innovize®
let's make it better

# The Maturity Model Journey

## Defining Requirements and Business Processes

Mark Rutkiewicz, VP Quality, Innovize

# Innovize

- Contract manufacturer to medical device companies for 10+ years
- In 2013, Innovize's Quality System certified to ISO 9001, ISO 13485 and built to meet 21 CFR 820
- Procedures written to meet requirements in the ISO standards and FDA QSR

# Innovize's Transformation

- In 2014, started conversion to a process-based business system architecture with 20 business processes
- Defined business process interactions as required per the ISO standards
- June 2016, CMMI Proof of Concept
- October 2016, CMMI Pilot Test
- 2017, Enrolled in the FDA Voluntary Quality Program Pilot

# Medical Device Company Business Requirements – sampling

FDA Regulations and Guidances

Canadian Regulations

- Quality System Re
- Labeling
- 21 CFR 803 – Medical Device Reporting
- 21 CFR 806 – Corrections and Re

Japanese Regulations

International Standards and Guidances

- 5 – Quality System
- 16 – Medical Device Quality System
- EU MDD to the new MDR 2017/745 MDR

Brazilian Regulations

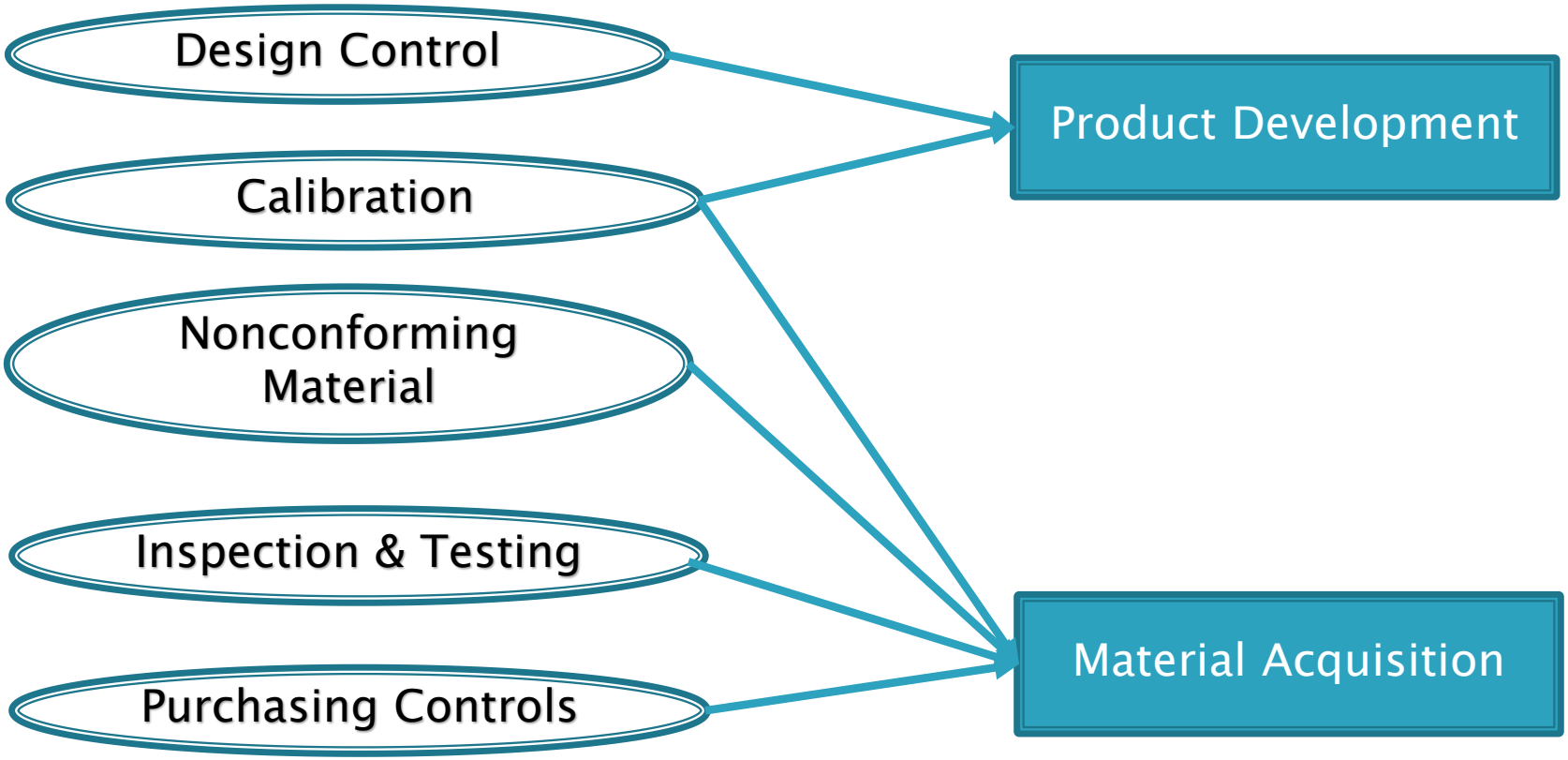
- SOR 98-202 – Canadian Medical ns
- RDC-59 – Brazilian GMP Regulations

