Good Software Requirements: Foundation for Predicate Rule and Part 11 Compliance

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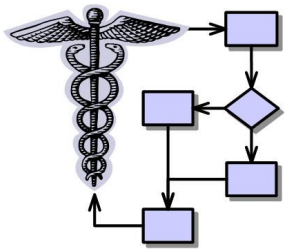


ShoeBar Associates

S/W Requirements for Predicate Rule / Part 11 Compliance

E-recs & e-sigs are a fact of life, but Part 11 is for some a source of confusion.

Requirements analysis helps clear the fog – but we don't have to invent it.

Requirements must include GxP and e-records management as well as all the other needs.

Effective requirements may show what's missing from regulations.

Good electronic records practices simply have to be part of our requirements development.

E-Records: a fact of life

- Part 11 - keeping and signing records electronically is voluntary …
  BUT IS IT?
- What processes don't involve software to collect the results, and often to control them?

So what's transforming Part 11?

From:

To:

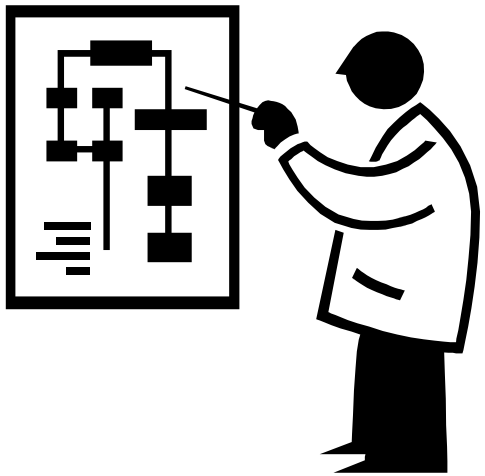
Why do some say "We'd like to carry out software validation, but we're not interested in Part 11" ??

- Fear
- Confusion
- Overwhelmed feeling
- Belief that "Part 11 is going away"

IT Needs to Shift Emphasis

The issue only becomes manageable when the focus moves from compliance . . .

. . . to careful *requirements development*.
Note this applies whether you write the software or purchase it!



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Requirements simply state the task we need to accomplish

- Buy it or build it: figure out up front what you need.
  If you don't know where you're going, how will you know when you get there?
- A requirement is not how we hope to solve the problem, but the problem that must be solved.
- Neither are requirements a laundry list of features we already see implemented (*are they what we need?*).

Requirements How-Not-To's

You don't need:

- A web interface
- Username / password login
- Radio button to select age group

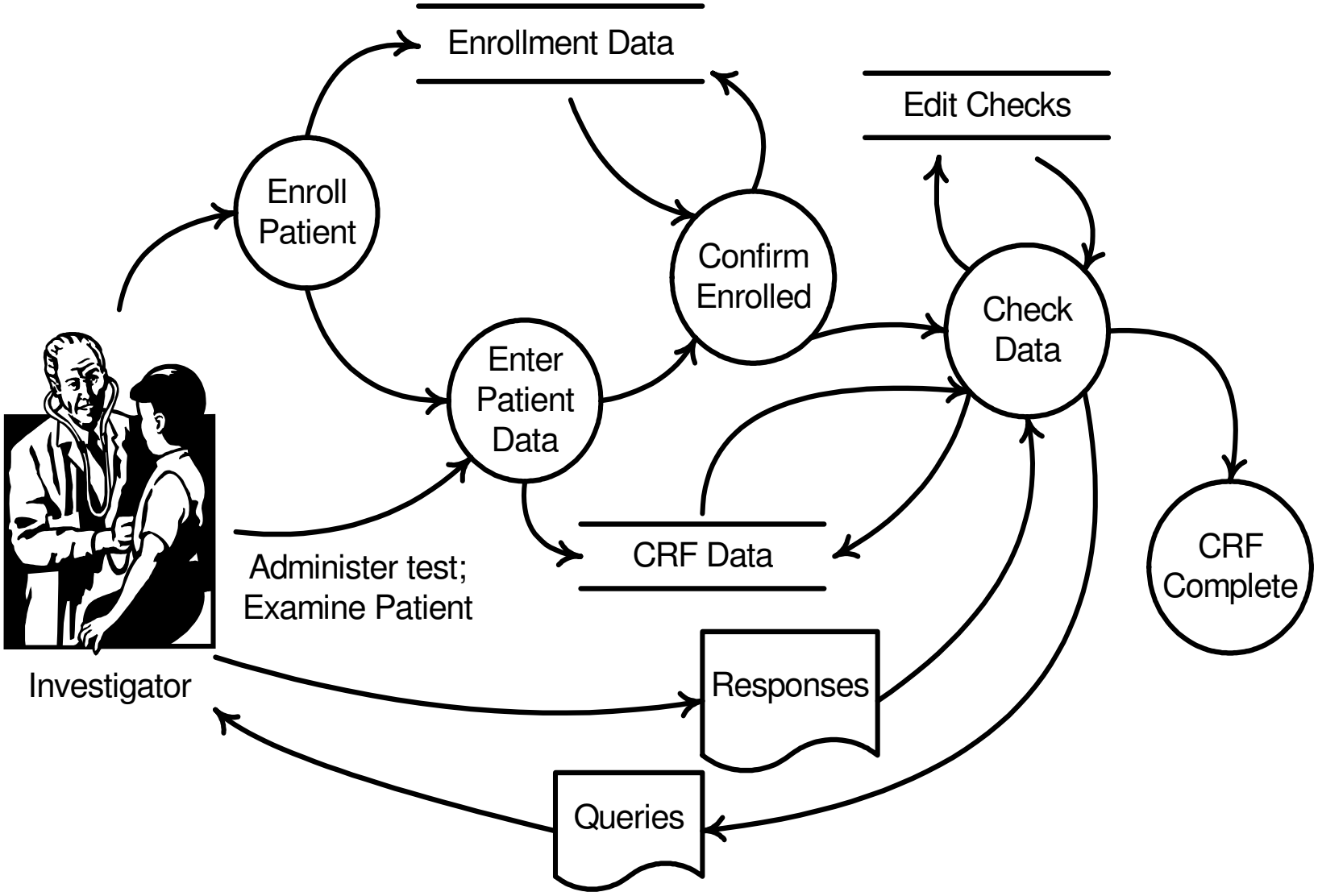
You *DO* need:

- Access for users outside the LAN
- Access only to authorized users
- Only one age group assigned each patient record

