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## In Search of a DataFax Validation Master Plan Template

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### Validation Is

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- Documented evidence
- To a high degree of assurance
- That the system performs its intended functions accurately and reliably



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Therefore requirements are the  
foundation of validation

Therefore, to the degree that our  
requirements are common, we  
could share the cost of validation



## Why do we use DataFax?

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- To collect clinical data
- To ensure that ***all*** data is collected
- To enter data into electronic records
- To perform pre-planned visual and automated inspections of the data
- To document queries and resolutions
- Etc.



## Consider the use of each DFsystem Icon

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- No one can use DataFax unless appropriate permissions are established
- The program will not run unless you can turn it on with a command or DFmaster
- You can't get data without an incoming daemon
- You can't establish a new protocol without setting up a new study



## What is specific to individual organizations?

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- Plate level definitions
- Edit checks
- Hardware
- SOPs
- Validation Protocols
- Document Formats



## How different does it need to be?

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- There are more common requirements than unique requirements.
- Many of the differences between Validation Plans are merely cosmetic (formatting).
- Some of the differences should be debated (somebody is wrong).



## It should be possible to create a DataFax master validation plan template with

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- Each requirement linked to design and test elements
- From which an organization could deselect those which did not apply to them
- Add requirements and tests to address unique needs
- Including common hazards and mitigations



## This approach

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- Reduces the cost of developing a master validation plan
- Decreases the chance that your organization will overlook something important
- Can be customized to address individual circumstances
- Improves the reputation of the user community as a whole



## How can we do it?

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I have an initial draft in FrameMaker which

- Links some requirements to the ATK
- Includes hazard analyses
- Suggests tests for other requirements



## Sample Traceability Matrix

Requirement	Risk	Design Elements	Test
5. Operational Requirements			
5.1 Organizational Need			
5.18 Database administrators to define databases capable of storing, displaying and exporting all data necessary to establish the endpoints defined for a clinical protocol;	2	SD 4.4.1 SD 5.5.2	ATK 3.2
5.2.1 Meeting the definition of a closed system under 21 CFR 11 in that	4	SD 3	ATK Chapter 1
5.2.1.1. the hardware and software which comprise the system are wholly contained on an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system,	4	SD 3.1.1 SD 3.1.2	IQ 1.b



### So (in this example)

- Section headings might be marked intentionally blank.
- Risk are assigned according to predefined categories
- SD = a Software Design element
- ATK = one or more items from the Acceptance Test Kit
- IQ = a step in the Installation Qualifications checklist.



## You can try it out

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- A sample is available at <http://dfquality.org> (no “www”).
- If there is sufficient interest, telephone conferences or an adjunct meeting could be organized to refine it.



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## The Cost of Compliance is Growing

As scientists, functioning in the public interest, we have an obligation to find more cost-effective ways of demonstrating the integrity of our data.

