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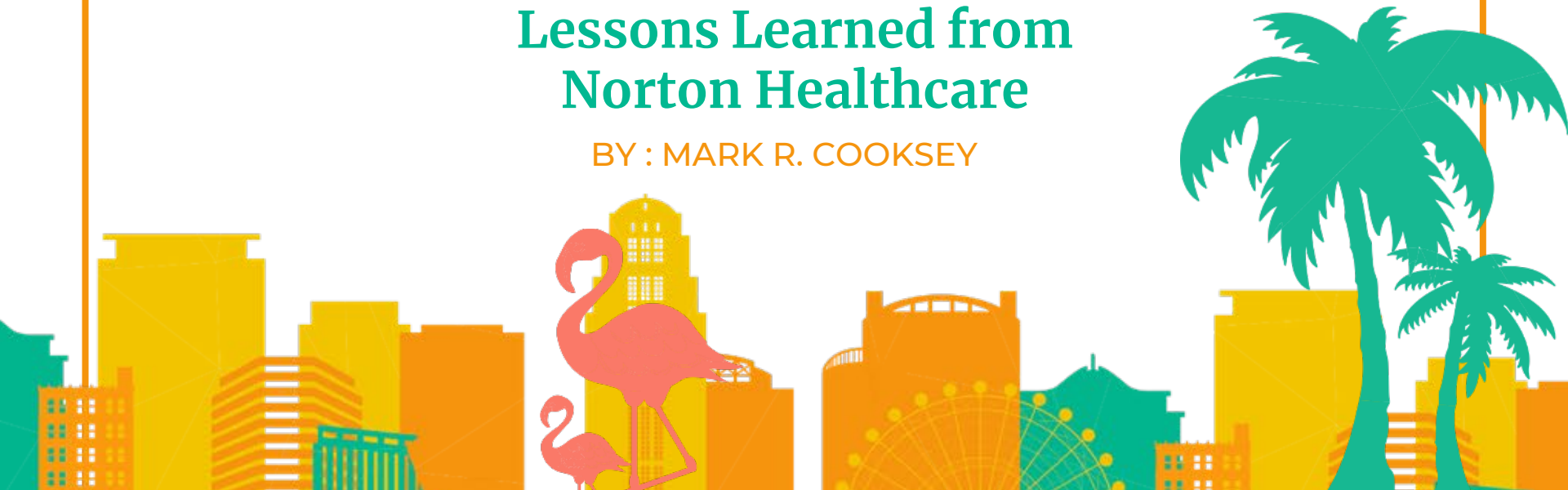
# Create an ISO 13485-ready QMS

## Lessons Learned from Norton Healthcare

BY : MARK R. COOKSEY



Meet “Crusty”

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**2003 Honda CRV**
228,000 miles
In the family-2003
Purchased:  2013
Cost:  $4,000

**Purpose Statement**: The quality management system (QMS) for the 2003 Honda CRV shall maintain its cost-effectiveness as a means of transportation

QMS for my 2003 Honda CRV

Let's Talk!

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# Orlando 2023

Mark Cooksey, DME Quality Engineer, Norton Healthcare

## Create an ISO 13485-ready Quality Management System: Lessons Learned from Norton Healthcare

**Tuesday, October 31, 4-5pm**

ISO 13485 is an often-misunderstood set of standards for a certified Quality Management System (QMS). ISO 13485 was created primarily for medical device manufacturers and has significant applicability to medical device servicers like Norton Healthcare Corporation's Clinical Engineering (NHC CE). NHC CE chose full implementation and ISO certification, but your company can reap significant benefits by creating an "ISO-ready" QMS today by leveraging existing systems and developing new processes to address common gaps such as vendor management and quality improvement. Come learn shortcuts to lead your organization to become an ISO-ready organization. It's closer than you think.

Welcome to MD Expo 2023!

