies arise, and the use of digital data analytics and artificial intelligence in performance analysis and knowledge management. Innovation is also directly linked to taking intelligent risks and managing resources to pursue opportunities for innovation. The model has a clear designated core concept and value called "Managing for Innovation" which is linked to the Strategy criteria and can be achieved by making meaningful changes with the purpose of creating new value for customers and stakeholders. Innovation and continuous incremental improvement are different, but complimentary concepts. Successful organizations embed both approaches in their cultures to improve performance, take intelligent risk and identify strategic opportunities.

10.8. Shingo Model

The Shingo model does not have a specific "Technical Excellence" category, however, there are several concepts emphasized in the Shingo approach which are aligned with how this standard has defined technical excellence in the context of quality culture particularly in the Guiding Principles section of the model.

"Embrace Scientific Thinking" is part of the Continuous Improvement guiding principle. The Shingo model describes using experimentation cycles, observation and learning to systematically explore new ideas. This is aligned with approaches in pharmaceutical drug development and with the principle of organizational learning. The Shingo model also emphasizes the need for well-designed and functioning processes and calls on team members to use their scientific expertise to continuously improve the processes. This lines up well with the concept of maturity of systems noted in this standard.

The Shingo model also emphasizes a focus on being data driven to achieve thorough process understanding, especially when implementing change which fits well with the concept of competence.

People development is demonstrated as more than just classroom training and calls on executive leadership to be committed to developing people and investing in education and training for all staff over the long term.

In the Supporting Concept 'Develop People' there is an emphasis on eliminating barriers by embracing innovation from the management level which is then taught to all that require it. This promotes continuous learning and development of staff and drives process improvements.

Highlighted principles include:

- Embrace scientific thinking.

1705	• Continuously learn.
1706	• Visual management.
1707	• Coaching is consistent.

1708 10.9. SIQ Model for Performance Excellence

1709 The SIQ model does not directly refer to technical excellence, however, aspects of technical excellence are
1710 rooted within. SIQ is an excellent model to help organizations 'do the right thing' in their business 'the right
1711 way' which then leads to success. In the model this is described as an organization having products or services
1712 that add value to a customer or stakeholder delivered using the right processes that are continuously improved
1713 to deliver the best product. The model focuses on building efficiencies that are relevant to a successful outcome.

1714 There are three cornerstones in the model, all of which have a link to technical excellence:

1715   1) Culture (Success Factors)

1716   2) Structure (Working Methods and Results)

1717   3) Systematics (Asking Questions to provide Insights to an organizations business)

1718 Throughout the model there are references to sustainability, innovation, and quality development, these directly
1719 link to technical excellence as explained by these success factors:

1720 • Involve Motivated Coworkers

1721 • Develop Value-Creating Processes

1722 • Improve Operations and Innovate

1723 10.10. ISPE Advancing Pharmaceutical Quality; Cultural Excellence Guide

1724 The ISPE APQ Cultural Excellence guide has technical excellence and operational excellence as a foundation
1725 for an effective PQS and for a robust quality culture. The program includes technical excellence in Corrective
1726 and Preventive Action, Management Responsibilities and Management Review, Process Performance and
1727 Product Quality Monitoring System, Change Management, Cultural Excellence, Knowledge Management, and
1728 Quality Risk Management.

1729 Technical Excellence is showcased throughout the Process Performance and Product Quality Monitoring guide
1730 with many technical references in each of the five guides. The daily practice of desired behaviors in technical
1731 excellence will impact the culture of the organization. This promotes leadership as a behavior that any employee
1732 can demonstrate leading to technical excellence.

1733 10.11. PDA Culture of Quality

1734 Technical Excellence is one of the five categories within the PDA Quality Culture Guided Assessment Tool.
1735 Technical excellence in the PDA model includes two attributes:

1736   1) Utilization of New Technologies, which lines up directly with Application/Use of Technology, and

1737   2) Maturity of Systems which includes training, business conduct and quality risk management.

1738 Within the 'Utilization of New Technologies' element, an organization uses newer technologies and proactive
1739 investment preventing equipment breakdown and loss of processing time. Where there is Maturity of Systems
1740 in Training, the program uses formal plans that are well structured based on individual skill needs and
1741 promote enhanced knowledge. For a mature system there is an advanced program including Data Integrity and
1742 Business Conduct where leadership is proactive, and the organization is well recognized in the community
1743 with stakeholders being involved formally at all levels. Quality Risk Management should be embedded in all
1744 processes in procedures with all personnel trained in formal QRM tools with clear responsibilities to manage
1745 and evaluate risk.

1746   To be considered a mature organization, the PDA tool indicates that the technological park in place at a company
1747   are seen as cutting edge and ahead of peer companies, playing an industry leading role while helping to shape
1748   the implementation of new technologies. On the Systems Maturity field, PDA tool indicates a company should
1749   excel in Training, Business Conduct and Quality Risk Management areas. In those areas, maturity is achieved
1750   by actively development of subject matter expertise, including advancing training technologies; DI and Business
1751   Conduct program is used to teach and coach authorities and Risk Management is ingrained into organization/full
1752   participation, respectively.

1753   **10.12. Summary**

1754   In the resources reviewed, Technical Excellence is tacit to the areas of technological advancement, innovation,
1755   continuous improvement, converting data into information and knowledge, and managing assets and resources
1756   to achieve operational excellence. Notably, Shingo and the PDA tool take a similar approach to include data
1757   integrity as part of the Technical Excellence category which, when used, shows the maturity of the QMS in an
1758   organization. Innovation is integral to building a foundation for technical excellence as is collaboration and
1759   knowledge management.
1760
1761   Innovation may arise from adapting changes in other industries to achieve a breakthrough. It builds on the
1762   accumulated knowledge of an organization and its people, and the creativity of its partners, collaborators,
1763   competitors, and other relevant organizations, including those outside its business segment. It may involve
1764   collaboration among people who do not normally work together and are in different parts of the organization.
1765   This can lead to the maximizing of learning through shared information and the willingness to use concepts
1766   from outside the organization as idea generators. Therefore, the ability to rapidly disseminate and capitalize on
1767   new and accumulated knowledge is critical to drive organizational innovation and achieve technical excellence.

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