Addressing Gaps in Pharmacy Standards for Cell and Gene Therapy Management

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BACKGROUND

The rapid growth of FDA-approved cell and gene therapies (CGTs) has elevated the role of pharmacies in the receipt, storage, handling, and dispensing of these complex and high-value treatments. While pharmacies play a critical role in safeguarding CGT integrity and ensuring patient safety, ***current pharmacy quality standards and accreditations are less suited to the specialized requirements for managing CGTs***. This gap underscores an urgent need for CGT-specific quality standards to ensure product potency and integrity, operational consistency, and patient safety.

METHODOLOGY

To capture frontline perceptions of pharmacy readiness, standards adequacy, and future accreditation drivers, we conducted a targeted survey of pharmacy stakeholders (n = 10). Despite the small sample size, the qualitative feedback offered valuable insights into current practices and highlighted opportunities to refine and implement the proposed standards (see Figure 1 for full survey results).

To address this gap, a multidisciplinary committee of pharmacy stakeholders convened to develop the 1st edition of the AABB Cell and Gene Therapy Standards for Pharmacy (see Figure 2 for committee composition and expertise).

These standards, grounded in established quality system essentials, aim to guide the safe and consistent management of CGTs across various pharmacy settings. They focus on core elements such as organizational structure, equipment qualification, agreements, processes and procedures, documentation and record retention, deviation management, and safety.

SURVEY RESULTS AND COMMITTEE COMPOSITION

Survey results confirm a clear recognition among pharmacy professionals:

- **90%** of respondents strongly agree that pharmacies will play a critical role in CGT dispensing within the next 3–5 years
- **Only 50%** felt that current standards are adequate for CGT management, while 40% say current standards are not adequate at all
- **100%** agree that adopting dedicated quality standards will reduce mishandling and deviations, and that payer and manufacturer requirements will soon compel pharmacies to seek formal accreditation

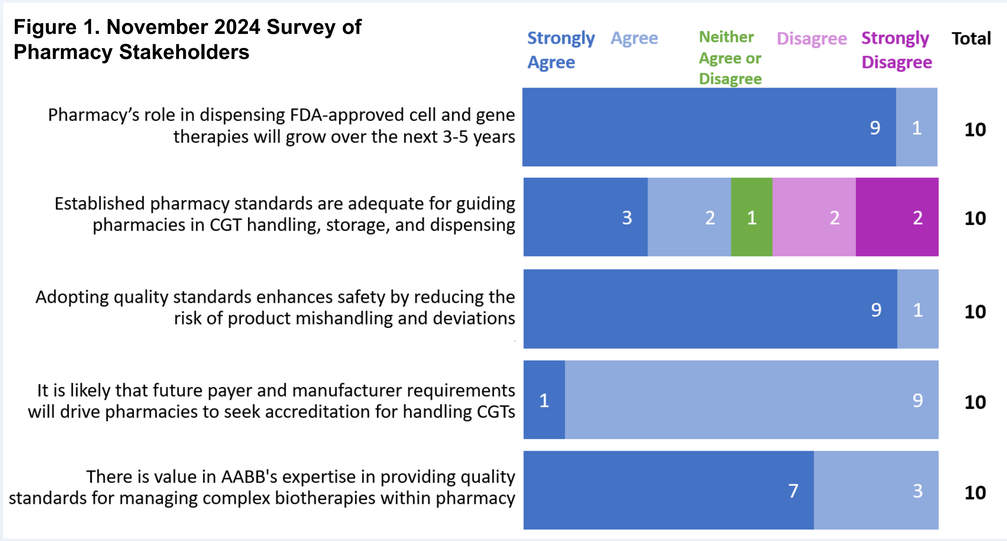
Collectively, these responses signal a profession that both expects—and is not yet prepared for—a surge in CGT responsibilities. The consensus on safety benefits and anticipated external pressure underscores the need for a unified quality framework with the pharmacy setting.

Figure 2. Committee Composition and Expertise

Name	Sector	Years of Relevant Experience
Eric Manuel Balmir, M.S., PharmD, CIM	Academic Hospital Pharmacy	20+ years
Jill E. Blind, PharmD, CCRP	Academic Hospital Pharmacy	17 years
Kim McConnell, PharmD, BCPS, CCRP	Academic Hospital Pharmacy	20+ years
Kimberly Tedesco, RPH.	Retail Specialty Pharmacy	20+ years
Jodi Sibell, RN	Retail Specialty Pharmacy	20+ years
Maribeth Bettarelli, PharmD	Retail Specialty Pharmacy	20+ years
Krystal Haynes, MOL	Pharmaceutical Distribution	11 years
Joe DePinto, MBA	Pharmaceutical Distribution	20+ years
Beth Shaz, MD, MBA	Clinical CT Manufacturing and Administration	20+ years
Corinne Goldberg, MD	Clinical CT Manufacturing and Administration	20+ years
Katherine Stewart Brown Ph.D.	Clinical CT Manufacturing and Administration	20+ years
Brenda Alder, CABP, MS, MT(ASCP)SBB	Clinical CT Manufacturing and Administration	20+ years
Mary Grable McLeod, CABP(H), MT(ASCP)SBB	Clinical CT Manufacturing and Administration	20+ years
Phil Wilson, Masters SCM	CGT Supply Chain and Logistics	20+ years
Jessica Chery, PhD	Regulatory Competent Authority, FDA (OGT)	8 years
Karin Knudson, PhD	Regulatory Competent Authority, FDA (OCTHT)	9 years
Linda S Barnes, CABP(H),DrPH,MHA	Biotherapies Industry Consultant	20+ years
Christopher Bocquet	Standards Development and Staff Liaison	20+ years

SURVEY DATA

Figure 1. November 2024 Survey of Pharmacy Stakeholders



DISCUSSION

Survey data reinforce the urgency of developing and implementing CGT-specific pharmacy standards. The AABB CGT Standards for Pharmacy provide a foundation for reducing variability, mitigating risk, and protecting patients. Without them, pharmacies must rely on fragmented protocols with limited safeguards. With them, pharmacies—and the broader CGT ecosystem—can build scalable, trusted quality infrastructures that preserve product integrity, secure payer and manufacturer confidence, and ensure safe patient access.

Adoption and accreditation of these standards should not be dismissed as just another box-checking exercise. Instead, they are a proactive readiness tool—particularly crucial as CGTs move beyond academic and specialty centers into community settings.

CONCLUSION

Rapid CGT growth is colliding with pharmacy infrastructure that was not built for living biologics. The first-edition AABB CGT Standards for Pharmacy close this gap by delivering a practical, accreditation-ready framework to reduce variability, protects product potency, and patient safety. Next steps include broad stakeholder education, alignment with payer and regulatory policies, and data-driven outcome tracking to demonstrate value. By adopting these Standards now, pharmacies can move from reactive compliance to proactive readiness—ensuring safe, equitable CGT access as therapies spread from tertiary centers to the community.

ACKNOWLEDGEMENT

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