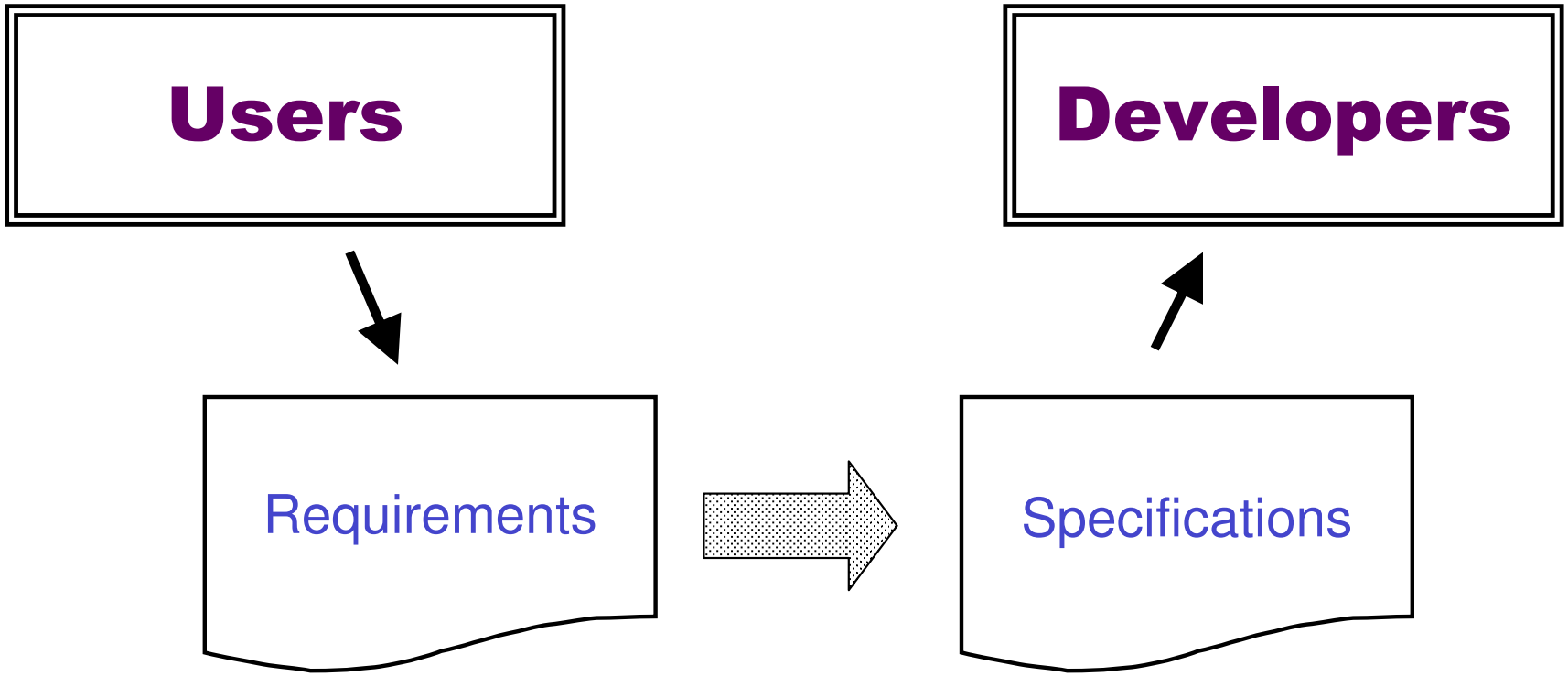
Another How-Not-To

- Customized tool for MedDRA coding; constraint = implemented via Oracle Forms
- Function: manage list of “words to remove”
- Requirement: “XYZ shall strip leading and trailing blanks from words to remove”
- QA review stalled; tests didn’t show that XYZ stripped leading blanks
- Leading blanks couldn’t be entered!

Review Process through Use Cases



Requirements vs. Specification



May not apply if you purchase OTS software – until you customize it.

Requirements gathering: learn from the experts

IEEE 830: “Recommended Practices for Software Requirements Specifications”

Characteristics of an SRS:

- Correct *(every item is one S/W shall meet)*
- Unambiguous
- Complete
- Consistent *(i.e. internally)*
- Ranked for importance / stability
- Verifiable
- Modifiable *(structured, not redundant)*
- Traceable

Requirements gathering: learn from the experts

Robertson and Robertson: *Mastering the Requirements Process*

Tests for each Requirement:

- Complete
  (source, rationale, identifier, use case, type, fit criterion)
- Traceable
- Consistent
  (terminology used uniformly)
- Relevant
  (to product purpose)
- Unambiguous
  (measurable fit criterion)
- Viable
  (within product constraints!)
- Solution Neutral
- Also tested: gold plating and creep

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In Search of Requirements (I)

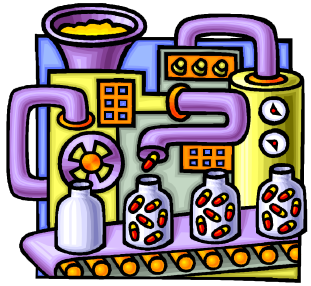
Where to search for requirements?

Robertson and Robertson (software development) suggest:

- Management
- Subject matter experts
- Developers
- **Inspectors**
- Market forces
- **Legal requirements**
- Opposition
- **Professional bodies**
- Public opinion
- **Government**
- Special interest groups
- Technical experts
- Cultural interests
- **Adjacent systems**

In Search of Requirements (II)

Pharma manufacturing requirements sources could be:



- Manufacturing operators
  (input of parameters, control of conditions)
- Quality Control *(batch checking and trending)*
- Quality Assurance
  (adherence to procedures)
- Pharma cGMP *(records that must be maintained)*

In Search of Requirements (III)

In nonclinical laboratories, requirements might come from:

- Analytical operators
  (sample input and tracking, analytical methods)
- Quality assurance
  (review of adherence to methods and study protocol)
- Good Laboratory Practices
  (records that must be maintained)

In Search of Requirements (IV)

For clinical study work, to find our requirements we'd consult:

- Investigators
- Data entry operators
- Statisticians
- Clinical monitors
- Sponsors
- Industry data standards
- Good Clinical Practices *(records that must be maintained)*
- Guidelines for Use of Computer Systems in Clinical Trials

In Search of Requirements (V)

For medical device design / manufacture, we'd need to check with:

- Design engineers
- Manufacturing engineers and operators
- Clinicians (users)
- Quality control
- Quality Assurance
- Quality System Regulation
  (for the records that must be kept)

In Search of Requirements (VI)

- Keeping reliable records is the common thread among all these lists.
- Consider – you produce two things:
  - Product (includes service) and Data (information, records)
  - Either without the other is useless.
- Whether it's:
  - *mandated by some regulation,*
  - *set forth in an industry standard, or*
  - *observed because it's just good sense,*

  reliable recordkeeping becomes a requirement for any system that saves information!

