

Whitepaper

Transforming CDMO partnerships through a holistic understanding of quality

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Partnership

Bringing your innovative therapy to market requires working with a CDMO partner that embraces quality as a holistic endeavor affecting every aspect of the development process.

Quality is the underpinning of success in pharmaceutical manufacturing. A commitment to quality is foundational to accelerating time to market, reducing unnecessary risk, improving return on investment, and ensuring effective medicines are available to the public, ultimately, saving lives.

Despite its critical importance, quality in pharma manufacturing is often mischaracterized, whether by conflating it with compliance, describing it as an end-of-the-line activity, or attributing responsibility for it to a single team within the manufacturing organization. While each of these considerations is relevant to quality, none of them define it.

For example, compliance with regulatory guidelines is required to bring a product to market, but it is not a reflection of product or process quality. It simply means that minimal acceptable standards have been met. Further, quality is not something that can be relegated to a single stage of the manufacturing process. It must be embedded deep into every stage and understood and analyzed continuously. Finally, while the quality team is responsible for managing and driving toward an aspired level of quality across all operations, quality is owned by everyone within an organization.

Quality is not one activity, role, process, strategy, or outcome. It's a combination of all of these—and more. Ultimately, quality performance is something that is perceived and experienced. In manufacturing, the final arbiters of quality are not only those who are striving to deliver it, but also those who are receiving it.

For pharmaceutical and biotech companies, the quality of their products is decided by the healthcare providers who prescribe the medications and the patients who take them, based on whether the drugs achieve their intended purpose and meet patient and provider needs. Similarly, for contract manufacturing organizations, the arbiters of quality are the pharma and biotech partners who contract for their services.

To determine the CDMO partnership attributes that are essential to sponsors' perception of quality performance, Thermo Fisher Scientific convened a focus group of high-performing pharma and biotech companies and conducted a series of independent interviews with participants. Based on the collective feedback, multiple product, process, and relationship variables were identified as key indicators of CDMO quality performance. Collectively, these criteria provide the foundation for a holistic definition of quality performance based not only on objective parameters, but also on customer needs and expectations.

This whitepaper takes an in-depth look at each of these criteria, identifying tools and best practices to drive continuous improvement, strengthen collaboration, and build trust.

At a glance



A holistic approach to quality is essential to building trust and ensuring a successful manufacturing partnership.



A critical competency to look for in a CDMO is a quality mindset that permeates processes, outcomes, and relationships across every stage of development.



Voice of the customer research has identified the partnership and performance attributes that are essential to sponsors' perception of quality for a CDMO.



Introduction

What is quality?

Quality is one of the most important concepts in pharmaceutical manufacturing, yet it's also one of the most difficult to define. This is largely because it is both objective and subjective with parameters that vary based on perspective.

For example, from a regulatory perspective, quality refers to the consistent delivery of label performance and lack of contamination and is operationalized through predefined specifications and limits and through current Good Manufacturing Practice (cGMP) regulations.¹ From a product and process perspective, quality is linked to the safety and efficacy of active pharmaceutical ingredients, formulation, manufacturing, and supply chain activities. From a value perspective, quality reflects the best combination of costs and features, with the least amount of waste. And from the customer perspective, quality is provided when the product or services meet or exceed the end user's expectations. Further, the various perspectives are interdependent. Process quality contributes to product quality which improves value and increases the likelihood of meeting customer needs and expectations.

Because quality is a holistic endeavor that affects all parts of the business, the definition of quality as well as the tools used to measure and improve it, should stretch to accommodate all of the relevant perspectives.

Arguably, the customer perspective is the most important. It is also the most challenging to understand. While the process, product, and value perspectives reflect specific producer-controlled attributes of quality, the customer perspective is more fluid and variable because needs and expectations differ by customer and can also change over time.

When defining quality in organizations, it is up to the organization itself to explore and identify how their customers perceive and define quality so that they can meet these expectations and eliminate gaps in understanding. In the absence of an all-encompassing

definition that is guided by the customer perspective, organizations often default to characterizing quality as a compliance or regulatory construct. This is understandable, particularly as drug products are becoming more complex and the standards being developed to regulate them explicitly incorporate minimum quality targets. Yet, meeting minimum quality targets does not guarantee that process, product, value, or customer criteria for quality will be met.

In a competitive marketplace where prospective customers face an array of options, quality should be examined through a wider lens. Organizations seeking to reliably deliver the highest-quality products and services must nurture and sustain a quality mindset that permeates processes, outcomes, and relationships across every stage of development.

In this regard, CDMOs play a critical role. To meet the increasing demand for highly complex drug products, pharmaceutical and biotech companies of all sizes are building relationships with CDMOs that have the core competencies in highly specialized formulation and process technology areas to support them through clinical and commercial-stage manufacturing. To be an effective and trusted partner, CDMOs must have not only the necessary infrastructure to meet development and manufacturing objectives but also the partnership insight and expertise to meet sponsors' specific quality expectations.