# What you will take back

- Gain insight into ISO 13485
- Learn why Clinical Engineering sought certification
- Conduct QMS ISO Readiness Assessment
- Investigate implementation strategies
- See the benefits of an “ISO 13485-ready” QMS

# QMS

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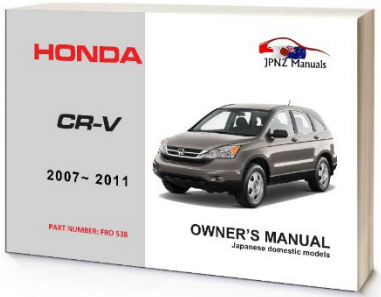
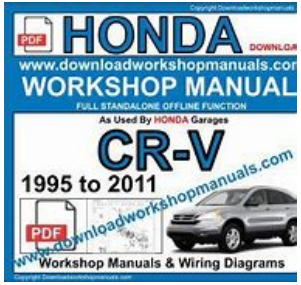



QUALITY MANUAL




QUALITY SYSTEM PROCEDURES

DIAGNOSTICS

REGULAR AUDITS

IMPROVEMENTS

What are the major QMS elements?

# ISO 13485 DOCUMENT HIERARCY

**Quality Manual** – Quality Management System Manual for all operations

**Policies** – Legacy and new ISO 13485 QMS Policies

**Procedures** – SOPs & new ISO Quality System Procedures (QSPs)

**Work Instructions** – Standard Work Instructions (SWIs)

**Records** – Used to show evidence of QSP compliance (CMMS, Training Logs, etc.)



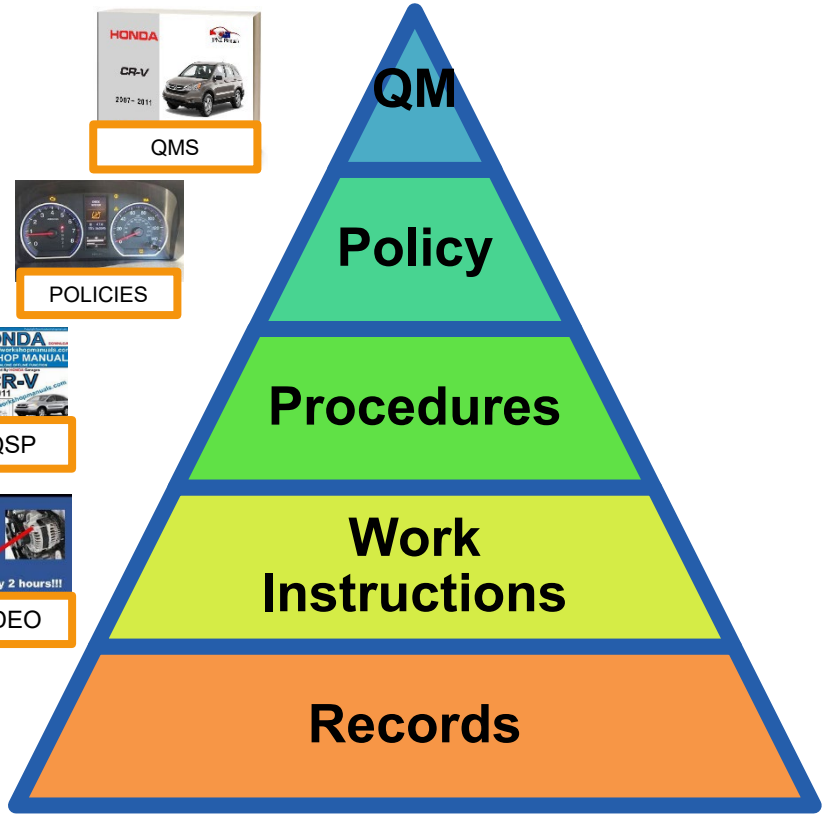
QMS


POLICIES

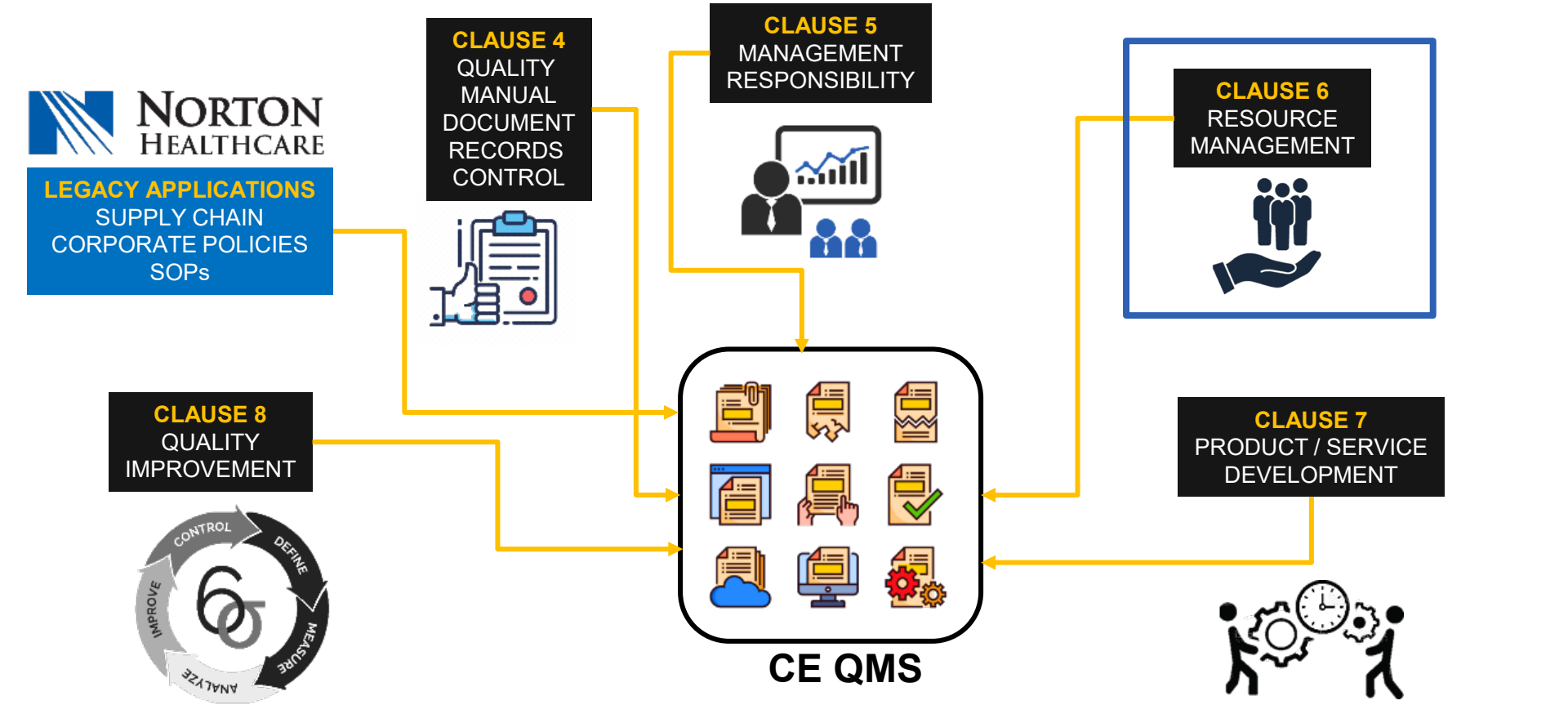
QSP

SWI VIDEO

AUDITS



