Electronic Equipment and Raw Data in Field Research

Joseph A. Franchetti
JAF Consulting, Inc.
NAICC 2011 Annual Meeting

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Agenda

- Develop Understanding of Electronic Data
  - Guidance and Regulations
  - What is the data?
  - Storage and Archival of Data
- Electronic Equipment – Implementation and Use in the field
  - What is the "V" word?
  - What do we need to do?

Lets look at Data in the Guidance & Regulation Documents

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Guidance & Regulations

- OECD Guidelines for the Testing of Chemicals
  - OECD Principles on Good Laboratory Practice - No. 1 (1998)
  - The Application of the Principles of GLP to Computerized Systems – No. 10 (1995)
- FDA
  - 21 CFR Part 11
  - 21 CFR Part 58
- EPA
  - 40 CFR Part 160
  - CROMERRR

OECD Guidelines

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Raw data means….

- …all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognized as capable of providing secure storage of information for a time period as stated in section 10, below.

Conduct of Study…

- Raw data includes any worksheets, records, memoranda, notes, or exact copies thereof that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g. tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. Examples of raw data include photographs, microfilm, or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

Conduct of Study…

- Data generated as a direct computer input should be identified at the time of data input by the individual(s) responsible for direct data entries. Computerized system design should always provide for the retention of full audit trails to show all changes to the data without obscuring the original data. It should be possible to associate all changes to data with the persons having made those changes, for example, by use of timed and dated (electronic) signatures. Reason for changes should be given.

Responsibility

- Test Facility Management … should minimally… establish procedures to ensure that computerized systems are suitable for their intended purpose, and are validated, operated and maintained in accordance with these Principles of Good Laboratory Practice.

- Study Director…. ensure that computerized systems used in the study have been validated

Apparatus, Material, & Reagents

- Apparatus, including validated computerized systems, used for the generation, storage and retrieval of data, and for controlling environmental factors relevant to the study should be suitably located and of appropriate design and adequate capacity.

Standard Operating Procedures

- Standard Operating Procedures should be available for, but not be limited to, the following:
  - **Computerized Systems** - Validation, operation, maintenance, security, change control and back-up.
  - **Record Keeping, Reporting, Storage, and Retrieval** - Coding of studies, data collection, preparation of reports, indexing systems, handling of data, including the use of computerized systems.

21 CFR Part 11

- **Electronic Records** are records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any requirements set forth in regulatory authority regulations. (FDA Definition)
- **Electronic Signature -** A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to the legally binding equivalent of the individual's handwritten signature. (FDA Definition)

CROMERRR

- The EPA has a companion rule to 21 CFR 11 (CROMERRR)
  - The Cross-Media Electronic Reporting Regulation (CROMERR) provides the legal framework for electronic reporting (ER) under all of the Environmental Protection Agency's (EPA) environmental regulations.
  - Very similar to Part 11, covers all EPA programs.
  - E-Reporting final rule issued in FR on 13Oct2005; effective 11Jan2006, recordkeeping part on hold
  - Final rule on EPA web site at
    - http://www.access.gpo.gov/su_docs/fedreg/a05103c.html

Electronic Data

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"When organizations proactively protect their intellectual property, they can significantly reduce their risk and the consequences of online compromise. While security breaches put finances and reputations on the line, regulatory non-compliance ramifications are quite arguably the most detrimental. Today's businesses and organizations must maintain extensive documentation to remain compliant with government regulations…. "

From IPfrontline.com: Data Auditing: How to Protect Your Valuable Assets Online, Tim Rhodes, August 17, 2007

So Protection of Electronic Data is not just a Regulatory Requirement ….it's more so a Business Requirement.!

Electronic Records

- Electronic Records are records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any requirements set forth in regulatory authority regulations. (FDA Definition)
- Electronic Records (Including Metadata) must be secure, controlled and unadulterated
- Changes must be tracked and indicate who changed, what changed (to and from values), and when it changed.

