



UL COMPLIANCE TO PERFORMANCE
LEADERSHIP FORUM 2016

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Track 1: The Enterprise Content Conundrum

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Areas Covered

This session will cover topics that challenge many training organizations such as:

- “Our team has too much training material to produce;”
- “We are using too much or not enough of our content library;”
- “We have many teams producing training content via authoring tools.”



“Current Learning / Training Environment”



Define:

conundrum 

noun | co·nun·drum | \kə-'nən-drəm\

a confusing and difficult problem or question



Today's Learners

- **Overwhelmed** - two-thirds of knowledge workers say they do not have time to do their jobs;
- **Impatient** -- makes training and retention more difficult;
- **Empowered** - more adult learners want to learn at their own pace, when they have time -- this changes trainers from content creators to content curators.



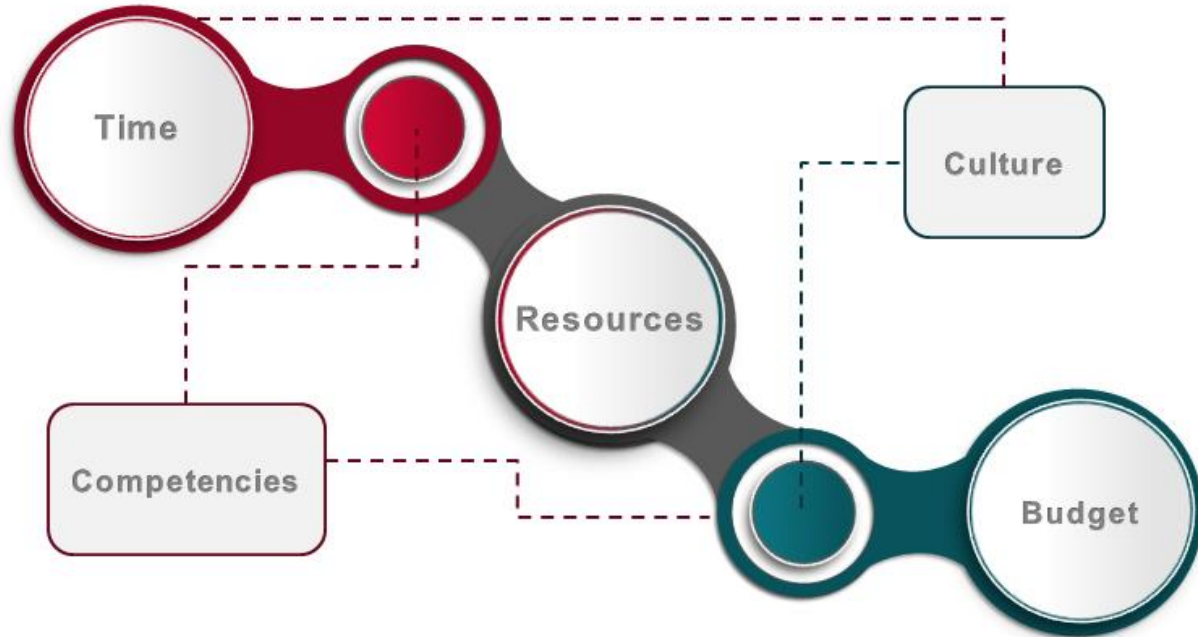
Today's Training Resources

- **Overwhelmed** – too much on their plate, do not have enough time to do it all with high quality and alignment with variety of learning styles;
- **Unrealistic Expectations** – working with requestors that needed it yesterday or delivered immediately with not enough pre-planning;
- **Underdeveloped** – resources not consistently and frequently developed enough to apply training methodologies into training materials developed and use authoring tools



Difficult Problem:

How to do more with less?



the challenge

“Our team has too much training material to produce”



