



# Integral Solutions for Quality & Regulatory Affairs



LUKE LIANG, PHD, RAC  
GLISLAND, INC.  
SAN JOSE, CALIFORNIA  
[HTTP://WWW.GLISLAND.COM](http://www.glisland.com)

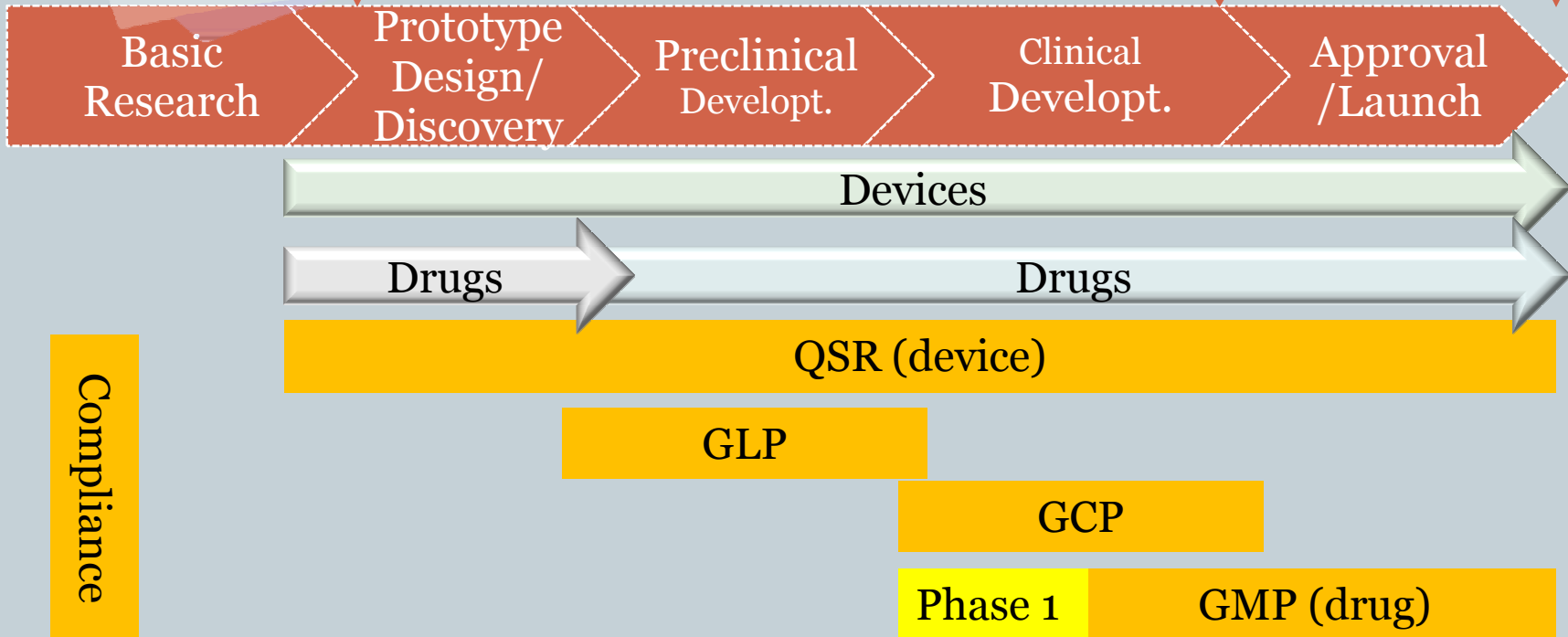


# Critical Path to Medical Products Development

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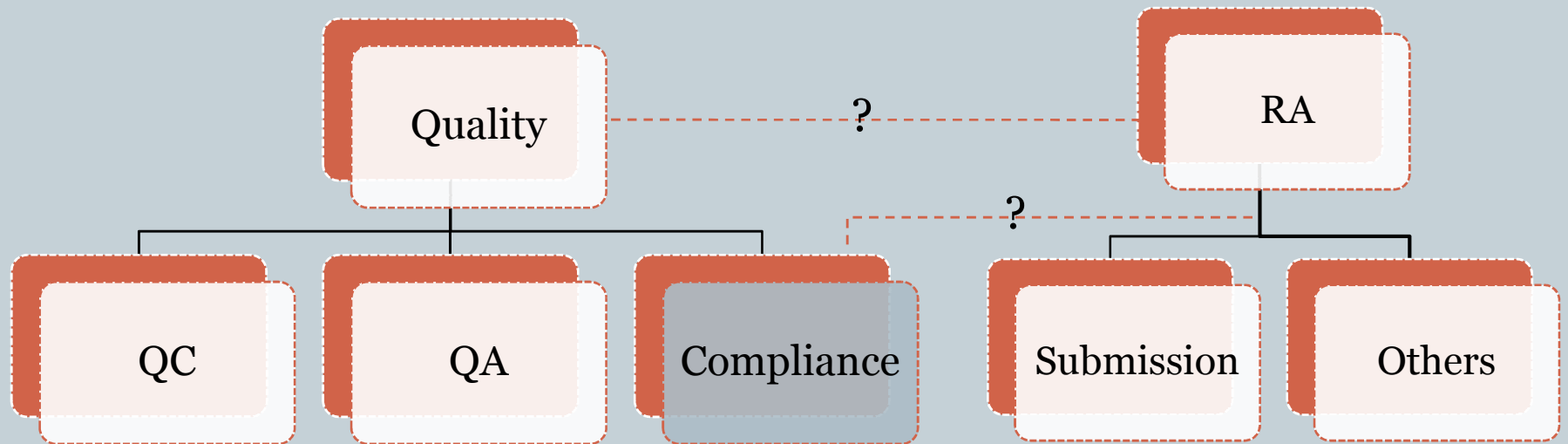
## Critical Path