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Requirements: go beyond the regulations

Consider the relative frequency of paragraphs containing certain terms in each regulation:

Term	GLP (Pt 58)	GMP (Pt 211)	QSR (Pt 820)
Document or *Documentation*:	19	8	50
Record:	22	50	26
Sign or *Signature*:	2	6	9
Approve or *Approval*:	9	21	18
Computer:	1	3	2
Software:	0	0	6

(Distinct occurrences only, not including subpart titles or multiple uses in the same paragraph.)

S/W Requirements in GLP (Part 58)?

- 58.3 defines "raw data" to include computer printouts, magnetic media, and recorded data from automated instruments.
- Software not mentioned at all

S/W Requirements in Pharma GMP (Part 210/211)?

- 211.68: "Computer" classed as equipment; controls mandated to assure integrity of data
  - changed only by authorized personnel
  - input/output checked for accuracy
  - backups to be maintained
- 211.80: Records accessible through a computer, though stored at some remote location, are considered accessible to an FDA inspector

S/W Requirements in Device QSR (Part 820)?

- 820.3 (Definitions): Software / firmware included in a device considered a "component;" S/W version can distinguish a lot or batch
- 820.30 (Design Controls): Class I devices automated through computer software subject to design controls; design validation includes software validation
- 820.70 (Production and Process Controls): Where computer systems used in production or quality system, S/W shall be validated for intended use, S/W changes shall be validated, validations shall be documented.
- 820.181: Software specifications included in Device Master Record

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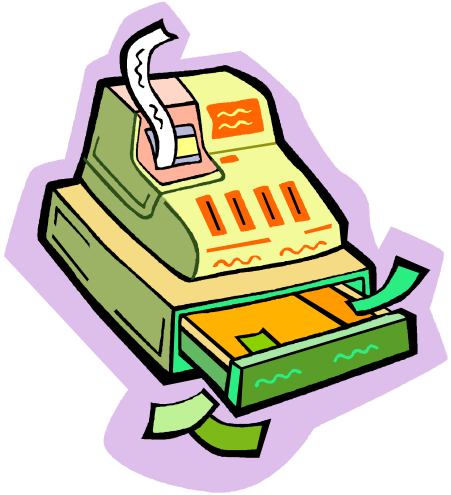
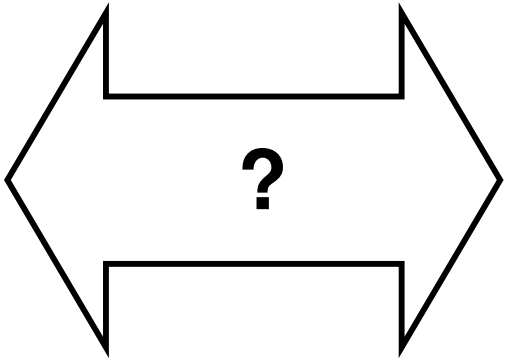
Good Electronic Records Management: Always a Requirement

- Face it: you generate records electronically no matter what.
- You can frame good electronic recordkeeping features (build or buy) through careful requirements writing.
- Documenting and recording your work is an explicit mandate in any of the GxP regulations.
- Though regulations say little about what software should do, they clearly mandate keeping records that are valid and accurate.

Compare with the financial industry

- Computerized systems are essential
- Record accuracy and integrity is an absolute demand
- Audit trails are expected
- Software is rigorously tested before installing





Do we as a society consider money more important than lives or health?

References

- Robertson, James and Suzanne, *Mastering the Requirements Process*, Harlow (England), Addison-Wesley / ACM Press, 1999.
- Institute of Electrical and Electronics Engineers, "Recommended Practice for Software Requirements Specifications" (IEEE 830-1998), 01-May-1998.
- Schneider, Geri, and Jason P. Winters, *Applying Use Cases: A Practical Guide*, Harlow (England), Addison-Wesley / ACM Press, 1998.