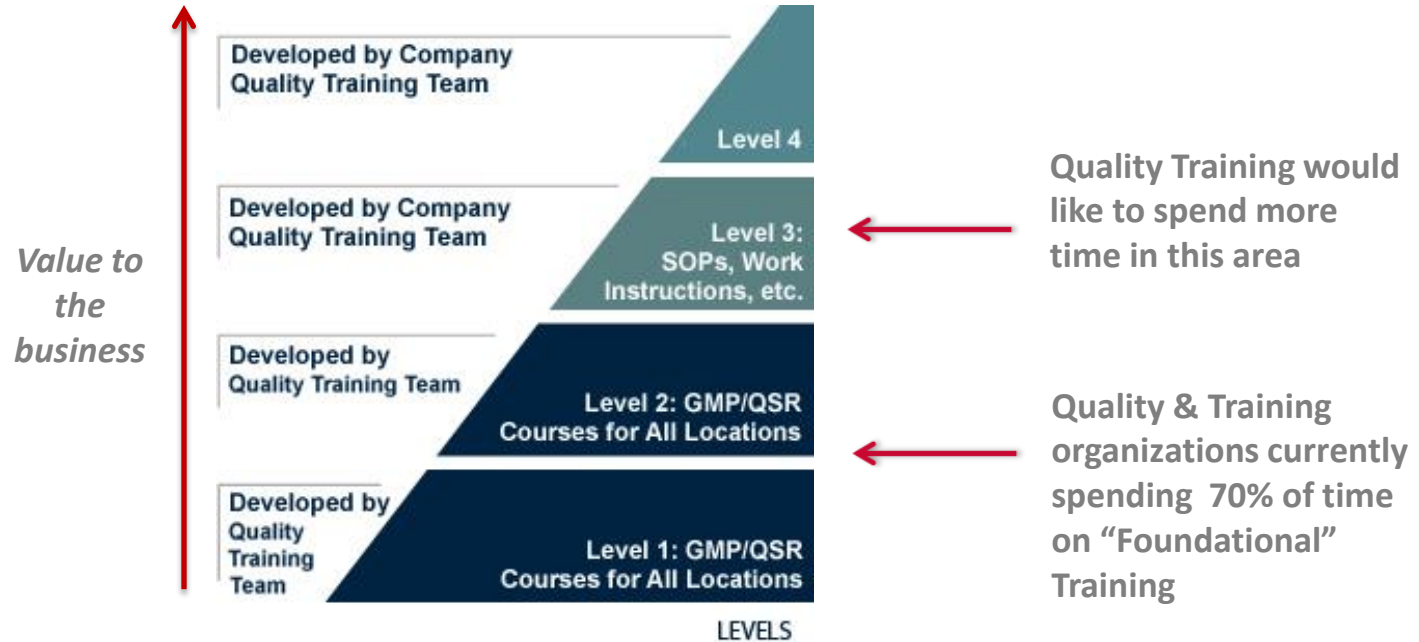
Reallocate Your Training Development Resources

“Our team has too much training material to produce.”

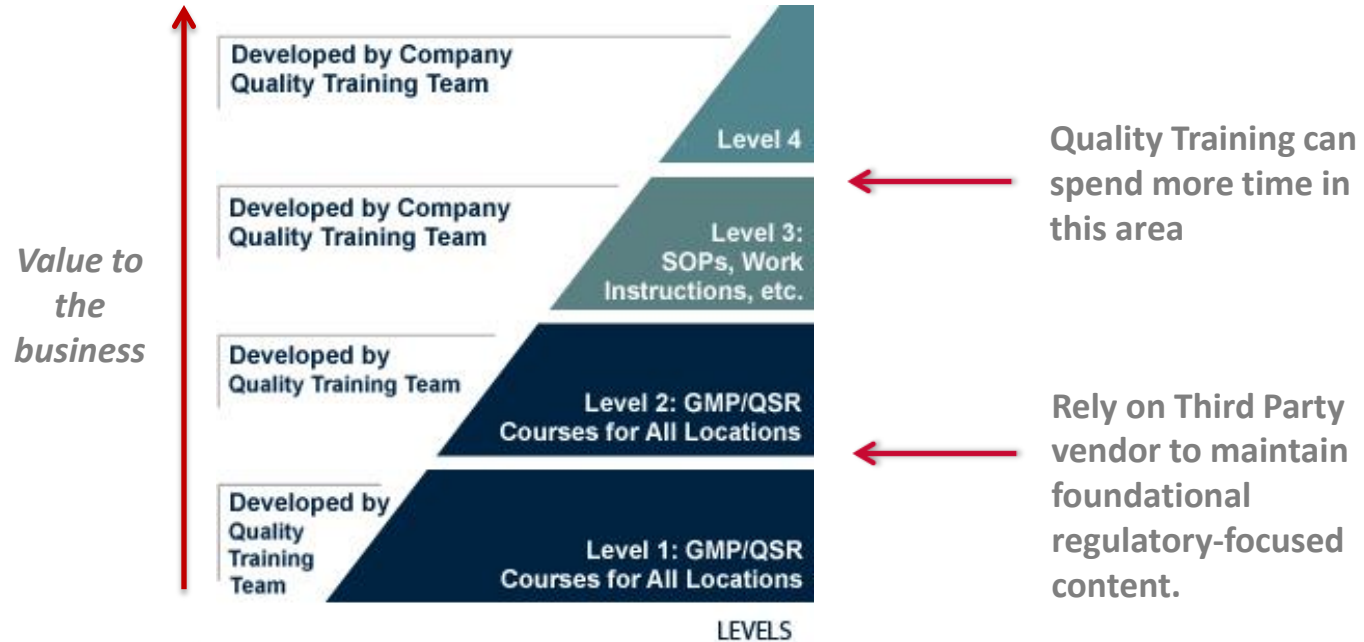
- Outsourcing “core” regulatory content
- Address “high-risk” topics with authoring tools
- Improve SOP Training Content



