Resilience of the US Medical Device Supply Chain

Mark Rutkiewicz - VP Quality Innovize

Founder Consiliso LLC

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Areas of Concern

- Shortage Risk/Examples
- US Medical Device Manufacturing
- Supply Chain Design
- Recommendation

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Shortage Risk Areas

- Pandemic
- Natural Disasters
- Recalls
- Trade Embargo
- Critical facility shutdowns by regulators
- Sudden changes in demand by other industries

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Examples of Supply Chain Concerns

- Largest US Syringe production: BD in Holdrege Nebraska (due to nuclear war mitigation)
- 80% of US sutures from Ethicon-Puerto Rico (hurricane prone area)
- Dupont changed some Tyvek (ETO sterile barrier) production equipment, 5 years to determine equivalence

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Examples of Supply Chain Concerns

- Illinois EPA shutdown Sterigenics ETO sterilizer, 594 products need new sterilizer
- Aluminum films are used in medical device and pharma packaging, China trade embargo delayed deliveries 6+ weeks
- Texas freeze causing delays in the adhesive deliveries 6+ weeks

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Types of Medical Device Suppliers

- Medical device manufacturers/specification developer
  - Vertically Integrated
  - Hybrid
  - Virtual
- Contract manufacturers
- Distributor
- Custom component manufacturer
- Service Providers
  - Packagers
  - Sterilizers
  - Analytical labs

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US Medical Device Manufacturing

FDA Registered Establishments - 2020

- 6,750 US Manufacturing sites (24% of total)
- 1,186 US Contract Manufacturing sites (41% of total)
- 62 US Sterilization sites (30% of total)

ISO Certified US Manufacturing Sites - 2019

- 3,354 ISO 13485 registered facilities (23K WW)
- 22,453 ISO 9001 registered facilities (1M WW)

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Critical Device Suppliers

- Raw plastic and processed films (device and packaging)
  - Dupont, Dow, 3M, Avery-Dennison, SWM, Berry, Amcor, SABIC, Bayer-Makrolon
- Plastic Injection Molders/Extruders
- Biological Tissues and Reagents
- Metals (titanium, nitinol, stainless steel, aluminum)
- Sterilizers
- Printed Circuit Board Assemblies (PCBAs)/Touchscreens
- Electronic Components/Batteries (custom and off the shelf)
- Tooling and Equipment
- Adhesives and Inks

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Information Supply Chain

- FDA/ISO sets requirements for document and record control, not how to implement.
- Product DMR can be one document or thousands.
  - Medical Device – Part-Centric (BOM based)
  - Pharma – Document-Centric (Recipe based)
- Each company determines their information infrastructure, methodology, tools and policies
- UDI now required (US and EU), but either GS1 or HIBCC
- No standards for product information sharing
  - Document/Part Types, Change Types, Event Types,
  - Part/BOM and Regulatory submission structures

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Recommendations

- Determine critical devices and volume ramp up goals
- Expand/incentivize the use of automation
  - Robotics, vision systems, AI, additive manufacturing
- Expand the use of US contract manufacturers
- Tax advantages for key products manufactured in the US/PR
- Define Quality System information/product architecture and standards
- Work with Medical Device Innovation Consortium (MDIC)