Market Application



# Typical Functions & Grouping

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# Segregation & Interfaces

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## Critical Path

Market Application



Compliance

QC

QA

Submission

# Regulatory Roles & Responsibilities

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- **Research & Strategic Planning**
  - Product regulatory classification
  - Regulatory pathways/options
  - Submission strategies
  - Compliance and submission costs
- **Design and Development**
  - Compliance requirements
  - QC/QA
  - Safety and effectiveness/substantial equivalence
  - Clinical trial monitoring
  - Risk assessments

# Regulatory Roles & Responsibilities

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- **Premarket Submissions**
  - Regulatory submissions
  - Negotiate/interact with regulatory authorities
  - Preapproval inspections/audits
  - Registration and listing
- **Manufacturing/Quality Systems**
  - SOPs
  - QC/QA
  - Validations
  - Internal audits
  - Training
  - Trending analysis
  - Management review and improvement

# Regulatory Roles & Responsibilities

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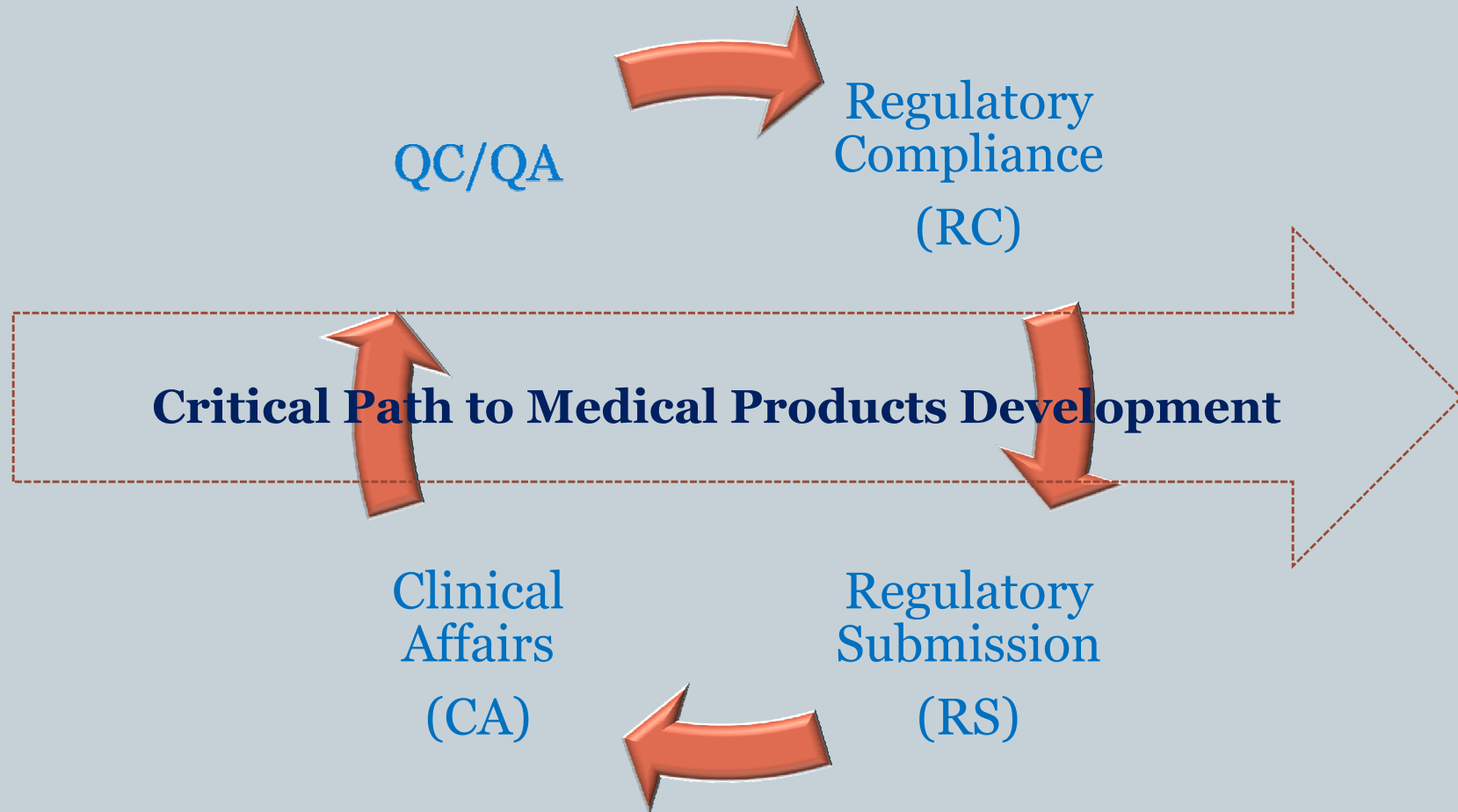
- **Marketing/Post-Approval**
  - Advertising/promoting/labeling
  - Post-marketing surveillance/vigilance
  - Post-approval studies and reports
  - Import/export regulatory compliance
  - Crisis management

