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Title 21 CFR Part 11 of the Code of Federal Regulations deals with the Food and Drug Administration (FDA) guidelines on electronic records and electronic signatures in the United States. **Part 11**, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records (Title 21 CFR Part 11 Section 11.1 (a)).

Practically speaking, Part 11 requires drug makers, medical device manufacturers, biotech companies, biologics developers, CROs, and other FDA-regulated industries, with some specific exceptions, to implement controls, including audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing electronic data that are (a) required to be maintained by the FDA predicate rules or (b) used to demonstrate compliance to a predicate rule. A predicate rule is any requirement set forth in the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or any FDA regulation other than Part 11. [1]

In the Validation of the HVAC and Cleanrooms there are typically three conditions that require validation, **Temperature**, **Humidity** and **Differential Pressure**.

To integrate the HVAC Systems, with the Validated System complicates all future expansion of the system, and can involve a large process at the end of a control systems life. When the system requires retrofit or replacement if it is integrated to the validated system, it is a major project.

At ESC we believe in a separate system should provide a validated system for your temperature / humidity and differential pressure in the Cleanrooms.

The control of HVAC/R systems can be supplied by any number of commercially available manufacturers, most of which will allow for trend data to be accumulated, and kept for reference at a later date. The major differentiation for the validated system is the ability to show that the data is accurate, and that it cannot be manipulated.

There are many systems available to provide a the 21 CFR Part 11 hardware and Software, many which come with prepared IQ / OQ Documentation.

122F Commerce Park Drive, Barrie, ON L4N 8W8
Phone: 705 797 8877 / 1 866 565 7055
Email: info@e-s-c.com WWW: www.e-s-c.com

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The cost for a validated system has three components;

1. The number of points contained within the critical system boundaries, with the ability to prove calibration, and

2. The method to maintain the integrity of the trend and alarm data collected.

3. The most important component is the time invested into the creation, and execution of the IQ / OQ.

Utilizing the approach to simplify the validated critical system components to only the required inputs simplifies the entire process.

All other functions are ancillary to the critical requirements. To simplify initial and future compliance issues, we believe how we satisfy the zone requirement is not critical to fact that we do satisfy the requirements. Therefore the DDC controller and ancillary components we utilize to provide the control should not be included within the system critical boundaries.

We will still believe in a complete commissioning of these systems, and detail all control functions, and log changes, they do not need to be part of the validated system. Keeping the number of "validated" points to a minimum keeps the cost of initial and future compliance manageable.

The advantage of this system is that it meets the FDA Title 21 CFR Part 11 (electronic records/electronic signatures) requirements, with only the critical inputs, and is an off the shelf product, complete with the IQ / OQ documentation, and it does not tie you to a complete one solution provider.

Contact us to review your requirements, that we can offer our advice of the solution that might best suit your requirements.

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