Organizations seeking to reliably deliver the highest-quality products and services must nurture and sustain a quality mindset that permeates processes, outcomes, and relationships across every stage of development.



The cost of poor quality

Poor quality in pharmaceutical manufacturing is expensive. Some of the costs are obvious and quantifiable, such as those associated with GMP deficiencies, wasted materials, scrapped batches, rework, supply disruptions, investigation and remediation activities, product recalls, delayed product launches, and loss of market share. Other costs are less tangible but more insidious. These include loss of reputation, diminished brand loyalty, and customer distrust. And others still are catastrophic, including patient harm or death.

Though highly variable, the cost of poor quality in the pharmaceutical sector is estimated to range from 25-40% of turnover² and up to 40% of operating expenses.³ At the industry level, manufacturing or product quality problems are the leading cause of drug shortages, according to an FDA report.⁴ And it is estimated that drug shortages add up to \$230 million every year to U.S. medication costs.⁵

Most manufacturing quality experts agree that the cost of a quality deficit increases exponentially the longer it goes unaddressed and far exceeds the investment required to prevent its occurrence. The often-cited 1-10-100 rule suggests that every dollar spent in preventing poor quality is equal to \$10 if the problem is taken to production without being addressed and \$100 dollars if it moves to the distribution stage.

Rather than reactively paying for poor quality, high-performing organizations proactively invest in good quality, with CDMO partners playing a critical role in optimizing their return on investment. Because the expense of fixing issues increases in later phases of development, building a strong working relationship with contract manufacturing partners early in the planning process can improve quality outcomes and decrease costs. When engaged early, experienced manufacturing partners can begin developing the manufacturing processes needed for successful production, identifying and rectifying any issues that could cause problems down the line.

With the understanding that customers' needs, values, and expectations are constantly changing, Thermo Fisher Scientific conducted voice of the customer research to identify the dynamic factors that influence customer perceptions of a good quality partner. As part of a larger project to develop a customer-driven quality metrics model for internal performance benchmarking, the project team developed a preliminary model that leveraged the US Food and Drug Administration's (FDA) Quality Metrics Reporting program⁶ and the FDA Quality Metrics Research 3rd Year Report conducted by the University of St. Gallen.⁷

The preliminary model was shared with members of a focus group comprising high-performing pharmaceutical and biotech companies for their input. Based on their feedback, the project team identified the key criteria for defining quality for a CDMO, listed below in order of importance.

Criteria for defining quality for a CDMO as identified by high-performing pharmaceutical and biotech companies

- Supply robustness
- Deviation rates and complaints (CFR definition)
- Resolution times (on-time closure)
- Corrective and preventive action (CAPA) effectiveness
- Activities related to health authorities
- Organization workforce stability
- Frequent communication
- Business consistency

Performance in each of these areas, as described above, is an indicator of a CDMO's quality culture a gauge of their ability to consistently meet sponsors' expectations.

Supply robustness

Supply robustness emerged as the top criteria for defining quality for a CDMO. Multiple focus group participants stressed that true robustness is measured by whether a delivery was made and whether safeguards are in place to avoid disruptions. This includes alerts and warning signals that indicate problems on the horizon before they manifest in customer-facing supply, such as downstream product or service interruptions that could cause gaps later in the supply chain.

Reactive metrics, such as on-time in-full rates, fill rates, disposition on time, and days of inventory on hand help paint a performance picture, and tools and activities that enable proactive planning are essential for avoiding disruptions. For example, data-driven processes for forecasting and predicting product needs enable CDMOs to create a demand signal that suppliers can use to guide decisions about how much product to produce and when.

Additionally, real-time visibility into the manufacturing lifecycle is a key consideration for nurturing a robust supply chain. Digital technologies that provide end-to-end supply chain transparency give stakeholders the ability to quickly sense and respond to disruptions that could otherwise put manufacturing programs at risk.

Finally, the breadth of the CDMO supplier network is a critical proactive indicator of supply robustness. Developing multiple sources and verifying that those systems and processes are reliable is more important than ever for ensuring access to sufficient amounts of GMP material in a timely manner. To ensure this, the supply chain teams in high-performing CDMOs engage regularly with key suppliers to review orders and communicate demand signals early. Additionally, they work with multiple qualified suppliers for the same materials to increase the stability of supply and ensure adaptability to variable demands in the supply chain.

Deviation rates and product quality complaints

Not surprisingly, deviation rates and quality complaints are heavily weighted in customers' assessment of quality for a CDMO. Both happen almost every day in the pharmaceutical industry and are important to track and classify, as some are more impactful than others (See, "Classifying deviations and complaints"). Equally important from a partnership perspective is how they are handled.

