Sarcouncil Journal of Multidisciplinary

ISSN(Online): 2945-3445

Volume- 05| Issue- 11| 2025

Research Article **Received:** 25-09-2025 | **Accepted:** 20-10-2025 | **Published:** 03-11-2025

Embedding Quality Ownership: A Behavioral Framework for GMP Culture in Cell and Gene Therapy Manufacturing

Prathyusha Guttikonda

Independent researcher USA

Abstract: The cell and gene therapy (CGT) industry is experiencing a pivotal shift from traditional compliance-focused approaches to a more holistic quality ownership culture. This article presents a comprehensive behavioral framework for transforming Good Manufacturing Practice culture in CGT manufacturing organizations. By addressing three core domains—process-focused quality consciousness, empowered critical thinking, and purpose-driven motivation—this framework enables organizations to build sustainable quality cultures where every team member actively participates in maintaining and improving quality standards. The framework recognizes the unique challenges presented by these "living medicines," including inherent variability, complexity, and patient-specific manufacturing processes that demand exceptional attention to quality. By embedding quality ownership throughout organizational hierarchies and connecting daily tasks to patient outcomes, CGT manufacturers can create a virtuous cycle where quality becomes self-reinforcing rather than externally imposed, ultimately leading to improved manufacturing reliability, enhanced patient access, and better treatment outcomes.

Keywords: Quality Culture Transformation, Cell and Gene Therapy Manufacturing, Behavioral Framework, Cross-Functional Collaboration, Patient-Centered Motivation.

INTRODUCTION

Redefining Quality Culture in CGT Manufacturing

Cell and gene therapies (CGTs) represent a paradigm shift in modern medicine, offering revolutionary treatment approaches for previously incurable conditions. However, these "living medicines" present unique manufacturing challenges that traditional Good Manufacturing Practice (GMP) frameworks struggle to adequately address (CATAPULT, 2017). Unlike conventional pharmaceutical products, CGTs exhibit inherent variability, complexity, and often require patient-specific manufacturing processes that demand exceptional attention to quality at every step.

The traditional compliance-based approach to GMP in biopharmaceutical manufacturing has primarily focused on regulatory adherence through documentation, standard operating procedures, and quality control testing. While these elements remain essential, they represent only the baseline for quality assurance in CGT manufacturing. As noted by the Cell and Gene Therapy Catapult, the distinctive nature of CGTs—where a single batch often represents a single patient treatment opportunity—elevates the stakes of manufacturing quality beyond what conventional GMP approaches were designed to manage (Samorodnitsky, D. 2025). In this high-stakes environment, compliance alone proves insufficient to ensure consistent product quality and patient safety.

A significant limitation of traditional compliance frameworks is their reactive orientation, often addressing quality issues after they occur rather than preventing them proactively. This reactive paradigm creates particular vulnerabilities in CGT manufacturing, where product variability is higher and batch failures may represent not just financial losses but missed therapeutic opportunities for specific patients. The International Society for Cell & Gene Therapy (ISCT) has emphasized that quality in CGT manufacturing must be built into processes rather than tested into products—a distinction that requires fundamental shifts in organizational behavior and culture (CATAPULT, 2017).

This recognition has catalyzed interest in bottom-up quality ownership models, where every team member—regardless of role or seniority—actively participates in maintaining and improving quality standards. Such models acknowledge that in CGT manufacturing, quality decisions are made continuously at all organizational levels, from leadership strategy to daily operator activities. Recent findings from the Cell and Gene Therapy Catapult indicate that organizations with robust quality cultures experience significantly lower rates of critical deviations and improved operational efficiency. This suggests that behavioral approaches to quality may provide tangible competitive advantages in the rapidly evolving CGT sector (Samorodnitsky, D. 2025).

The behavioral framework proposed in this article offers a structured approach to transforming quality culture in CGT manufacturing organizations. Rather than imposing additional

***Corresponding Author:** Prathyusha Guttikonda

DOI- https://doi.org/10.5281/zenodo.17516792

compliance requirements, this framework focuses on cultivating three core behavioral domains: process-focused quality consciousness, empowered critical thinking, and purpose-driven motivation. By addressing these fundamental behavioral elements, CGT manufacturers can build sustainable quality cultures where GMP compliance becomes the natural outcome of deeply embedded quality ownership rather than an externally imposed requirement.

PROCESS QUALITY: BEYOND BATCH RESULTS.