What is Electronic Data?

- Direct Entry
  - Recording data where an electronic record is the original capture of the data
    - Keying in original observations
    - Automatic recording by the system of the output of a balance …
- Audit Trial
  - A secure, computer generated, time-stamped electronic record that allows reconstruction of the course of event relating to the creation, modification, and deletion of an electronic record.

Data Quality

- The common thread running through all the regulations and guidance documents on computer systems validation is a concern with data quality
- The elements of data quality
  - Attributable
  - Legible
  - Contemporaneous
  - Original
  - Accurate and complete

Electronic Data Summary

- Original test facility records generated by means of computer system and stored on digital media.
- In a broader sense, it may include data that is processed or derived and subsequently stored on digital media…which is necessary for reconstruction of the final data.
- Electronic Data must also be defined with respect to the measured values as well as the metadata, audit trail and specifications.

Data Storage & Archival

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This question has been asked for over a decade:

"How do we identify, manage, preserve and provide ongoing access to e-mail, word processing documents and other kinds of electronic records that are proliferating in formats, mushrooming in quantity and vulnerable to quick deletion, media instability and system obsolescence?"

John Carlin, National Archivist
USA Today 25 Sep 98

Current Approaches to Data Preservation

- Various government organizations rely on a mixture of evolving approaches that generally fall short of solving the long-term preservation problem
  - Technology preservation
  - Emulation or Reader/Viewers
  - Migration
  - Encapsulation
  - Conversion

Data Warehousing is NOT Archiving

- Data warehouses may change the characteristics of archival records
- The data warehouse should not become the archive by default

Data Storage Summary

- In most cases, migration will be an acceptable strategy but...
- Companies still need to be prepared for the possibility of reconstruction
- Take into account government regulations for archiving data – some countries like Canada have more stringent requirements.

Electronic Equipment

Implementation and Use in the Field

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Different Types of Electronic Equipment

- Field Equipment / Systems
  - GPS
  - Wind Speed Devices
  - Temperature / Humidity Recording Device (Data Loggers)
  - Field Electronic Notebooks
  - Spreadsheets
- Lab Equipment / Systems
  - Electronic Field Trial Notebooks
  - Temperature Recording Device
  - Analytical Equipment
  - Data Capture and Reporting Systems

What is the "V" word?