For deviations specifically, prospective manufacturing partners should have robust systems and processes in place for identifying the deviation, understanding its criticality, conducting root cause analyses, and suggesting corrective and preventive action (CAPA). Importantly, an effective root cause analysis will look beyond "human error" as the cause of a deviation. The objective must be to identify the defect or deficiency that caused the human to make the error in order to systemize correction and prevention.

Product quality complaints should be handled methodically as well, in compliance with GMP

guidelines. Typically, the sponsor receives and investigates product complaints and adverse events. When the complaints are related to product manufactured by the CDMO, the partners will collaborate to establish an investigation plan, corrective actions, and a response timeline.

One of the most important considerations for managing deviations and complaints is upfront alignment on a communication and escalation plan. This should include provisions for real-time notification and contact procedures, an assessment and triage process for risk identification and deviation classification, root cause analysis execution and CAPA determination, and business continuity and contingency plans.

Learn more about the crushing cost of poor quality in biopharma [in this webinar](#)



Classifying deviations and complaints

According to the Code of Federal Regulations (CFR), a deviation in pharma manufacturing occurs when there is a failure to follow the instructions guiding how an activity should be executed for optimal results. Product quality complaints are problems reported by customers "related to the identity, quality, safety, or effectiveness of any product manufactured or distributed."⁸ Not all deviations and complaints are equal in their severity or potential impact, but all should be investigated and rectified.

Deviations that affect the quality of a critical process parameter, equipment, or instrument and those that are immediately life threatening or compromise patient safety are considered "critical" deviations. Those that impact a product's quality, safety, or efficacy but do not have a direct impact on patients are considered "major" deviations, and those that affect equipment, material, component, or documentation but not product quality or the physical state of the product or its labeling are "minor" deviations.⁹

Complaints about product quality are classified as routine or expedited. The latter are potentially serious issues warranting an accelerated investigation and submission to the appropriate regulatory body. Examples of expedited complaints include allegations of product tampering, improper labeling, or compromised integrity of a sterile product.

CAPA: More than a compliance tool

Out of necessity, CAPA is highly focused on compliance, but high-performing organizations use the CAPA process as a problem-solving tool to drive improved product and process quality. Above and beyond helping organizations comply with regulatory standards and guidelines, the benefits of an effective CAPA include:

- ✓ **Risk mitigation**

By identifying and addressing the root cause of a problem and guiding recurrence prevention, CAPA reduces the risk of product recalls, safety hazards, and compliance issues.

- ✓ **Improved efficiency**

A well-designed CAPA can streamline processes and optimize workflow, reducing the likelihood of errors and improving efficiency.

- ✓ **Continuous improvement**

CAPA encourages continuous improvement by identifying process improvements and providing opportunities to implement best practices and upgrades.

Resolution times

Resolution time refers to the length of time from deviation detection to rectification. It encompasses identification, reporting, assessment, investigation, and appropriate CAPA to prevent recurrence. This measure ranks high in sponsors' priority list because it is a gauge of the CDMO's ability to effectively minimize disruptions that can impede market access.

The resolution process is a function of the deviation-management program, which is guided by policies that detail every step that should be taken when a deviation occurs until it is closed. If a deviation is not closed within 30 working days of the initiation date, initiators are expected to request a 30-day extension and continue to do so until it's closed.

