A CQV Checklist for Gene Therapy Facilities

As more cell and gene therapies receive approval, the commercial demand for these groundbreaking medical treatments will increase rapidly.

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The commissioning, qualification, and validation (CQV) activities at a gene therapy facility present unique challenges that are specific to the production of these novel therapies.

There are several steps that biopharmaceutical companies should take to keep greenfield and brownfield gene therapy facility projects ahead of schedule and under budget.

1. Process Equipment and Design

The equipment used in the manufacturing process for gene therapies is a highly important component that requires much planning. Does your equipment meet your process requirements and what is the lead time for procurement? If you use the equipment for automated processes, you should have fail-safes built into the design of the hardware and software.

Seek a partner that can help you through the early basis of design stages to ensure you meet manufacturing timing and requirements as well as achieve regulatory compliance.

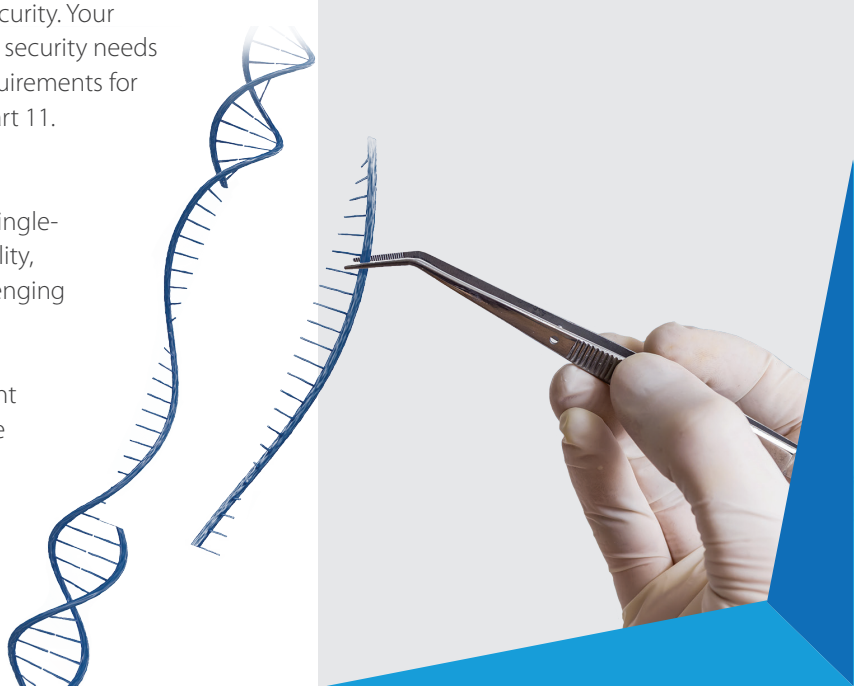
2. Vendor Audits

Establish a single point of contact to avoid miscommunication when it comes time to conduct a vendor site audit for data integrity and security. Your vendor's quality system needs to be rigorous, and their data security needs to pass your audit with flying colors and meet the FDA's requirements for Computer System Validation (CSV) guidelines and 21 CFR Part 11.

3. Procurement Timelines

Production of gene therapies requires the procurement of single-use technologies (SUT) that can meet requirements for sterility, stability, physical integrity, and strength. Still, it can be challenging to find a reliable supplier.

It's crucial to align the procurement of specialized equipment around timelines for construction, utility installation, and the facility plan. Allow for additional time to find a supplier for customized manufacturing equipment.



4. Follow ISPE GAMP 5 Guidelines

Focus on computer system validation in the areas with the highest risk and impact on your manufacturing processes. Work with a CQV expert that can demonstrate an efficient use of ISPE GAMP 5 guidelines to stay within important business and regulatory areas while eliminating redundant testing during the CQV activities at your gene therapy facility.

5. Apply Custom Off-the-Shelf (COTS) Applications

The use of custom off-the-shelf (COTS) solutions, especially for gene therapies, has significantly increased over the last decade. Innovative COTS qualification strategies can produce significant cost savings and help you reach your capital project milestones months ahead of schedule.

6. Invest in Isolators

Your production process needs to be protected from contamination by pathogenic microorganisms, and isolators offer a closed area where the manufacturing process happens in an HVAC cleanroom. The right custom isolator setup can reduce the use of protective safety suits, airlocks, and energy.

7. Use a Flexible Approach

Facilities for the production of gene therapies are still evolving, and there is no one-size-fits-all method for designing them. It's essential to have a flexible approach that can accommodate your facility's future needs, which will reduce downtime when expansions or changes arise.

The CQV Plan for the Future of Gene Therapy

Find an experienced CQV partner with a proven grasp on the constantly changing gene therapy manufacturing field. Together, you can develop a plan to eliminate costly mistakes, maximize utilization of critical materials, and prepare for the production of future treatments.

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About ICQ Consultants

ICQ partners with biopharma and life sciences companies to help engineering and quality teams proactively solve complex commissioning, qualification, and validation challenges to facilitate safe, timely medication delivery.

Our transparent, data-first communication and project management philosophy ensures strict adherence to continually evolving industry regulations, site-specific requirements, schedules, and budgets.

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