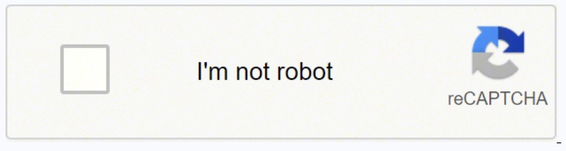

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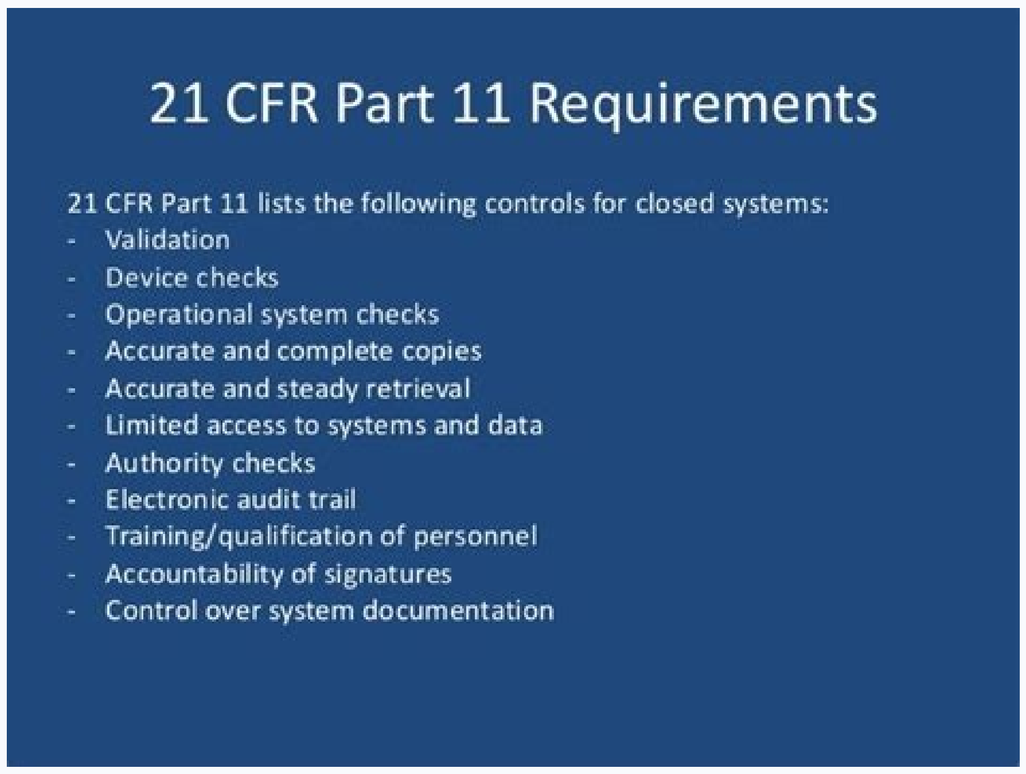

PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

Subpart A—General Provisions

Sec.

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110.110 Natural or unavoidable defects in food for human use that present no health hazard.

Authority: 21 U.S.C. 343, 371, 374, 42 U.S.C. 264.

Source: 51 FR 24475, June 19, 1986, unless otherwise noted.

21 CFR 110 Subpart A—General Provisions

§ 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions shall also apply:

(a) *Acid foods or acidified foods* means foods that have an equilibrium pH of 4.6 or below.

(b) *Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.

