

## OfficePLM Key Takeaways for Computer System Validation(CSV)

**1. Electronic Records and Signatures:** 21 CFR Part 11 mandates that electronic records must be secure, tamper-proof, and easily retrievable. Additionally, electronic signatures must be linked to specific individuals, ensuring accountability and traceability throughout the data lifecycle. **OfficePLM is compliant.**

**2. Validation Requirements:** For CSV professionals, the regulation emphasizes the importance of proper validation of computerized systems. Rigorous validation processes are necessary to demonstrate that these systems function consistently and reliably, producing accurate results. **OfficePLM is compliant.**

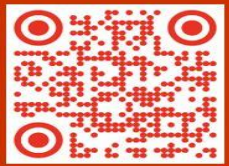
**3. Audit Trails:** The regulation requires computerized systems to maintain comprehensive audit trails, capturing and recording significant events, such as data changes and access attempts. These audit trails play a pivotal role in identifying potential risks and ensuring data integrity. **OfficePLM is compliant.**

**4. Data Integrity:** 21 CFR Part 11 stresses the significance of safeguarding data integrity in electronic records. Implementing data integrity controls, such as data encryption and access restrictions, is essential to prevent unauthorized modifications or data loss. **OfficePLM is compliant.**

**5. Access Controls:** Robust access controls are essential to ensure that only authorized personnel have access to electronic records. This includes employing unique user IDs, strong password controls, and proper user privilege management. **OfficePLM is compliant.**

**6. Electronic Signature Requirements:** CSV professionals must understand the requirements for electronic signatures, ensuring they are as legally binding as traditional handwritten signatures. Unique, secure, and verifiable electronic signatures play a critical role in maintaining compliance. **OfficePLM is compliant.**

In the realm of Computer System Validation, 21 CFR Part 11 stands as a pillar of regulatory compliance. Understanding its key principles and takeaways is vital for CSV professionals and organizations operating within FDA-regulated environment. As we navigate the complexities of modern technology and regulatory landscapes, adherence to 21 CFR Part 11 ensures that our computerized systems maintain data integrity, generate reliable electronic records, and stand the test of regulatory scrutiny.



## Included in this document are: 21 CFR Part 11 A-K

Validation of Systems – 21 CFR 11.10(a)

21 CFR 11.10(b): Accurate Generation of Records

21 CFR 11.10(c): Protection of Records

21 CFR 11.10(d): Limited System Access

21 CFR 11.10(e): Audit Trails

21 CFR 11.10(f): Operational System Checks

21 CFR 11.10(g): Authority Checks

21 CFR 11.10(h): Input Checks

21 CFR 11.10(i): Education, Training and Experience

21 CFR 11.10(j): Policies for Using Electronic Signatures

21 CFR 11.10(k): Document Control