Industry Coalition on part 11

FDA Part 11 Public Meeting

June 11, 2004

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- We appreciate the opportunity to present our views.
- We support and applaud the FDA in its efforts to protect public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- We also support initiatives such as the GMP initiative to enhance drug quality through better science and risk management.)

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- Review of this rule and the guidance issued in 2003 are consistent with FDA's mission and current thinking.

- Our goal is to work with you to attain a practical and enforceable outcome that allows both FDA and industry to meet our primary objectives.

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- The Industry Coalition on Part 11 represents 13 Trade Associations whose products include human and veterinary drugs, animal feed, cosmetics, medical devices, foods, and dietary supplements.

- As principal stakeholders these associations represent the bulk of the industry sector affected by this rule.

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- Advanced Medical Technology Association
- America's Blood Centers
- Animal Health Institute
- Biotechnology Industry Organization
- Consumer Healthcare Products Association
- Cosmetic, Toiletry, and Fragrance Association
- Council for Responsible Nutrition
- Council on Radionuclides and Radiopharmaceuticals
- Generic Pharmaceutical Association
- Medical Device Manufacturers Association
- National Electrical Manufacturers Association
- National Food Processors Association
- National Grain and Feed Association
- Pharmaceutical Research and Manufacturers of America

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- Our remarks follow the comments made by Dr. Goldhammer, Mr. Liebler and the other coalition representatives on the objectives of the coalition.

- We maintain that prescriptive regulation of computer technology tools used in the manufacture of regulated products is neither practical nor enforceable.

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Reasons

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- Prescriptive rule-making creates obsolescence at inception. Technology in general, and this one in particular is subject to continuous, rapid and dynamic innovation and does not follow along the predicted track contemplated by a rule.

- Computer technology is only a tool used by manufacturers and regulators in multitudes of ways and applications to facilitate and realize the primary goals of meeting safety, efficacy and quality in regulated products. We have had success focusing on what we know best. The predicate rules already contain the primary provisions.

- Stand alone enforcement has been difficult. FDA has recognized the need to reference the underlying predicate rules in all compliance

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- Assuring complete compliance has proven unattainable. Generally industry as well as the regulators are users of software products and lack the software manufacturers expertise.

- The tremendous effort shown by the solution providers have fallen short of expectations as determined by the regulator or industry.

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- Understanding, acceptance and standards have evolved significantly since the rulemaking process began.

- Identifying Hardware as equipment and software as record is an example of rule making difficulties that is in contrast to reality in many instances.

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General comments on the questions posed by the FDA

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- The significant and still relevant portions of the rule are already contemplated and interpreted as acceptable practice within the predicate rules, clarify such with a guidance if appropriate e.g. autheticity, security, record requirements and electronic submissions.

Part 11 Requirement	GxP Reference	Discussion
11.10(a) Validation	211.68(a) Routinely calibrated, inspected, or *checked (validated and maintained in a validated state)* according to a written program *(protocol)* designed to assure proper performance *(fit for intended use)*.	The elements of a good validation program have been well documented in GAMP and the "General Proncples of Software Validation: Final Guidance for Industry and FDA Staff".
11.10(b) Copies of Records	211.180 (c) Copies of records shall be available for inspection.	The fact that the records are complete and in human readable format is implied.
11.10 (c) Retrieval of Records	211.180 (c) and (d) Records must be available for inspection.	Available for inspection implies that records are maintained and retrievable.
11.10(d) Access to systems	211.68(b) Changes in master production records or other records are instituted by authorized personnel.	In the case of electronic records, it is implied that the ability to create, modify, delete, or change these records requires access to a computer system. The existing GMP requirement applied to electronic systems requires that access to the systems is limited to authorized users.
11.10 (e) Audit Trails	No reference	For paper records predicate rules were silent since fraud detection techniques had been established. Audit trials could be considered within the context of technology and enforceability.
11.10 (f) System checks (sequencing)	211.100 (b) Process controls shall be written, followed and deviations documented.	In an electronic system this can only be through well-defined control over the order of process operations that are implemented and verified through validation of the system. This is implied from the GMP requirement.