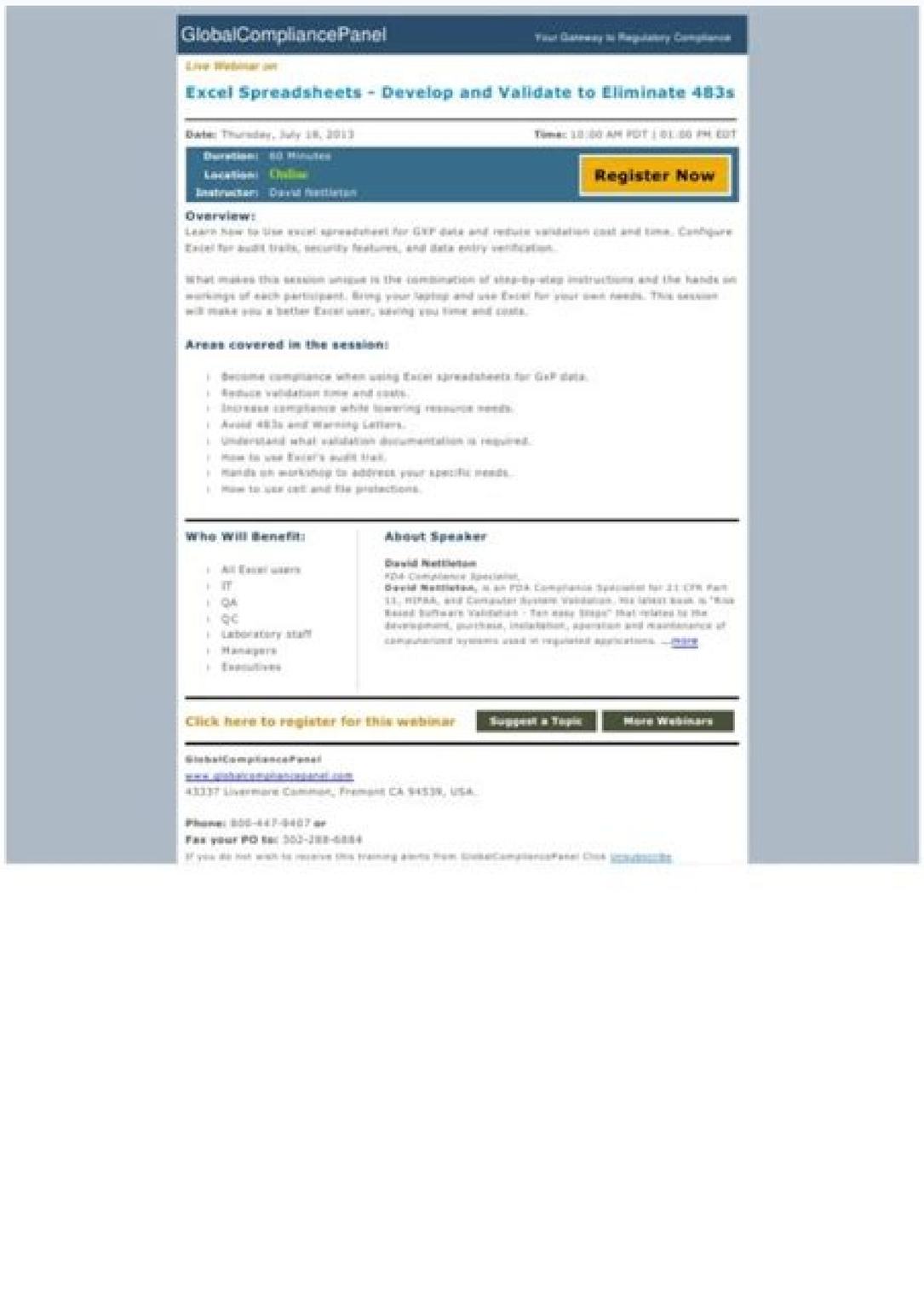
(c) *Batter* means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) *Blanching*, except for nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the enzymes present in the food and to effect other physical or biochemical changes in the food.

(e) *Critical control point* means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) *Food* means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) *Food-contact surfaces* are those surfaces that contact human food and those surfaces from which food normally drains, drips, or is normally aspirated onto food surfaces during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.



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About Speaker

David Nettleton
FDA Compliance Specialist,
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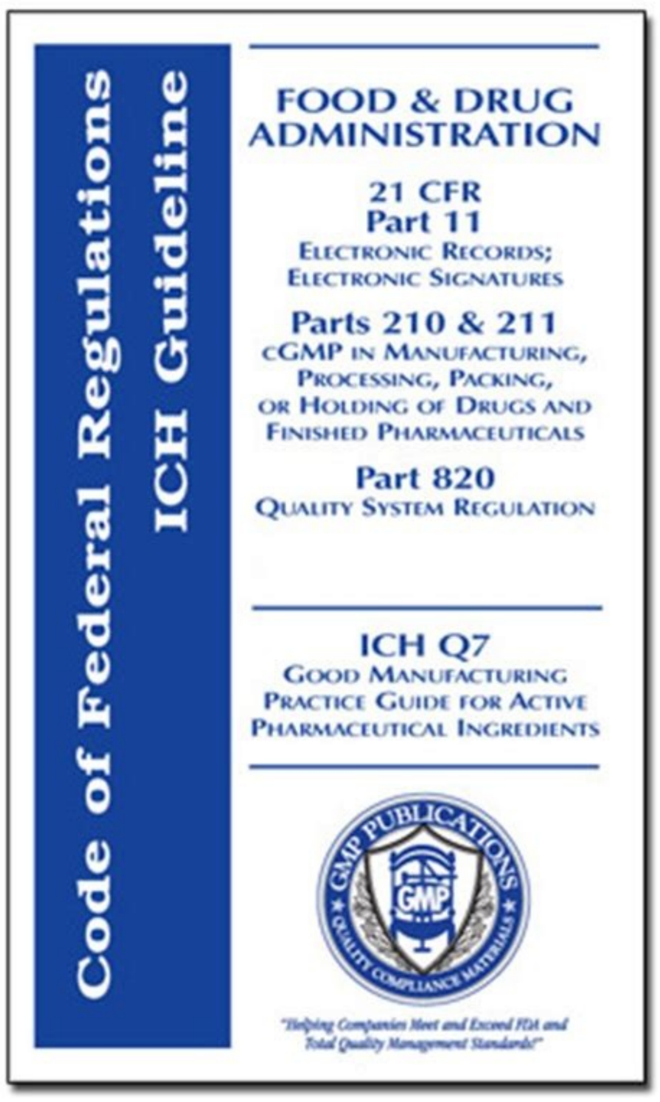

