Roundtable Session 1 – Table 6 – *Breaking Down Silos in Technology and Knowledge Transfer*

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Abstract

Successful technology transfer in cell and gene therapy (CGT) extends beyond the transfer of processes and analytical methods. It requires the effective sharing of critical product, process, and organisational knowledge across development, manufacturing, quality, regulatory, and commercial functions. As programmes progress through development and scale-up, knowledge can become fragmented across teams, sites, and external partners, creating risks to product quality, operational efficiency, and long-term lifecycle management.

This roundtable will explore practical approaches to preserving and transferring knowledge throughout the CGT product lifecycle. Participants will discuss strategies for enabling successful technology transfer, fostering cross-functional collaboration, and maintaining continuity of product and process understanding across internal teams, CDMOs, and manufacturing sites. Through the exchange of experiences and lessons learned, the session aims to identify best practices for breaking down organisational silos and building more connected and knowledge-driven CGT organisations.

Discussion questions

1. What are the biggest barriers to effective knowledge transfer in CGT programmes, and how have you successfully overcome them?

2. How can organisations ensure that critical product and process knowledge is preserved during technology transfer, particularly when working across multiple teams, CDMOs, or manufacturing sites?

3. To what extent do regulatory expectations drive effective knowledge transfer and cross-functional collaboration within CGT organisations?

Notes

Summary of discussion

The discussion brought together perspectives from product and process development, manufacturing, quality assessment, consulting and technology-transfer activities. The central message was that successful transfer is not simply the handover of a process description. It depends on preserving the scientific rationale, practical experience and organisational context needed to reproduce and control the process at another team, site or external partner.

1. Main barriers to effective knowledge and technology transfer

• **Organisational and geographical separation.** Development and manufacturing are often located in different teams, organisations or countries. This creates distance between those who understand how the process was developed and those expected to operate it routinely. The constraints of the partners, even internally, may not be clear to all which may lead to issues that could be relatively easily resolved if discussed. Participants stressed that transfers must

therefore be planned with precision, with clear interfaces, responsibilities and communication channels.

• **Loss of tacit knowledge.** Written procedures capture what should be done, but not always why a parameter matters, how a step behaves in practice, or which warning signs experienced staff recognise. When the people who developed the process are no longer available, this knowledge can be difficult to reconstruct. Staff continuity, direct interaction and practical observation were considered important complements to formal documentation.

• **Different objectives and ways of working.** Research, development, quality and manufacturing teams may use different language, work to different timelines (although timelines are in general tight) and focus on different risks. A process that is acceptable in development may not yet be sufficiently robust, scalable or well controlled for routine manufacturing. Early cross-functional engagement helps expose these differences before transfer begins.

• **Immature processes and analytical methods.** Technology transfer becomes more difficult when the process, control strategy or analytical package is still evolving. Participants noted the need to understand process variability, define critical parameters and ensure that methods are suitable for the receiving environment. Otherwise, normal development changes may be mistaken for transfer failures, or real differences may remain unexplained.

• **Transfer to external partners.** Working with a contract organisation can introduce additional challenges related to access to expertise, data ownership, prioritisation and staff turnover. Selecting a partner should therefore consider not only technical equipment and capacity, but also relevant experience, analytical capability, quality culture, communication practices and willingness to share knowledge transparently.

2. Approaches that support a successful transfer

Early transfer planning was repeatedly emphasised. The receiving site or partner should be involved before the process is considered final, so that manufacturability, scale, equipment fit, raw-material strategy, sampling, testing and data requirements can be addressed while changes are still manageable.

A structured transfer package should combine procedures, development reports, risk assessments, process descriptions, method information, acceptance criteria, deviation history and the rationale behind key decisions. The package should identify what is known, what remains uncertain and which elements require enhanced monitoring during engineering or qualification runs.

Direct exchange between sending and receiving teams remains essential. Joint workshops, on-site observation, hands-on training, shadowing and participation of development staff in initial manufacturing runs can reveal practical details that documents alone do not convey. A clearly identified transfer lead, subject-matter experts and decision-making route help prevent questions from remaining unresolved.

Transfer should be managed as an iterative, risk-based activity rather than a single handover event. Readiness assessments, gap analyses and predefined success criteria can be used to determine whether equipment, materials, methods, personnel and quality systems are sufficiently prepared. Lessons from trial runs, deviations and comparability assessments should be fed back into the knowledge package.

Knowledge must remain accessible after formal transfer completion. Participants supported maintaining controlled, searchable information and a clear record of decisions, assumptions and changes. Digital tools can help, but they do not replace scientific discussion, ownership or effective collaboration.

3. Regulatory expectations and cross-functional collaboration

Regulatory requirements were viewed as an important driver for disciplined knowledge management. Expectations for process understanding, control strategy, analytical method performance, comparability and traceability encourage organisations to document how knowledge was generated and how it supports manufacturing decisions.

At the same time, compliance alone does not guarantee an effective transfer. A package assembled only to meet submission or inspection needs may omit operational insight that is essential to the receiving team. Regulatory, quality, development and manufacturing functions should therefore work together from an early stage rather than reviewing the transfer sequentially.

Participants also noted that programmes may need to meet expectations across different regions and at different development stages. The approach should be phase-appropriate, while anticipating later clinical and commercial requirements so that early choices do not create avoidable rework. Where a process or product evolves, the impact of changes and the need for comparability should be considered proactively.

Overall conclusions

The discussion highlighted five priorities: involve the receiving organisation early; transfer the rationale as well as the instructions; retain access to experienced people; establish clear ownership and governance; and build a living knowledge base that continues through development, scale-up and lifecycle management. Effective technology transfer in cell and gene therapy is therefore best understood as a sustained cross-functional collaboration, supported by robust documentation but dependent on active exchange between people.