

Zen and the Art of DataFax Validation

(Following the Path to Nirvana)

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Overview

- Why Zen?
- Small is Big
- Slow is Fast
- Less is More
- Future is Now
- The Eightfold Path

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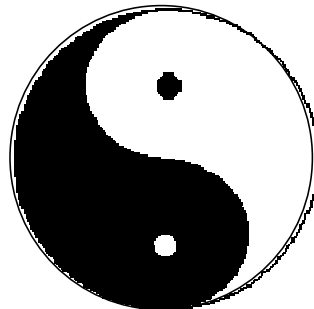
Why Zen?


- Zen is:
 - The coexistence and harmony of seemingly opposite components
- Our ability to work requires a balance between two seemingly opposite components
 - If we spend our time validating we'll never get any work done
 - If we don't validate we may lose data and our work may be thrown out

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The Key


- Balance



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Small is Big

- Validation is an enormous task
 - You CAN'T test everything
 - If you try you WILL miss things
- Plan what you want to test
 - Make it reasonable
 - Make it small
 - Cover what you plan and you will cover everything

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Slow is Fast

- We often don't start the validation because we don't have time
- Delay increases the time it will take to validate
- Rushing may leave holes that will need to be filled later
 - Back-filling takes much more time than completing it correctly the first time
- Do it once, do it right, take your time
 - You'll save time

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Less is More

- The FDA uses a “risk assessment” approach to auditing
 - So should you:
 - What are your risks for:
 - Data corruption
 - Data Fraud
 - Data Mistakes
 - What are the consequences?
 - Patient risk
 - Cover completely your areas of risk
 - Ignore areas that are low risk
 - You will be better covered for covering less

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The Eightfold Path

- 1. Right Understanding**
- 2. Right Thinking**
- 3. Right Speech**
- 4. Right Action**
- 5. Right Livelihood**
- 6. Right Effort**
- 7. Right Mindfulness**
- 8. Right Concentration**

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Right Understanding (View)


- How do Auditors view the validation effort?
- What is expected
- What is a risk
- What would constitute a “validated” system
- What are the criteria for a “pass”

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Right Thinking


This is your intention

- Is the auditors' view consistent with what you intend
- Are you covering all of your risks
- Have you adequately addressed the internal SOPs
- What is your overall philosophy regarding validation?

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Right Speech

- Keep a consistent message
- Ensure that everyone agrees with the direction of validation and will make the same argument

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Right Action

- Keep things simple
- Address all issues
- Complete your risk assessment
- Complete your user requirement specifications
- Take the time necessary

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Right Livelihood

- Keep everyone involved and informed of what is happening
- Ensure consensus is reached and everyone understands

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Right Effort

- Take the time necessary
- Plan your efforts wisely
 - Can you combine steps?
 - Can you eliminate intermediaries
 - Maximize “black box” testing

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Right Mindfulness

- Re-assess as you proceed
 - Have you completed the correct actions
 - Are you keeping everyone involved and understanding
 - Are you properly focusing your efforts
 - Are you minimizing everything you can


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Right Concentration

- Focus on areas of risk
- IGNORE low risk areas
 - If it is not on your user requirements it is low risk!!
 - Remember:
 - Most of the requirement documents were written with manufacturing in mind
 - People don't generally die if your data gets corrupted
 - It's not as important as you think
 - What is the risk

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Conclusions

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