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**BSR/PDA Standard 006-201x, Assessment of Quality Culture
Guidance Documents, Models, and Tools**

Committee Draft

10 **BSR/PDA Standard 006-201x, Quality Culture Assessment of Quality**
11 **Culture Guidance Documents, Models, and Tools**

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114 1. Introduction

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

122
123 The purpose of this standard is to identify key focus topics with attributes, characteristics, and measurements
124 that should be considered to effectively establish, measure, and maintain a mature quality culture as an
125 important fundamental element of a robust quality management system.

126
127 This standard also reviews several available quality culture assessment resources and what approach each
128 takes in addressing the recommended key focus topics to allow an organization to determine whether one of
129 these programs may be a best fit for their needs.

130
131 Quality Culture refers to an organizational culture that intends to enhance a quality mindset. This is
132 characterized by two distinct elements. The first is a cultural/psychological element of shared values, beliefs,
133 expectations, and commitment towards quality. The second is a structural/managerial element with defined
134 processes that enhance quality and drive for continuous improvement at all levels of the organization.

135
136 The United States Food and Drug Administration (US FDA) initially focused on the use of quality metrics to
137 modernize pharmaceutical quality systems and advance innovation [9]. They conducted pilot programs to
138 refine their risk-based inspection model. Over time it became clear that both a strong compliance program
139 containing metrics and a mature quality culture are fundamental to achieving continuous improvement and
140 thereby reducing risk to product quality and ensuring patient safety.

141
142 The concept of quality culture has been evolving as an auditable focus area for regulators. Beginning in 2015,
143 The U.S. FDA, Medicines and Healthcare Products Regulatory Agency (MHRA), Pharmaceutical Inspection
144 Scheme (PIC/S), and the World Health Organization (WHO) have all issued guidance on data integrity [9,31-
145 33]. These guidance documents advise companies to address quality culture as a means to foster transparent
146 communication to management from all levels as a foundation for pharmaceutical quality systems. This standard
147 includes key source documents that span the topic of quality culture as a foundational element of a strong quality
148 management system.

149
150 In 2022, FDA sponsored a virtual workshop on a quality management maturity model that included assessment
151 of both metrics and quality culture along with other factors. In 2023 they published a White Paper titled: *CDER's*
152 *Quality Management Maturity (QMM) Program: Practice Areas and Prototype Assessment Protocol*
153 *Development*. This paper discussed the assessment approach planned to be used at establishments participating
in their QMM program [28].

154
155 The ISO 9000 and 10000 document series have been adopted as global standards to describe many aspects of
156 quality management systems. ISO 9000:2015, 2.2.1, states that “an organization focused on quality promotes
157 a culture that results in the behavior, attitudes, activities and processes that deliver value through fulfilling the
158 needs and expectations of customers and other relevant interested parties” [11]. ISO 10018:2020(E) identifies
159 a “strong, positive quality culture, where people agree upon and care deeply about organizational values, can
160 improve organization performance, motivate people and coordinate their behavior towards a vision and specific
161 performance goals” [1]. ISO 10010:2022 *Quality Management – Guidance to understand, evaluate and*
162 *improve organizational quality culture to drive sustained success* [10] describes the importance of assessing
163 quality culture and calls on the organization to “determine the appropriate tools and techniques to obtain
meaningful data which will contribute towards an understanding of the organization’s quality culture.”

164
165 There are models that have demonstrated the business benefits of a strong quality culture in other industries,
166 such as the Corporate Executive Board (CEB) and PricewaterhouseCoopers (PwC) [15-16]. However, they are
167 not adapted specifically for current Good Manufacture Practice (cGMP) environments and are not reviewed in
168 this standard.

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This standard is intended to guide organizations to determine which tools or techniques are most appropriate for assessment of quality culture maturity given their specific circumstances. In addition, it includes common vocabulary to describe the various terms and concepts that are applicable to quality culture.

175 2. Scope

176 This proposed American National Standard (ANS) identifies various guidance documents, models, and tools to
177 measure and provide a better understanding of quality culture for the pharmaceutical/medical device industry.
178 The standard identifies 5 key focus topics with attributes, characteristics, and measurements that should be
179 considered to effectively establish, measure, and maintain a mature quality culture as an important fundamental
180 element of a robust quality management system. The 5 key focus topics were selected from the PDA Quality
181 Culture Assessment Tool for their comprehensiveness.

182 The key focus topics selected were:

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- Leadership Commitment
- Communication and Collaboration
- Employee Ownership and Engagement
- Continuous Improvement
- Technical Excellence

190 This standard supports the assessment of an existing quality culture and the establishment of a mature quality
191 culture that is compatible with Health Authority and industry regulatory expectations in the context of the
192 current GxP landscape for the pharmaceutical/medical device industry. It provides a holistic review of the
193 references and summarizes best practices.

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A quality culture assessment that conforms to this standard will:

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- a) Collect verifiable data to assess culture at all levels of the organization
- b) Identify opportunities to facilitate and sustain positive changes and continuous improvement within their organization
- c) Determine at what level a quality mindset and behaviors are embedded into the daily work of the individuals
- d) Involve employees at all levels to ensure a broad overview across the organization.

205 3. Relevant References

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

210

211 3.1. ISO10018:2020 Quality management — Guidance for people engagement [1]

212 The *ISO10018:2020 Quality management — Guidance for people engagement* document gives guidelines for
213 engaging people in an organization's quality management system and guidance on enhancing their
214 involvement and competence within it.

215 This document is applicable to any organization, regardless of its size, type or activity.

216 The standard describes the importance of establishing a quality culture and the need for leadership and
217 management "to establish a unity of purpose and shared values." In general, this standard lays out concepts
218 for quality culture and considerations for its implementation including potential actions steps. It also discusses

219 how the concepts are linked to and supportive of other ISO quality management standards. This document
 220 generally serves as a framework to identify any large gaps in an existing quality culture program as well as a
 221 reference to other quality related ISO standards and is a starting point for a high-level overview of quality
 222 culture concepts.

223 **Figure 1:**

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226 <https://qsmgroup.com.au/2020/09/01/quality-management-and-employee-engagement/>

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229 3.2. ICHQ10 Pharmaceutical Quality System [2]

230 The International Conference on Harmonisation's (ICH) quality guidelines Q8, Q9, Q10 and Q11 identify
 231 important key focus areas for a pharmaceutical quality system. [2,12-14].

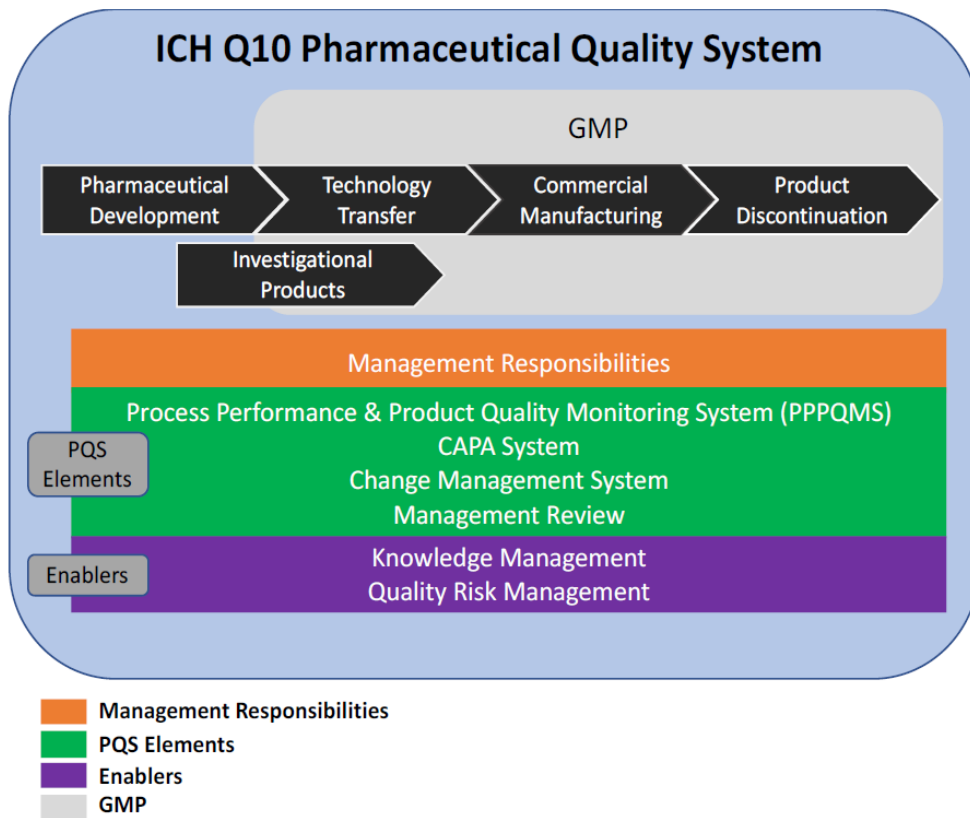
232 Of these, ICH Q10 is the most relevant for quality culture because it describes a comprehensive model for an
 233 effective pharmaceutical quality management system. It is based on International Organization for
 234 Standardization (ISO) quality concepts, including applicable good manufacturing practice (GMP) regulations,
 235 and also integrates with ICH Q8 Pharmaceutical Development and ICH Q9 Quality Risk Management.
 236 The ICH Q10 guidance provides the following parameters: Management Responsibilities and Review;
 237 Knowledge Management, Corrective and Preventive Action, Change Management, Quality Risk
 238 Management, Process Performance and Product Quality Monitoring, and Cultural Excellence Enablers
 239 (Organizational, technical, and tools enablers).

240 ICH Q10 is a model for a pharmaceutical quality system that can be implemented throughout the different
 241 stages of a product lifecycle. Much of the content of ICH Q10 applicable to manufacturing sites is currently
 242 specified by regional GMP requirements. ICH Q10 is not intended to create any new expectations beyond
 243 current regulatory requirements. Consequently, the content of ICH Q10 that is additional to current regional
 244 GMP requirements is optional. ICH Q10 demonstrates industry and regulatory authorities' support of an
 245 effective pharmaceutical quality system to enhance the quality and availability of medicines around the world
 246 in the interest of public health. Implementation of ICH Q10 throughout the product lifecycle should facilitate
 247 innovation and continual improvement and strengthen the link between pharmaceutical development and
 248 manufacturing activities.

249 This guideline applies to the systems supporting the development and manufacture of pharmaceutical drug
 250 substances and drug products, including biotechnology and biological products, throughout the product
 251 lifecycle. Although not implicitly explained in ICH Q10, it does align with the foundational elements/concepts
 252 in this standard that are critical for a successful quality culture (0).
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Figure 2:



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<https://journal.pda.org/content/74/4/456/tab-figures-data>

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262 **3.3. European Foundation for Quality Management (EFQM) Excellence Model [3]**

263 The EFQM is a not-for-profit organization founded in Brussels in 1989 that partners with more than 50 thousand
264 organizations across the globe to provide the skills to develop a culture of continuous improvement. The EFQM
265 Model “is a globally recognized management framework that supports organizations in managing change and
266 improving performance.” It is a model, essentially developed within the European environment and taking into
267 account regulations in the EU market. The Model structure is based on the 3 key sections labeled Direction,
268 Execution, and Results.

269 The model has the purpose to help organizations to achieve success by measuring where they are on the path to
270 create sustainable value. It helps understand the gaps and possible solutions available, empowerment to progress
271 and significantly improve an organization’s performance.