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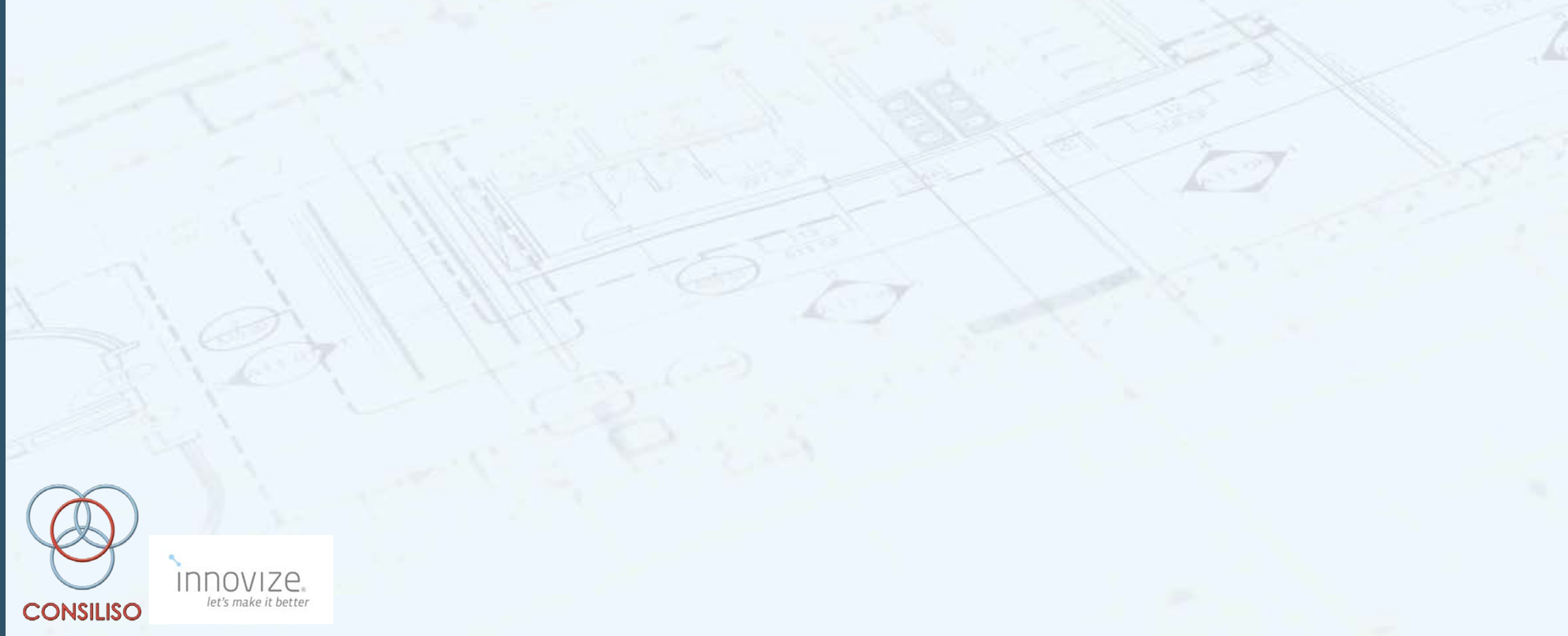
Backup



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Medical Device Industry

- Worldwide Sales
  - Medical Device (IVD 13%) $457 B
  - Pharma – $1,228 B
- FDA Registered Facilities
  - Medical Device Mfr 28,269 (US Only – 6,750) $16M/site
  - Pharma – 7,538 (US Only 3,568) $162M/site
- FDA Product Codes – 6657
- FDA Consensus Standards - 1388
- FDA Guidance Documents – 569
- FDA Product Areas 19

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Types and Levels of Devices

CLASS	RISK LEVEL	CONTROLS	DEVICE EXAMPLES
I	Low	General	Surgical instruments/Bandages/PPE
II	Moderate	Special/510K	Syringes/Ventilators/Pulse Oximeter
III	High	Special/PMA	Implantables/Stents/Angioplasty Catheters

- Anesthesia
- Biocompatibility
- Cardiovascular
- Dental/ENT
- General Plastic Surgery/General Hospital
- InVitro Diagnostics (IVD)
- Nanoscale
- Neurological
- ObGyn/Gastroenterology
- Ophthalmic
- Orthopaedics
- Physical Medicine
- Radiology
- Software/ Informatics
- Sterilization
- Tissue Engineering

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Top 12 US Medical Device Companies by Medical Device Revenue ($193B - 42% of all)

Name	Type	US/PR Sites	Revenue
Medtronic	Mfr	25	$31B
JNJ	Corp Div/Mfr	20+	$26B
Abbott	Pharma/Mfr	11	$20B
GE	Corp Div/Mfr	14	$20B
BD	Mfr	31	$17B
Cardinal Health	Mfr/Dist	10+ (600)	$16B
Stryker	Mfr	14	$15B
Medline	Distributor	8	$12B
Baxter	Mfr	5	$11B
Boston Sci	Mfr	9	$10B
Zimmer Biomet	Mfr	8	$8B
3M	Corp Div/Mfr	44	$7B