EU Directives and the MEDDEVs

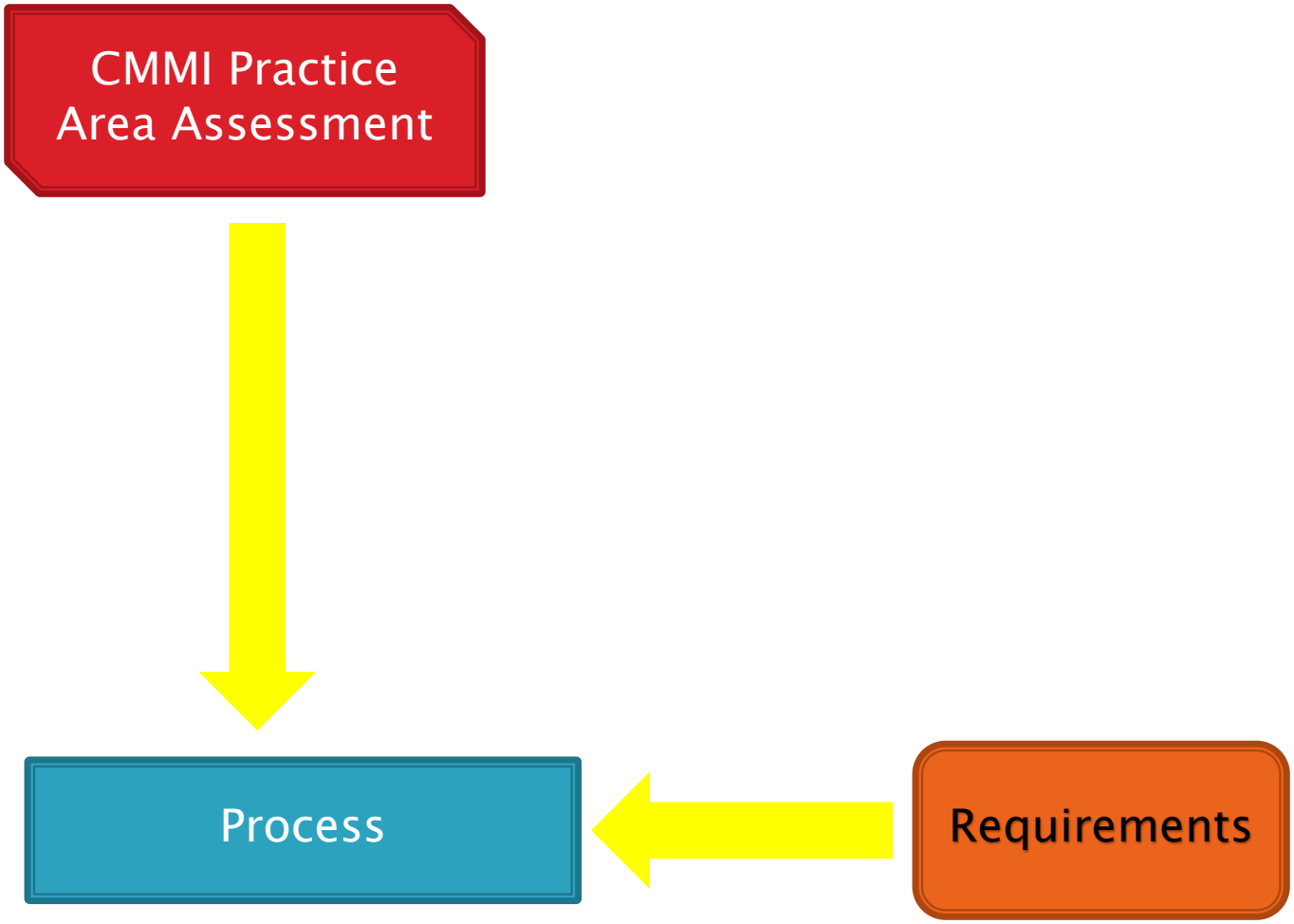
- & Quality Control for Medical Devices
- DDEV documents