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

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281 **Figure 3:**

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<https://efqm.org/the-efqm-model/>

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285 3.4. Malcolm Baldrige Excellence Framework [4]

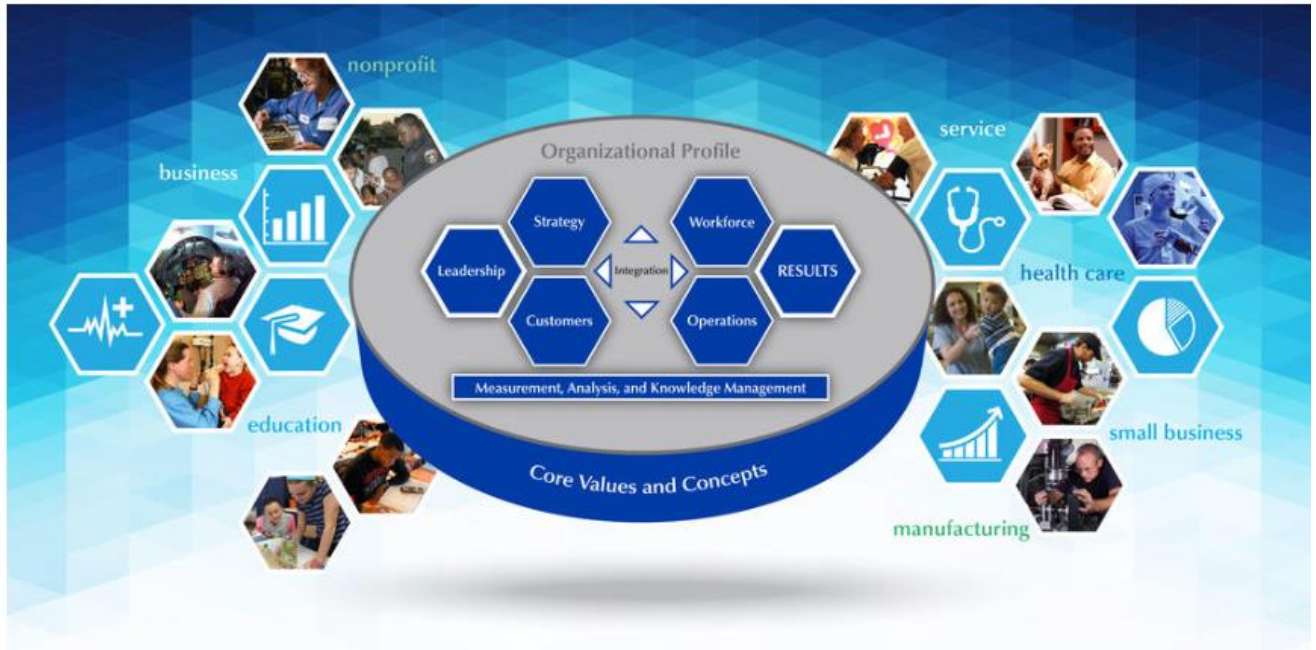
286 The Baldrige Performance Excellence Program is designed around a set of core values and concepts which are
 287 embedded in systematic processes leading to measurable performance results in the following categories:
 288 Leadership and Governance, Financial, Market and Strategy, Product and Process,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

- 292 a) Systems Perspective
- 293 b) Visionary Leadership
- 294 c) Customer- (or Patient-, or Student-) Focused Excellence
- 295 d) Valuing People
- 296 e) Organizational Learning and Agility
- 297 f) Focus on Success
- 298 g) Managing for Innovation
- 299 h) Management by Fact
- 300 i) Societal Contributions
- 301 j) Ethics and Transparency
- 302 k) Delivering Value and Results

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304 The below diagram from the Malcom Baldrige framework illustrates interdependency of the core concepts
 305 just discussed.
 306

307 **Figure 5:**
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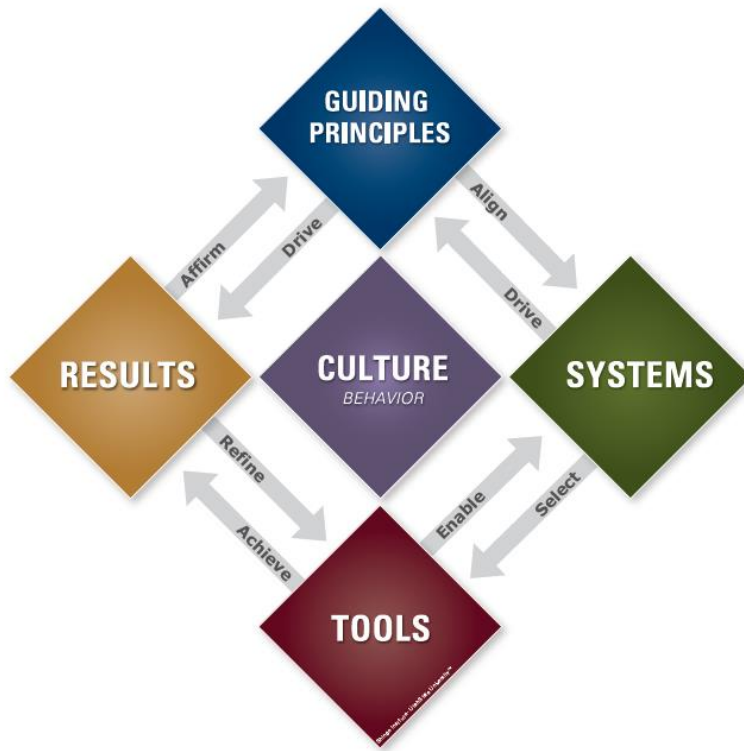
310 (This figure (or figure used on slide) is used with permission of the Baldrige Performance Excellence Program. 2023. 2023–2024
 311 *Baldrige Excellence Framework: Proven Leadership and Management Practices for High Performance*. Gaithersburg, MD: U.S.
 312 Department of Commerce, National Institute of Standards and Technology. Purchase a copy of the Baldrige Excellence
 313 FrameworkK@.)
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320 **3.5. Shingo Model [5]**

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



The Shingo Model™

<https://shingo.org/shingo-model/>

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351 **3.6. SIQ Model for Performance Excellence [6]**

352 Swedish Institute for Quality (SIQ) is an excellence model designed to address the 5th wave of Quality (Q5)
353 which is described as focused on societal satisfaction and how global technological development has erased
354 borders. SIQ calls out “the inefficiency arising from uncommitted employees” as a key weakness in Q5. To
355 address this the model focuses on doing the “right things” in the “right way”. The most recent update of the
356 SIQ model includes a focus on sustainability principles to achieve societal satisfaction which is unique to the
357 other models addressed by this standard. As sustainability becomes a greater focus of many businesses, this
358 model is well positioned to support its assessment.

359 The three pillars of the SIQ model are culture, structure, and systematics (a way of asking questions that leads
360 to insights and motivations.) Similar to PDA’s approach, the SIQ model is backed by research [17] and built
361 around a focus on working methods and the idea that in order to improve results we have to change the way we
362 work. For purposes of this standard, we will focus on the culture portion of the SIQ model which includes five
363 success factors: creating value with customers and stakeholder; leading for sustainability; involving motivated
364 co-workers; develop value-creating processes and improve operations and innovate.

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369 **Figure 6:**



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

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375 **3.7. ISPE Advancing Pharmaceutical Quality (APQ), Cultural Excellence Guide [7]**

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

381 The APQ program recognizes that the ability to advance quality management maturity lies within the
382 pharmaceutical industry and builds upon the ICH Q10 model. The APQ enhances the PQS elements with the
383 aspects of cultural excellence, operational excellence (OPEX), knowledge management, and continual
384 improvement. It provides a comprehensive approach for assessing and improving an organization's quality
385 management maturity to advance the state of quality within the organization.

386 The APQ program focuses on eight overarching aspects:

- 387 a) Integrate quality management maturity, cultural, and operational excellence principles, tools, and
- 388 approaches
- 389 b) Support and incentivize continual improvement
- 390 c) Foster industry ownership of quality beyond compliance
- 391 d) Promote effective and efficient use of resources
- 392 e) Encourage self-improvement and supplier improvement
- 393 f) Enable structured benchmarking, knowledge sharing, and learning among organizations

394 g) Increase the reliability of supply for quality products

395 h) Offer routes to delivering sustainable competitive advantage

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

399

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

- 407 • Leadership and Vision
- 408 • Mindsets and Attitudes
- 409 • Gemba and Employee Engagement
- 410 • Leading Quality Indicators with Metrics that Matter
- 411 • Proactive Management Oversight, Review and Reporting
- 412 • Cultural Enablers

413

414 **Figure 7:**



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417 **3.8. PDA Quality Culture Assessment Tool [8]**

418 The PDA has designed a comprehensive *Quality Culture Assessment Tool and Training* [8] to guide
 419 companies to a better understanding of quality culture, how to assess it, and what actions to take to improve it.
 420 The tool helps a company effectively collect verifiable data that will help them to assess their culture at all
 421 levels of their organization. The PDA model identifies 21 elements of Quality Culture over five categories
 422 that can be objectively assessed. The tool defines criteria for five levels of maturity enabling a site to compute
 423 a maturity score by element and category. The individual site scores are collected by PDA who produces an
 424 industry benchmarking report where sites can use to find their relative strengths and weaknesses as compared
 425 to overall industry results. The PDA Tool has been developed based on research demonstrating a positive
 426 correlation between culture behaviors and quality system elements and refined through industry testing and
 427 user feedback. The research demonstrated that the presence of specific quality system elements can be a
 428 surrogate for more positive culture and behaviors within a pharmaceutical manufacturing environment. The
 429 model is based on ICH Q10 principles as well as incorporating mature quality system elements that go beyond
 430 GMP requirements such as process ownership, safety culture, rewards and recognition, and level of
 431 technology implementation.

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434 **Figure 8:**
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437 http://www.pda.org/docs/default-source/website-document-library/chapters/presentations/australia/data-integrity---focus-on-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 and 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 [11,19-22]. 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 [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). It is an opportunity for management and support staff to break away from their day-to-day tasks to walk the floor of their workplace to identify wasteful activities. The objective is to understand the

value stream and its problems, rather than review results or make superficial comments from their office or conference room [24].

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 [26].

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 [11].

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 compliance-led approach 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 [2,11].
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].
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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452 **5. Acronyms**

ANSI	American National Standards Institute
CAPA	Corrective and preventive 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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457 **BSR/PDA Standard 06-201x, Quality Culture Assessment of Quality Culture Guidance**
458 **Documents, Models, and Tools**

459

460 **6. Leadership Commitment**

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462 **6.1.Introduction to Leadership**

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

470 Behaviors are driven from the values defined by the organization as well as the attributes that an individual
471 demonstrates each day. Since culture is often implied and felt rather than directly stated, leadership has the
472 responsibility to define the values important to the organization as well as the expected behaviors. Leaders
473 must then consistently and transparently demonstrate the behaviors that align with the organization's values.
474 This brings clarity to the workforce on how to embody the values. When people care deeply about the
475 organization's values, and they are behaving as expected, people can improve performance and they are
476 motivated to work toward the company vision.

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

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

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

493 **6.2. Resource Review of Current Guidance, Models and Tools**

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

500

- 501 • Leadership Commitment in Quality Culture
- 502 • Measurements of Leadership Commitment
- 503 • Criteria for Success of Leadership Commitment
- 504 • Suggestions for Improvement in Leadership Commitment

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Using **Table 1**, the organization can decide which reference document(s) may be more pertinent for them to use as part of their Quality Culture journey. Resource documents denoted with an “X” indicates where additional information can be found in that resource on the specific column heading for Leadership criteria.