# How Does an ISO 13485 QMS Work?



# Document Numbering

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**Quality Manual** – Quality Management System Manual for all operations

**Policies** – ISO 13485 QMS sub sections in QM

**Procedures** –Quality System Procedure (QSP)

**Work Instructions** – Standard Work Instructions (SWIs)

QM

POLICIES

QSP

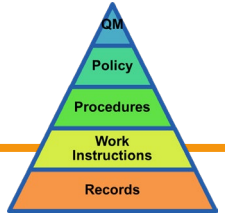
SWI VIDEO

**CLAUSE 6** RESOURCE MANAGEMENT

**SECTION 6.3** INFRA-STRUCTURE

**QSP 6.3-1** EQUIPMENT MAINTENANCE

**SWI 6.3-1.1** ALTERNATOR REPLACEMENT




Cascading ISO 13485 document numbering system

# Why ISO?

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**TJC**

FOCUS:
**ORGANIZATION**
OF QUALITY

**DNV**

FOCUS:
**QUALITY** OF
THE
ORGANIZATION

- **NHC accreditation moved to DNV**
- **DNV is ISO 9001-based**
- **NHC chose to align with ISO 9001**
- **Clinical Engineering chose ISO 13485**

**ISO 13485** is based on 9001 but specific to **device manufacturers** and **servicers**

Why did Norton seek ISO 13485?

