



# ComplianceWire® Success Guide



## Validation Process

When you choose UL EduNeering as your partner, be assured that your knowledge solution is meeting the highest security standards of regulatory compliance required of FDA-regulated organizations.

The ComplianceWire Platform provides full compliance with 21 CFR Part 11 requirements and supports quality and validation constructs as defined by Good Automated Manufacturing Processes (GAMPs) and current Good Manufacturing Practices (cGMPs) as specified in CFR 820 (Quality Systems Regulations):

- Electronic records and electronic signatures
- Audit logs
- Record versioning
- Data security
- Fully documented Software Development Life Cycle (SDLC)
- Support of Quality systems over the system's lifespan

To date, ComplianceWire is the first and only compliance solution specifically designed to meet the demanding security standards required to serve FDA-regulated organizations.

Our process begins with a validation plan that will help you build a marketing communications strategy tailored to your specific roll-out, based on your goals and objectives.

Part 11 requires that organizations store regulated electronic data in its electronic form once a record has been saved to durable media.



## Secure Data Centers

UL ensures that all systems run smoothly and securely in our wholly-owned data center facilities, based in Princeton, New Jersey; London, UK; Beijing and China.

Our data centers include best-of-breed, state-of-the-art equipment hosted in the data center with 24x7x365 security. The data centers have been designed from the ground up to assure security of user information.

## ASP Model

Our engineered knowledge solutions are offered via an Application Service Provider (ASP) model. This widely-used outsourcing model allows us to design and maintain the computer hardware, software, security and personnel we need to deliver our solutions without our customers incurring excessive capital investments and operational commitments. UL provides the expert IT staff for creating, managing and supporting our technology-based solutions and assures that all systems run smoothly and securely in our wholly-owned data center facility.

## Physical Security

UL's best-of-breed, state-of-the-art equipment is hosted in the data center with 24x7x365 on-site security, backup electrical generator capacity and other equipment designed to keep servers up and continually running.

## Perimeter Defense

Networks are protected by multiple state-of-the-art firewall systems. In fact, entry requires three levels of key card access. The data center network is automatically monitored for intrusion detection and other malicious activity including viruses.

## Reliability and Backup

All key networking components – routers, firewalls, web servers, database servers and data arrays – include six layers of redundancy to remove single points of failure.

Data are backed up daily and stored onsite in a fire resistant vault. Weekly backups are made and stored off-site in a fire resistant vault.



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