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Table 1: Current Guidance, Models and Tools for Leadership

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

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6.2.1. ISO10018:2020 Quality Management Guidance

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

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- Accountability

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- Integration

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- Support

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

527 6.2.2. ICHQ10 Pharmaceutical Quality System

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

- 533
- 534 a) Senior management has the ultimate responsibility to ensure an effective pharmaceutical quality
 535 system is in place to achieve the quality objectives, and that roles, responsibilities, and authorities are
 536 defined, communicated, and implemented throughout the company.
- 537 b) Management should:
- 538 • participate in the design, implementation, communication, monitoring and maintenance of an
 539 effective PQS;
 - 540 • demonstrate strong and visible support for the PQS and ensure its implementation throughout
 541 their organization;
 - 542 • ensure a timely and effective communication and escalation process exists to raise quality
 543 issues to the appropriate levels of management;
 - 544 • define individual and collective roles, responsibilities, authorities, and inter-relationships of
 545 all organizational units related to the PQS and ensure that these interactions are
 546 communicated and understood at all levels of the organization;
 - 547 • provide governance and establishment of an independent quality unit/structure with authority
 548 to fulfil certain PQS responsibilities as required by regional regulations;
 - 549 • determine and provide adequate and appropriate resources (human, financial, materials,
 550 facilities and equipment) to implement and maintain the pharmaceutical quality system and
 551 continually improve its effectiveness;
 - 552 • ensure appropriate communication processes are established and implemented within the
 553 organization.
 - 554 • conduct governance management reviews of process performance, product quality, and of the
 555 PQS to ensure its continuing suitability and effectiveness;
 - 556 • advocate continual improvement;
 - 557 • commit appropriate resources, and
 - 558 • assess the conclusions of periodic reviews of process performance and product quality and of
 559 the pharmaceutical quality system.

560

561 6.2.3. EFQM Excellence Model

562 The EFQM model uses a criterion entitled “Organizational Culture and Leadership’ under Direction which
 563 describes the aspiration required for a company. The fundamental concept of leadership within EFQM is
 564 ‘leading with vision, inspiration and integrity’ and “Excellent organizations have leaders who shape the future
 565 and make it happen, acting as role models for its values and ethics”[3] .

566 Organizational Leadership applies to all employee levels rather than the traditional top-down management
 567 style. When the organization is described as outstanding it is due to Leadership behaviors being evident across
 568 all levels. The so called ‘model leadership behavior’ steers organizational culture by inspiring others to adapt
 569 the values required. An organization achieves success by following the concepts below:

- 570 a) Steer the Organization’s Culture & Nurture Values
- 571 b) Create the Conditions for Realizing Change
- 572 c) Enable Creativity & Innovation
- 573 d) Unite Behind & Engage in Purpose, Vision & Strategy

574 6.2.4. Malcolm Baldrige Excellence Framework

575 The Baldrige Excellence Framework uses a systems approach with leadership as one of the seven criteria
 576 categories. There are eleven core values and concepts which are embedded in the systematic processes including
 577 Leadership. The systematic processes yield performance results, of which ‘Leadership and Governance Results’
 578 is one. Leadership commitment is referenced across the 11 core values as listed in the introduction above.
 579

580 From the Baldrige foundation there has been a set of leadership behaviors developed to reinforce these core
 581 values in high-performing organizations. These behaviors typify role-model leaders and can form the basis for
 582 leadership development and design of senior leadership teams. It is expected that senior leaders utilize their
 583 strengths in these behaviors and make sure that their leadership team includes others who complement their
 584 strengths or who possess strengths in behavior other leaders do not. The leadership behaviors are aligned with
 585 the 11 Baldrige core values and concepts, respectively. To be an effective leader Baldrige expects senior
 586 leaders to possess and personally exhibit the executive behaviors associated with visionary leadership, systems
 587 perspective’, ‘ethics and transparency’, and ‘delivering value and results.’
 588

589 6.2.5. Shingo Model

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

595 6.2.6. SIQ Model for Performance Excellence

596 The model was designed based on the characteristics of Swedish culture and principles of leadership which
 597 focus on the following:

- 598 • Decentralization
- 599 • Employee participation and co-determination
- 600 • Employee mandate for decision-making
- 601 • Equality, diversity, and a sense of security and safety
- 602 • Short decision-making processes
- 603 • Transparency
- 604 • Trust, sustainability, and innovation
- 605

606 Where these principles exist, it is a sign of excellence and success in an organization.

607 Of the three cornerstones (Culture, Structure, and Systematics) it is in Culture where there is a focus on
 608 leadership with ‘Lead for Sustainability’ being seen as a success factor. There are five main criteria with
 609 Management being number two and including reference to Leadership. This criterion consists of sub-criteria
 610 with points that ask for information about the working methods chosen by the organization and the extent to
 611 which these are applied.

612 Information is requested about the way in which the organization evaluates and improves its chosen working
 613 methods within each sub-criterion. It deals with working methods used to plan and lead the organization based
 614 on the needs, requirements, wishes and expectations of customers and stakeholders. There is a clear link to the
 615 criteria for customers and stakeholders. It describes how managers on all levels practice committed leadership
 616 that creates the conditions for all employees to take part in the development of the organization and how the
 617 organization leads and develops its business processes in general. In criterion four, Results, there is reference
 618 to leading and improving processes.
 619

620 Figure 9: Concept of Cultural Enablers

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622 https://www.xcelliumconsulting.com/_files/ugd/5f29c4_0c926ca80e214874b81078ea329025aa.pdf?index=true
 623

624 **6.2.7. ISPE Cultural Excellence Report**

625 The ISPE Cultural Excellence Report places a strong emphasis on the importance of Leadership in Quality
 626 Culture. Leadership and Vision are combined as one of the six dimensions of a quality excellence framework.
 627 Leaders establish and promote the vision for the organization to establish and maintain a culture of operational
 628 excellence. Therefore, Leadership and Vision are key in establishing the culture at all levels. Within the tool,
 629 this section identifies desired states and possible improvement actions such as:

- 630 • Create a quality vision
- 631 • Share the quality vision throughout the organization
- 632 • Model the desired behaviors in support of the quality vision

633 **6.2.8.PDA Quality Culture Guided Assessment Tool**

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

- 636 a) **Accountability and Quality Planning** – measures the level of commitment to establishing a robust
 637 Quality Manual, formally documented quality improvement projects and accountability for quality
 638 extended across the company including quality goals for all staff.
- 639 b) **Safety Program** – measures the maturity of the Environmental Health & Safety (EH&S) formal
 640 program including ergonomic and health related issues with the expectation that safety prevention is
 641 embedded in everyone’s goals and being actively measured and communicated.
- 642 c) **Rewards & Recognition (R&R)** – measures the focus of the R&R programs for the prevention of
 643 quality issues.
- 644 d) **Feedback & Staff Development** - where Leadership is mentioned, the tool identifies where
 645 improvements in roles and communication are required with the emphasis on visibility of staff
 646 engagement and recognition linked to quality improvement.

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649 **6.3. Role of Leadership and Management at All Levels**

650 **6.3.1. Top Leadership**

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

657 Through effective leadership, top management is held accountable for ensuring the overall effectiveness of the
 658 quality management system by keeping the quality policy and quality objectives in alignment with the strategic
 659 direction of the organization, by integrating the quality management system requirements into the organization’s
 660 processes, and by supporting other members of the management team in their respective areas of responsibility.

661 **6.3.2. Managers**

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

666 **6.3.3. All Colleagues**

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

670 All colleagues should lead and contribute to a strong, effective Quality culture and have sufficient understanding
 671 and awareness of quality policies, quality objectives, benefits of improved performance and consequences of
 672 nonconformance.

673 **6.4. Role of Management (Sphere of Control)**

674 **1) Senior Management**

675 Senior Management establishes unity of purpose and the direction of the organization. They should create
 676 and maintain the internal environment in which people can become fully involved in achieving the
 677 organization's objectives. They provide a clear focus for people throughout an organization and enable
 678 them to follow a path to achievement of the organizational objectives. They should also promote continuous
 679 improvement and provide a strongly positive influence on other relevant Senior management peers to
 680 demonstrate their leadership as it applies to their area of responsibility.

681
 682 Through effective leadership, top management is held accountable for ensuring the overall effectiveness of
 683 the quality management system by keeping the quality policy and quality objectives in alignment with the
 684 strategic direction of the organization.

685 A strong quality culture is achieved by integrating the quality management system requirements into the
 686 organization's processes, championing the behaviors and framework for a strong culture and by supporting
 687 other members of the Senior management team in their respective areas of responsibility.

688 **2) Middle Management**

689 Senior Management define objectives and designates resources, and they act in a more strategic role.
 690 Middle management are leaders of individual contributors and supervisors who organize resources to
 691 achieve a result by engaging the people in the organization, and they act in a blended role combining
 692 strategic objectives implementation with an oversight of tactical operations. Managers coordinate activities
 693 to direct an organization to meet performance and quality objectives and are accountable for the effective
 694 Quality culture in the ecosystem they manage.

695 **3) Supervisors**

696 Supervisors could include various roles in the organization such as Production Supervisors, Lab
 697 Supervisors, Administrative, Team Leaders, etc. and report to Middle Management. Their role is highly
 698 tactical in nature, and they manage the day-to-day operations. They are expected to provide solid examples
 699 of expected behavior and can emote and promote the foundation for a strong Quality Culture.
 700

701 **6.5. Leadership Attributes**

702 Leadership Attributes are the inner or personal qualities that constitute effective leadership. These are relatively
 703 stable and coherent integrations of personal characteristics that foster a consistent pattern of leadership
 704 performance across a variety of group and organizational situations. These characteristics reflect a range of
 705 stable individual differences, including personality, temperament, motives, cognitive abilities, and expertise.
 706 World class leaders must create a positive environment to nurture talented employees and recognize their
 707 polarized needs, ambitions, and values. They must possess the ability to create a sustainable organizational
 708 capacity while making efficient use of resources. Below, key attributes are discussed in more detail.

709 **a) Visionary**

- 710 • Vision is the ability to concentrate on the most important aspects of business, such as what the
 711 organization aims to achieve. Vision embodies the desired optimal state of an organization to achieve
 712 world class quality culture based on a core set of values. The vision of leadership permeates the
 713 workplace and is manifested in the actions, beliefs, behaviors, and goals of the organization. This
 714 requires a vision that is clearly articulated, energetically shared, and passionately owned ensuring others
 715 will follow and share the vision and enables success by providing the necessary resources, removing
 716 barriers, and promoting collaboration.
- 717 • Transparency involves gaining the trust of others by openly sharing information. Sharing visibility
 718 with the team will promote the vision in achieving the goal.

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- Creativity is being open to new ideas, possibilities, and perspectives, and understanding that there's no "right" way to do things. The creative leader is able to listen, observe, and be willing to change course when necessary. Innovation distinguishes between a leader and a follower.