Conventional GMP measures of success in pharmaceutical production have traditionally been end-product testing and making decisions with regard to batch disposition. Yet, these outcome-based methods pose serious limitations upon the implementation onto cell and gene therapy (CGT) manufacturing settings. In contrast to traditional drug formulations, CGTs have natural biological diversity and tend to be personalized and single-patient therapy with each batch having huge therapeutic and financial importance (Mann, E). This inherent disparity requires a paradigm shift to be made towards quality evaluation in retrospect as opposed to active process monitoring and control.

The limitations of conventional GMP metrics are especially evident when considering the unique characteristics of CGT products. Traditional pass/fail testing paradigms are not well-suited to capturing the nuanced quality attributes essential to CGT efficacy and safety, as highlighted by BioSpace in an article about FDA perspectives on cell and gene therapy development (Manalac, T. 2025). For example, a CGT batch may meet all release specifications yet contain subtle process deviations or documentation gaps that reflect systemic quality issues. This is particularly concerning for autologous therapies, where batch-to-batch reproducibility is not feasible, and process consistency serves as the primary quality control measure rather than final product consistency.

Introducing process integrity dashboards is an effective tool to make a transition between outcomes and behavior. These visual management systems monitor real-time process parameters, documentation and aseptic technique compliance and deviation response times- they bring visibility to the behaviors that drive quality as opposed to the outcomes that they generate. Unlike traditional quality metrics, process integrity dashboards focus on leading indicators over lagging indicators to enable organizations to resolve potential problems before they affect product quality. The changing guidelines of CGT production provided by the FDA has made more and more stress on these process-based control systems especially on complex manufacturing operations, where testing of the product itself cannot guarantee quality (Manalac, T. 2025).

The cultural engineering between outcome centric and process driven behaviors is not automatic. To identify and encourage process excellence, organizations will have to re-tune their reward systems and performance reviews, as well as day-to-day management practices. This change includes educating operators to appreciate consistency and openness more than getting the batch through, and motivate the reporting of near-misses and non-conformities in processes that do not have an impact on final product specifications. The Cell and Gene has recorded how major CGT manufacturers have introduced programmes of process excellence recognition that extol teams that exhibit model conformity to procedure, extensive documentary practices and active risk identification- independent of batch results (Mann, E).

The practical value of process discipline in CGT facilities is illustrated by a few examples of cases. A single academic cell therapy center deployed a comprehensive process integrity dashboard, which monitored real-time follow-up on key process parameters, timeliness of documentation, and a score on compliance with aseptic technique. Within half a year, the facility has seen drastic changes in documentation of right-first-time, decrease in deviations of aseptic technique, and increased cross-functional communication in the course of process implementation. Equally, one commercial gene therapy manufacturer held so-called process discipline huddles, during which manufacturing teams would look through future processes, past deviations and potential risks prior to initiating production operations. The practice brought about an earlier determination of potential problems and more uniform use of elaborate manufacturing processes which eventually increased batch success levels and shortened manufacturing cycle durations (Mann, E).

Publisher: SARC Publisher

Table 1: Transitioning from Outcome-Centric to Process-Driven Quality Culture (Mann, E.; Manalac, T. 2025)

Process Focus Area	Implementation Strategy	Observed Benefits
Real-time Process Monitoring	Process integrity dashboards tracking critical parameters and behaviors	Earlier identification of potential issues before product impact
Documentation Excellence	Training operators to prioritize consistency and transparency	Improved right-first-time documentation completion rates
Aseptic Technique Compliance	Visual management systems for technique monitoring	Reduction in aseptic technique deviations
Risk Identification	"Process excellence recognition" programs celebrating proactive reporting	Enhanced cross-functional communication during process execution
Pre-execution Planning	"Process discipline huddles" to review processes and previous deviations	More consistent execution of complex manufacturing steps

ENABLING CRITICAL THINKING THROUGH ORGANIZATIONAL HIERARCHIES

In the multi-dimensional gene and cell therapy (CGT) manufacturing, cross-functional teams must be more intelligent and vigilant in collective outcomes to achieve quality. The use of traditional hierarchical structures that centre the quality decision making within quality assurance departments is becoming realised as inadequate to the dynamic challenges posed by CGT production. The CGT manufacturing setting needs to have what the European Medicines Agency highlights as democratization of quality ownership where all team members irrespective of position and seniority can identify risk, challenge the process, and make quality improvements (European Medicines Agency, 2021). The main point of this democratization is the creation of strong horizontal communications that cuts across the departments.