# ISO Family

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9001 is a **general** quality model for continuous improvement

Norton Clinical Engineering

13485 is a quality model for **medical devices** incorporating **risk management**

13485 is complementary with 9001

# Getting Ready

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- Step 1 - Identify all *applicable* ISO 13485 clauses, sub clauses
- Step 2 – Assess readiness of each clause / sub clause
  - Scale of 1 to 5 (1=No evidence  5 = Well documented evidence
  - Questions:
    - Do you have specific [ISO 14585 QM, QSP, SWI] documents present?
    - Is there a set of procedures, processes, and training in place?
    - Are there records to support this?
- Step 3 – Develop strategies to close readiness gaps
  - Develop documentation
  - Develop training
  - Improved records management

# Getting Ready

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| | Section 1.0: Scope and Applicability | 1-5 Rating |
|---|---|---|
| 1 | Has your organization clearly defined the scope of your quality management system (QMS) with respect to the servicing of medical devices? | |
| 2 | Have you determined the regulatory requirements that apply? | |
| 3 | Are there procedures in place to review and update the QMS scope and regulatory requirements as needed? | |
| | **Section 2.0: Quality Management System** | |
| 4 | Do you have a documented quality management system (QMS) in place? | |
| 5 | Has your organization defined and documented its quality policy and quality objectives? | |
| 6 | Are there processes and procedures in place to manage documentation and records as required by ISO 13485? | |
| 7 | Is there a process for identifying and managing risks and opportunities related to the QMS and medical devices? | |
| | **Section 3.0: Top Management Requirement** | |
| 8 | Is top management committed to the establishment and continual improvement of the QMS for medical devices? | |
| 9 | Has a quality manual been established that outlines the structure of your QMS? | |
| 10 | Are there processes in place to ensure that all levels of the organization are aligned with and understand the quality policy and objectives? | |

ISO Readiness Assessment from AAMI course

# Section 4: Quality Management System

## READINESS QUESTIONS

- Do you have a quality manual for implementing and maintaining a QMS for medical devices?
- Management commitment with responsibilities and resources?
- Control of records & documents and QMS software validation.
- Documented evidence to support this?

Establishes the QMS management structure for medical device production and servicing.

# Section 5: Management Responsibility

## READINESS QUESTIONS

- Top Management's clear role in ensuring the effectiveness of the QMS?
- Established quality planning and management review?
- Documented evidence to support this?

Defines Top management commitment to quality and roles to support it.

# Section 6: Resource Management

## READINESS QUESTIONS

- Adequate resources (human, infrastructure, etc.) to support the QMS and medical device servicing?
- Training and qualification for effective equipment maintenance
- Documented evidence to support this?

Managing infrastructure: people, facilities & devices.

# Section 7: Product Realization

## READINESS QUESTIONS

- Active assessment of customer requirements?
- Supply chain monitoring: service, contracting, purchasing, receiving, inspection, and handling?
- ISO-ready functionality in place? (Installation, ESD protection, calibration, and risk management).
- Documented evidence to support this?

Developing, producing, or servicing medical devices, including (product) & process design and validation.

# Section 8: Measurement, Analysis, and Improvement

## READINESS QUESTIONS

- Do you monitor customer satisfaction and complaint handling?
- Do manage nonconformities with CAPAs (corrective and preventive actions)?
- Do you perform internal & external audits?
- Active Continuous Improvement to improve the QMS?
- Documented evidence to support this?

Monitoring, analyzing, and improving processes and product and servicing performance.

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## Average Readiness Scores

# Norton CE Readiness Profile (2020)

# Team Readiness 2020

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| | |
|---|---|
| Effective in-house medical device management | High |
| Senior leader champion buy-in | High |
| Understanding of ISO 13485 principles | Low |
| ISO-Based Quality System Procedure | Low |
| Applicability to existing systems | Low |
| Buy-in at local leadership level | Low |
| Buy-in at staff level | Low |

Senior Leader wanted aggressive 12 month implementation

# Implementation



- Realign Resources for ISO
- Hire Proven Change Agent Quality Leader
- Use ISO Consultant as developer and advocate
- Develop Leadership Champions
- Roll out quality training to entire staff
- Complete audits for accreditation