724 **b) Strategic Thinking**

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

747 **c) Effective Enabler**

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- Enablers bring visibility to all the work necessary to support efficient development and delivery of future business requirements to create the desired Quality Culture. They identify and initiate opportunities for key improvements, continuously challenge and find ways to improve systems, processes, and practices to ensure long term success. Additional considerations include:
 - i. Motivation through Empowerment is demonstrated by delegating authority and allocating more autonomy and responsibilities to people in a team, by enhancing the meaningfulness of work, fostering participation in decision making, and by expressing confidence in other people's decisions.
 - ii. Delegation is critical to a leader's success because it allows them time to focus on more strategic planning to accomplish the vision of the organization. Delegation also allows the team members to grow and demonstrate their leadership capabilities.
 - iii. Passionate leaders are successful because they believe that their work is important. Sharing that enthusiasm is motivating for all people involved and is a way to leverage greater success.
 - iv. Empathy is when supportive leaders take into consideration other people's points of view.
 - v. Authenticity is demonstrated by consistency and transparency in values, beliefs, and actions; integrating values and principles to create a purposeful vision and to contribute to the growth of others. Authentic leaders are self-aware enough to understand their strengths and weaknesses and how these translate to the workplace. Authenticity in leadership includes the capacity of a leader to be open, honest, and forthright and factual with their team.
 - vi. Team building is important in an organization. Collaborative leaders understand that the organization achieves more when its people work together. Working across roles and functions brings energy, ideas, and new solutions to any task. Leadership welcomes the opinions of others in the team to support decision making which encourages a participative open culture. Discussions are open and frank, which leads to innovative new ideas being utilized to promote the quality culture. When managers act in a collaborative fashion, all staff come together to work as a team where information is shared organically, and all involved take responsibility.

774 **d) Ensures Accountability**

- 775 • Accountability occurs when individuals reliably deliver on their commitments, showing others they can
776 be trusted to do what they say they'll do. Leaders further demonstrate accountability by taking
777 responsibility for the outcomes of their actions and decisions and successfully transforming effort into
778 results.
- 779 • Confidence in an effective leader is demonstrated when they ensure that others follow their plans.
780 Assertiveness and confidence enable the leader to gain the respect of their followers/team.
- 781 • Learning from failure is an excellent tool of knowledge building and understanding of self. It allows for
782 survival, renewal, and reinvention of oneself and the organization. How a leader manages and learns
783 from failure often defines one's character as a leader.
784

785 **6.6. Leadership Values**

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

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

795 **a) Trust**

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

804 **b) Integrity**

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

808 **c) Excellence**

809 Organizational excellence can be about Respect for people is product quality, people, and customers.
810 Strong leadership ensures employees own product quality and promote excellence in their organization.
811 Leadership Excellence means being on a path towards what is better and more successful. This requires
812 the leader to be committed to development and improvement.

813 **d) Respect for People**

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

822 e) **Joy**

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

- 827 • Workload
- 828 • Workload Efficiency
- 829 • Flexibility at work
- 830 • Work life integration
- 831 • Meaning in work

832 f) **Equity**

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

838 g) **Courage**

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

842 h) **Humility**

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

848

849 **6.7. Leadership Behaviors**

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

856 While culture is not easy to capture in written statements, leaders should communicate the behaviors that they
 857 expect within the organization. Stated behaviors such as "speak-up when issues are observed" or "be solution-
 858 oriented" help the employees understand what is expected and motivate the organization to align with the
 859 behavior. It is crucial that the leadership engage with employees, discuss the behaviors so that they are visible
 860 and known, serve as role models, use recognition to reinforce desired behaviors, and hold employees
 861 accountable for undesired behaviors. To change the behavior of employees, the context in which they work
 862 within processes, organizational structures, performance metrics, incentive systems, or the distribution of roles
 863 and tasks may also need to change. Leaders who define the expected behaviors and adjust the way work is done
 864 help the organization adopt and demonstrate the behaviors required to support the vision and values and achieve
 865 a robust quality culture.

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

869 **a) Driving Innovation**

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

873 **b) Influence and Credibility**

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

879 **c) Sharing the vision**

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

883 **d) Teacher**

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

888 **e) Master Delegator/Empower Others**

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

893 **f) Acting with Integrity**

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

898 **g) Accountability**

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

904 **h) Servant Leadership**

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

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

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

911 **j) Supporting others**

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

915 **6.8. Summary**

916 This Leadership section described the critical elements of leadership that are required to promote an effective
917 and sustainable Quality Culture at all levels of an organization. Using **Table 1** readers can review existing
918 Quality Culture references and determine which is relevant to their organization and Quality Culture journey.

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

925

926 **7. Communication and Collaboration**

927 **7.1. Introduction**

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

936 **7.2. Role of Communication and Collaboration in Quality Culture**

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

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

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

949 **7.3. Resource Review of Current Guidance, Models and Tools**

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

- 954 • Communication and Collaboration in Quality Culture
- 955 • Measurements of Communication and Collaboration
- 956 • Criteria for Success of Communication and Collaboration
- 957 • Suggestions for Improvement in Communication and Collaboration

959 Using **Table 2 below**, the organization can decide which reference document(s) may be more pertinent to use
 960 as part of their Quality Culture journey. Resource documents denoted with an “X” indicates where additional
 961 information can be found in that resource on the specific column heading for Communication and Collaboration
 962 criteria.
 963

964 **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			
ISPE APQ Cultural Excellence Guide	T	X	X	X	X
PDA Quality Culture Guided Assessment Tool	T	X	X	X	X

965
 966

967 **7.4. ISO10018:2020 Quality management — Guidance for people engagement**

968 There are many ISO standards that address quality, however, 10018:2020 is uniquely focused on the
 969 engagement of people within the context of their “cultures, work values, perceptions and practices”. An

970 important feature of this standard defines employee engagement as the “emotional commitment that people
971 have to the organization and its goals”.

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

979 **7.5. ICHQ10 Pharmaceutical Quality System**

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

984 **7.6. EFQM Excellence Model**

985 The EFQM Excellence Model indirectly incorporates the need for communication and collaboration
986 throughout the document. Example includes:

- 987 • Leadership and Constancy of Purpose: Excellent organizations have leaders who set and communicate
988 a clear direction for their organization. In doing so they unite and motivate other leaders to inspire
989 their people.
- 990 • Management by Process and Facts: Excellent organizations have an effective management system
991 based upon, and designed to deliver, the needs and expectations of all stakeholders. The systematic
992 implementation of the policies, strategies, objectives, and plans of the organization are enabled and
993 assured through a clear and integrated set of processes. These processes are effectively deployed,
994 managed and improved on a day-to-day basis. Decisions are based on factually reliable information
995 relating to current and projected performance, process and systems capability, stakeholder needs,
996 expectations and experiences, and the performance of other organizations, including, where
997 appropriate, that of competitors
- 998 • Partnership Development: Excellent organizations recognize that in the constantly changing and
999 increasingly demanding world of today success may depend on the partnerships they develop. They
1000 seek out, and develop, partnerships with other organizations. These partnerships enable them to
1001 deliver enhanced value to their stakeholders through optimizing core competencies. Partners work
1002 together to achieve shared goals, supporting one another with expertise, resources and knowledge and
1003 build a sustainable relationship based on mutual trust, respect, and openness.

1004 **7.7. Malcolm Baldrige Excellence Framework**

1005 The Malcolm Baldrige Excellence Framework deals with communication and collaboration in their leadership
1006 section. A portion of the leadership section of the Baldrige framework specifically probes whether senior
1007 leaders encourage frank, two-way communication across the entire workforce. Baldrige has a measurement,
1008 analysis and Knowledge Management component which includes “how do you track data and information on
1009 daily operations?”. Also, in this section the Baldrige model assesses how to review the organization’s
1010 performance and capabilities.

1011 Collaboration and shared learning are essential to the Baldrige approach as demonstrated by a requirement
1012 that all Baldrige award winners present at the next annual Baldrige Quality Conference to share with others
1013 who are pursuing similar improvements. Both the conference and the awards are divided into focused
1014 disciplines so those with similar organization types (Education, Healthcare, and Business) can learn from each
1015 other.
1016

1017 **7.8. Shingo Model**

1018 The Shingo model does not directly refer to communication and collaboration; however, *Communication* is
 1019 mentioned in the first dimension, *Cultural Enablers*, and in the third dimension, *Enterprise Alignment* which
 1020 also has inferences to Collaboration.

1021 **7.8.1. Cultural Enablers**

1022 Cultural enablers have two key principles focusing on the foundation of an organization:

1023 **a) Respect every Individual.**

- 1024 • “Respect for every individual naturally includes respect for employees, customers, suppliers, the
 1025 community, and society in general.”

1026 **b) Lead with Humility**

- 1027 • “Humility is an enabling principle that precedes learning and improvement.”
 1028

1029 Information transparency is expected and promoted. Within the principle ‘Respect every Individual Shingo
 1030 promotes the idea of open communication which will clearly lead to the best collaboration.
 1031

1032 **7.8.2. Enterprise Alignment**

1033 Enterprise Alignment details the following three key principles supporting the purpose of an organization:

1034 **a) Think Systemically**

- 1035 • "By understanding the relationships and interconnectedness of a system, people will make better
 1036 decisions and improvements that will more naturally align with the desired outcomes of an
 1037 organization."
 1038

1039 **b) Create Constancy of Purpose**

- 1040 • "An unwavering understanding of why the organization exists, where it is going, and how it will
 1041 get there enables people to align their actions, as well as to innovate, adapt and take risks with
 1042 greater confidence."
 1043

1044 **c) Create Value for the Customer**

- 1045 • “Ultimately, value must be defined through the lens of what a customer wants and is willing to
 1046 pay for. Organizations that fail to deliver both effectively and efficiently on this most fundamental
 1047 outcome cannot be sustained long term.”
 1048

1049 To achieve an effective quality culture, an organization must establish clear and effective communication to
 1050 ensure a clear connection between purpose and the work being performed.
 1051

1052 **7.9. SIQ Model for Performance Excellence**

1053 As described above, SIQ calls out “the inefficiency arising from uncommitted employees” as a key weakness
 1054 in the 5th wave of Quality (i.e. Q5). To address this, the model focuses on doing the “right things” in the “right
 1055 way” with the most recent update including a focus on sustainability principles to achieve societal satisfaction.

1056 The three pillars of the SIQ model are culture, structure, and systematics (a way of asking questions that leads
 1057 to insights and motivations). This is backed by research [17] and built around a focus on working methods and
 1058 the idea that in order to improve results organizations have to change the way they work. The culture portion of
 1059 the SIQ model includes five success factors:

- 1060 • creating value with customers and stakeholders
- 1061 • leading for sustainability
- 1062 • involving motivated co-workers
- 1063 • develop value-creating processes
- 1064 • improve operations and innovate
 1065

1066 One of the success factors for communication and collaboration in the SIQ model, is the involvement of
 1067 motivated coworkers as described by the following language: “A precondition of a successful organization is
 1068 motivated co-workers who feel appreciated and respected. Leaders and co-workers are committed to developing
 1069 a good working environment. Everyone sees their role in the whole and has a clear mandate to contribute to the
 1070 organization’s development.”

1071 In addition, the SIQ assessment focuses on communication of visions that include measuring co-workers’
 1072 creativity and participation.

1073 The concept of collaboration is woven throughout the SIQ Model in how the seven quality levels are described.
 1074 The manual describes levels two or three as the most common level with seven as “unattainable.” Collaboration
 1075 is mentioned in the descriptions of these levels. For example, the lowest level, one, is described as “no
 1076 integration of collaboration between the different divisions in the organization” while level two still has
 1077 “deficient collaboration.” Level four description includes “activities well planned and documented with good
 1078 collaboration and integration.” Level seven is achieved when organizations have a long term firmly established
 1079 quality culture and results are exceptional, lasting, and competitive.

1080 **7.10. ISPE Advancing Pharmaceutical Quality, Cultural Excellence Guide**

1081 ISPE has a very detailed assessment, aspire, act, and advance framework with a deep-dive, five-level assessment
 1082 process. It highlights the importance of management communicating quality topics and ensuring support is
 1083 provided to staff to help improve quality. In addition, the tools highlight the importance of management
 1084 engagement with employees, and their empowerment to provide ideas and feedback for continuous
 1085 improvement. Also, the tool indicates that management should enable employees at all levels to identify and
 1086 communicate risk across the organization. The ISPE APQ Cultural Excellence Guide further establishes a
 1087 robust rewards and recognition program distinguishing the difference between the two important elements and
 1088 formalizing the program.