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Interested Parties

- FDA
  - CDRH – Center for Device and Radiological Health (2020 re-organization includes IVD)
  - NEST - National Evaluation System for health Technology
- IMDRF – International Medical Device Regulators Forum (e.g. FDA, PMDA, Health Canada, etc.)
- Advamed – Industry business/lobbying group
- AAMI – Association for the Advancement of Medical Instrumentation – Standards Body
- MedAccred – Supply Chain Compliance
- MDIC - Medical Device Innovation Consortium

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MDIC and NESTcc (Critical Expertise)

- MDIC established 2011 as a Public-Private Partnership (PPP) with the FDA CDRH
- FDA Office of Science and Engineering Laboratories works with NESTcc (National Evaluation System for Health Technology-Coordinating Center)
- Working Groups:
  - Case of Quality
  - Clinical Diagnostics
  - Cybersecurity
  - Digital Pathology
  - Science of Patient Input
  - Data Sciences and Technology
  - Early Feasibility Studies
  - External Evidence Methods
  - Computational Modeling and Simulation
  - Health Economics and Patient Value
  - Clinical Science and Medical Officers

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Innovize

- Medical device contract manufacturer in St Paul, MN.
  - Family owned with 210 employees
- Primary products: converted products and components
  - Innovize does not own any product designs
  - Printing, die cutting, laser cutting, laminating, assembly, and packaging
- Over 150 medical device customers
  - Over 2500 different products and components
- ISO 13485 and ISO 9001 Certified
- FDA registered with 35 finished medical devices
- CfQ VIP initial CMMI assessments and current participant

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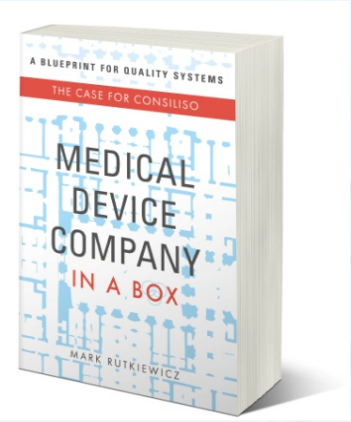
Bio – Mark Rutkiewicz



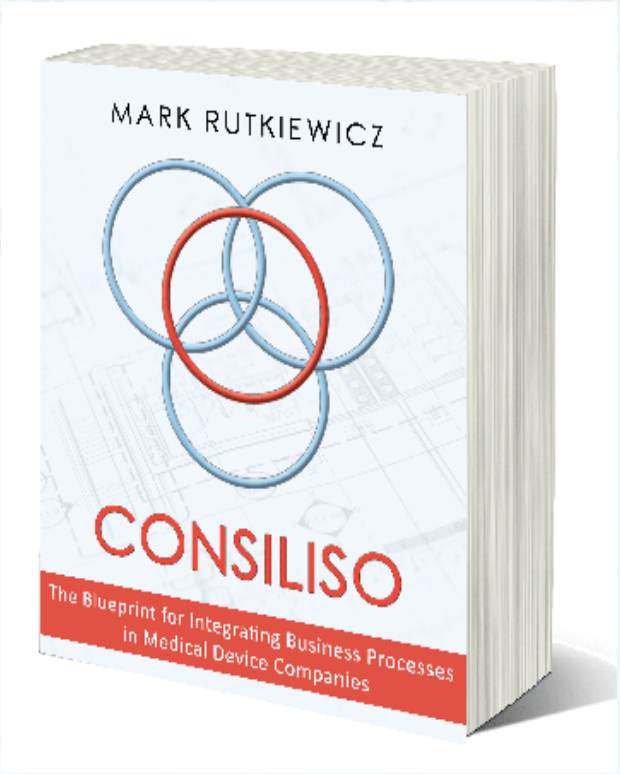
For over 30 years, Mark Rutkiewicz has managed most medical device company business processes. He has designed Quality Management Systems for active and non-active implantables, disposables, combo devices, software and capital systems.

Mark built and rebuilt online integrated corporate-wide quality/business systems.

Bachelor of Electrical Engineering from the University of Minnesota and a Masters of Applied Liberal Studies from Hamline University.

Since July 2013, Mark has been the VP of Quality at Innovize. He is on the MDIC's Case for Quality (CfQ) Voluntary Improvement Program (VIP) Governance Committee.

Author of two books on Consiliso, which define how to implement integrated business processes.



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