Traditional Life Science Training Org – Current Content Approach & Efforts



Best Practices for Content Management – The Content Partnership Architecture



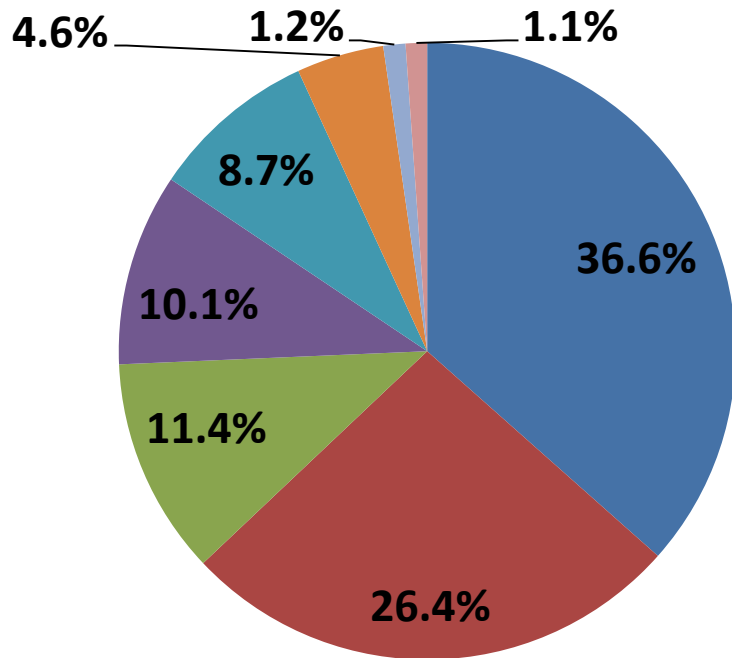
Reallocate Your Training Development Resources