1089 The ISPE guide also demonstrates tools to assess and engage with third parties, and provides key case studies
 1090 to demonstrate the Assess, Aspire, Act and Advance model. Fundamental to this program is changing culture
 1091 by changing behaviors.

1092 **7.11. PDA Culture of Quality**

1093 In PDA’s Model, the category of Communication and Collaboration consists of four attributes:

- 1094 1) Quality communication,
- 1095 2) Management review and metrics,
- 1096 3) Internal stakeholder feedback, and
- 1097 4) Collaboration with assessors (optional)

1098 To be considered a mature organization, the PDA tool looks for consistent and frequent communication
 1099 around the importance of quality from Senior Management as well as readily accessible programs to raise
 1100 quality related issues available to associates in all areas.

1101 Mature organizations also focus on preventive metrics which are routinely reviewed through the management
 1102 review program and visible to all levels of the organization. Maturity is assessed by leaders who are actively
 1103 collecting stakeholder feedback through direct interactions on the shop floor as well as periodic internal
 1104 surveys.

1105 **7.12. Summary**

1106 The various resources reviewed for this standard refer to communication and collaboration as key elements in
 1107 establishing a mature quality culture. The strategic responsibility to create an environment in which ideas for
 1108 improvement can be freely exchanged lies with senior management. Once this environment is established it is
 1109 the tactical responsibility of the employee to inform management of inefficiencies in their job functions, offer
 1110 solutions, and implement improvements. The level of employee engagement is critical to maintaining a
 1111 positive quality culture. The quality culture becomes stronger and more mature when employees at all levels

1112 of an organization feel free to offer suggestions and voice their opinions on various aspects of continuous
 1113 improvement.
 1114 Effective communication and collaboration must be driven in both directions: from the top down and from the
 1115 bottom up.

1116 **8. Employee Ownership and Engagement**

1117 **8.1. Introduction to Employee Ownership and Engagement**

1118 Employee ownership and engagement is critical in establishing a robust quality culture, resulting in a significant
 1119 investment in an organization by its employees. Essentially, it is where employees have a voice in how the
 1120 organization operates for successful outcomes. When staff are empowered, this leads to engagement and there
 1121 is an increase in performance and productivity.

1122 **8.2. Role of Employee Ownership and Engagement in Quality Culture**

1123 When employees are engaged and take ownership the organization benefits because there is a lower risk of
 1124 employee turnover, elevated productivity levels, increased company and employee growth, and better
 1125 satisfaction at work. Highly engaged employees produce better outcomes, which leads to long-term business
 1126 success. The introduction of a focus on quality culture in an organization succeeds when employees feel
 1127 involved and engaged at every level. One of the hallmarks of a positive quality culture is shared ownership,
 1128 where good leadership promotes engagement with all employees during the decision-making process.
 1129 Through active participation of employees and by giving them substantial responsibilities, the employee’s
 1130 sense of ownership increases and ultimately leads to positive changes and improvement (i.e., ownership by
 1131 empowerment).

1132 There are 5 positive outcomes from employee ownership and engagement:

- 1133 • improves quality culture
- 1134 • reduces staff turnover
- 1135 • increases productivity and quality
- 1136 • builds better work and customer relationships, and
- 1137 • affects profits positively

1140 In this section, the available resources that provide further direction on Employee Ownership and Engagement
 1141 were reviewed. Using **Table 3** below, the organization can decide which reference document(s) may be more
 1142 pertinent to use as part of their Quality Culture journey. Resource documents denoted with an “X” in **Table 3**
 1143 indicate where additional information can be found in that resource on the specific column heading for
 1144 Employee Ownership and Engagement criteria.

1145 **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

1147
1148

1149 **8.3. ISO10018:2020 Quality management — Guidance for people engagement**

1150 In this model, engagement with those at operational levels is key and the leadership must prove how an
1151 employee’s role is relevant to the quality system. In an immature quality culture, an employee’s perception can
1152 be that the quality management system (QMS) is just a set of interrelated documents stored in an office used by
1153 auditors to identify flaws and inconsistencies in business and operational processes. In a mature quality culture,
1154 employees engage with the QMS and drive positive outcomes. Knowledge and awareness (training and
1155 development) are required for engagement. Improvement in engagement allows resiliency when there are
1156 challenges. Attributes that are important include:

- 1157 a) Leadership responsibility in employee engagement,
- 1158 b) Employee engagement requires the employees to connect with the quality management system,
- 1159 c) Knowledge and awareness (training and development) are required for engagement, and
- 1160 d) Improvement in engagement allows resiliency when there are challenges.

1161 Successful methodologies to enhance employee ownership include establishing a strategy and set of targets,
1162 involving key stakeholders, clearly defining roles and responsibilities, and improving employee commitment to
1163 align with the strategy. Methodologies to enhance knowledge and understanding include:

- 1164 • using effective communication based on role and /or situation
- 1165 • use tools such as coaching and mentoring
- 1166 • motivate ongoing enhancement of knowledge
- 1167 • nurture the development and retention of personnel

1168
1169 Methodologies for improving employee engagement include leveraging development, knowledge, skills, and
1170 awareness of the policies, strategies, and actions that drive the business. To improve the culture and enhance
1171 leadership and management processes, personnel at all levels should be engaged when making strategic
1172 improvement in response to internal and external challenges.

1173 **8.4. ICHQ10 Pharmaceutical Quality System**

1174 Although quality culture is foundational throughout the ICH Q10 guidance document, employee engagement
1175 and ownership are only indirectly addressed. There is an emphasis on Management Responsibilities and Review
1176 that cascades to how an organization manages their personnel, processes, systems, and technologies.

1177 Success is captured/measured by The ICH Q10 set of parameters- it does not include a maturity model, an
1178 assessment process, or tools for improvement of Cultural Excellence (CE). It looks to an organization to use
1179 CE as a foundation for the PQS.

1180 For more information, see the ICH Q10; ISPE Advancing Pharmaceutical Quality Program.

1181 8.5. EFQM Excellence Model

1182 The EFQM Excellence Model states that employees must be given ownership in decision-making and must take
 1183 part in creativity and innovation. Excellent organizations (i.e., organizations that rate at the top of the model)
 1184 invest in developing the skills of their employees, who are empowered to use their skills to improve and advance
 1185 the organization. Additionally, there is clear communication with personnel, and they are recognized through
 1186 reward programs. Company goals are achieved when employees share common values and are truly empowered.

1187 Ownership in company success, empowered decision-making, employee development and skills building,
 1188 recognition, rewards, and a strong communication system are necessary in establishing a culture that promotes
 1189 employee ownership and engagement. Success can be recorded by Employee performance (measured
 1190 objectively), absence rate, job satisfaction, and injury rate.

1191 8.6. Malcolm Baldrige Excellence Framework

1192 The Baldrige Excellence Framework uses a systems approach with workforce as one of the six criteria
 1193 categories, however, employee ownership and engagement is not explicitly described. Workforce Results
 1194 aligns as the performance result from the program. The following core concepts and values would be used to
 1195 display some level of employee ownership:

- 1196 • Valuing People
- 1197 • Managing for Innovation

1198 From the excellence framework there are 10 recommendations that can be made to improve employee
 1199 engagement:

- 1200 a) **High ethical standards:** People want to work for an ethical organization that has clear values which
 1201 are displayed at all levels of an organization.
- 1202 b) **Vision:** There is better employee engagement when an organization has a clear vision for the future.
- 1203 c) **Segment your workforce:** All employees will not have the same expectations or desires, by
 1204 understanding the needs of different work groups leaders can pay attention to all needs.
- 1205 d) **Provide learning and development opportunities:** One of the most powerful motivators of
 1206 engagement is the opportunity to continue growing through training, coaching, and new opportunities.
 1207 It is important to make learning relevant to the person and the organization by showing the employee
 1208 they are appreciated.
- 1209 e) **Encourage career progression:** Look for the ability to promote from within and reward employee
 1210 development and loyalty especially during difficult times where career progression is difficult.
- 1211 f) **Never lose focus on employee health and safety:** When employees are valued their health and safety
 1212 is valued above everything else. Employees will disengage if there is a demonstrable lack of concern.
- 1213 g) **Provide a sense of ownership:** Let employees own their work processes and ensure they understand
 1214 the link between their work and what is important to the organization, so they have a sense of
 1215 ownership in the organization's success. Encourage them to fully participate in the organization and to
 1216 be sources of innovation.
- 1217 h) **Reward and recognize:** Always find the time and occasions to recognize the contributions of
 1218 employees. This is especially important in uncertain times.
- 1219 i) **Draw from diversity:** When an organization has a diverse workforce, this results in diverse ideas,
 1220 and diverse thought processes showing gains from capitalizing on this diversity. Employees know
 1221 their opinions are values which ultimately benefit the organization.
- 1222 j) **Communicate, communicate, communicate:** Leaders need to be visible, especially during a
 1223 challenging or uncertain time. Communications must be open, honest, and transparent when sharing

1224 information on the organization's status and challenges. They also need to be good listeners to gain
1225 insights and be responsive to peoples' ideas and needs.

1226 **8.7. Shingo Model**

1227 Empowered team members are essential to success. This means that employees are engaged in the success of
1228 the company and take ownership of their job responsibilities. Enterprise Alignment (interdepartmental) is one
1229 of three dimensions of the guiding principles for determining the commitment of employees. Cultural Enablers
1230 and Continuous Improvement are the other two dimensions. The following statements taken directly from the
1231 Shingo Model demonstrate the importance of employee ownership and engagement: "The results of an
1232 organization depend on the way its people behave."

1233 **8.8. SIQ Model for Performance Excellence**

1234 The SIQ Management Model (Excellence Model) is a tool that can be used to lead to success. It champions
1235 centralized employee ownership where knowledgeable, motivated employees step forward and take
1236 responsibility for the bigger picture, beyond traditional roles. When there is a culture in place to add value to
1237 processes with continuous improvement and visible ease of adaptation the employee engages with the leadership
1238 and organization. This culture should also encourage openness, a willingness and courage to innovate, and the
1239 engagement of employees leading to improved processes and ultimately better products.

1240 In the culture cornerstone of the five success factors there are two which relate to employees - involving
1241 motivated co-workers and improving operations with innovation. For employee engagement, there are sub-
1242 criteria with points that ask for information about the working methods chosen by the organization and the
1243 extent to which these are applied. Information on how the organization does what it does, and which working
1244 methods have been chosen in the area is requested to be successful.

1245 The main criterion describes methods for drafting relevant employee development plans that detail how skills
1246 development is carried out based on strategies, objectives, and action plans for the organization's overall
1247 competence. Within the Employees criteria there is a sub-criterion that deals with creativity and innovation,
1248 with innovation referring to both continuous improvement and radical innovations. There are descriptions of
1249 how to deal with issues concerning working methods to promote a good work environment and employee
1250 satisfaction. Additional sub-criteria for Employees are provided in the "Results" section.