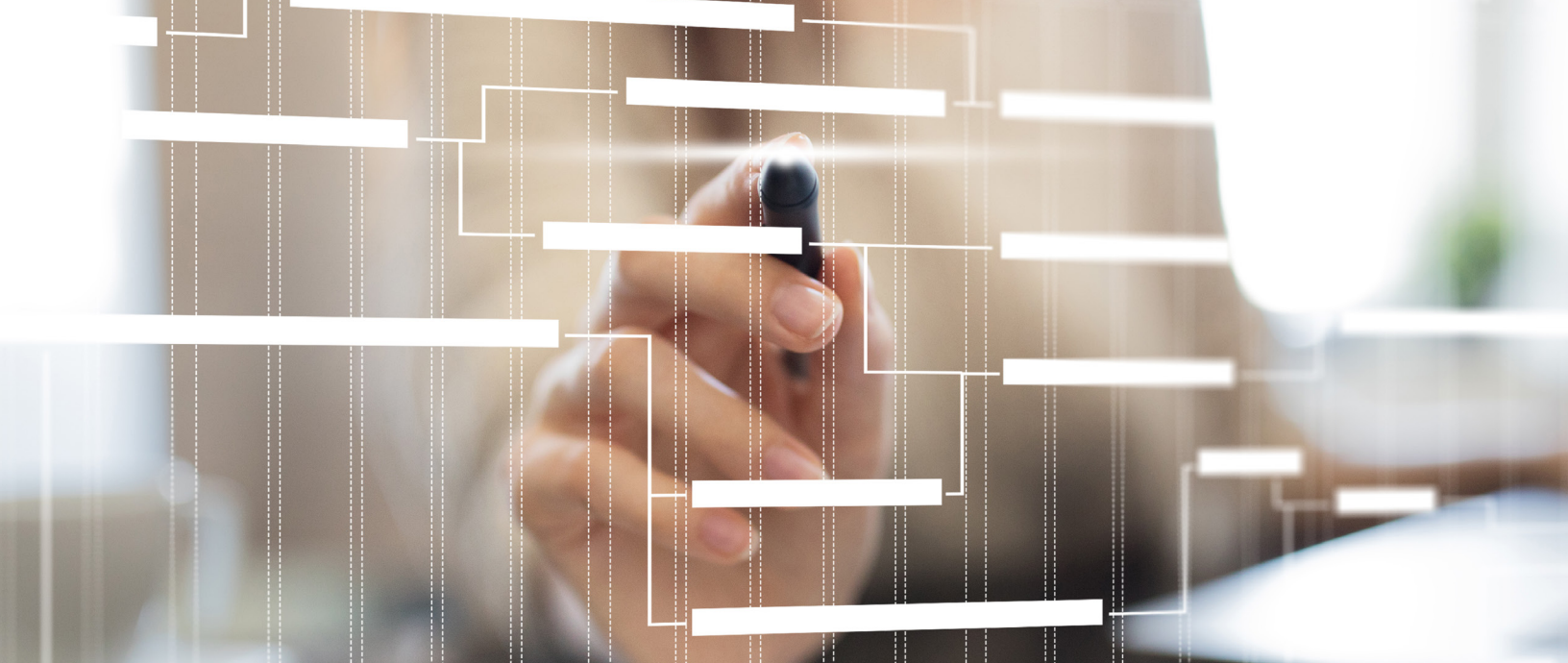
The cycle time for finishing a job, the number of deviations that exceed 30 days, and the number of repeat deviations are common measures for evaluating quality processes.¹⁰ Extended cycle times and deviation extensions may not be signs of a process problem, especially for major or critical investigations involving more complicated issues. Repeat deviations, on the other hand, suggest that the true root cause was not identified in the initial investigation or that the appropriate CAPA was not implemented. Subsequent analyses should address both possibilities and adjust contributing variables to avoid recycling the deviation.¹¹

CAPA effectiveness

CAPA is a concept within cGMP that focuses on the systemic investigation of root causes of deviations and nonconformities and actions to correct them and prevent them from recurring. In addition to having CAPA processes in place, regulatory bodies expect manufacturers to include appropriately timed effectiveness checks. Examples include trend analyses to determine whether the deviation or problem occurred again following CAPA implementation; periodic check-ins to review the processes that were remediated; surprise audits to make sure the operators or equipment are following the prescribed corrective action; and

interim sampling of the finished product to verify expected quality values.¹²

On-time closures of CAPA investigations and the number of repeats for both audit observations and deviations are essential indicators of CAPA effectiveness, according to the focus group feedback. Participants agreed that the following questions are top-of-mind for sponsors: "Are we getting to true root cause and implementing appropriate CAPA? Are we completing CAPA in decent time to prevent recurrence? Are we applying the learnings across sites and activities, not just those affected by the deviation or problem?"



To increase the likelihood of a “yes” answer to these questions, best practices for successful CAPA implementation should be followed. Some examples include:

- The creation of clear, well-structured action plans for the entire CAPA process with specific responsibilities delineated by role and phase.
- Timely, transparent, and thorough communication across all stakeholders.
- Integration of key CAPA performance indicators (CAPA aging, number of open CAPAs, overdue CAPAs, CAPA trends by root cause) into management reviews to build awareness and drive accountability.
- A shared appreciation of CAPA processes as long-term improvement solutions vs. short-term failure fixes.

Activities related to health authorities

Health authorities such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA), and industry groups such as the Organization for International standards (ISO), develop requirements, guidance documents, and standards to regulate the pharmaceutical industry and safeguard patients.

Establishing policies and procedures in accordance with the applicable requirements and standards puts

manufacturers on the path to market access, but it doesn’t guarantee how fast, or even if, they will get to their destination. They must also navigate through multiple checkpoints, including audits and inspections, and manage unforeseen obstacles as they arise, such as warning letters and inspection citations.

In most scenarios, an organization’s ability to anticipate and meet the demands of international regulatory agencies can be the difference between success and failure in securing marketing approval for a new drug. This is especially true given the growing complexity of drug compounds, the large number of dosage forms, and evolving manufacturing processes and technologies. The challenges are exacerbated by the fact that regulations and quality standards are dynamic. What is state-of-the-art today may not be appropriate tomorrow. This is particularly true in the rapidly changing area of biopharmaceutical development and analysis.