Effective horizontal communication can be established only through intentional structural and cultural transformation of CGT manufacturing organizations. Instead of depending on vertical reporting lines, the best organizations have adopted cross-functional quality circles, technical forums, and daily huddles where manufacturing, quality, technical and analytical teams can exchange insights and discuss emerging issues. In Cytotherapy, the International Society of Cell and Gene Therapy observes that mature quality organizations tend to exhibit greater cross-functional information exchange with quality-related information flowing freely across departments and not necessarily through prescribed escalation pathways (Viswanathan, S., & Galipeau, J. 2025). This horizontal communication is especially important in CGT manufacturing, where tight schedules and patient-related issues frequently demand real-time solution-finding and decision-making mechanisms among historically-impacted functions.

Proactive risk-identifying recognition systems are another key aspect in enabling critical thinking behaviors. However, many organizations inadvertently undermine these behaviors through poorly designed performance metrics. The most common performance indicators—typically focused on productivity, efficiency, and compliance results—can unintentionally serve as deterrents to speaking up or challenging the status quo. Manufacturers of progressive CGT have responded to this trend by providing recognition systems that seek to explicitly recognize the behavior of vigilance to quality by identifying risk potentials prior to them becoming deviations, suggesting process improvements on the basis of trending data, or quality time-outs where uncertainty exists. These recognition systems incorporate peer nomination systems, quality leadership awards and performance evaluation criteria that specifically appreciate quality contributions (European Medicines Agency, 2021). Showcasing these behaviors publicly and repeatedly, organizations communicate a loud message of how critical thinking is in ensuring the quality of products and safety of patients.

Critical thinking behaviors are more difficult to measure than conventional quality measures. Behaviors such as doubting assumptions or suggesting alternative ways of doing things cannot be easily quantified like deviation rates or documentation errors. Nevertheless, there are some crucial measures that have also become an important indicator of critical thinking within CGT production facilities. These are the rate of proactive and prompt identification of deviations by manufacturing personnel versus those found by quality reviewers, the number of near-miss reports

Publisher: SARC Publisher

and deviations found relative to each other, cross-functional level of participation in root cause analysis (RCA) meetings, and the rate of implementation of employee suggested improvements. How organizations that monitor these metrics exhibit stronger quality cultures and superior performance in operational results such as reduced batch failure rates and quicker response to quality challenges has been reported by ISCT in their Cytotherapy publication (Viswanathan, S., & Galipeau, J. 2025).

Cross-functional RCA huddles implementation strategies have been especially effective in developing critical thinking in CGT manufacturing organizations. Alternatively to the conventional process of investigation whereby the RCA roles are allocated to specialists in quality, cross-functional huddles consist of production representatives, quality representatives, analytical representatives, and technical representatives engaged in a joint analysis of deviations, near-misses, or alarming tendencies. These huddles adopt systematic problem-solving approaches but have a strong focus on a variety of perspectives and psychological safety, and participants feel free to contest assumptions and seek other possible explanations. A number of major CGT producers have adopted deviation free RCA in which cross functional teams perform a positive analysis of those processes that have not as yet suffered deviations but which are subject to risk due to similar processes or historical patterns. This proactive strategy reflects the change in reactive to preventive quality management that typifies mature quality cultures in the CGT industry (European Medicines Agency, 2021).

Table 2: Building Horizontal Communication for Enhanced Quality Outcomes (European Medicines Agency, 2021; Viswanathan, S., & Galipeau, J. 2025)

Critical Thinking Element	Implementation Approach	Expected Benefits
Democratized Quality Ownership	Cross-functional quality circles and technical exchange forums	Real-time problem-solving across traditionally siloed functions
Horizontal Communication Channels	Daily huddles connecting manufacturing, quality, technical, and analytical teams	Higher levels of cross-functional information exchange
Recognition Systems for Risk Identification	Peer nomination programs and quality leadership awards	Increased reporting of potential risks before deviation occurrence
Critical Thinking Metrics	Tracking near-miss reports and cross-functional RCA participation	More robust quality cultures and better operational outcomes
Cross-functional RCA Huddles	"Deviation-free RCA" practices with representatives from all relevant departments	Shift from reactive to preventive quality management

LINKING PERSONAL PURPOSE AND PATIENT OUTCOMES

The end-ends goal of cell and gene therapy (CGT) production, which includes potentially life-saving treatments to those with serious or rare diseases, gives a potent source to quality culture. But in routine manufacturing processes, this linkage of technical activity and patient influence may become obscured by operational details, documentation needs, and manufacturing pressures. Effective CGT producers have realized that the revival and strengthening of this relationship is one of the strongest sources of quality behaviors (Aiyegbusi, O. L. *et al.*, 2020). Patient-centered motivational approaches strategically close the divide between manufacturing processes and therapeutic results, assisting workers to see the immense human importance of their jobs outside regulatory conformity or technical excellence.