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**System Director, Clinical Engineering**
Scott Skinner

**Quality / ISO Leader**
Mark Cooksey

**Director, Biomedical Engineering**
Carlos Ramirez

**Director, Imaging & Med Device Security**
Doug Elmore

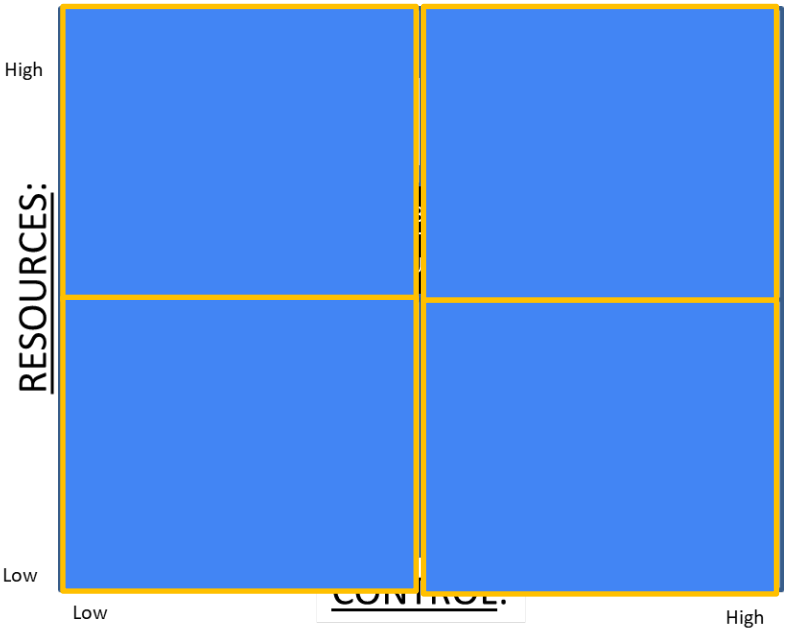
**Admin**
Anne Jefferson
Admin

Admin, ISO Support
Jackie Kininmonth
Admin, ISO Support

**Mark Cooksey**
30 Years Quality Leadership

Certified Lean 6 Sigma
Master Black Belt Trainer

# Leadership Realigned for ISO Implementation




# Various QMS Development Strategies

# Norton Strategy

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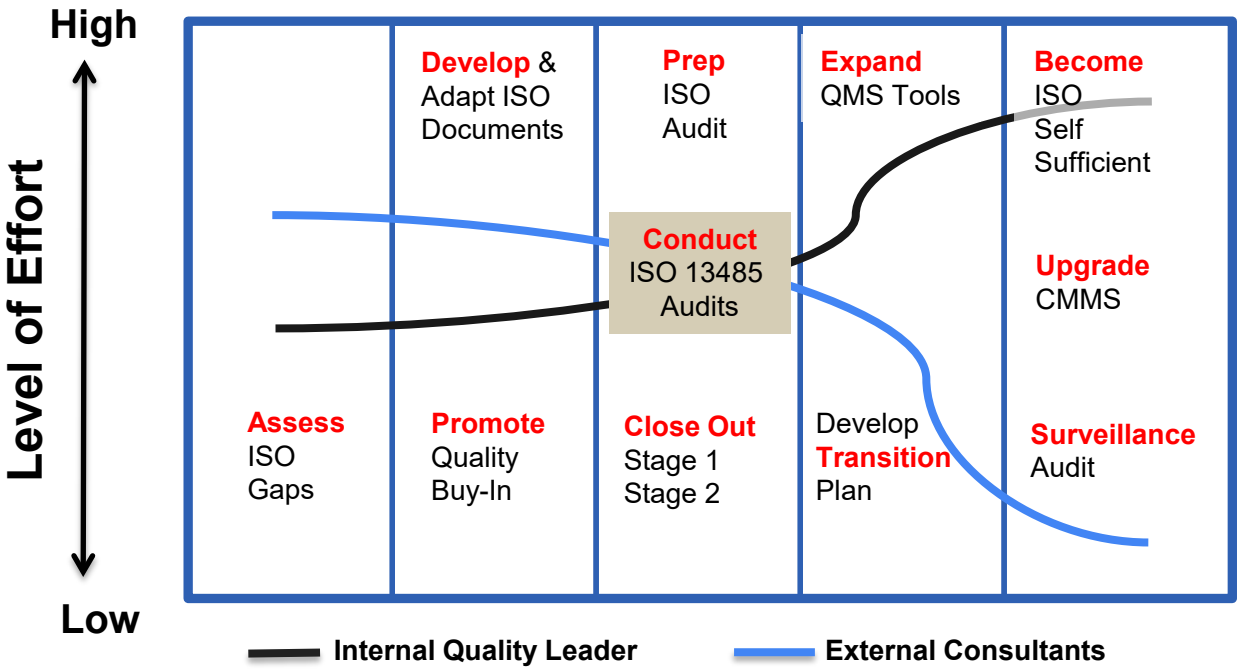