Because the regulatory process is one of the most challenging hurdles pharmaceutical companies face, identifying a development and manufacturing partner that can offer the support needed to smooth the regulatory path should be a strategic priority (See “Partnering on the road to quality: Getting the regulatory support you need.”)

Partnering on the road to quality: Getting the regulatory support you need

Preparing for and working with the FDA, EMA, and other regulatory bodies requires multiple steps, a copious amount of work, and countless opportunities for avoidable glitches and delays that can hinder progress in bringing a new drug to market. CDMOs have an important role to play in ensuring a swift and seamless product approval by various regulatory authorities. The degree to which that role can be fulfilled depends on the CDMO's competencies and track record across the pharmaceutical quality ecosystem. Some of the foremost contributing factors to consider include:

- The maturity of the CDMO's quality management system and quality controls for production, facilities and equipment, packaging and labeling, laboratory, and materials
- Past regulatory performance, including successful regulatory filings, inspection observations, notifications, and warnings
- The subject matter expertise needed to understand the evolving regulatory landscape and its impact on key processes and timelines
- A flexible, collaborative, and integrated approach across key business stakeholders to be ready to respond to changing conditions
- Well-established data frameworks and governance practices to meet regulatory obligations.
- Organizational investment in technology and process innovation including advanced analytics, artificial intelligence, and machine learning to better predict and mitigate quality risks and ensure compliance.
- History of constructive engagement with regulatory authorities
- Involvement in industry associations that help shape the regulatory agenda



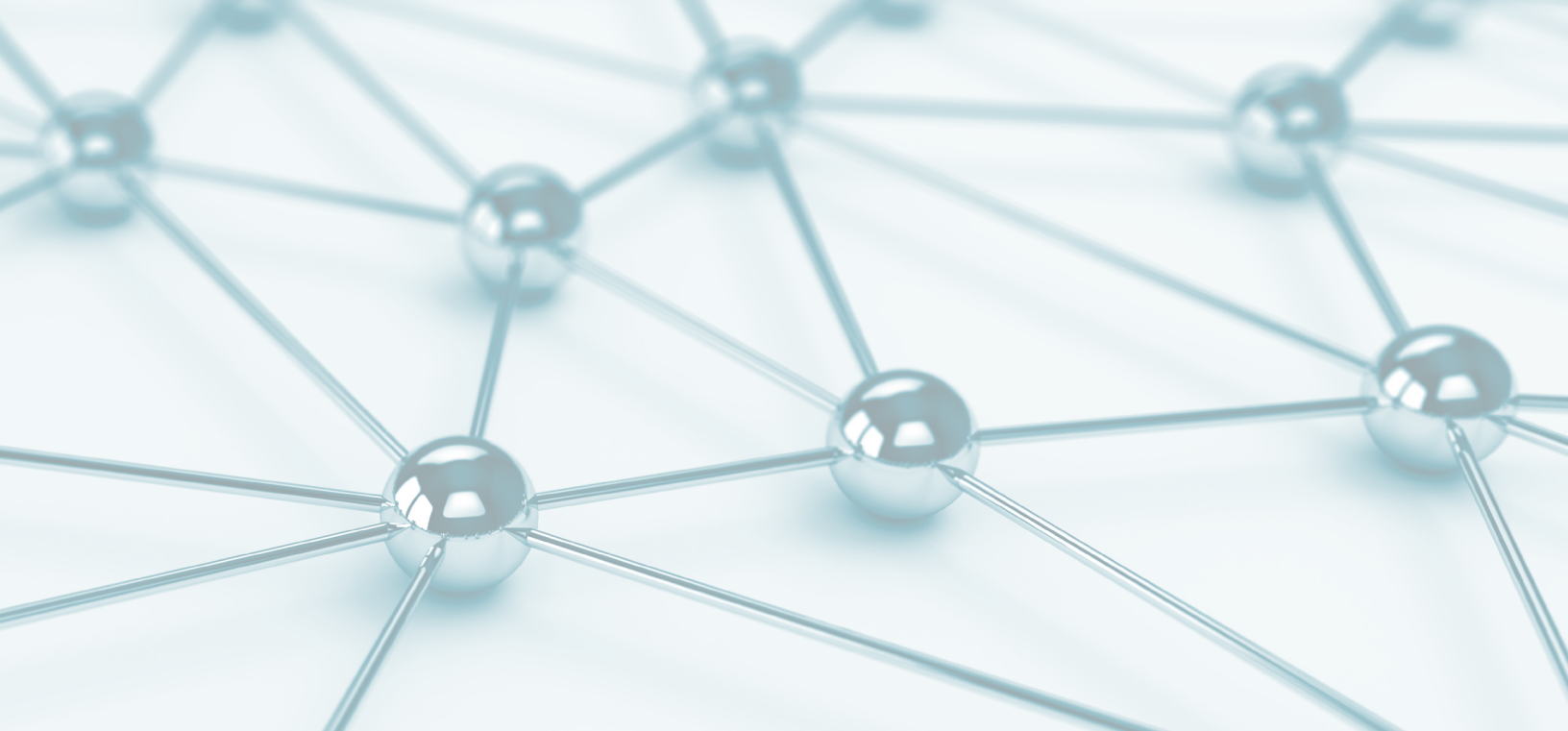
A key consideration is the depth and breadth of development and manufacturing partners' experience across submission types. The regulatory submission process is highly complex, and the need to understand and manage the requirements of different regulatory agencies and multiple pathway options means there is no one-size-fits-all mechanism for regulatory support.