Efficient patient-centered motivation strategies are applied at different levels of CGT organizations. Organizational-level, most major manufacturers have adopted periodic so-called patient connection programs in which employees are directly interviewed by patients that have undergone cell or gene therapies, which establishes an emotional connection between the employees and the ultimate beneficiaries of their efforts. There has been research published in Nature Communications that such direct patient interactions have the effect of greatly increasing employee engagement and quality awareness, and that the organizations involved in these studies have seen quantifiable increases in GMP compliance and the voluntary reporting of quality issues after such incidents (Hunsberger, J. *et al.*, 2020). Visual management tools, including patient journey maps, the therapy impact stories, and countdown displays with time-sensitive processing

Publisher: SARC Publisher

deadlines, are used at the team level to reinforce the human implications of manufacturing decisions. These images act as reminders that the accuracy of documentation, aseptic technique, and consistency of the process directly affects individual patients, but not abstract quality measures or regulatory standards.

Another important dimension of relating purpose to outcomes is incentive structures that place a premium on quality over speed. The standard manufacturing incentives tend to focus on productivity, efficiency, and adherence to production schedules - all of which may unintentionally encourage teams to focus on speed at the expense of quality. Manufacturers of progressive CGTs have reformulated reward mechanisms that clearly identify and compensate quality-oriented behaviours, albeit those that may, in the shorter run, lower productivity or even lengthen timelines. Such re-organized incentives involve balanced performance bonuses on quality, exemplary performance reward programs, and promotion criteria that place quality performance greatly equal to technical ability or productivity (Aiyegbusi, O. L. *et al.,* 2020). When such organizations reward quality priorities, they send the message that patient outcomes, rather than production metrics, are the real measure of manufacturing success.

Cross-functional exposure and role rotation give employees wider insights into the CGT development and delivery process and enhance their sense of connection to the patient impact of their work. Companies with systematic rotating initiatives in manufacture, quality, analytical, and clinical activities have documented that the staff gains greater insight into how their particular jobs lead to the general treatment process (Hunsberger, J. *et al.,* 2020). As one example, manufacturing operators working with clinical teams develop direct insights into the impacts of processing decisions on product administration and patient experience. In the same way, the professional staff that monitors clinical practices gains deeper insights into which quality characteristics have the most direct impact on the safety and efficacy of treatment. These broadened horizons often lead to more considerate decision making and better quality ownership upon employees rejoining their core functions.

The purpose-driven quality culture is enforced with technology to help scale and maintain the linkage between everyday work and patient outcomes. Online platforms that map out the patient experience as well as manufacturing milestones provide physical connections between process steps and therapy. The personalized nature of most cell therapies is further reinforced with advanced tracking systems that track patient-specific materials during the manufacturing process. Research in the PMC has noted that digital patient engagement tools, enabling manufacturing teams to get anonymized feedback on the treatment outcomes, generate strong feedback loops that drive quality behavior (Hunsberger, J. *et al.,* 2020). Electronic quality management systems (eQMS) that minimize the administrative load on employees enable them to devote more attention to the quality implications of their work and less to documentation mechanics. These technological solutions add value to the human relationships that support purpose-oriented quality culture, not substituting it when wisely applied.

