Updated!

Industry Leading Quality System

innovize®
let's make it better

About the Author

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Mark has been in the medical device industry for over 30 years and has been in leadership positions at a half-dozen different medical device companies. In his time at each company he has built or rebuilt the entire Quality, Regulatory, Clinical, Financial, and Environmental Business Systems, essentially changing the fundamental aspects of how each company performed its work.

Introduction

Each Iteration is a Step toward Higher Quality

Innovize is committed to continuous quality improvement, in the management of our own operations and in the projects and processes deployed for our customers. We listen to requirements, deliver on commitments and seek to streamline processes by eliminating non-value-added steps.

Our quality policy states:

> *We are committed to providing products that meet or exceed quality and regulatory requirements by continually improving the effectiveness of our Quality System through process improvement.*

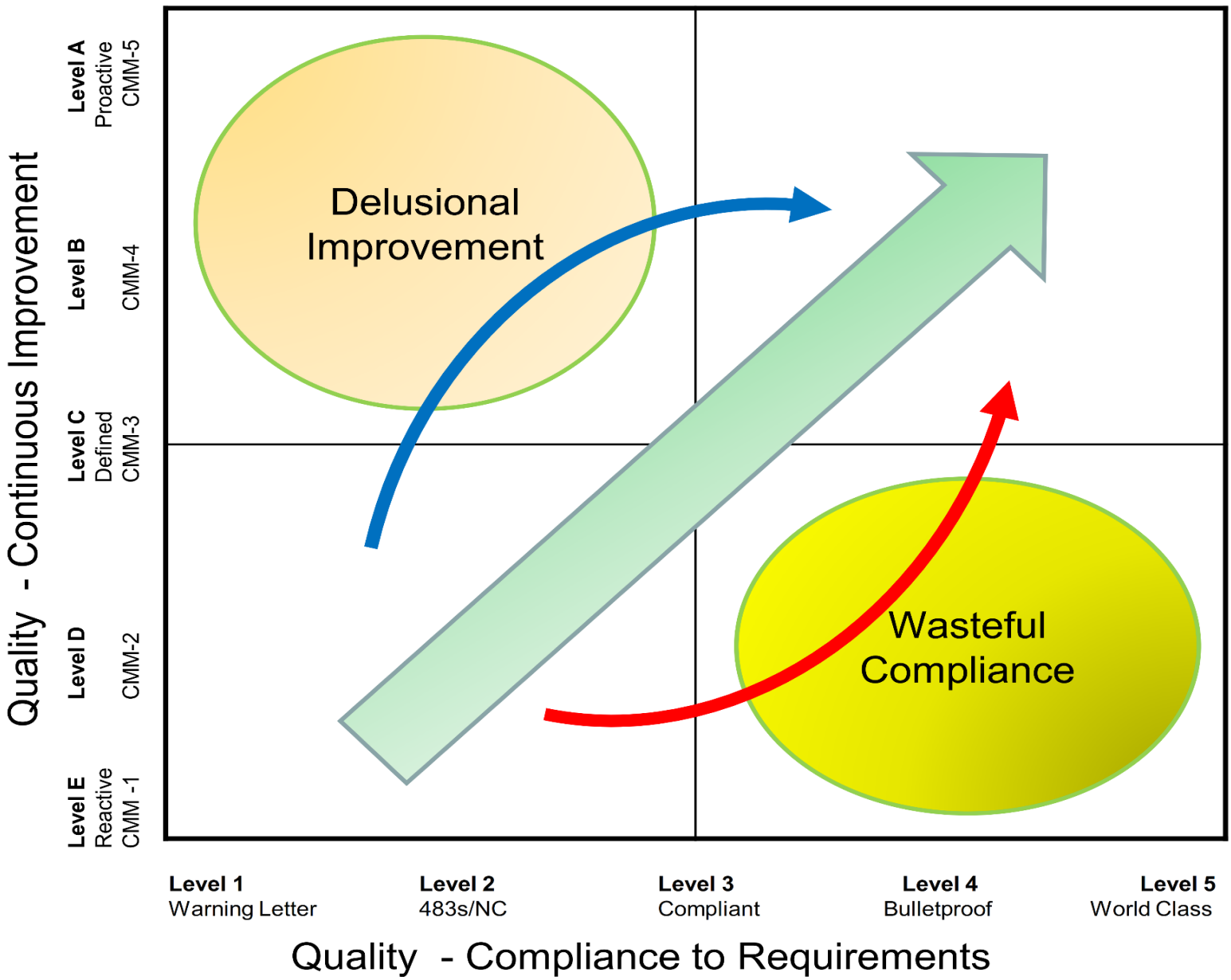
Innovize uses the medical device industry's first blueprint for medical device company quality system architecture. This blueprint is defined in the *Consiliso* textbook written by our Vice President of Quality, Mark Rutkiewicz. Mark's two books on this Consiliso architecture provide industry best practices for all types of medical device companies. www.consiliso.com