Very

Arduous

Involved

D

Attempt to

Test

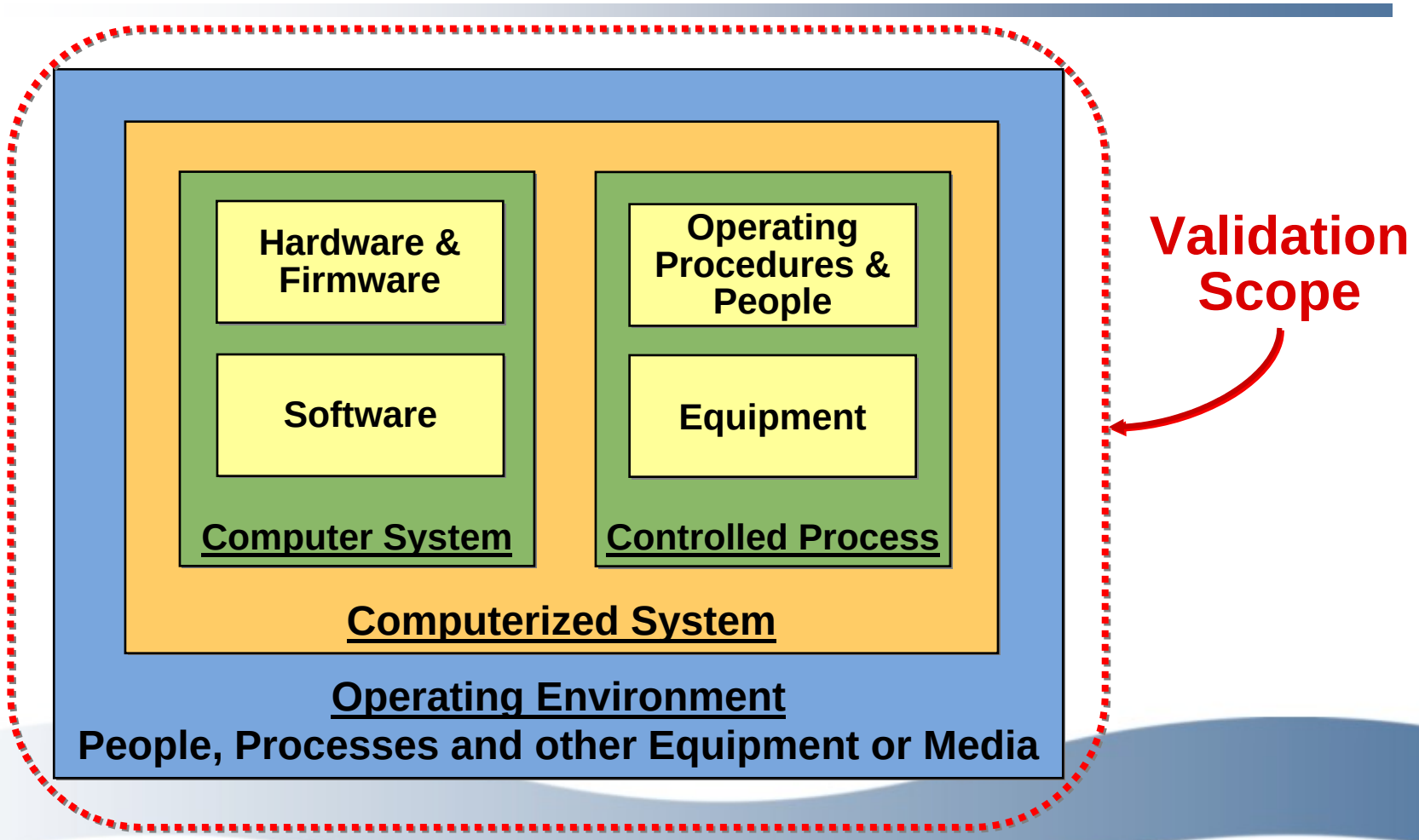
Everything

Validation Scope

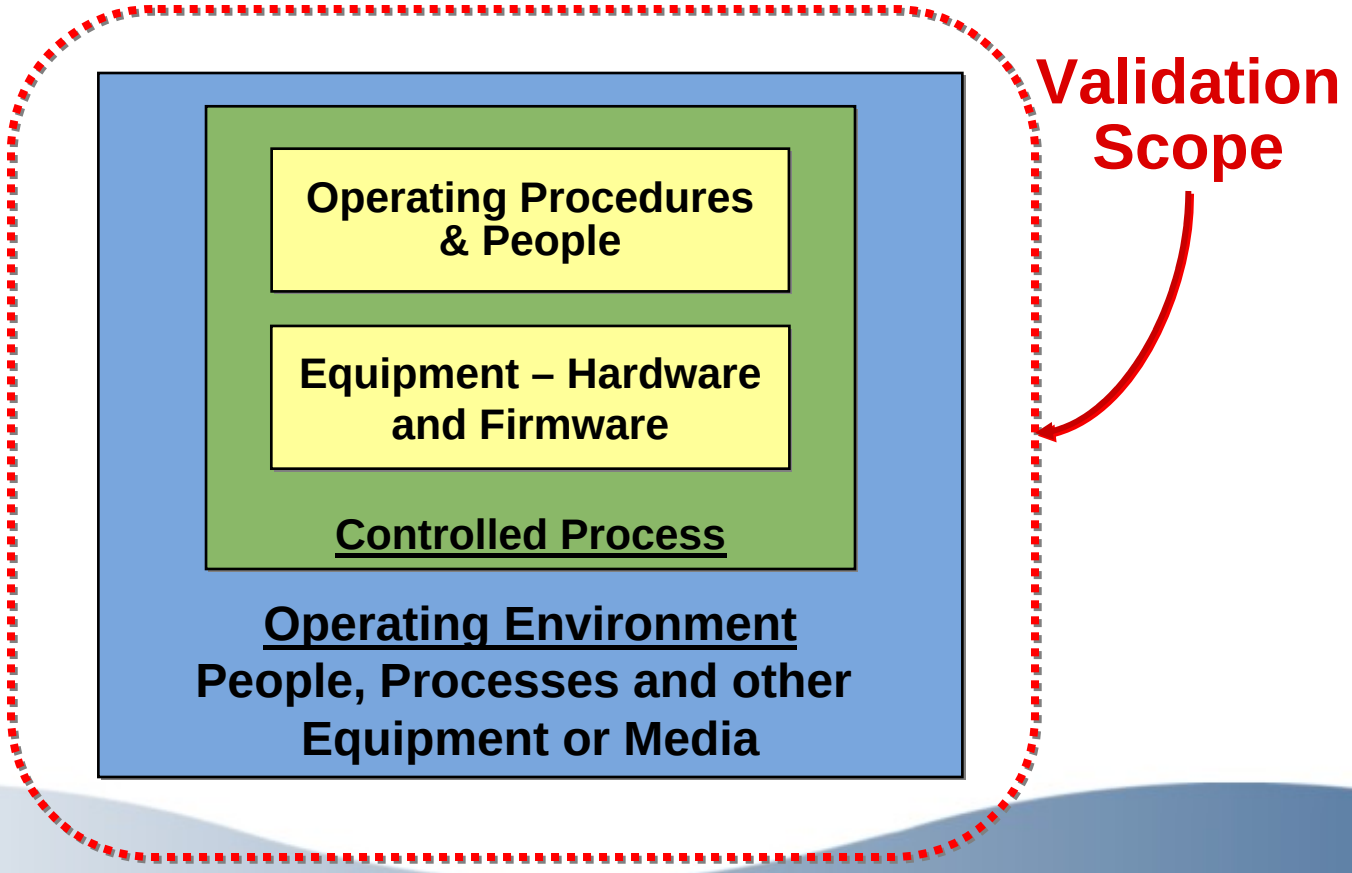
Validation is the entire process…

- It begins with the initial concept
- It ends with decommissioning the system.

Computerized System



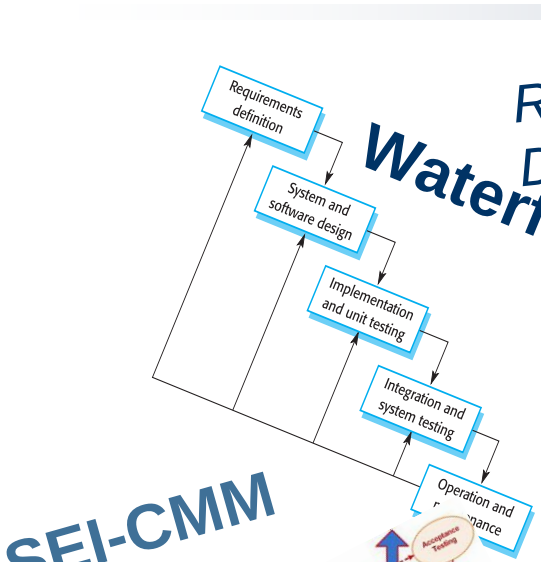
Computerized System



What is Validation?