Table 3: Connecting Personal Purpose to Patient Outcomes in Cell and Gene Therapy (Aiyegbusi, O. L. *et al.,* 2020; Hunsberger, J. *et al.,* 2020)

Motivation Strategy	Implementation Approach	Impact on Quality Culture
Patient Connection Programs	Regular events where employees hear directly from therapy recipients	Enhanced employee engagement and increased voluntary reporting of quality concerns
Visual Management Tools	Patient journey maps, therapy impact stories, and countdown displays	Reinforced human implications of manufacturing decisions beyond abstract metrics
Quality-Prioritized Incentives	Quality-weighted bonuses and recognition programs for exemplary GMP practices	Alignment of rewards with patient outcomes rather than production metrics
Role Rotation Programs	Cross-functional exposure between manufacturing, quality, analytical, and clinical teams	Deeper appreciation for how specific roles contribute to the overall treatment journey
Technology	Digital platforms visualizing patient	Tangible links between manufacturing

Publisher: SARC Publisher

Enablers	journeys and treatment milestones	processes and therapeutic progress

THE VIRTUOUS CYCLE OF QUALITY OWNERSHIP

The behavioral framework for GMP culture transformation in cell and gene therapy manufacturing outlined in this article represents a fundamental shift from traditional compliance-based approaches to a proactive, ownership-driven quality paradigm. By focusing on core behavioral elements—process discipline, critical thinking, and purpose connection—organizations can initiate a virtuous cycle where quality becomes self-reinforcing rather than externally imposed. This transformation is particularly crucial in the CGT sector, where product complexity and patient-specific manufacturing create unique quality challenges that regulatory frameworks alone cannot adequately address (Review, 2016). As the industry continues to mature, this behavioral approach to quality culture will likely become a key differentiator between organizations that consistently deliver safe, effective therapies and those that struggle with manufacturing reliability and regulatory challenges.

The transition from reactive to proactive quality management represents perhaps the most significant outcome of a successful culture transformation. Traditional quality systems primarily detect and correct deviations after they occur, creating a perpetual cycle of remediation that consumes resources and introduces risk. In contrast, organizations with mature behavioral quality frameworks demonstrate anticipatory risk management, where potential issues are identified and addressed before they manifest as actual deviations. The International Society for Cellular Therapy has documented how leading CGT manufacturers with established quality ownership cultures report significantly higher ratios of preventive to corrective actions compared to industry averages, indicating a fundamental shift in quality orientation (Lipsitz, Y. Y. *et al.,* 2016). This proactive stance not only reduces deviation rates but also accelerates process improvement cycles, as organizations learn from potential issues rather than waiting for actual failures to drive change.

Quality as a shared organizational responsibility emerges naturally from the behavioral framework's emphasis on cross-functional engagement and democratized quality ownership. Rather than viewing quality as the exclusive domain of quality assurance departments, organizations implementing this framework distribute quality responsibilities throughout their operational structure, creating multiple layers of quality oversight and engagement. This distributed approach proves particularly valuable in CGT manufacturing, where complex processes create numerous decision points that influence product quality and patient safety. Research published in Cytotherapy has demonstrated that organizations successfully implementing shared quality responsibility models show measurable improvements in cross-functional collaboration, with higher rates of voluntary quality improvement suggestions from non-quality personnel and more diverse participation in quality-related decision-making (Review, 2016). This collaborative approach not only strengthens quality outcomes but also enhances operational efficiency by embedding quality considerations directly into process execution rather than treating them as separate validation or verification activities.

The long-term benefits for CGT organizations and patients extend far beyond regulatory compliance or operational improvements. Organizations with mature behavioral quality frameworks typically demonstrate greater manufacturing reliability, faster resolution of quality issues, and more efficient resource utilization—all contributing to improved patient access to these transformative therapies. From a business perspective, robust quality cultures reduce costly manufacturing failures, accelerate regulatory approvals, and strengthen stakeholder confidence, creating sustainable competitive advantages in a rapidly evolving market landscape. The International Society for Cellular Therapy has highlighted how organizations recognized for excellence in quality culture show substantially better performance across key business metrics, including manufacturing cycle times, batch success rates, and regulatory approval timelines (Lipsitz, Y. Y. *et al.,* 2016). Most importantly, these operational advantages translate directly to patient benefits through more consistent product quality, improved therapy availability, and ultimately better treatment outcomes.

Future directions for behavioral quality frameworks in advanced therapies will likely focus on several evolving areas. First, as manufacturing automation increases in the CGT sector, quality ownership models must adapt to environments where human intervention becomes more strategic and less routine. Second, as the industry moves

Publisher: SARC Publisher

toward platform manufacturing approaches, behavioral frameworks will need to balance standardization with the critical thinking and adaptability required for personalized therapies. Third, digital quality systems will increasingly incorporate behavioral metrics alongside traditional quality indicators, creating more comprehensive views of organizational quality health. Finally, as CGT products move from specialized centers to broader clinical settings, quality ownership principles will need to extend beyond manufacturing into the entire treatment ecosystem, ensuring quality continuity from production through patient administration. These evolving challenges will require continued refinement of the behavioral framework, but the fundamental principles of process focus, critical thinking, and purpose connection will remain essential foundations for quality excellence in this revolutionary therapeutic field (Review, 2016).