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The Docusign Part 11 module is an improvement of product available for Docusign's life science clients. Title 21 CFR Part 11 is the part of the Title 21 of the Federal Regulations Code that establishes the regulations of the Food and Drug Administration of the United States on electronic records and electronic signatures. Subsection 11,300 d) A procedure for the initial and periodic verification of devices such as cards or cards that carry or generate a code of identification or password information will be established, in order to ensure that they work correctly and that have not been altered Unauthorized. In 21 CFR Part 11, the Food and Drug Administration (FDA) establishes its requirements for records and electronic signatures. Subsection 11,100 (b) People using electronic signatures should, before or at the time of their use, certify the agency that electronic signatures in their system, used as of August 20, 1997, have the intention of Be jurden equivalently binding to traditional handwritten signatures. Subsection 11,100 (c.2) Electronic signatures that are not based on biomeric data should use at least two different identification elements, such as a code of identification and a password. Subsection 11.200 a) 1) i) When a person executes one or more unrealized firms during a system controlled access to the system, each signing must be executed using all the components of the electronic signature. The forest development direction also published an orientation document entitled «Part 11, electronic records; Electronic signatures Â «Scope and Application» to provide additional clarifications on electronic records and electronic signatures. Subsection 11.200 a) 1) ii) The of each ³ of identification ³ and contrast combined so that there are no two people who have the same combination of identification ³ and contrast ³. Subsection³ n 11,300 b) ³ procedures for managing losses should be followed in order to disauthorize³ only electronically³ Chips, missing or other potentially compromised, lost devices or other devices that carry or generate identification code information or password. To be compatible with electronic signatures, you should include: Ã, the signing name of the signer The date and time The signature of a digital unique user ID adopted Signature The meaning of the signature (labeling "reason") was executed. What are they? Other requirements for electronic signatures? The FDA allows electronic signatures to be used instead of pen and ink signatures on paper documents so that the business can be done digitally. Subsection 11,300 (c) The system must use the transaction safeguards to avoid unauthorized use of passwords and / or identification codes, and to detect and immediately inform and urgently any attempt at unauthorized use. What is 21 cfr part 11? Subsection 11,200 (a) (1) Ã, When a person executes a series of signatures during a continuous and continuous period of controlled access of the system, the first signature must be executed using all electronic signature components. Subsection 11,100 (c) People using electronic signatures must, after the request of the agency, provide an additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signature firm of the signer. These regulations, which apply to all the areas of the FDA program, were allocated to allow the most widely possible use of electronic technology, compatible with the responsibility of the FDA to protect public health. Subsection 11,300 (a) The identification code and password emissions should be verified, reminded or reviewed periodically (for example, to cover events as a password aging). We have a full guide for CFR 11 and electronic signatures with examples .sacin³Ârtcele .sacin³Ârtcele samrif ed osu le noc sodanoicaler sotisiuqer sol ebircsed euq ,11 etraP 12 olutÃT RFC ed C etrapbus al somerimuser ÃuqA .n³Âiccafsitas ed sotisiuqer sol necafsitas ngisUcoD senoiculos sal om³Ãc The signatures must be executed using at least one electronic signature component that is only executable by the person and designed to be used only by it. Includes additional security and controls, resulting in a different signature experience in relation to unregulated use cases. cases

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