An organization with deep and varied regulatory experience has intimate knowledge of what the submission planning process should entail and how to execute it. They also have the benefit of frequent, close collaboration with regulators, which helps them stay abreast of evolving expectations and, ideally, feeds into continuous improvement processes to build strengths across teams and facilities.

Organization workforce stability

Workforce turnover, particularly in customer-facing positions, can have a significant impact on sponsors' perception of a CDMO's commitment to quality. The worry is that the loss of personnel may create knowledge and communication gaps that can affect development timelines or introduce quality risks.

While some degree of turnover is inevitable, one focus group participant noted, "it is always concerning for a sponsor to see a lot of frequent turnover, particularly in



“An organization with deep and varied regulatory experience has intimate knowledge of what the submission planning process should entail and how to execute it.”

key management roles, such as site GM or site Quality head. This triggers them to look a bit closer.”

To allay sponsors’ fears, the onus is on the CDMO to manage transitions carefully and transparently. Consistent and clear communication across projects, teams, and organizations is a necessary first step, and thoughtful change management is the next. This can be achieved through a regular cadence of team meetings to discuss personnel changes and the impact they will have on the program; establishing mechanisms for keeping all workstream leads abreast of changes in roles and responsibilities; updating and sharing detailed project schedules; and reporting out on major milestone progress.

Building team unity through open and honest communication is foundational to achieving the trust and confidence that feeds successful partnerships.

Frequent communication

The importance of frequent, meaningful communication between CDMO project teams and sponsors was a common theme in the focus group interviews. To be most effective, communication has to be deliberate.

A detailed communication plan that spells out how and when project team members and stakeholders will communicate with each other is essential to ensuring that everyone has the information they need at every stage of the project and under every circumstance (See, “Quality communication plan: What to include”). In particular, having a plan for communicating about changes and resource requirements when a problem occurs is arguably at least as important as identification of the problem itself.

As part of communication planning, CDMOs and sponsors should have an open dialogue to establish a common understanding of what, when, and how information should be shared. Aligning on priorities and information requirements from the outset enable the transparency that is needed for a successful partnership.

Quality communication plan: What to include

According to the ISO 9001:2015, which provides structured communication guidance for achieving quality objectives, there are 5 questions that should be addressed when developing a strategy and foundation for communication:¹³

1. What is to be communicated?

Identify and describe communication around quality-related issues including the quality policy, quality objectives, quality management system requirements, processes, customer requirements, organizational performance, customer satisfaction, purchase orders, specifications, drawings, requests for quotation, changes etc.

2. When will it be communicated?

Clearly articulate specific communication cadence based on frequency, urgency/importance, significance, scheduled meetings, ad-hoc briefings, staff shift patterns.

3. With whom will it be communicated?

Provide specific information about where the respective messages should go and who needs to see them, including which external stakeholders (customers, suppliers, regulators, government agencies, external providers, investors, etc.) and internal parties (employees, contractors, unions, etc.)

4. How will it be communicated?

Specify the communication tools and channels, such as scheduled formal meetings, informal briefings, e-mails, telephone, text, intranet, internet, directives, management review, visual management, etc.

5. By whom will it be communicated?

Identify individuals and teams (including names, titles, and contact information) who are responsible for executing the respective communications and ensuring that the messages are received.



Business consistency

Among the benefits of working with a single CDMO are the time and cost efficiencies associated with running multiple manufacturing steps in tandem, accelerating technology transfers, and removing the need for revalidation measures.¹⁴

For the relationship to deliver the most value, however, the various sites, capabilities, and personnel across the CDMO network must embrace and embody the same quality mindset and culture. An important step in this direction is harmonization of quality management systems, which involves creating a standard process for all quality and compliance activities, regardless of location and operational area.

As organizations grow, whether organically or through mergers or acquisitions, variations in quality systems emerge. Even though all of the individual facilities or divisions adhere to standards and regulations, there may be differences in how they comply with QMS requirements.