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Compliance Content



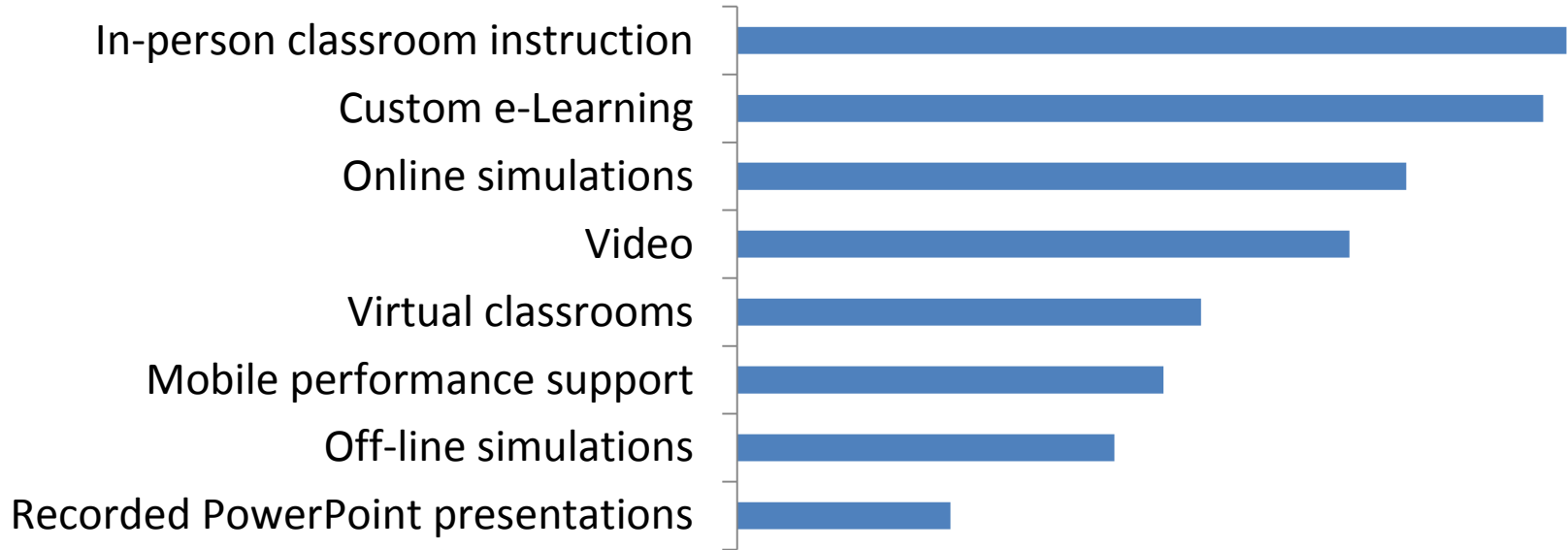
Source: Brandon Hall Group, Compliance, 2014

- Custom e-Learning
- In-person classroom instruction
- Online simulations
- Virtual classrooms
- Recorded PowerPoint presentations
- Video
- Mobile performance support
- Off-line simulations



“How Effective is Compliance Training?”

Very/Extremely Effective

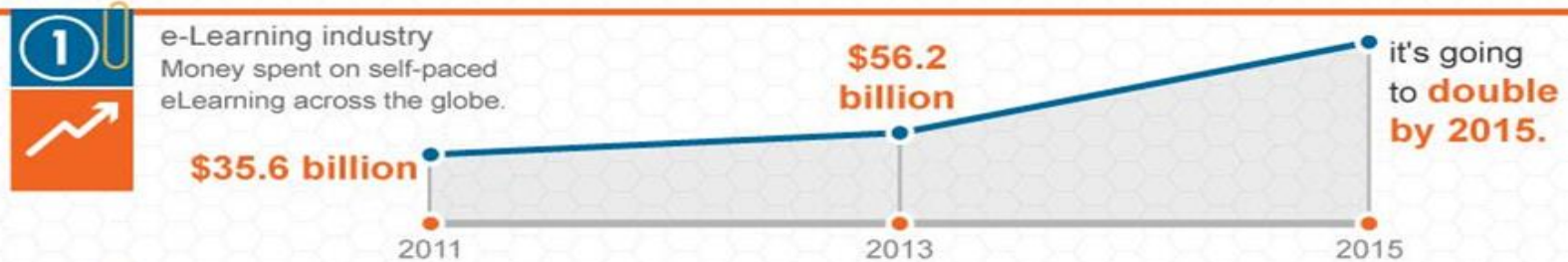


Source: Brandon Hall Group, Compliance, 2014



Growth of eLearning

The rise in eLearning's popularity isn't showing any signs of slowing. In fact, judging by the following Top 10 eLearning statistics for 2014, the future of the eLearning Industry is brighter than ever:



- <http://elearninginfographics.com/elearning-statistics-2014-infographic/>

Growth of eLearning



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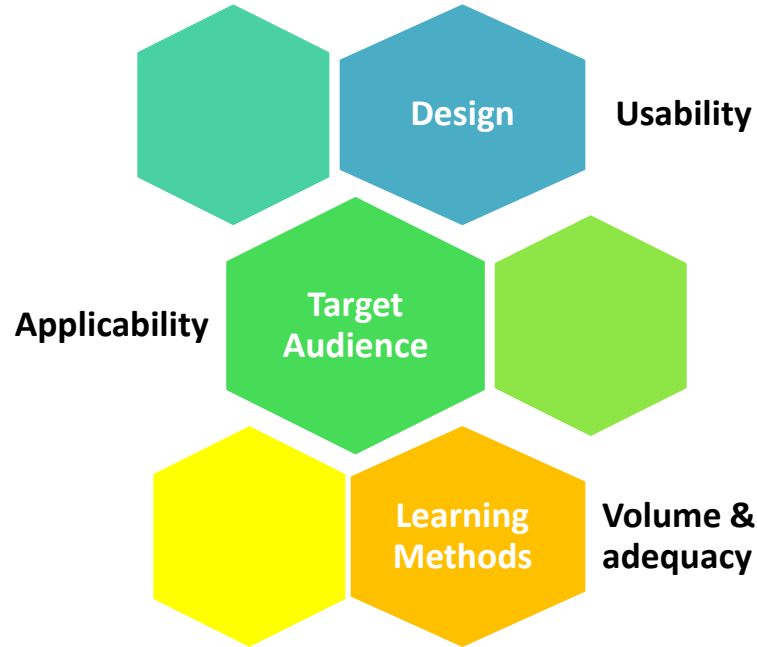
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- Outsourcing “core” regulatory content
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- **Improve SOP Training Content**



SOP Training Content



the challenge

*“We are using too much or not enough of
our content library”*



Training Matrix Mapping

“We are using too much or not enough of our content library.”

- Map courses to existing role based curricula AND add to tiered competency levels
- Use content curriculum templates to get started



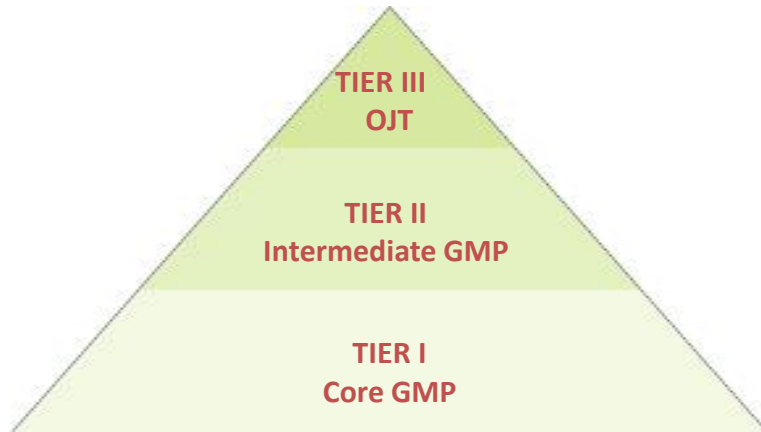
Training Matrix Mapping

Competency / Curriculum:

Quality Assurance Operations

Role-based
curriculum life cycle

Quality Professional



TIER III – OJT- Role Specific Knowledge/Skills Qualification

1. Role-based Qualification Curriculum (ex. Batch Disposition)
2. Internal SOPs, Policies, Mentoring, OJT
3. Demonstrated Knowledge and Skills Evaluated
4. Qualifications by Functions Achieved
5. Cross-training to other Functions
6. Additional Qualifications Achieved
7. Annual GMP Refreshers (Tier I review)
8. Continuous Learning (Compliance trends/issues)

TIER II – Intermediate Quality GMP Curriculum

1. Principles of Process Validation
2. Principles of Process Controls
3. Aseptic Processing
4. Vendor Certification
5. Packaging and Labeling
6. Change Control and Risk Management
7. Conducting Failure Investigations
8. Auditing/FDA Inspections
9. Responding to FDA