Chinese Regulations

# Map Business Requirements to Business Processes (not 1-1)

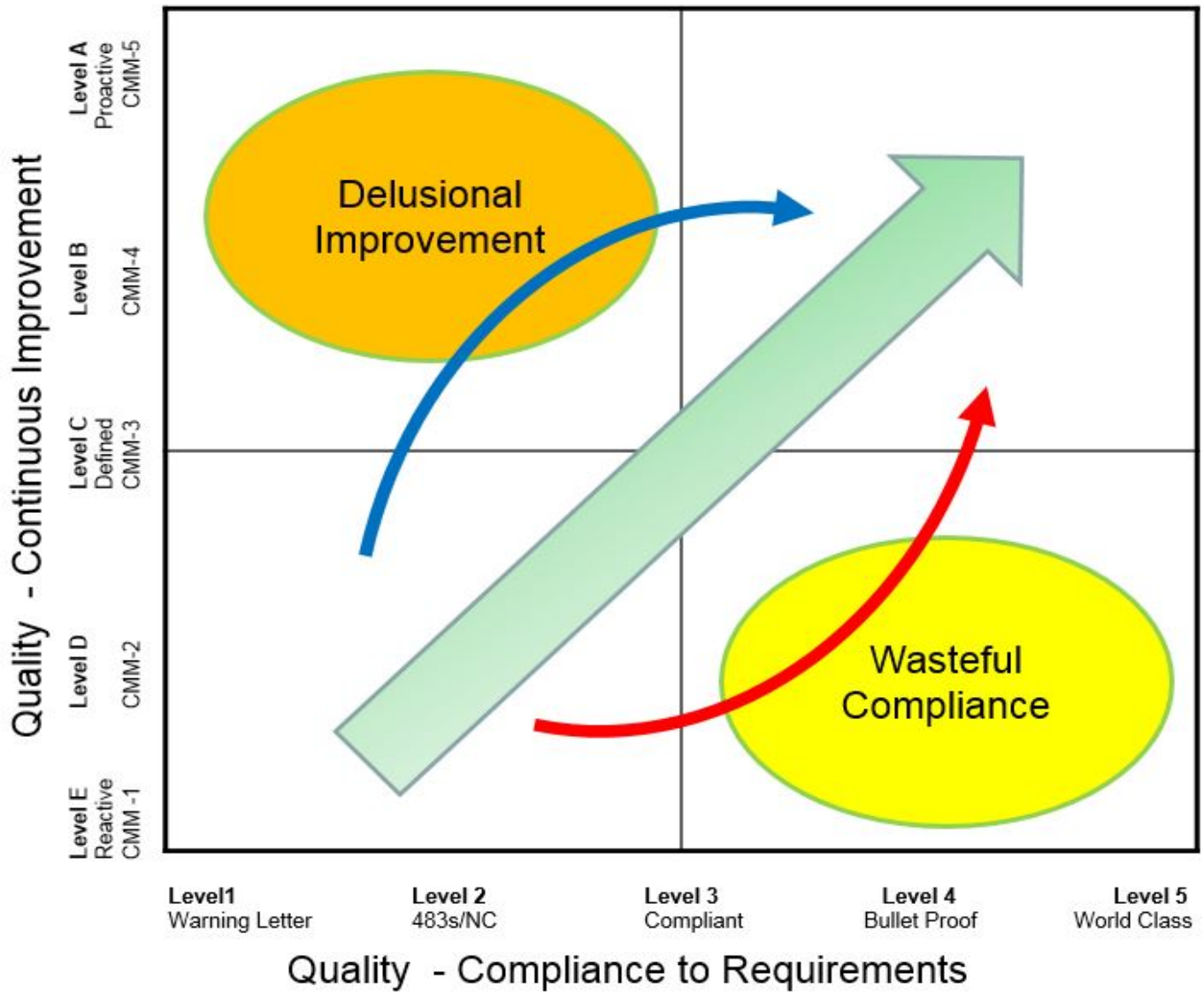


# Quality System – Compliance and Improvement




Courtesy of Consiliso LLC

# Quality System – Compliance and Improvement




Courtesy of Consiliso LLC

# CMMI Assessments

- Assessments use the CMMI Model's general and level-specific practice areas
- CMMI does not assess to FDA regulations
- Does not ensure compliance to all applicable requirements – that is the company's job
- We need to map practice areas to medical device company business processes, not regulatory requirements

# Maximizing the Value of CMMI Assessments

- For each company:
  - Define your business requirements
  - Define your business processes
  - Define your process interactions
- Assessments need to be done against business processes
- As your processes mature, CMMI will review more practice areas

# Expectation for the Next Assessments

- Assessors talk to people doing the work; there is no front room or backroom
- Provides new ideas to improve, not just comply
- Ongoing journey
- Even if you reach level 5 you are never done

*Thank You*