BLOG

21 CFR Part 11 Compliance

Understanding 21 CFR Part 11 Compliance in GMP Facilities for Cell Therapy

logos biosystems
by ALIGNED GENETICS

Introduction

Cell therapy is an innovative approach to treating various diseases, including cancer and autoimmune disorders. The process involves the use of living cells to stimulate the body's natural healing mechanisms. Due to its immense potential, the field of cell therapy has gained significant attention from the medical community and investors alike. As a result, there is a growing need for cell therapy products to meet regulatory requirements to ensure safety, efficacy, and quality. This is where Good Manufacturing Practices (GMP) come into play. GMP ensures that products are consistently produced and controlled according to established quality standards.

One of the key regulations that GMP facilities must comply with is 21 CFR Part 11. This regulation outlines the requirements for electronic records and electronic signatures in the context of GMP facilities. In this blog post, we'll discuss the importance of 21 CFR Part 11 compliance in GMP facilities for cell therapy and how Logos Biosystems' products and services can help achieve this compliance.

Understanding 21 CFR Part 11 Compliance :

21 CFR Part 11 is a regulation that was introduced by the US Food and Drug Administration (FDA) in 1997. Its purpose is to provide guidelines for the use of electronic records and electronic signatures in FDA-regulated environments. The regulation applies to all electronic records that are created, modified, maintained, archived, retrieved, or transmitted in the context of FDA-regulated activities. It also applies to electronic signatures that are used to sign electronic records.

The key requirements of 21 CFR Part 11 compliance include:

- **Validation** : All electronic systems used to create, modify, maintain, archive, retrieve, or transmit electronic records must be validated to ensure that they are operating correctly and consistently.
- **Security** : Electronic records must be protected from unauthorized access, alteration, or destruction.
- **Audit trails** : Electronic records must include an audit trail that documents any changes made to the record, including the date, time, and identity of the person who made the change.
- **Electronic signatures** : Electronic signatures must be unique to the individual and must be authenticated by a secure means.

Examples of how 21 CFR Part 11 compliance is relevant to GMP facilities include:

- **Manufacturing records** : GMP facilities must maintain records of all manufacturing processes, including batch records, equipment logs, and environmental monitoring data. These records must comply with 21 CFR Part 11 requirements for electronic records and electronic signatures.
- **Laboratory records** : GMP facilities must maintain laboratory records, including data from analytical testing and quality control. These records must comply with 21 CFR Part 11 requirements for electronic records and electronic signatures.
- **Clinical trial data** : GMP facilities involved in clinical trials must maintain electronic records of patient data and study results. These records must comply with 21 CFR Part 11 requirements for electronic records and electronic signatures.

Cell Therapy and GMP Facilities

Cell therapy involves the use of living cells to treat various diseases. Due to the sensitive nature of cell therapy products, it's crucial to maintain high-quality standards and ensure that products are produced consistently. This is where GMP facilities come into play. GMP facilities ensure that cell therapy products are manufactured and controlled according to established quality standards.
GMP facilities must comply with regulatory requirements, including those set forth by the FDA. The FDA's guidance for cell therapy manufacturing highlights the importance of complying with GMP regulations, including 21 CFR Part 11. In addition to complying with GMP regulations, cell therapy manufacturers must also follow specific requirements related to cell sourcing, characterization, and manufacturing processes.

Logos Biosystems and 21 CFR Part 11 Compliance

Logos Biosystems is a leading provider of innovative tools and solutions for the life science research and biopharmaceutical industries. With over 15 years of experience, the company has a proven track record of helping its customers achieve compliance with regulatory requirements, including 21 CFR Part 11.

Logos Biosystems' products and services that help with 21 CFR Part 11 compliance include:

- **LUNA-FX7™ automated cell counter** : Logos Biosystems offers the award-winning LUNA-FX7™ automated cell counter that is designed to meet the requirements of GMP facilities and comply with 21 CFR Part 11.
- **CountWire™ software system** : Logos Biosystems' CountWire™ software system takes care of the data security, electronic signatures, and everything else relating to 21 CFR compliance.
- **Validation services** : Logos Biosystems offers validation services to help its customers validate their equipment and software in accordance with 21 CFR Part 11. This includes documentation and testing to ensure that the equipment and software meet the regulatory requirements, notably through the use of validation slides. Validation slides contain pre-spotted patterns or prefixed fluorescent beads with a known number of objects, eliminating issues such as concentration manipulation caused by sample loading, evaporation during storage, or uneven distribution. Furthermore, validation slides allow for the verification of total cell count and viability using both brightfield and fluorescence optics of a cell counter. Cross-validation with other equipment is also straightforward, and their stability ensures that measurement values remain consistent even with long-term storage or repeated use. By incorporating validation slides, researchers can save time and resources that would otherwise be spent conducting additional experiments to ensure accuracy.
- **Training and support** : Logos Biosystems provides training and support to its customers to help them understand and comply with 21 CFR Part 11. This includes training on equipment operation, software use, and regulatory compliance.

It's worth noting that Logos Biosystems' CountWire™ software solution complies with the CFR Title 21 Part 11 guidelines for electronic records and signatures. CountWire™ is specifically designed for use with the LUNA-FX7™ platform and is used to acquire and analyze data from the platform's assays. By using CountWire™, researchers can ensure that their data is secure, traceable, and accurate. The software provides a comprehensive audit trail of all actions taken during the assay process.

CountWire™ also offers advanced data analysis tools that allow researchers to perform in-depth analysis of their data and generate reports that comply with industry standards. In conclusion, 21 CFR Part 11 compliance is a critical requirement for GMP facilities in the cell therapy industry. Non-compliance can result in serious consequences, including product recalls, fines, and loss of reputation. However, achieving compliance can be challenging, particularly for small and mid-sized companies with limited resources.

Logos Biosystems' products and services provide a comprehensive solution for achieving and maintaining 21 CFR Part 11 compliance. The company's commitment to regulatory compliance, combined with its expertise in cell therapy manufacturing, makes it an ideal partner for companies in the industry. If you're looking for a partner to help you achieve 21 CFR Part 11 compliance, consider working with Logos Biosystems. Contact them today to learn more about their products and services.

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