11.10 (g) Authority checks	211.68(b) Changes in master production records or other records are instituted by authorized personnel.	In electronic systems, the only way to insure that changes are by authorized personnel is through authority checks (defined roles and capabilities assigned to the roles verified through validation of the system). The role definitions would include access rights, signature rights, data modification rights.
11.10 (h) Device checks	211.68 (b) Input to and output from the computer or related system of formulas shall be checked for accuracy.	In an electronic system, the first check for accuracy is implied to be that the signal, data, or other information is coming from the correct device. This can be accomplished in a number of ways including checking for the proper data format of the incoming data.
11.10 (j) Creation of policies that hold individuals accountable for actions under their electronic signature	No Reference.	In law, it is understood that a handwritten signature is a testament to the meaning applied to that signature (accountability). This same meaning is becoming the norm in the case of an electronic signature. Requiring a policy to dictate accountability for a different form of signature is redundant.
11.10 (k) (1) Controls over system Operations and Maintenance documentation.	No Reference.	This requirement is fulfilled by secure access to authorized individuals appropriate to paper and electronic records.
11.10 (k) (2) Revision and change control of system documentation	211.180 (c) and (d) Records must be available for inspection.	System documentation (vendor supplied or created in-house) are part of the records related to those systems. Change control of systems and their related documentation is well defined in the "General Principles of Software Validation" in section 5.2.7.
11.30 Control of records in open systems.	211.68 (b) Input to and output from the computer or related system of formulas shall be checked for accuracy.	The checking of records for accuracy should include those records outside the control of the system.

11.50 (a) Signature manifestation	211.186(a) Master production and control records shall be dated and signed. 211.194 (a) (7) The initial or signature who performs each test and the dates the test were performed.	Although this is defined for laboratory records in the GMPs, it (date) is implied and understood for all records requiring signature (in whatever form).
11.50(b) Same control of electronic signature as electronic records and must be part of the record.	No reference	Just as the handwritten signature becomes a part of the paper record, the electronic signature becomes a part of the electronic record and as such the completeness of the record implies that the signature is available for review as a part of the record.
11.70(a) Electronic record linked to the electronic record.	No reference	Just as the handwritten signature becomes a part of and linked to the paper record, the electronic signature becomes a part of and linked to the electronic record and as such the completeness of the record implies that the signature is available for review as a part of the record.
11.100(a) Electronic signature shall be unique.	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).
11.100 (b) Known identity before issuance of electronic signature	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).
11.100 (c) Certification to agency	No reference	There is no certification required for a handwritten signature. Once unambiguously defined by the company as an 'electronic' signature, why is the certification for an electronic signature required?

11.200(a)(1) Components of the electronic signature	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).
11.200(a)(1)(i) Continuous signings	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).
11.200(a)(1)(ii) Continuous signings	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).
11.200(a)(2) Signature used by genuine owner	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).
11.200(a)(3) Unauthorized use requires collaboration	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).
11.200(b) Biometrics use by genuine owner	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).

11.300(a) Uniqueness of codes and passwords	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).
11.300(b) Password aging	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).
11.300(c) Procedure for lost codes	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).
11.300(d) Safeguards against unauthorized use.	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).
11.300(e) Periodic testing of tokens or cards	No reference	•The 2000, Electronic Signature in Global and National Commerce Act (E-SIGN).

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- We recommend FDA rescind the rule.

- Use technical definitions as they appear in current recognized standards. Keep the vocabulary away from jargon and close to predicate rule language.

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- An organization's internal standard operating procedures are the appropriate place for identifying records subordinating to how predicate rules are adhered to and executed (electronic or paper).
- Prescriptive approach in this instant is limiting. Recognizing the capabilities of software products and flexibility in a variety of applications obviate the benefits of outlining general requirements (security, authenticity, authority). Making a list of critical items or rules may fall short of communicating clear and comprehensive expectations.

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- To fully benefit from the lessons learned, the appropriate use of risk management would be warranted subject to promulgation of FDA guidance or recognized risk management guidelines and standards. The diversity and the continuous evolution of software controls are challenges to clear detailed requirements.

  The objective of assurance of record security and authenticity using enabling guidance in conjunction with existing predicate rules and risk methods is an integrated approach that may be both practical as well as enforceable.

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- Clarity is provided by technical standards and identification of expected regulatory outcomes (e.g record security). Our mutual goal should be to encourage the use of electronic records technology as a tool to facilitate and continuously improve regulated product quality within the context predicate rules including record security, authenticity, and organizational accountability.

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- We call on all part 11 solution providers to refocus their efforts and help the industry and regulators to meet their objectives as framed here:
  - Provide support for use of technology tools
  - Predicate rule interpretation and application
  - Practical solutions and implementation
  - Compliance with enforcement expectations

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- We will continue to support this effort and inform the policy making process by sharing our experience and knowledge from investments in operations and technology.
- Thank you Mr. Famulare and the part 11 team