A standardized framework links disparate quality activities in a meaningful and documented way, allowing leaders to measure quality and compliance across the organization. It also provides greater end-to-end control of quality manufacturing and supports data-driven decisions that contribute to performance excellence. One of the most important ways in which standardization can help to guarantee quality is by minimizing the chances that crucial details will be overlooked.

Harmonization does not mean that all locations have to follow the same business processes. By necessity, certain site-level processes will be unique, requiring local control. The goal of harmonization is to ensure that all key quality processes cascade from a unified base via a common technology platform to ensure consistency across the enterprise.

Sponsors want to have confidence that regardless of who they are working with and at what location, the same quality culture and standards will be evident, according to feedback from the focus group.

What does holistic quality look like in practice?

Achieving holistic quality based on the collective criteria described in this report requires:

- Deep product knowledge and experience, combined with advances in process and analytical technology and internal innovation
- A quality-driven, GMP-compliant supply chain with a quality control strategy
- Redundancy and flexibility in the supply chain to deliver adequate supply in the event of production interruptions or forecast changes
- A method for implementing manufacturing process modifications that ensures consistency of product across phases and confirms continued adherence to specifications for target parameters
- A clear understanding of partnership expectations, open communication and information exchange, mutual trust, and a common direction for the future

In practice, this approach to quality can take many forms, as illustrated by the two examples below. In the first, an aligned mission of patient centricity together with the supply chain resources and expertise needed to achieve requisite speed and scalability helped get an innovative CAR T cell therapy to clinical trial patients on time. The second example showcases the successful execution of seamless, collaborative process development and an integrated, proactive Quality by Design approach to the development and manufacture of a small molecule drug to treat an autoimmune disease.

Learn more about Quality by Design holistic approach [in this whitepaper](#)



Saving lives, one patient at a time

To help bring a next-generation CAR-T cell therapeutic candidate to patients in a phase III clinical trial without delay, Thermo Fisher's cell and gene therapy supply chain team partnered with the sponsor to streamline pre-production planning (ordering and receiving materials, quality checks on consumables), storage, kitting, clean room preparation, and final qualified person check in advance of manufacturing because they did not have the expertise or resources to achieve the speed and scalability needed for project success.

As with all advanced therapy medicinal products (ATMP), the turnaround time to get the customized manufactured medication to patients is of utmost importance. Teams have limited time to transport cells from the patient and prepare them for manufacture, as delays could mean the difference between life and death for the patients. Because there is no room for error in the process, working with a partner that understands the timeline, is aligned with the mission, and has experience, resources, and quality-first mindset to achieve the objectives is essential.

For this project, the customer initially handled pre-production and storage in-house, at small scale, and relied on Thermo Fisher for quality review and release. As the numbers grew, they struggled with scalability and storage capacity, so it made sense to outsource the material management so they could focus solely on manufacturing the ATMP. As a reliable partner with a patient-centered mission, Thermo Fisher worked closely with them, starting with the pre-production and clean room activities, gaining their trust, and ultimately introducing distribution capabilities. With a 98.9% on-time in-full delivery, Thermo Fisher's end-to-end support enabled the sponsor to scale and take the product through to commercial.

Managing project complexity through seamless collaboration

The more complex a development project is, the more points of vulnerability there are along the quality journey. A mid-size pharmaceutical company planning a development project for a small molecule therapy for an autoimmune disease knew this first-hand from their experience developing treatments for a different indication. The new project, which was planned for multiple markets, had a number of complexities that would dictate outsourcing decisions, including the following.

- The drug was highly potent, thus required special handling.
- The tablets needed to be produced in 10 different strengths, shapes, and colors.
- Production lines had to be set up for several batch sizes with different scalability requirements.
- Different commercial packaging requirements for each of the markets would have to be met.

Collectively, these complexities threatened the sponsor's ambitious timeline. To tackle the project, a team of expert scientists and technicians from throughout Thermo Fisher's EMEA network convened to define an end-to-end solution and map a partnership plan. Collaboration started with drug product manufacturing at a small scale to address early development phases. Scalability into the network allowed the Thermo Fisher teams to address clinical needs while the company's oral solid dose facility in Bourgoin, France supplied the product through the clinical phases. As registration approached, the customer decided to transfer advanced pharmaceutical ingredient (API) production from its current suppliers to the Thermo Fisher API production facility in Linz, Austria. As the product progressed through validation and after a successful launch in 2021, the Linz and Bourgoin sites supplied the market with the different strengths.

The Bourgoin site used state-of-the-art equipment, including a fully contained high-shear mixer, tablet

Read [this case study](#) on ATMP fast track from clinical to commercial to learn more

press, and coater, and ensured handling of a highly potent product from development to commercialization. A Quality by Design (QBD) approach was applied with Design of Experiments (DOE) studies to address the complexities of the project. This approach increases product and process knowledge and results in less rework, less product deviation, fewer out-of-specification, fewer rejection products, and improved quality.

