Voluntary Quality Program Considerations

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Our Focus is Med Device Startups

- Medical and Life Science Product Development
  - Prototyping
  - Program Management Consulting
  - Educational Intensive Offerings for Startups
  - ~~Development + Regulatory + Quality~~
  - Regulatory and Quality Conversant Developers
- 7 years in business, 42 employee years of startup experiences
- Our audience: Doctors, entrepreneurs, small/mid-companies, VC's
- Intent on demystifying the regulated development process

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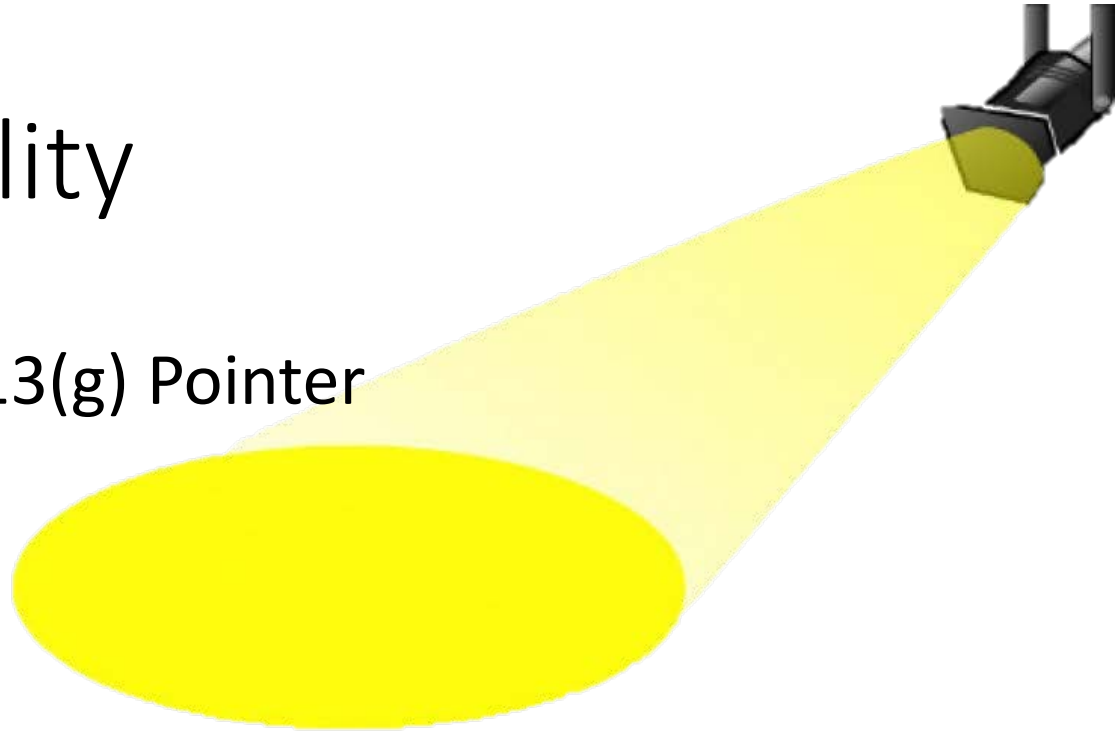
We Like to Illuminate Reality



- Explained Classification Analysis w/ 513(g) Pointer
  - vs. “Regulatory Expert” Pronouncement
- Lean, Stage Appropriate QMS Growth
  - vs. “Stack of paper” Drop-In-Place with “Best Practices”