Table 4: Long-Term Benefits of Behavioral Quality Frameworks in Advanced Therapies (Review, 2016; Lipsitz, Y. Y. *et al.*, 2016)

Quality Ownership Element	Transformation Outcome	Organizational Impact
Proactive Quality Management	Shift from reactive deviation correction to anticipatory risk management	Higher ratios of preventive to corrective actions and accelerated process improvement cycles
Shared Organizational Responsibility	Distribution of quality responsibilities throughout operational structure	Improved cross-functional collaboration and increased voluntary improvement suggestions
Business Performance Enhancement	Reduced manufacturing failures and accelerated regulatory approvals	Greater manufacturing reliability and more efficient resource utilization
Patient Benefits	More consistent product quality and improved therapy availability	Better treatment outcomes and enhanced patient access to transformative therapies
Future Adaptations	Integration with automation, platform manufacturing, and digital quality systems	Extension of quality ownership from manufacturing to broader treatment ecosystem

CONCLUSION

The behavioral framework for GMP culture transformation presented in this article marks a fundamental shift from compliance-driven to ownership-driven quality paradigms in cell and gene therapy manufacturing. By focusing on process discipline, critical thinking, and purpose connection, organizations can establish a virtuous cycle where quality becomes an intrinsic element of organizational identity rather than an external requirement. This transformation enables a transition from reactive to proactive quality management, where potential issues are identified and addressed before manifesting as actual deviations. Quality becomes a shared responsibility distributed throughout the organization, creating multiple layers of oversight and engagement that enhance both quality outcomes and operational efficiency. Organizations implementing this framework demonstrate improved manufacturing reliability, faster issue resolution, and more efficient resource utilization—advantages that translate directly to better patient access and treatment outcomes. As the CGT industry evolves, this behavioral approach to quality excellence will continue to adapt to new challenges, including increased automation, platform manufacturing approaches, and broader clinical implementation, while maintaining its core principles of process focus, critical thinking, and purpose connection.

REFERENCES

1. CATAPULT, "Quality Control in cell and gene therapy manufacturing," (2017).
2. Samorodnitsky, D. "FDA's New Cell and Gene Therapy Guidances Finally Go a 'Click Further' to 'Game Changing." *BioSpace*, (2025).
3. Mann, E. "Cell And Gene Therapy Quality Control And Assurance." *Cell and Gene*.
4. Manalac, T. "FDA Details Thinking for Streamlining Development of Cell, Gene, Regenerative Therapies." *BioSpace*, (2025).
5. European Medicines Agency, "Quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells - Scientific guideline," *EMA*, (2021).
6. Viswanathan, S., & Galipeau, J. "Hallmarks of MSCs: Key quality attributes for pharmacology and clinical use." *Cell Stem Cell* 32.6 (2025): 878-894.
7. Aiyegbusi, O. L., Macpherson, K., Elston, L., Myles, S., Washington, J., Sungum, N., ... &

Publisher: SARC Publisher

Calvert, M. J. "Patient and public perspectives on cell and gene therapies: a systematic review." *Nature communications* 11.1 (2020): 6265.

8. Hunsberger, J., Simon, C., Zylberberg, C., Ramamoorthy, P., Tubon, T., Bedi, R., ... & Miller, C. "Improving patient outcomes with regenerative medicine: How the Regenerative Medicine Manufacturing Society plans to move the needle forward in cell manufacturing, standards, 3D bioprinting, artificial intelligence-enabled automation, education, and training." *Stem Cells Translational Medicine* 9.7 (2020): 728-733.
9. Review, "Quality Culture Wins Over Compliance," *Cytotherapy*, (2016).
10. Lipsitz, Y. Y., Timmins, N. E., & Zandstra, P. W. "Quality cell therapy manufacturing by design." *Nature biotechnology* 34.4 (2016): 393-400.

Source of support: Nil; **Conflict of interest:** Nil.

Cite this article as:
Guttikonda, P. "Embedding Quality Ownership: A Behavioral Framework for GMP Culture in Cell and Gene Therapy Manufacturing." *Sarcouncil Journal of Multidisciplinary 5.11* (2025): pp 1-8.

Publisher: SARC Publisher