Partnership with ISO Consultant to close gaps

Off-site Training

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# ISO 13485 Quality Tools introduced to *entire* team

From ISO-Ready

to ISO 13485 - ***Certified***

1. Conduct ISO Gap Analysis
2. Develop ISO Compliant Documentation
3. Offsite training for ISO and Quality Improvement tools
4. Employ ISO consultant to get Norton ISO 13485 ready
5. Internal Audit by **EMERGO - UL**
6. External Audits by **Intertek**
7. Use Non-Conformities to improve Operations
8. Achieve certification
9. Maintain certification

# CE Payoff

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What have been the benefits of ISO 13485?

# Case Study: Technician-Led Quality Improvement

QUALITY TASK FORCE USES LEAN 6 SIGMA TOOLS TO IMPROVE ON CALL PROCESS

# QMS at Work

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## The Problem.

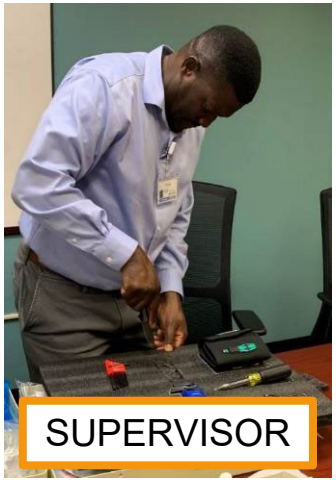
30% technician turnover combined with variations in tool storage impacted weekend “on-call” coverage.

## The Solution.

Quality Task Team assigned to solve system-wide problem

**Task Force Converted Discarded Carts to 5S Tool "Crash Carts"**

- Improved Tool Access
- Standardization
- Productivity
- Conformity to Standards



STANLEY
CONTROL GRIP
IRWIN
VISE-GRIP
CHANNELLOCK

STANLEY

PHILIPS

CHANNELLOCK
ADJ WRENCH
VISE GRIPS
NEEDLE NOSE
ELEC PLIERS

## Payoff: Techs

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- Supports ISO 13485 Quality Planning and auditing
- Practical Quality Improvement - team building
- Collaborative effort – directors, supervisor, staff
- Tangible application of Lean concepts
- Standardized tools yet adaptable for unique hospital devices (adult vs. infants)
- Quick solution / High buy in

Benefits of 5S Tool “Crash Carts”

## Payoff – CE Leaders

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Promoting quality culture at *all* levels

# Payoff - ISO 13485 Supports Norton Healthcare's Growth

## 50% MARKET SHARE

**Louisville employer rankings, according to Forbes**

1 Norton Healthcare (18,000 employees)
8. Baptist Health (Kentucky) (23,000)
9. Humana (67,100)
13. Brown-Forman (2,600)
18. Texas Roadhouse (82,000)
24. University of Louisville (7,016)
39. KentuckyOne Health (12,000)

**Top 5 employers in Kentucky, according to Forbes**

1. University of Kentucky (12,000 employees)
2. U.S. Department of the Treasury (100,000)
3. Norton Healthcare (18,000)
4. Microsoft (122,000)
5. Flowers Foods (13,200)

**1,993** licensed

**18,000** employees

**1,700** providers

4,200,000 patient visits = 55,000 medical devices

# Payoff - HTM Professionals

Sharing NHC ISO 13485 journey with HTM the nation-wide

## Purpose Statement

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Clinical Engineering ***maintains and supports*** Norton Healthcare's **clinical technology** to ensure the best possible patient outcomes through risk reduction, continuous quality improvement, stewardship of resources, compliance with regulatory requirements, and exceptional customer service."