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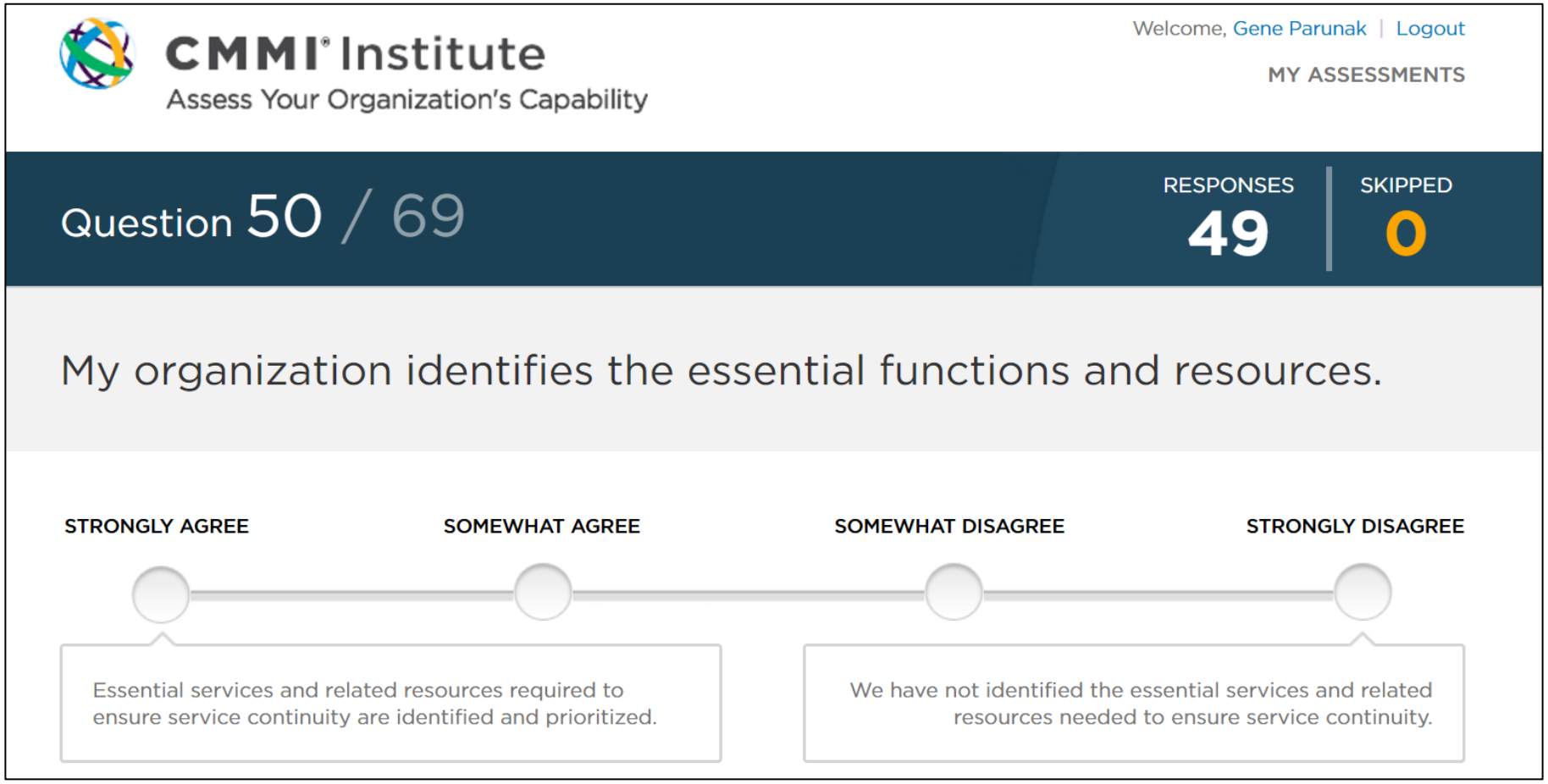
CMMI Homework



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Startup Questions (Concerns?)

- Will startups understand the questions, or will it promote further confusion?
- Will stage-consciousness be a part of the pathway, or will it promote even more “drop-in-place” opacity?
- How will early stage investors view this program? Will it be forced as a premature benchmark?
- How should we view it in light of the already existing QSR and ISO 13485?
- Will it truly be “voluntary” as time passes? Will there end up being a publicly mandated private provider?
- Finally, an instructive ~~FDA~~ *FAA* example…

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Final Thoughts

- FDA is truly “the new FDA” in recent years – a good thing!
- Startup comprehension of the process has NOT caught up
- Tools which increase stage appropriate education and benchmarking are welcomed
- Programs with compelling value propositions but increased opacity and bottlenecks are death to startups

- Thank you!

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