*More information about medical device regulatory compliance:*

[http://www.glisland.com/Pub/SampleSlides/Medical\\_Device\\_Compliance\\_US.pdf](http://www.glisland.com/Pub/SampleSlides/Medical_Device_Compliance_US.pdf)

# Is Your Process Working?

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# Key Ingredients of Success

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- a sound regulatory strategy and its effective execution;
- lean and check balanced quality system;
- team work;
- effective use of regulatory options and tools;
- competent skills and training.

# Small Entity Dilemma

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- Limited resources and core competency for the same amount of regulatory requirements

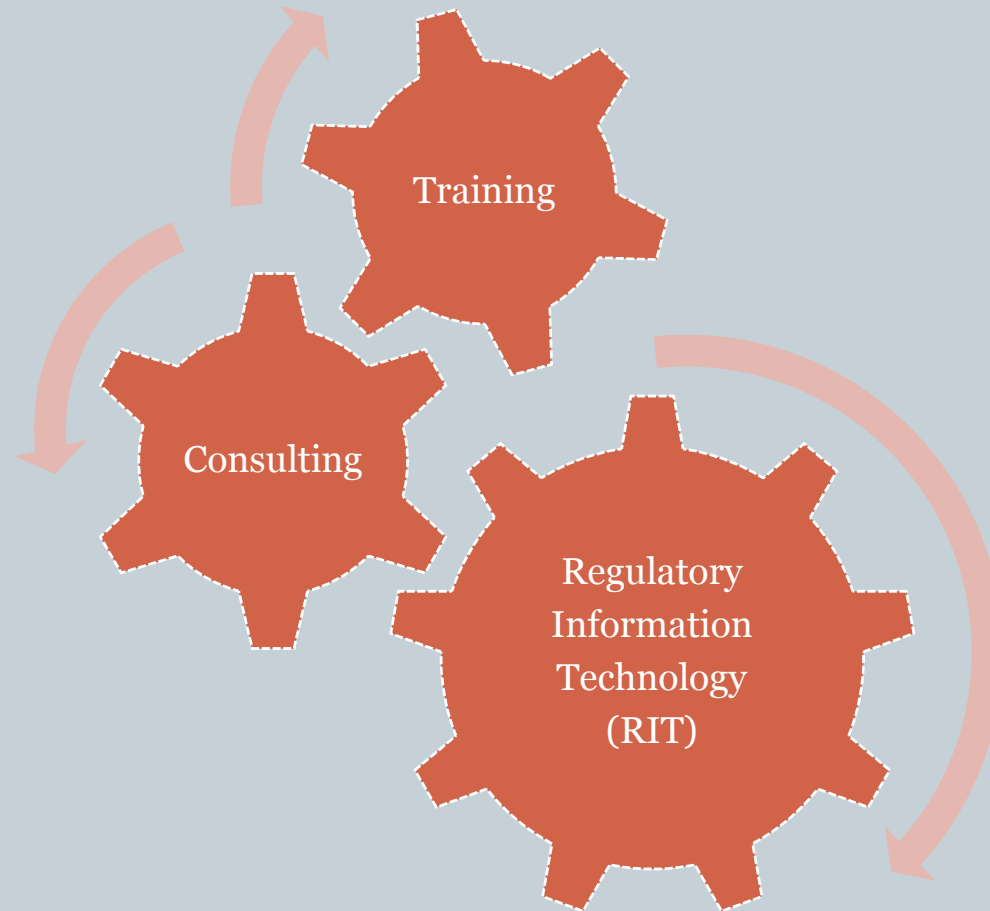
麻雀雖小，五臟俱全

*“Small as it is, the sparrow has every organ it needs.”*

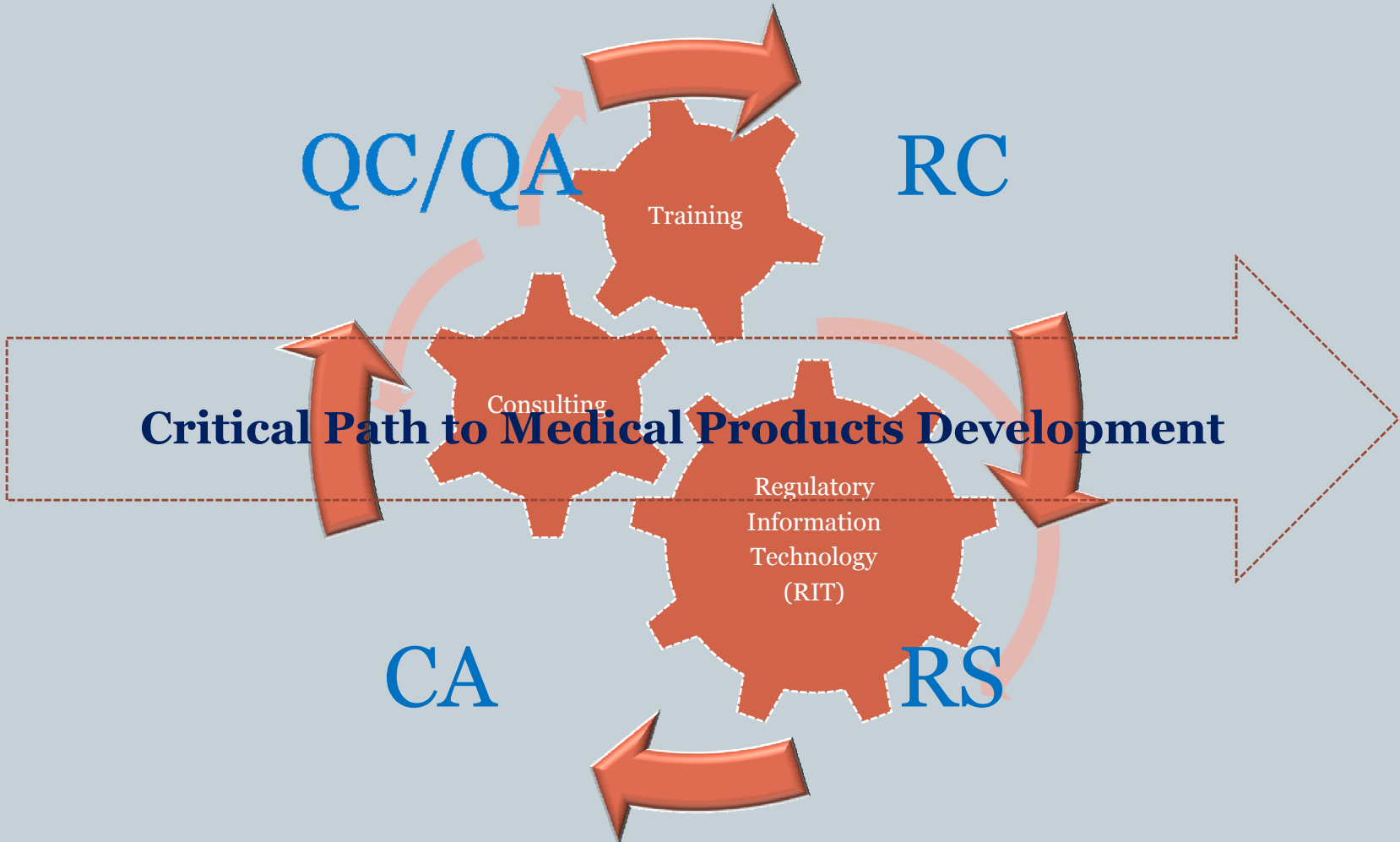
*-Chinese Proverb*

# Glisland Integral Solutions – Mechanism and Driving Force

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# Synergy



# Thank You

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Glisland, Inc.  
2059 Camden Avenue, #299  
San Jose, CA 95124  
U.S.A.

Phone: (408) 796-1883  
email: [info@glisland.com](mailto:info@glisland.com)  
<http://www.glisland.com>