1251 **8.9. ISPE Advancing Pharmaceutical Quality; Cultural Excellence Guide**

1252 The ISPE Advancing Pharmaceutical Quality (APQ): Cultural Excellence Guide is a wholistic model based
1253 upon six dimensions of cultural excellence, and follows the framework of Assess, Aspire, Act, and Advance. It
1254 includes a five-level scale assessment, aspirational plan for improvement, action tracking, and aspirational tools
1255 to measure this improvement. The six dimensions of Cultural Excellence include:

- 1256 • Leadership and Vision
- 1257 • Mindsets and Attitudes
- 1258 • GEMBA & Employee Engagement
- 1259 • Leading Quality Indicators: Measures that Matter
- 1260 • Proactive Management Oversight, Review, and Reporting, and
- 1261 • Cultural Enablers

1262 The model assesses behaviors at all levels of the organization, includes systematic improvement processes, and
1263 includes reward and recognition programs. The APQ contains bonus content that aids assessors in evaluation of
1264 third-party relationships.

1265 The ISPE APQ Cultural Excellence Guide model helps to assess, foster, develop, monitor, measure, learn,
1266 aspire, and ultimately act upon improvement to advance Cultural Excellence. Employee ownership and

1267 engagement starts with Leadership and Vision. Leadership establishes the foundational elements that engage
1268 employees to commit to establishing a mature quality culture.

1269 Behavioral measures are very important to employee ownership and engagement. These measures are included
1270 within the 21-behavior assessment tool in the pre-assessment and the full deep-dive, five-level scale APQ
1271 Cultural Excellence Assessment.

1272 GEMBA is the key dimension that defines the employee ownership and engagement plans. It includes
1273 leadership and employee communications, goals, performance enablers, and monitoring behaviors in a
1274 transparent and visual manner to assess the PQS and the culture of the organization at multiple levels. The
1275 dimension of cultural enablers provides tools needed to track and measure behaviors and resulting cultural and
1276 business performance. Additionally, a key element in GEMBA is a recognition and reward system that
1277 establishes the behaviors and measures actions associated with quality culture excellence. Success is captured
1278 via employee behaviors, and performance aligned to the business strategy and cascading goals and criteria that
1279 show success.

1280 For more information, see ISPE Cultural Excellence Report; ISPE APQ Cultural Excellence Guide, ISPE
1281 Reward and Recognition Webinar; ISPE Advancing Pharmaceutical Quality Program, ISPE Cultural Excellence
1282 Report (2017) [7].

1283 **8.10. PDA Culture of Quality**

1284 In the PDA Quality Assessment Tool Employee Ownership and Engagement define two attributes:
1285 Understanding Quality Goals and Staff Empowerment and Engagement.

1286 The metrics ‘Impact on Product Quality’ and Patient Impact’ are measured under ‘Understanding Quality
1287 Goals’ and ‘Process Ownership and Engagement’ and ‘QMS Processes’ are linked to ‘Staff Empowerment
1288 and Engagement.’

1289 The tool allows the organization to assess if process owners are engaged with the processes and products they
1290 work with and if they feel able to make decisions and drive change. If employees have ownership and are
1291 engaged in the success of the organization, they will have the ability to ascertain if processes are clear and
1292 when necessary, they can make changes that result in improvements to the processes.

1293 **8.11. Summary**

1294 Employee ownership and engagement is inherently linked to Leadership. With strong effective leadership,
1295 employees feel empowered and valued which results in a strong Quality Culture.

1296 As shown in **Table 3** above, several of the models give criteria for success and detail how success can be
1297 measured when employees have ownership and are engaged within the company. ISPE and SIQ place a detailed
1298 emphasis on employee engagement and are excellent resources.

1299

1300 **9. Continuous Improvement (CI)**

1301 **9.1. Introduction to Continuous Improvement**

1302 Continuous/continual improvement is the ongoing advancement of products, services or processes through
1303 incremental and breakthrough improvements gained from process knowledge and experience. ISO 9001:2015
1304 Quality management systems [29], describes improvement in general and in relation to nonconformities,
1305 corrective actions and continual improvement. Clause 10 states “The organization shall continually improve
1306 the suitability, adequacy and effectiveness of the quality management system” [29].

1307 Continuous improvement not only includes processes, but also the state of striving towards a better and more
1308 cohesive quality culture. An effective way to sustain and spread a continuous improvement culture is by
1309 focusing on solving real problems inside an organization.

1310 The five components of continuous improvement are as follows.

- 1311 • **Plan:** Identify an opportunity and plan for change.
- 1312 • **Do:** Implement the change on a small scale.
- 1313 • **Check:** Use data to analyze the results of the change and determine whether it made a difference.
- 1314 • **Act:** If the change was successful, implement it on a wider scale
- 1315 • **Re-check:** Continuously assess the results.

1316 When the following eight key elements are in place, an organization is demonstrating a culture of continuous
1317 improvement:

- 1318 a) **Customer Focused**
1319 Making decisions based on the best interest of the client.
- 1320 b) **Total Employee Involvement**
1321 Employees are empowered and engaged at every level of the organization.
- 1322 c) **Process Centered**
1323 Use of methods, (e.g., PDCA, Lean, etc.) to understand the elements that transform inputs into outputs
1324 whilst removing emotion from decision making
1325 Integrated System: Understanding how all areas of an
1326 organization function together and fostering a culture of cohesion and communication.
- 1327 d) **Strategic Approach**
1328 Use of organizational and departmental plans to describe the vision and how to implement changes.
- 1329 e) **Continual Improvement**
1330 Foster an understanding that improvement is constant and encourages improvements in processes and
1331 systems.
- 1332 f) **Fact-Based Decision Making**
1333 Gather the data on how a process looks to understand how it can be improved.
- 1334 g) **Communication**
1335 Open communication removes the fear of failure and in turn sparks creativity whilst engaging
1336 employees at every level of the organization.
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1340 9.2. Role of Continuous Improvement in Quality Culture

1341 Continuous improvement can be perceived in two distinct ways. The first is to view continuous improvement
1342 as the outcome, a state of an organization. The second is to view it as an enabler or integral part of a larger
1343 goal. This logic also applies to continuous improvement and quality culture. While higher levels of quality
1344 culture will achieve the continuous improvement of products, processes, and systems, striving for continuous
1345 improvement is fundamental to a quality- and patient-focused culture. The former refers to continuous
1346 improvement when it is reflected in key performance indicators that improve over time. The latter refers to
1347 continuous improvement when it is further broken down into practices that will lead to improved results (e.g.,
1348 Shingo Model).

1349 Subsequent subsections outline how each guide, model, and tool views the role of Continuous
1350 Improvement in Quality Culture. Organizations looking to evaluate communication and collaboration
1351 can refer to **Table 4** below for resources that discuss the topic's attributes as well as provide some
1352 measurements, criteria for success, and suggestions for improvement. Resource documents denoted with
1353 an "X" in **Table 4** indicate where additional information can be found.

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1359 **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

1360

1361 **9.3. ISO 10018:2020 Quality management — Guidance for people engagement**

1362 ISO 10018:2020 states, “Improvement should be routinely celebrated as a proactive strategy to support broader
1363 organizational development and outcomes. The organization can support improvement by training, knowledge,
1364 and awareness to improve the effectiveness of its people engagement strategies, policies, and activities”.

1365 The standard links to ISO 9001:2015 *Quality management systems* [29] regarding continual improvement of the
1366 quality management system whilst suggesting possible action steps and potential benefits.

1367 **9.4. ICH Q10 Pharmaceutical Quality System**

1368 ICH Q10 has an objective to identify and implement appropriate product quality improvements, process
1369 improvements, variability reduction, innovations, and pharmaceutical quality system enhancements, thereby
1370 increasing the ability to fulfil quality needs consistently. A focus on quality risk management as a tool for
1371 identifying and prioritizing areas for continual improvement. This lifecycle approach, using four specific
1372 pharmaceutical quality systems, drives continuous improvement. Ultimately, Management Review guides the
1373 prioritization of continuous improvement activities.

1374 **9.5. EFQM Excellence Model**

1375 The EFQM Excellence Model recommends challenging the status quo and effecting change by utilizing learning
1376 to create innovation and improvement opportunities. A key driver to measuring change is the use of
1377 benchmarking while maintaining a future focus. The EFQM standard defines performance (results) in two sub-
1378 dimensions: Stakeholder Perceptions, and Strategic & Operational Performance. A second category is the
1379 “Direction”, which comprises Purpose, Vision, and Strategy as well as Organizational Culture and Leadership
1380 as sub-categories. Culture in the understanding of the EFQM is “*the specific collection of values and norms*”

1381 *that are shared by people and groups within an organization that influence, over time, the way they behave with*
 1382 *each other and with Key Stakeholders outside the organization” [3]. An important perspective here is, that the*
 1383 *external link to stakeholders outside the organization is explicitly mentioned. The Execution category highlights*
 1384 *the sub-categories of Engaging Stakeholders, Creating Sustainable Value and Driving Performance &*
 1385 *Transformation. Continuous Improvement is reflected in the Driving Transformation part within the latter sub-*
 1386 *category. The need to transform, and thus to improve, is driven by both internal and external changes that the*
 1387 *organization needs to adapt to remain successful [3].*

1388 The inherent logic of the EQFM excellence model is that the entire “Direction” category, which in turn includes
 1389 the culture, should guide the “Execution” category, incorporating transformation or continuous improvement,
 1390 which will eventually drive performance “Results”. Leaders are a key factor in steering the organizational
 1391 culture. Based on that, the organization can prepare for the future, which is driving transformation or
 1392 continuously improving performance.

1393 **9.6. Malcolm Baldrige Excellence Framework**

1394 The Baldrige Excellence Framework includes criteria for performance excellence along with a set of values and
 1395 concepts designed to help an organization carry out their mission and improve results. Self-assessment using
 1396 the scoring system identifies opportunities for improvement and increased productivity while also measuring
 1397 the progress of organizational goals.

1398 Baldrige scoring is strongly weighted towards results. Organizations focused on continuous improvement and
 1399 measuring results often have a competitive edge. In healthcare, results often have the patient as the focus.
 1400 Results can include patient outcomes, customer engagement, workforce engagement, financial performance,
 1401 and leadership communication with patients and the workforce.

1402 Culture is an important attribute that guides ethical behavior, contributes to company values and increases
 1403 resiliency. This in turn creates a patient-focused environment that can adapt to changing circumstances.