ISO 13485 helps CE live out its Purpose Statement

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# THANK YOU!

## CONTACT ME

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MCOOKSEY6@GMAIL.COM
(502) 554-5206

# What did we do today?

- Gained insight into ISO 13485
- Learned why Clinical Engineering sought certification
- Conducted QMS ISO Readiness Assessment
- Investigated implementation strategies
- Saw the benefits of an “ISO 13485-ready” QMS

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# We value your feedback!

Please scan the QR code to submit a survey for this session.

**Thank You!**

Which Comes First?

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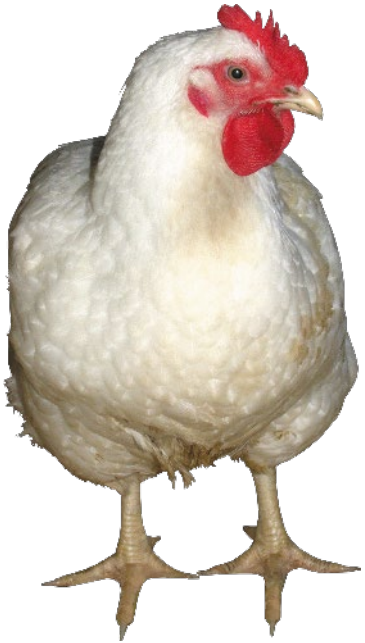


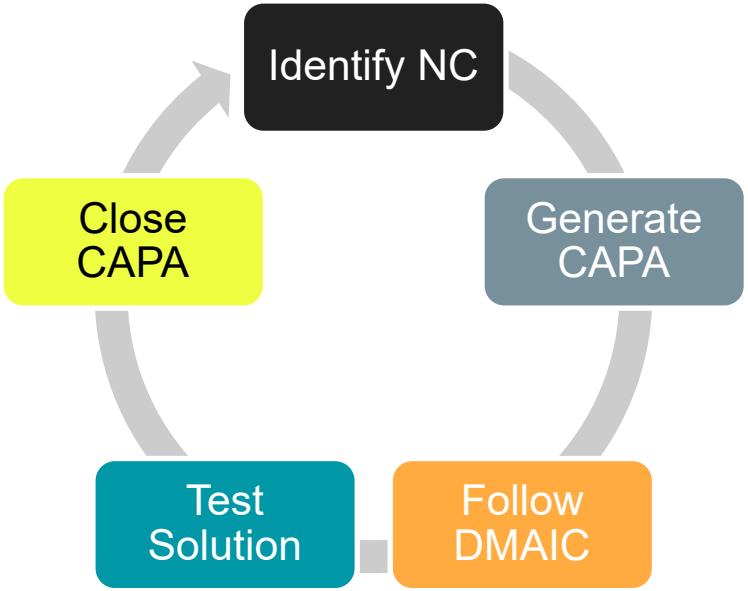
Quality Management System or Quality Tools?

# Better Problem Solving



PRE-ISO 13485

POST-ISO 13485



# DMAIC

The Lean 6σ DMAIC Process

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| DEFINE | MEASURE | ANALYZE | IMPROVE | CONTROL |
|---|---|---|---|---|
| Define the Problem | Measure the Current State | Identify Causes | Brainstorm Solutions | Monitor New Process |

## Lean 6 Sigma Problem Solving

# Best Practice: sdix Highlights its ISO 13485 certification

An ISO 13485 certified Immuno-solutions company.

