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

PSB January 3–7, 2026 | Big Island, Hawaii

Organizers: Eric Neumann IQUrium, Karen Weisinger Cell X Technologies, Tom Londo TRL Enterprises

Cell and gene therapies (CGT) 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, often because their foundations are built on insufficient early characterization.
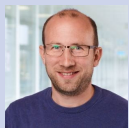
This workshop highlights how AI/ML technologies are beginning to be applied to biomanufacturing and bioengineering of cell and gene therapies. The hope is that the these technologies will effectively address the challenges described above. AI/ML have demonstrated their utility in biocomputing and biomedical 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 will speak of their experience in leveraging these new intelligent technologies.

Objectives

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

• Have the ability to recognize the core bottlenecks in advanced therapy development.

• Have an understanding of the informatics needs that link operational data systems to deeper analytics and workflow optimizations.

• Have an understanding why characterization is the foundation of therapeutic success and how CQAs/ CPPs are defined.

• Understand how automation reduces variability, increases throughput, and secures data integrity.

• Learn how AI transforms data into actionable insights, accelerating discovery and regulatory readiness, and how this can be captured using Knowledge Graphs.

• 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.

Agenda

	9:05 **Welcome & Introduction** (Eric Neumann & Karen Weisinger)
	9:15 **Karen Weisinger** (Cell X Technologies) - Breaking the House of Cards: Characterization, QbD, and Automation for Reliable Innovative Advanced Therapies
	10:00 **Timo Schmidberger** (Sartorius) - Digital Integration: Hardware's Key Role in AI/ML Advancement
	10:45-11:00 **Break**
	11:00 **Eric Neumann** (IQUrium) - Cell Processing - Combining Knowledge Models with AI
	11:45 **Closing Remarks**.

Speakers' Background

Eric Neumann - IQUrium
Dr Eric Neumann is a knowledge systems specialist and has created knowledge graphs models for several biopharma companies in support of scientific knowledge discovery and clinical programs, including Foundation Medicine, Cell X Technologies, and Sanofi. He has supported and participated in standards activities for data, ontologies, and knowledge graphs for over 20 years. Dr Neumann is co-founder and CKIO of IQUrium, integrating knowledge systems with AI applications. He holds a PhD in neurobiology, developmental genetics, and pharmacology from Case Western Reserve University.

Timo Schmidberger - Principal Data Scientist , Sartorius
Timo Schmidberger, PhD, began his career at Novartis in 2008, specializing in mammalian cell culture process development. Over nine years, he excelled in scaling, process transfer, characterization, and statistical evaluation, eventually leading an in – process control QC laboratory. In this role, he provided analytical support to three production lines. In 2018, Timo joined Sartorius, leveraging his extensive bioprocessing and GMP knowledge. At Sartorius, he is known for his expertise in data analytics, including ML and hybrid model development for bioprocesses. Timo's contributions advance data science in biotechnology, keeping Sartorius at the forefront of innovation and customer enablement.

Karen Weisinger - Cell X Technologies
Karen is academically trained as a stem cell scientist in neuro-developmental biology and has applied that expertise in industry to advance innovative iPSC-based therapeutics. Having worked with over 25 companies as an R&D specialist, process development scientist, and consultant, she repeatedly encountered the same fundamental process bottlenecks across the field—experiences that now drive her conviction to solve them through automation and AI. She joined Cell X Technologies to focus on enabling scalable, reliable cell therapy manufacturing, believing that overcoming these core challenges is essential for the field to reach its full potential