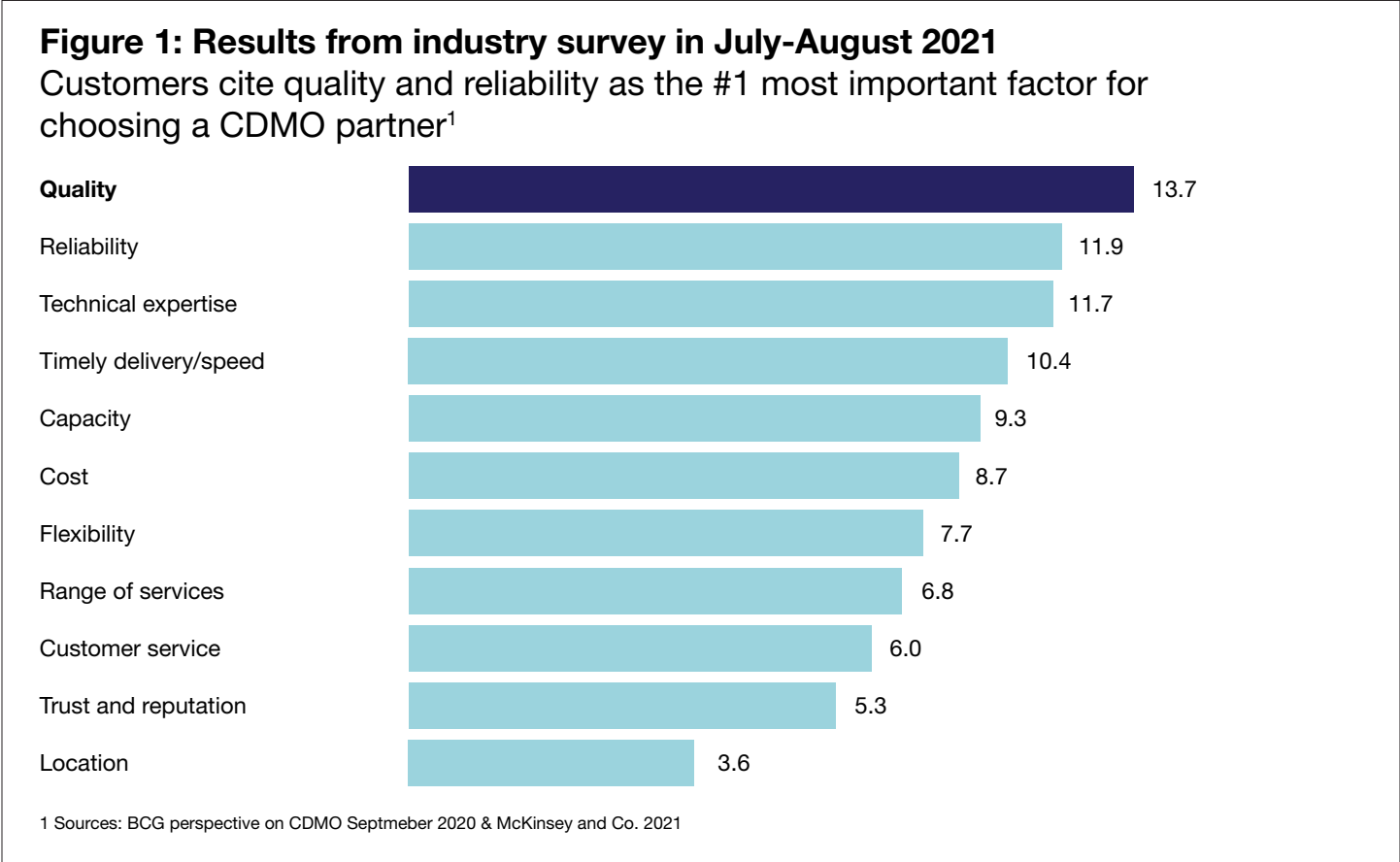
A focus on seamless collaboration across sites, teams, operations, and the sponsor enabled the team to deliver on differing primary and secondary packaging and serialization requirements for the various strengths, as dictated by region-specific regulatory oversight.

Conclusion

Research has shown that quality is the most important key buying factor for sponsors choosing a CDMO partner (Figure 1).

But quality does not exist in a vacuum. It is supported and bolstered by all of the partnership variables that contribute customer’s perception of excellence above and beyond product integrity alone. While it is identified as the leading driver of choice on this list, it is really the outcome of success across all of the measures below it, and it is a reflection of an organization’s ongoing commitment to excellence across all departments, individuals, and processes involved in developing a product.

Organizations that embrace holistic quality and weave it into the fabric of their existence reap the greatest rewards: increased efficiency, reduced waste, optimal collaboration, stronger customer relationships, more value, and, ultimately, the successful delivery of safe, effective, and potentially life-saving therapies to patients.



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