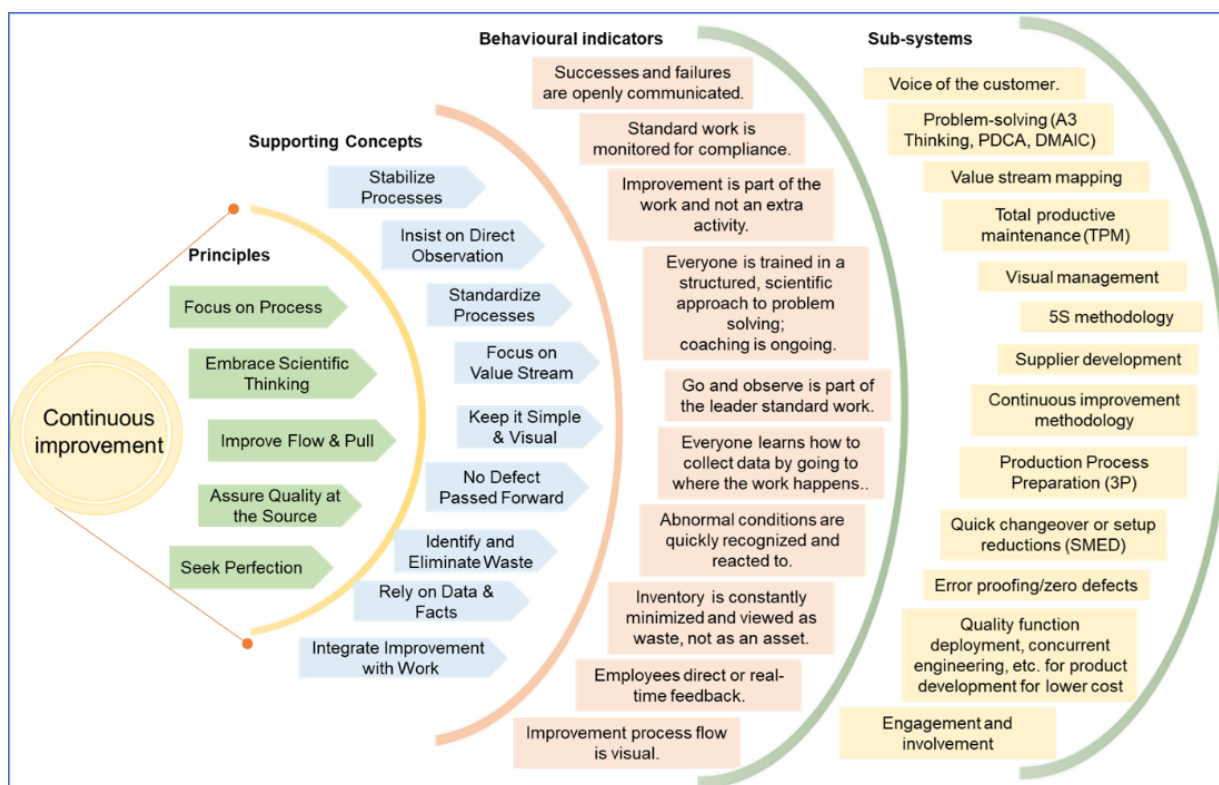
1404 **9.7. Shingo Model**

1405 Continuous Improvement is 1 of 3 dimensions of the guiding principles in the Shingo Model, and guiding
 1406 principles drive results. Every element of work is done right the first time. If a defect occurs, it must be detected
 1407 and corrected at the time it is created. There is a large focus on process understanding and continuous
 1408 improvement. For any organization to be successful, it must be engaged in a relentless quest to make things
 1409 better. Therefore, continuous improvement is a key in the Shingo model.

1410 According to Shingo “Improvement means the elimination of waste, and the most essential precondition for
 1411 improvement is the proper pursuit of goals.” Additionally, the four goals of improvement are to make things
 1412 easier, better, faster, and cheaper.

1413 In a culture of continuous improvement, the organization incorporates aspects of value such as innovation,
 1414 quality, cost, flexibility, quick delivery, and a comprehensive view of environment, health, and safety.
 1415 According to the Shingo model, continuous improvement focuses on principles, Supporting Concepts,
 1416 Behavior indicators, and Subsystems as indicated in **Figure 10** below:
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 1418

1419 **Figure 10: Continuous Improvement in the Shingo Model**



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1422 **9.8. SIQ Model for Continuous Improvement**

1423 The SIQ model defines Continuous Improvement as “The constant improvement of processes that helps the
 1424 organization reach ever-higher results through gradual change.” Part of the culture in the model is to improve
 1425 the organization and create innovations which can be achieved in the Systematics section based on Deming’s
 1426 PDSA wheel—Plan, Do, Study, Act. It is believed that continuous improvement is achieved by asking a series
 1427 of systematic questions:

- 1428 • What do we do to...?
- 1429 • To what extent do we do it?
- 1430 • What are the results?
- 1431 • How do we monitor, learn from, and improve what we do?

1432 This provides insight into the working of the organization, by increasing awareness and prioritizing what needs
 1433 to be improved.

1434 **9.9. ISPE Advancing Pharmaceutical Quality; Cultural Excellence Guide**

1435 The ISPE APQ Cultural Excellence Guide states that a cultural excellence program seeks to enhance
 1436 organizational capability and performance outcomes through increased employee engagement, the use of
 1437 systematic improvement processes and rigorous proactive performance management practices.

1438 The ISPE model shows that Cultural Excellence is driven by leadership example, requires management
 1439 ownership and accountability, performance metrics that promote continual improvement, and a strong risk-
 1440 management framework. All are key to the proactive identification and prevention of poor-quality outcomes.

1441 The ISPE guide demonstrates that engaged employees proactively identify risks, communicate opportunities for
 1442 improvement, speak up openly, motivate their peers to do what is right and demonstrate the desired behaviors
 1443 through their actions.

1444 Another aspect that ISPE address is the key purpose of Gemba is to identify continuous improvement
 1445 opportunities, it is critical to record commitments and agreed actions. The culture impact survey and the deep
 1446 dive APQ assess, aspire, act, advance model focuses on behavioral metrics that impact business outcomes. The
 1447 guide demonstrates multiple case studies, a Cultural Excellence Improvement tool, and an Act and Advance
 1448 improvement action plan.

1449 **9.10. PDA Culture of Quality**

1450 The PDA Culture of Quality tool focuses on root causes and human error issues. When the culture needs
 1451 improvement a more formal corrective action plan is required to achieve a higher level of quality culture that
 1452 relies on routine improvements. Attributes that are important include functional quality culture with preventative
 1453 measures and continuous improvement integrated into the fabric of the organization. The use of a metric scale
 1454 to identify where an organization is on the continuum is important. This tool integrates root cause analysis tools
 1455 into the quality culture.

1456 **9.11. Summary**

1457 Continuous improvement is an integral part of any quality system and is necessary to establish an effective
 1458 quality culture. At the same time, an effective quality culture guides an organization towards continuous
 1459 improvement.

1460 Most published standards show that continuous improvement is supported by management commitment.
 1461 Inherent in the quality culture is the idea that continuous improvement is driven by good metrics that assess the
 1462 overall health of the organization.

1463 The best practices for continuous improvement include a proactive strategy, self-assessment, strong leadership,
 1464 and a lifecycle approach to quality culture. Continuous improvement vision is established by management, and
 1465 the plan is implemented by all levels of the organization. Continuous improvement is viewed as a progressive
 1466 process which is focused on increasing the effectiveness and/or efficiency of an organization to fulfil its policy
 1467 and objectives with respect to internal, customer focused, and external regulatory requirements.

1468

1469 **10. Technical Excellence**

1470 **10.1. Introduction to Technical Excellence**

1471 Technical excellence is the ability to foresee and eliminate issues that may affect patient safety, schedule,
 1472 budget, quality, and employee ownership. Technical excellence in the context of quality culture is achieved by
 1473 implementing innovative technological advancements with talented resources, resulting in the best quality
 1474 product. Technical excellence includes elements related to agility, competence, maturity of systems,
 1475 organizational learning, and use of technology. A foundational requirement is the ability to manage people
 1476 successfully by hiring and retaining skilled personnel, providing relevant training, and effective knowledge
 1477 management tools to achieve the highest level of competency. Management's guidance, direction, and sense of
 1478 urgency are integral in achieving a high level of technological success aligned with the organization's vision
 1479 and mission.

1480 **10.2. The Role of Technical Excellence in Quality Culture**

1481 Technical excellence includes the ability to be innovative, allowing employees to utilize their experiences
 1482 and knowledge to streamline processes, and enhance outcomes within an organization. This ability directly
 1483 impacts and influences the quality culture within an organization. For the purposes of this standard, five key
 1484 elements have been identified that are critical to technical excellence in the context of quality culture.

1485 a) **Agility** is the capacity for rapid change and flexibility in operations enabled by a foundation of
 1486 performance excellence. It is the ability to identify and respond quickly in an efficient manner to both
 1487 opportunities and issues. Agility influences effective continuous improvement including, for example,
 1488 implementation of corrective and preventive actions in a timely manner to reduce recurring deviations
 1489 for improved performance.

- 1490 b) **Competence** is the combination of practical and theoretical knowledge, skills, behaviors, and values.
 1491 It is a state of being suitably qualified where a person has the ability to apply knowledge, skills, and
 1492 experience to improve performance. This leads to increased employee engagement and sense of
 1493 fulfillment.
- 1494 c) **Maturity of Systems** is the state of having reached a stage of full or advanced development of
 1495 relevant elements supporting the Pharmaceutical Quality System (PQS). For example, training and
 1496 development, quality risk management, knowledge management, business integrity and compliance.
- 1497 d) **Organizational Learning** is the ability to increase and retain knowledge in the organization to
 1498 enhance the organization's capacity for performance. This includes both continuous improvement of
 1499 existing approaches and training and coaching (e.g., GEMBA, Lean, Six Sigma etc.) to use an
 1500 optimum approach to embed knowledge and maximize use of resources. It is driven by opportunities
 1501 to bring about significant, meaningful change utilizing innovative practices, processes, and
 1502 procedures.
- 1503 e) **Use of technology** is the degree of the utilization of advanced systems and automation in operations.
 1504 Technology functions as a change assistant in the use and adaptation of best-in-class knowledge
 1505 sharing processes, so that the organization can improve its use of critical data.

1506 10.3. Technical Excellence Measurement

1507 Technical excellence can be measured by the maturity level of each element, by using the key performance
 1508 indicators listed below:

1510 **Agility:**

- 1511 • Response times
- 1512 • Cycle time
- 1513 • Problem solving time (e.g., investigations on time, actions execution on time)
- 1514 • Recurring errors

1515 **Competence:**

- 1516 • Training plan completion linked to job description
- 1517 • Training compliance and comprehension
- 1518 • Training effectiveness
- 1519 • Human-related errors

1520 **Maturity of Systems:**

- 1521 • Right first time
- 1522 • Proactive goals and objectives
- 1523 • Significant Regulatory observations

1524 **Organizational Learning:**

- 1525 • Workforce cross-training rates
- 1526 • Workforce turnover
- 1527 • Waste reduction

1529 **Use of technology:**

- 1530 • Existing technologies meet or exceed regulatory requirements and industry standards
- 1531 • Proactive investments for implementation of new technologies
- 1532 • Budgeting for continual improvement

1533 The available resources provided limited direct reference to technical excellence; the guidance documents
 1534 infer its importance on quality culture. Organizations looking to evaluate technical excellence can refer to
 1535 **Table 5** for resources that discuss the key elements listed above.

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1539**Table 5: Key Elements of Technical Excellence**

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	
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

1540 **10.3.1. Overview of Current Models and Tools for Technical Excellence**

1541 Subsequent subsections outline how each guide, model, and tool views the role of Technical Excellence in
 1542 Quality Culture. Organizations looking to evaluate this can refer to **Table 6** for resources that discuss the topic's
 1543 attributes as well as provide some measurements, criteria for success, and suggestions for improvement.

1544 Resource documents denoted with an "X" indicates where additional information can be found in that resource
 1545 on the specific column heading for Technical Excellence criteria.

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1556 **Table 6: Current Guidance, Models and Tools for Technical Excellence**
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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

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1559 **10.4. ISO10018:2020 Quality management — Guidance for people engagement**

1560 There are no specific references to technical excellence in ISO10018:2020 *Quality management — Guidance*
1561 *for people engagement*. However, the guidance does include some relevant commentary on how competence
1562 and organizational learning impact performance and cultural excellence. ISO 9000:2015 *Quality management*
1563 *systems* [11] defines competence as the ability to apply knowledge and skills to achieve intended results.
1564 Training and development create value for the organization and its customers while increasing employee
1565 engagement. The result is improved operational performance. A learning organization focuses on increasing
1566 and retaining its knowledge to enhance the organization's capacity for improvement.

1567 **10.5. ICHQ10 Pharmaceutical Quality System**

1568 Related to technical excellence, ICH Q10 discusses management's responsibility for ensuring there are
1569 appropriate processes, resources, and oversight of outsourced suppliers and service providers. Competence
1570 within management and the assigned resources are needed to successfully provide oversight for third party
1571 services related to manufacturing operations. Proposed changes should be evaluated by a cross functional team
1572 contributing the expertise and knowledge from relevant areas (e.g., Pharmaceutical Development,
1573 Manufacturing, Quality, Regulatory Affairs, and Medical) to ensure the change is technically justified and meets
1574 regulatory requirements.

