Applications of AI & ML in Biomanufacturing of Cell and Gene Therapies

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This workshop highlights how AI/ML technologies are beginning to be applied to biomanufacturing and bioengineering of cell and gene therapies (CGT). AI/ML have demonstrated their utility in biocomputing and biomedical research applications, and are poised to become central to design, scaling, and optimization of bioengineering processes such as CAR-T cells, iPSC, and biomolecule production. Invited speakers from academia and industry will speak of their experience in leveraging these new intelligent technologies.

Keywords: Cell and Gene Therapeutics, Biomanufacturing, Knowledge Systems, Artificial Intelligence, Lab Automation

1. Introduction

Cell and gene therapies are transforming medicine, offering the possibility of cures rather than just treatments. Yet, despite their promise, the path from idea to market is long, costly, and fraught with failure. Nearly half of advanced therapy programs collapse before reaching manufacturing[3], often because their foundations are built on insufficient early characterization.

Process development in cell therapies is the critical phase in which every step —from induced pluripotent stem cells (iPSCs) reprogramming and expansion, to differentiation and scale-up—is systematically optimized and validated to ensure reproducibility and quality. Each parameter must be carefully tuned and statistically understood before the process is "locked down," because once it transitions into GMP manufacturing, no further changes can be made without resetting the entire regulatory pathway. The painstaking, iterative experimentation that defines process development is therefore not an academic exercise—it is the foundation that determines whether a cell therapy will function reliably, scale successfully, and ultimately reach patients safely.

To deliver a safe, effective product, developers must define Critical Quality Attributes (CQAs) (what "good" looks like) and Critical Process Parameters (CPPs) (which "levers" truly matter to

produce quality). This is the cornerstone of Quality by Design (QbD): ensuring quality is built in from the start, not inspected in at the end [3].

But today, the characterization process is slow, manual, and expensive. Biologists rely heavily on experience and intuition, while lacking the statistical frameworks needed for robust process design. As a result, companies often cut corners, locking down processes before they're truly understood—creating a fragile "house of cards" that collapses later in development.

1.1 Where automation fits in

Automation is not just about efficiency; it is about removing variability, ensuring consistency, and capturing every piece of data. In current practice, many of the most variability-prone steps—cell passaging, media changes, imaging, and offline assays—are performed manually by multiple operators. Each subtle difference adds noise and uncertainty to the process.

By automating these steps, we achieve:

1. Consistency: Robots perform the same actions identically every time, reducing operator-to-operator variability[4].
2. Throughput: Automated systems can run more experiments in parallel, compressing timelines.
3. Data integrity: Every action is logged, time-stamped, and linked to process metadata, ensuring traceability.
4. Contamination control: Automation reduces human handling, lowering risk in processes that often take months per dose.

Automation Systems (e.g. Celligent™ and BioPAT©) already integrate imaging, media handling, and culture interventions with automated, regulatory-compliant data capture. This ensures not only reproducibility, but also a digital record ready for regulatory review.

1.2 Automation combined with AI

AI is already being applied in therapeutic R&D to identify drug targets, design novel molecules, simulate drug effects, and optimize clinical trials[1]. However, this does not address the need to define and optimize the process development phase and quality assurance for therapies. Specifically, how can it address the needs of automation and quality management? While automation provides consistency and scale, AI unlocks the full value of the data generated. Together, they enable a new paradigm:

- Robust, multimodal data integration: AI combines imaging, omics, and metadata into holistic datasets, overcoming the "needle in a haystack" problem of finding meaningful quality metrics.
- Sentinel panels and predictive modeling: AI can detect early signals of drift, giving developers actionable insight long before failure becomes visible.
- Automated Design of Experiments (DoE): Instead of manual trial-and-error, AI can propose statistically rigorous experimental designs, test hypotheses, and iteratively refine CQAs and CPPs.

- Continuous learning: Each automated run feeds back into the knowledge base, improving predictive power over time—creating a "self-improving" ecosystem.
- Regulatory readiness: The combination of structured automation data and AI-driven analysis makes for powerful, evidence-rich submissions[5].

In short, automation creates reliable data at scale; AI transforms that data into knowledge and action. Together, they form the bedrock needed to de-risk advanced therapies, shorten timelines, and build confidence for investors and regulators alike.

2. Objectives

This workshop explores the different forms of applying AI to Process Development, and how this augments the larger picture. Specifically:

1. Have the ability to Recognize the core bottlenecks in advanced therapy development.
2. Have an understanding of the informatics needs that link operational data systems to deeper analytics and workflow optimizations.
3. Have an understanding why characterization is the foundation of therapeutic success and how CQAs/CPPs are defined.
4. See how automation reduces variability, increases throughput, and secures data integrity.
5. Learn how AI transforms automated data into actionable insights, accelerating discovery and regulatory readiness, and how this can be captured using Knowledge Graphs[2].
6. Envision a future where automation + AI enable Quality by Design in biology and aggregation of Therapeutic Process Knowledge , reducing cost and risk while increasing investor and patient confidence.

By embedding automation and AI into the earliest stages of development, we can create robust processes where quality is not an afterthought but a design principle. This will not only reduce wasted investment and accelerate speed to market but also build reusable knowledge frameworks that benefit the entire field[6].

This workshop will explore how to move from fragile, manual, corner-cutting practices to a future where automation and AI enable quality by design for biology—delivering therapies that are consistent, scalable, and accessible.

3. Workshop Program

- Introduction (Eric Neumann & Karen Weisinger)
- Presentations:
  - **Karen Weisinger** (Cell X Technologies) - Breaking the House of Cards: Characterization, QbD, and Automation for Reliable Innovative Advanced Therapies
  - **Timo Schmidberger** (Sartorius) - Digital Integration: Hardware's Key Role in AI/ML Advancement
  - **Eric Neumann** (IQUrium) - Cell Processing Combining Knowledge Models with AI
- Closing Remarks

4. References

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