- Establishing …
  - documented evidence
  - which provides a high degree of assurance
  - that a specific process
  - will consistently produce a product
  - meeting its predetermined specifications and quality attributes
  - **in its operating environment.**

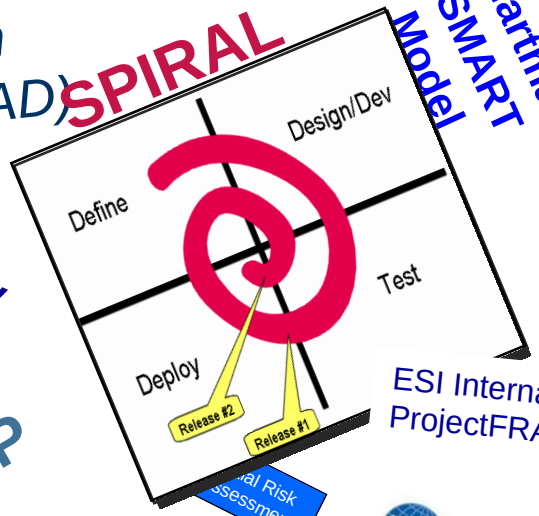
Which methodology is RIGHT?



Waterfall

Rapid Application Development (RAD)

SPIRAL



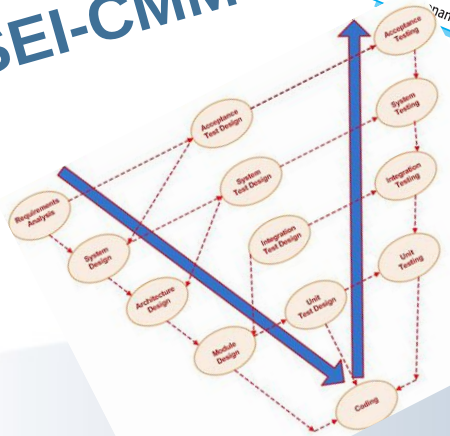
Hartman's SMART Model

ISPE GAMP IV

ITIL

ESI International's ProjectFRAMEWORK

SEI-CMM



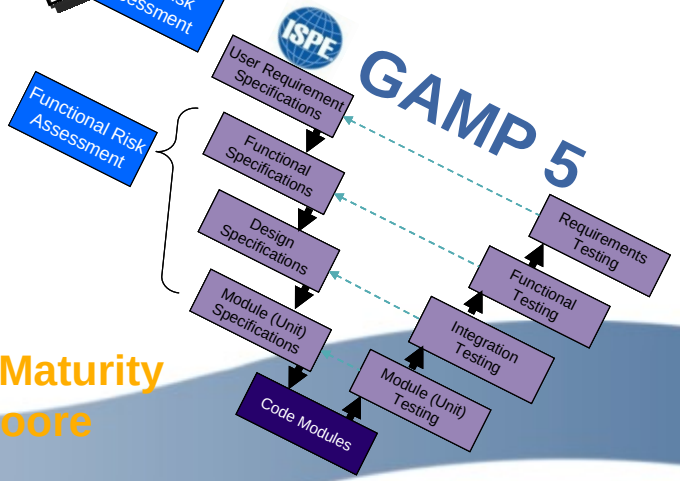
IDEAL

RUP

SCRUM

AGILE

JAD



Project Management Maturity Model, by Knapp & Moore Pty Ltd.

Why Validate?

- Computerized systems must provide the same degree of confidence as paper
  - "Paper Standard" is surprisingly hard to meet
- Most validation requirements can be traced to concerns with
  - Data Integrity
  - Management Control
  - System Reliability
  - Auditability

How Do We Accomplish Validation?

- Calibration
- Qualification
- Testing
- Documentation
- Standard Operating Procedures
- Training

All to a Plan!