1575 ICH Q10 defines both knowledge management and quality risk management as enablers to achieve the
1576 following key objectives in pharmaceutical operations:

- 1577 • Achieve product realization,
- 1578 • Establish and maintain state of control,
- 1579 • Facilitate continual improvement.

1580 Both enablers are also important to achieving technical excellence in the context of quality culture and
 1581 providing the means for science-based and risk-based decisions related to product quality throughout the
 1582 product lifecycle

1583 10.6. EFQM Excellence Model

1584 Technical Excellence is considered within the EFQM Excellence model mainly in the Execution section
 1585 which includes **Criterion 5: Driving Performance & Transformation** and the Results section which
 1586 includes **Criterion 6: Stakeholder Perceptions**.

1587 **Criterion 5:** Driving Performance & Transformation contains five elements associated with driving
 1588 performance and managing risks, transforming the future organization, while continuing to deliver results
 1589 using current resources. Additional elements also include the innovative use of technology; converting data
 1590 into information and knowledge and managing assets and resources to achieve operational excellence.

1591 Agility is embedded in driving transformation; it is linked to a company's need to ensure readiness for the
 1592 future. This brings both internal and external challenges, that need to be addressed efficiently and in a timely
 1593 manner, to ensure successful outcomes. In the competence space, "Leverage Knowledge" is a major element
 1594 linked to outstanding performance related to an organization's ability to prepare for transformation.

1595 **Criterion 6:** Stakeholder Perceptions criteria of the EFQM model bridges with Organizational Learning and
 1596 Agility when it recommends the use of past and current performance perceptions to predict future
 1597 performance. Intentional search for feedback and inputs, obtained from various sources provides increased
 1598 visibility into areas for improvement. As well as being an assessment tool, the model offers a framework and
 1599 methodology to help individuals and organizations to measure their current state and to understand the
 1600 existing gaps related to performance.

1601 This influences the organization's pathway allowing for predictive measures for the future and ensuring rapid
 1602 response to eventual future opportunities and threats.

1603 10.7. Malcolm Baldrige Excellence Framework

1604 Elements within the Baldrige model that are linked to Technical Excellence as defined by this standard are:
 1605 Agility, Competence/Expertise, Organizational Learning, Maturity of Systems, and Innovation.

1606 Agility is widely cited in the Baldrige framework and is a critical factor for success. It is interconnected with
 1607 "resilience", when considering the required ability to anticipate, prepare for, and recover from disasters,
 1608 emergencies, and other disruptions. When these occur, it is necessary to protect and enhance workforce and
 1609 customer engagement, supply network and financial performance, organizational productivity, and community
 1610 well-being.

1611 Competence is another key element within the Baldrige framework and is closely linked to Organizational
 1612 Learning. Building core competencies and preparing the workforce for future challenges is essential to reach
 1613 the required expertise leading to technical excellence. Competence and expertise are closely connected with
 1614 Workforce capability, which can include the ability to build and sustain relationships with customers and the
 1615 business community, to innovate and transition to emerging technologies, to develop new services and work
 1616 processes and to meet challenging market and regulatory demands.

1617 Organizational Learning is an essential attribute of high-performing organizations, and it connects with other
 1618 elements of Technical Excellence (e.g., Competence, Knowledge Management, Innovation and Agility).
 1619 Effective, well-deployed learning can help an organization improve from early stages of reacting to problems
 1620 to the highest levels of organization-wide improvements, refinement, and innovation. It includes continuous
 1621 improvement of existing approaches; the adoption of best practices; rapid response to change leading to new
 1622 goals, approaches, and system optimization.

1623 Organizational Learning is achieved through research and development, evaluation and improvement cycles,
 1624 ideas and input from the workforce and stakeholders, the sharing of best practices, and benchmarking.
 1625 Workforce learning is embedded through education, training, and developmental opportunities that further
 1626 individual growth. To be effective, both kinds of learning should be embedded in the way organizations operate,
 1627 contributing to a competitive advantage and ongoing success for the organization.

1628 Maturity of Systems is mainly covered by the Knowledge Management element. It is important in building and
 1629 managing the knowledge assets of an organization and integrating with the other core values and concepts. It
 1630 defines knowledge assets as the organization's accumulated intellectual resources; the knowledge possessed by
 1631 the organization and its workforce in the form of information, ideas, learning, understanding, memory, insights,
 1632 cognitive and technical skills, and capabilities. Knowledge assets are the know-how that organizations have
 1633 available to use, invest, and grow. Managing organizational knowledge is a vital asset and a key component of
 1634 creating value to stakeholders and sustaining competitive advantage.

1635 Use of Technologies highlights the importance of considering the need for innovation, including emerging
 1636 technologies, into the organization's strategic plan, preparing staff for changes and incorporating new company
 1637 processes. It also emphasizes the use of digital and web-based technologies in internal processes, the need for
 1638 agility when disruptive technologies arise, and the use of digital data analytics and artificial intelligence in
 1639 performance analysis and knowledge management. Innovation is also directly linked to taking intelligent risks
 1640 and managing resources to pursue opportunities for innovation. The model has a clear designated core concept
 1641 and value called "Managing for Innovation" which is linked to the Strategy criteria and can be achieved by
 1642 making meaningful changes with the purpose of creating new value for customers and stakeholders. Innovation
 1643 and continuous incremental improvement are different, but complimentary concepts. Successful organizations
 1644 embed both approaches in their cultures to improve performance, take intelligent risk and identify strategic
 1645 opportunities.

1646 **10.8. Shingo Model**

1647 The Shingo model does not have a specific "Technical Excellence" category, however, there are several
 1648 concepts emphasized in the Shingo approach which are aligned with how this standard has defined technical
 1649 excellence in the context of quality culture particularly in the Guiding Principles section of the model.

1650 "Embrace Scientific Thinking" is part of the Continuous Improvement guiding principle. The Shingo model
 1651 describes using experimentation cycles, observation and learning to systematically explore new ideas. This is
 1652 aligned with approaches in pharmaceutical drug development and with the principle of organizational learning.
 1653 The Shingo model also emphasizes the need for well-designed and functioning processes and calls on team
 1654 members to use their scientific expertise to continuously improve the processes. This lines up well with the
 1655 concept of maturity of systems noted in this standard.

1656 The Shingo model also emphasizes a focus on being data driven to achieve thorough process understanding,
 1657 especially when implementing change which fits well with the concept of competence.

1658 People development is demonstrated as more than just classroom training and calls on executive leadership to
 1659 be committed to developing people and investing in education and training for all staff over the long term.

1660 In the Supporting Concept 'Develop People' there is an emphasis on eliminating barriers by embracing
 1661 innovation from the management level which is then taught to all that require it. This promotes continuous
 1662 learning and development of staff and drives process improvements.

1663 Highlighted principles include:

- 1664 • Embrace scientific thinking.
- 1665 • Continuously learn.
- 1666 • Visual management.
- 1667 • Coaching is consistent.

1668 **10.9. SIQ Model for Performance Excellence**

1669 The SIQ model does not directly refer to technical excellence, however, aspects of technical excellence are
 1670 rooted within. SIQ is an excellent model to help organizations ‘do the right thing’ in their business ‘the right
 1671 way’ which then leads to success. In the model this is described as an organization having products or services
 1672 that add value to a customer or stakeholder delivered using the right processes that are continuously improved
 1673 to deliver the best product. The model focuses on building efficiencies that are relevant to a successful outcome.

1674 There are three cornerstones in the model, all of which have a link to technical excellence:

- 1675 1) Culture (Success Factors)
- 1676 2) Structure (Working Methods and Results)
- 1677 3) Systematics (Asking Questions to provide Insights to an organizations business)

1678 Throughout the model there are references to sustainability, innovation and quality development, these directly
 1679 link to technical excellence as explained by these success factors:

- 1680 • Involve Motivated Coworkers
- 1681 • Develop Value-Creating Processes
- 1682 • Improve Operations and Innovate

1683

1684 **10.10. ISPE Advancing Pharmaceutical Quality; Cultural Excellence Guide**

1685 The ISPE APQ Cultural Excellence guide has technical excellence and operational excellence as a foundation
 1686 for an effective PQS and for a robust Quality Culture. The program includes technical excellence in Corrective
 1687 and Preventive Action, Management Responsibilities and Management Review, Process Performance and
 1688 Product Quality Monitoring System, Change Management, Cultural Excellence, Knowledge Management, and
 1689 Quality Risk Management.

1690 Technical Excellence is showcased throughout the Process Performance and Product Quality Monitoring guide
 1691 with many technical references in each of the five guides. The daily practice of desired behaviors in technical
 1692 excellence will impact the culture of the organization. This promotes leadership as a behavior that any employee
 1693 can demonstrate leading to technical excellence.

1694 **10.11. PDA Culture of Quality**

1695 Technical Excellence is one of the five broad categories within the PDA Quality Culture Guided Assessment
 1696 Tool. Technical excellence in the PDA model includes two attributes:

- 1697 1) Utilization of New Technologies, which lines up directly with Application/Use of Technology, and
- 1698 2) Maturity of Systems which includes training, business conduct and quality risk management.

1699 Within ‘Utilization of New Technologies’ the organization is advised to use the best and newest technologies
 1700 available with proactive investment preventing equipment breakdown and loss of processing time. Where
 1701 there is Maturity of Systems in Training the program uses formal plans that are well structured based on
 1702 individual skill needs and promote enhanced knowledge. For a mature system there is an advanced program
 1703 including Data Integrity and Business Conduct where leadership is proactive, and the organization is well
 1704 recognized in the community with stakeholders being involved formally at all levels. Quality Risk
 1705 Management should be embedded in all processes in procedures with all personnel trained in formal QRM
 1706 tools with clear responsibilities to manage and evaluate risk.

1707 To be considered a mature organization, the PDA tool indicates that the technological park in place at a company
 1708 are seen as cutting edge and ahead of peer companies, playing an industry leading role while helping to shape
 1709 the implementation of new technologies. On the Systems Maturity field, PDA tool indicates a company should

1710 excel in Training, Business Conduct and Quality Risk Management areas. In those areas, maturity is achieved
1711 by actively development of subject matter expertise, including advancing training technologies; DI and Business
1712 Conduct program is used to teach and coach authorities and Risk Management is ingrained into organization/full
1713 participation, respectively.

1714 **10.12. Summary**

1715 In the resources reviewed, Technical Excellence is tacit to the areas of technological advancement, innovation,
1716 continuous improvement, converting data into information and knowledge, and managing assets and resources
1717 to achieve operational excellence. Notably, Shingo and the PDA tool take a similar approach to include data
1718 integrity as part of the Technical Excellence category which, when used, shows the maturity of the QMS in an
1719 organization. Innovation is integral to building a foundation for technical excellence as is collaboration and
1720 knowledge management.

1721
1722 Innovation may arise from adapting changes in other industries to achieve a breakthrough. It builds on the
1723 accumulated knowledge of an organization and its people, and the creativity of its partners, collaborators,
1724 competitors, and other relevant organizations, including those outside its business segment. It may involve
1725 collaboration among people who do not normally work together and are in different parts of the organization.
1726 This can lead to the maximizing of learning through shared information and the willingness to use concepts
1727 from outside the organization as idea generators. Therefore, the ability to rapidly disseminate and capitalize on
1728 new and accumulated knowledge is critical to drive organizational innovation and achieve technical excellence.

1729

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