TIER I – Core Quality GMP Curriculum

1. Orientation to GMP Compliance
2. GxPs
3. GMP Principles for SOPs
4. GMP Principles for Batch Records
5. Principles of Good Documentation
6. Part 11; Electronic Records; Electronic Signatures
7. Awareness of FDA Inspections
8. Company Policies and Practices



the challenge

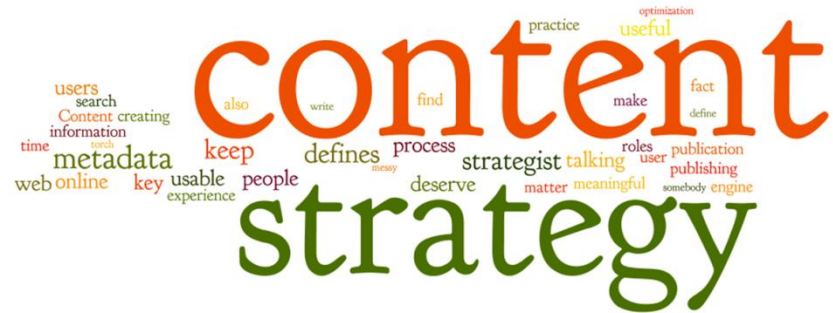
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Consistent Content Creation Strategy

“We have many teams producing training content via authoring tools .”

- Create a Content Governance Strategy
- Partnering with LMS vendor to deliver content in consistent manner
- Develop internal resources’ competencies in content creation



Best Practices For Course Creation

Key actions:

- Select a common tool
- Create an approved vendor list
- Define user experience requirements

Key actions:

- Define instructional design strategies
- Establish testing/release approach



Resources Development

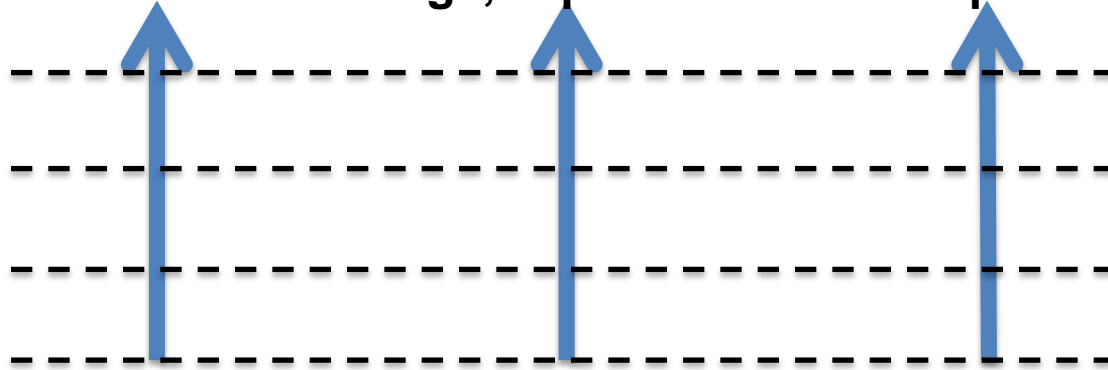
Increase knowledge, experience and competencies

Mastery

Advanced

Intermediate

Basic



tools



purchased / developed

SME's



Specialists

“Evolve your Learning / Training Environment”

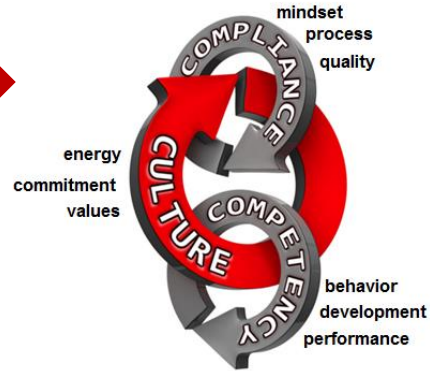
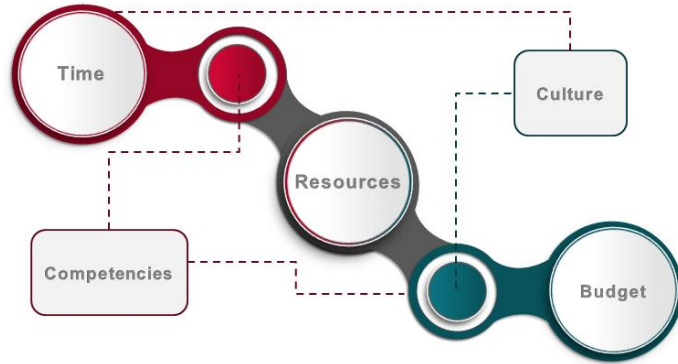


Difficult Problem:

Solutions:

How to do more with less?

Strategize, Plan & Invest



Thank You

