

Mitigating Risk = Tangible Value

Regulated Environments

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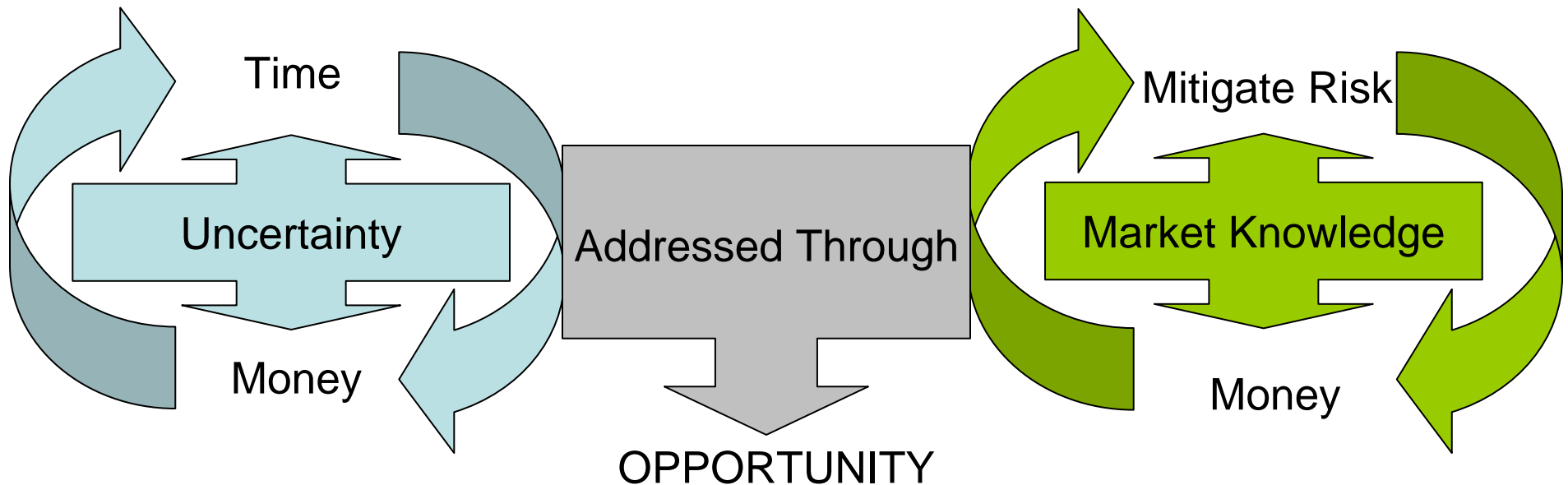
- Regulated Environments = any facility that manufactures products which are regulated by a governing body
 - Examples (<http://www.fda.gov/>)
 - Pharmaceutical (21 CFR Part 210/211/11)
 - Biotechnical (21 CFR Part 210/211/11)
 - Medical Device (21 CFR Part 820/11)
 - Non-clinical Lab Space (21 CFR Part 58/11)
 - Food and Beverage (21 CFR Part 110/11)
 - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

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- What is critical?
 - Time = \$\$
 - Uncertainty = Risk = \$\$ + Time

Owner's Perspective

Solution Provider



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- What are these customers looking for?
 - Someone who understands their needs
 - Compliant solutions
 - Speed to market
 - Designs-in validation
 - Creates solutions with change control in mind
 - Someone who speaks their language
 - Someone who mitigates their risk
 - Someone who helps them get to market faster

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- What can we do to meet these needs?
 - Partner with companies that understand these needs and have compliant solutions
 - Develop a quality manual and live by it
 - Verify that solutions are compliant through testing and GAP analysis
 - Learn the language (GAMP V-Model, CFRs, Change Control)

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A basic framework for specification and qualification
(Figure 6.2 GAMP 4 Guide, Dec 2001)

