Syner-G

Accelerating the Delivery of Advanced Therapies

The Challenge

Innovation is moving faster than operational readiness

- Biotech innovation has never moved faster
- Early-stage risk isn't always technical, it's also operational
- Facility, utility, and manufacturing readiness often lag development

Why It Matters

Quality is inseparable from how therapies are produced

- Advanced therapies offer extraordinary therapeutic potential
- They also introduce higher operational and GMP risk
- Quality is intrinsically linked to process design, control, and execution

What's Driving the Pressure

Advanced modalities are compressing timelines and increasing complexity

- Accelerated clinical pathways
- Platform technologies
- Novel modalities:
  - Cell & gene therapies
  - mRNA
  - Viral vectors
  - Combination products
- Tighter integration of:
  - Facilities
  - Utilities
  - Manufacturing processes

The Problem

CQV often starts too late

- Validation planning begins after key design decisions
- Inefficiencies compound over time
- Results include:
  - Development delays
  - Increased cost
  - Inspection risk
  - Suboptimal operations

The Opportunity

Start CQV early and treat it as a lifecycle discipline

- Day 1 clarity on the validation lifecycle
- Shift the mindset:
  - From "Did we test everything?"
  - To "Did we control what matters most?"
- Focus effort on patient and product risk

The Impact

Strategic CQV accelerates time to market

- Facilities, utilities, and processes aligned to the validation lifecycle
- Faster transition from development to GMP manufacturing
- Stronger inspection readiness
- Reduced rework and delays

How Syner-G Helps

Phase-Appropriate, Risk-Based CQV for Advanced Therapies

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1 Risk-Based Validation from the Start

- Identify critical systems based on product and patient risk
- Define qualification expectations by system type
- Align:
  - ✓ Facilities
  - ✓ Utilities
  - ✓ Equipment
  - ✓ Process
  - ✓ Automation

Outcome: Focused, defensible validation effort where it matters most

2 Anchor CQV in Product & Patient Risk

- Advanced therapies are highly sensitive to:
  - Environmental conditions
  - Operator technique
  - Process variability
- We evaluate:
  - ✓ Critical process steps
  - ✓ Open processing and manual interventions
  - ✓ Automation and monitoring strategies

Outcome: Evidence of control for CQAs and CPPs

3 Align Validation to Phase-Appropriate GMP Expectations

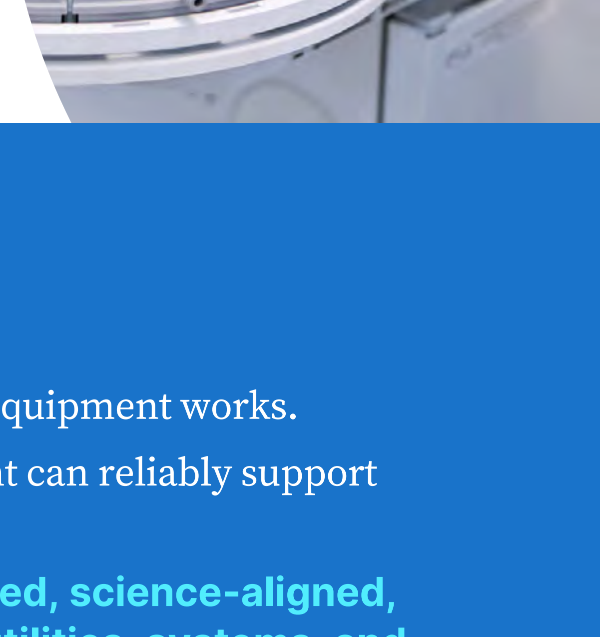
- Early-phase processes evolve—but must remain defensible
- Key focus areas include:
  - ✓ Cleanroom pressure cascades
  - ✓ Environmental monitoring integration
  - ✓ Alarm strategies for critical systems
  - ✓ Data integrity for batch-associated data
  - ✓ Risk-based staged validation

Outcome: Facilities that support the process at every phase of development

The Result

From process science to GMP compliance

- Translate process intent into qualified systems
- Enable reliable, repeatable GMP operations
- Support clinical manufacturing, process performance qualification, and regulatory inspections



Bottom Line

CQV for advanced therapies is not about proving equipment works.

It is about proving the manufacturing environment can reliably support current strategic and operational goals.

Syner-G helps organizations build documented, science-aligned, inspection-ready confidence that facilities, utilities, systems, and processes are ready to deliver advanced therapies to patients, safely and efficiently.

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