Lean, Clean, Certified and Compliant

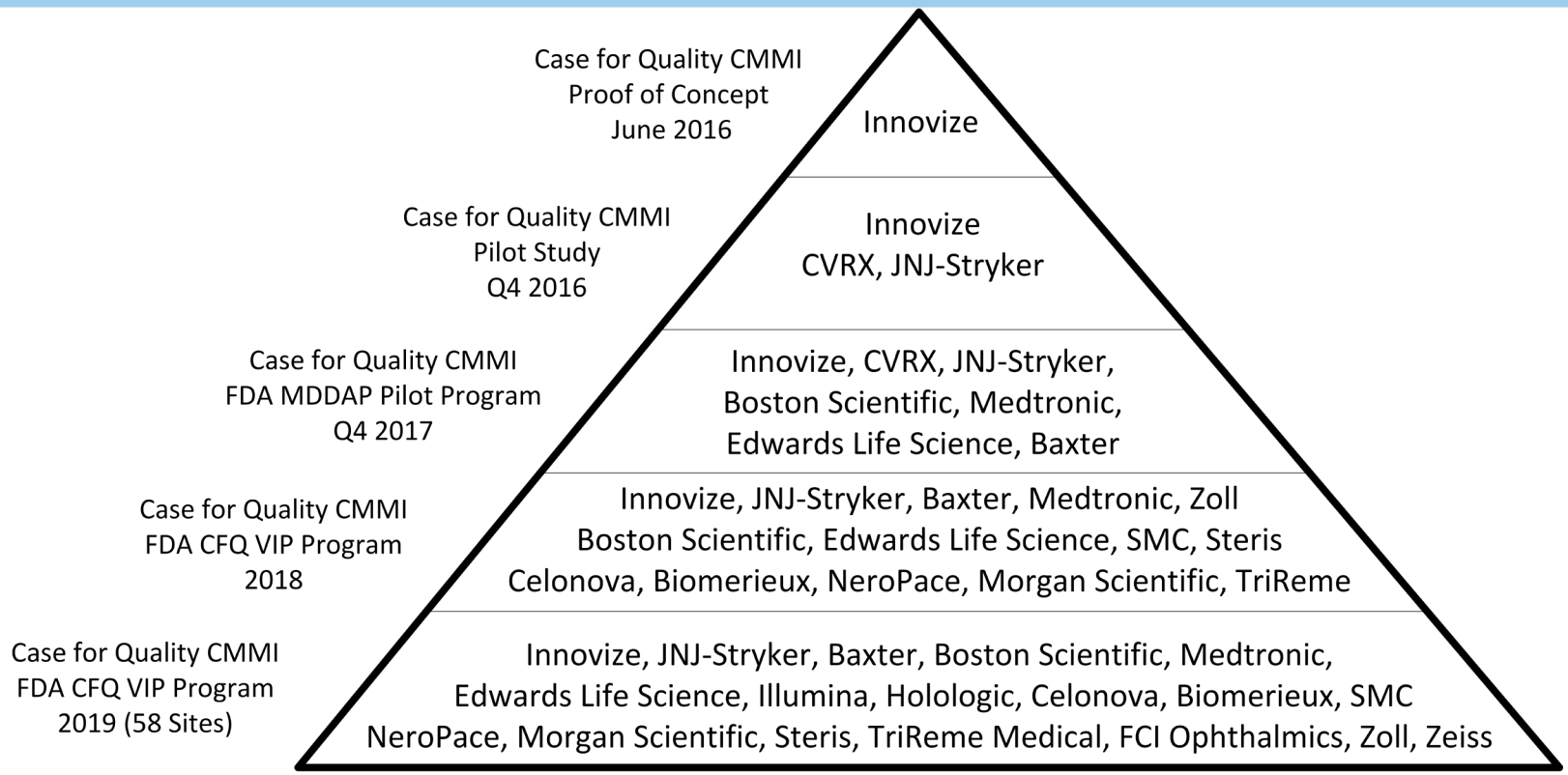
With Innovize, you'll find:

- ISO 9001:2015 Certification
- ISO 13485:2016 Certification
- FDA Registered
- GMP Compliant
- Korean GMP
- Case for Quality - CMMI MDDAP Assessed
- Clean-room/ dry-room environments
- Lean manufacturing
- UL-approved labels
- Consiliso Compliant

Case for Quality Maturity Assessments



Innovize Leads the Industry



Innovize led the way for "The Voluntary Manufacturing Product Quality Program Results."

This program is expected to be formally adopted by the FDA in 2020.

To sign up for this FDA program, a company needs to be in good standing with the FDA.

Companies Assessed to the CMMI Model have benefits of:

- Standard FDA inspections are not required
- 510K 30-day notice (approved in 2 days)
- Pre-Market approval inspections waived
- Manufacturing site transfer inspections waived

The biggest benefit to the industry and customers working with these companies is that they don't just pass minimum FDA standards, they also have a culture of high quality and continuous improvement!

FDA launched the Case for Quality

In 2011, the FDA launched their Case for Quality. They saw that just being compliant to the Quality System Regulations (QSR) did not make companies produce better products. The FDA worked with Medical Alley to create a new public-private partnership so the FDA could work directly with the industry. The Medical Device Innovation Consortium was formed in 2012. The MDIC had five original projects and one was the Case for Quality (CfQ). In the CfQ, there were multiple sub-projects, but the development of a Medical Device company maturity model assessment was the pillar of the project.

Innovize and CMMI Partnership with the FDA

In 2015, Innovize's VP of Quality (Mark Rutkiewicz) joined the small team to implement the maturity model assessment concept. The CfQ project had chosen the CMMI Institute's model that was developed out of Carnegie-Mellon University-Software Engineering Institute for defense contractors. The model is called the Capability Maturity Model Integration (CMMI).

Maturity Model Implementation

With Mark's 30 years of experience building and rebuilding Quality Systems in all size medical device companies, Mark took on the leadership of the Maturity Model implementation sub team. The first challenge was to get the FDA to agree the CMMI assessment would work, so Mark volunteered Innovize to be the Proof of Concept. Innovize had just passed an FDA QSIT inspection in January of 2016 with no findings. This is a pre-requisite for the CMMI assessment. In June of 2015, this two-day assessment was done at Innovize with the FDA watching the entire interaction over a video feed. The FDA was pleased with the process and it was agreed that a larger pilot was needed.

Innovize taking a lead

Innovize took the lead again; in October of 2016, Innovize was one of three companies to participate in the larger five-day assessment. Coincidentally, Innovize had implemented a new ERP system between the two assessments. The results of the second assessment showed the ERP implementation had improved Innovize's maturity score.

In August of 2017, the FDA formally launched an industry-wide pilot program. Innovize was the first company to sign up. Innovize had their first full assessment to CMMI Level 2 under the program in December 2017 and a second assessment to CMMI Level 3 in December of 2018.

Resources

- **Case for Quality** = https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/case-quality
- **Pilot Program** = https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/case-quality-pilot-activities
- **Case for Quality** = https://mdic.org/program/case-for-quality/
- **Pilot Program enrollment** = http://mdic.org/cfq/enroll/
- **CMMI's MDDAP used in the Pilot Program** = https://cmmiinstitute.com/medicaldevice

Articles on the topic:

- https://www.medtechintelligence.com/feature_article/fda-shares-secret-stopping-inspections/
- https://www.mddionline.com/qa-developing-maturity-model-assessment-device-makers
- https://www.consiliso.com/improve-your-cmmi-medical-device-maturity-ranking-with-consiliso/

Custom Medical Development & Manufacturing

Innovize offers 60+ years of custom medical development and manufacturing solutions including converting, contract manufacturing and packaging for components or finished medical devices and personal care products.

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