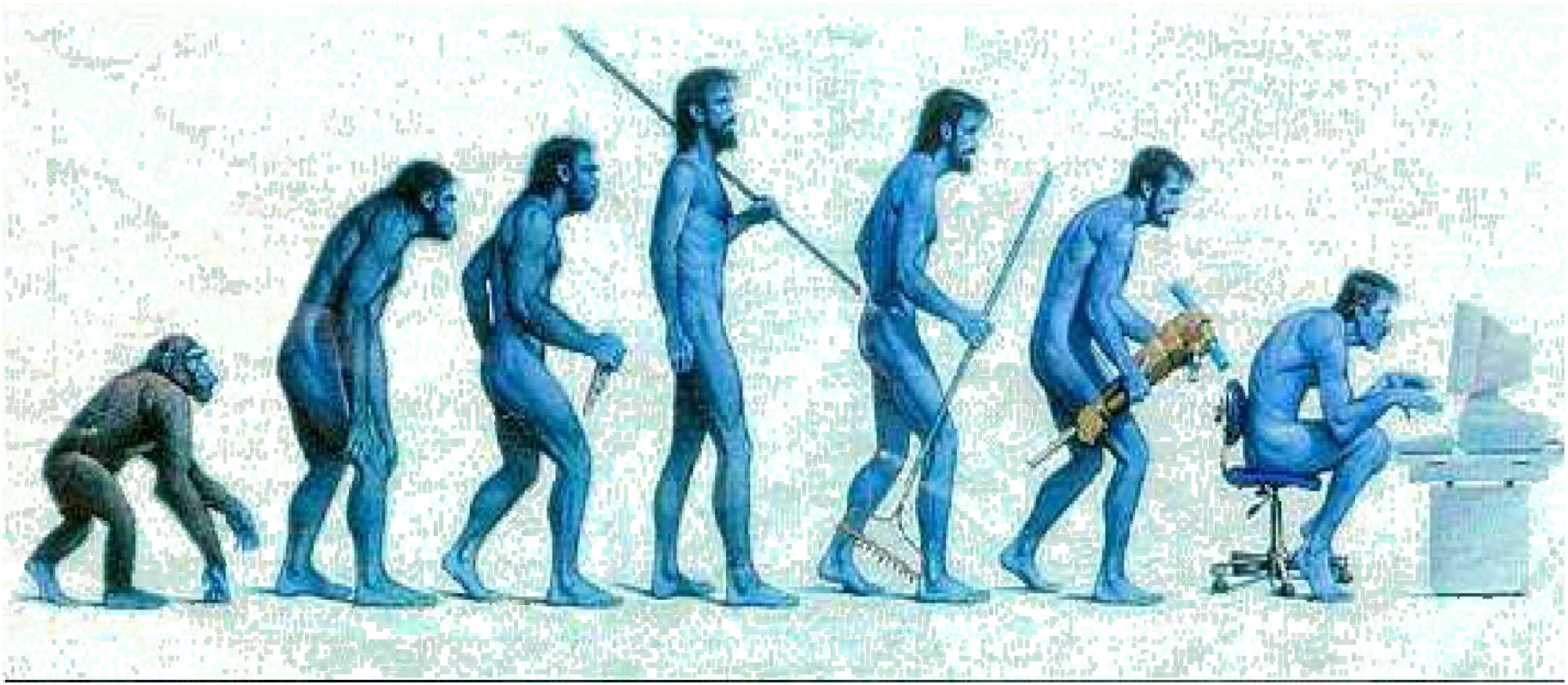
Do We Validate or Qualify or Calibrate?

- Field Equipment / Systems
  - GPS
  - Wind Speed Devices
  - Temperature / Humidity Recording Device (Data Loggers)
  - Field Electronic Notebooks
  - Spreadsheets
- Lab Equipment / Systems
  - Electronic Field Trial Notebooks
  - Temperature Recording Device
  - Analytical Equipment
  - Data Capture and Reporting Systems

Summary – Electronic Equipment

- What do we need to do to use the Electronic System in a Trial??
- What activities do we execute to ensure we meet the definition of Validation?
- How do we preserve the data on the electronic systems in the field?

Questions???



Special Thanks

Society of Quality Assurance - Computer Validation Initiation Committee (SQA-CVIC)

&

Kathryn Hackett-Fields

Joseph A. Franchetti
jfranchetti@jafconsulting.com
856-241-1900

Thank You!!

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