sdix
An OriGene Company
ISO 13485:2016 CERTIFIED

Home Products & Services

## About Us

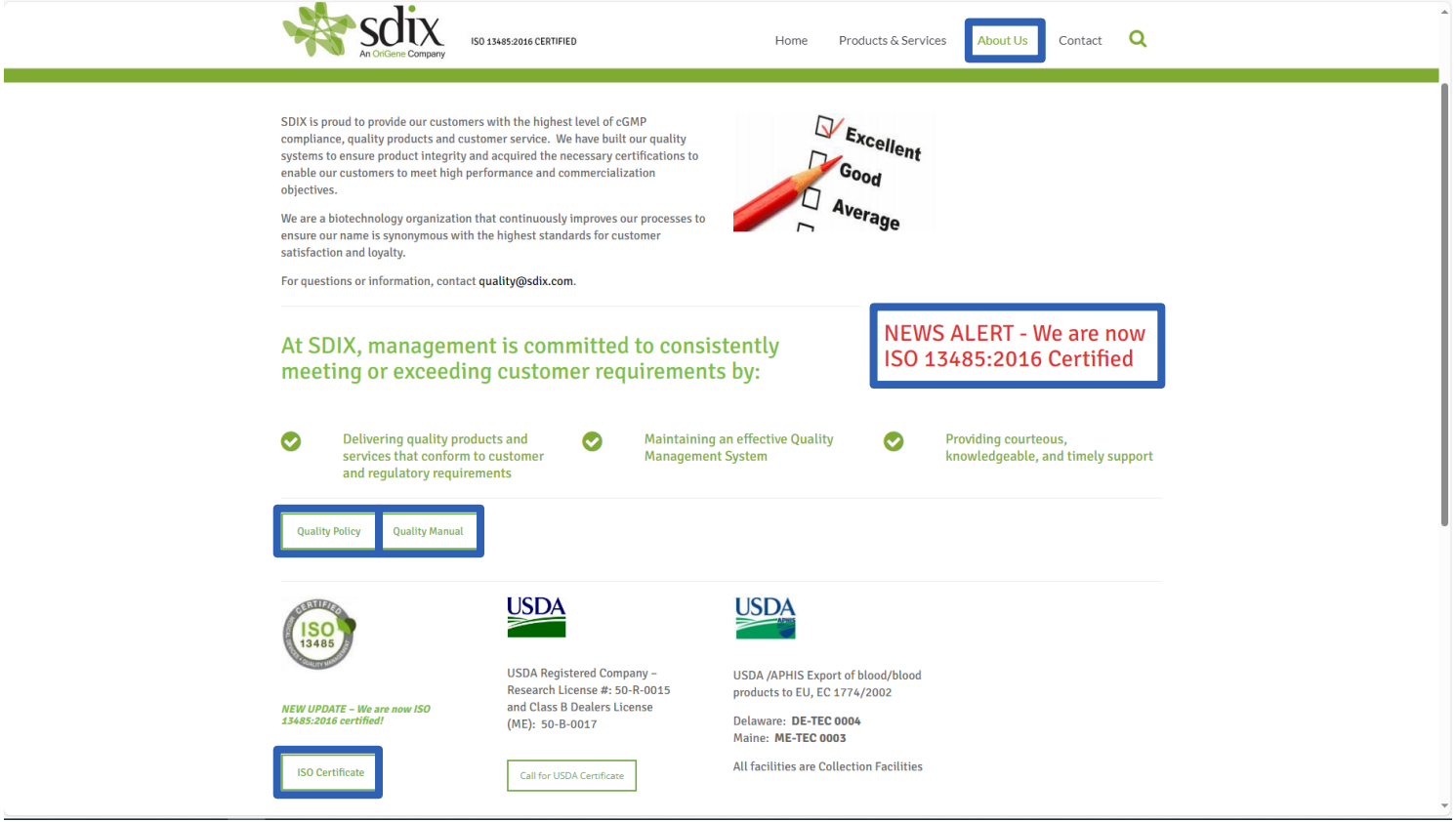
### About SDIX

SDIX is a wholly owned subsidiary of **OriGene Technologies**, specializing in high quality, large-scale GMP antibody production in the U.S, Delaware and Maine.

For over 30 years, SDIX has been a leading immuno-solutions company, developing results-oriented and innovative antibody-based solutions that enable customers, world-wide, to meet high performance diagnostic and commercialization objectives. All sites are ISO 13485:2016 certified.

Products include critical reagents such as antibodies to Troponin I, Strep A, CRP, Apo A1, ApoB, Micro-albumin and Calibrators. SDIX's services include Polyclonal Development and production in a variety of species as well as large-scale Monoclonal Antibody Production (ascites and in vitro).

# ISO 13485 is front and center



# Quality Policy

***At SDIX, management is committed to consistently meeting or exceeding customer requirements by:***

***Delivering quality products and services that conform to customer and regulatory requirements***

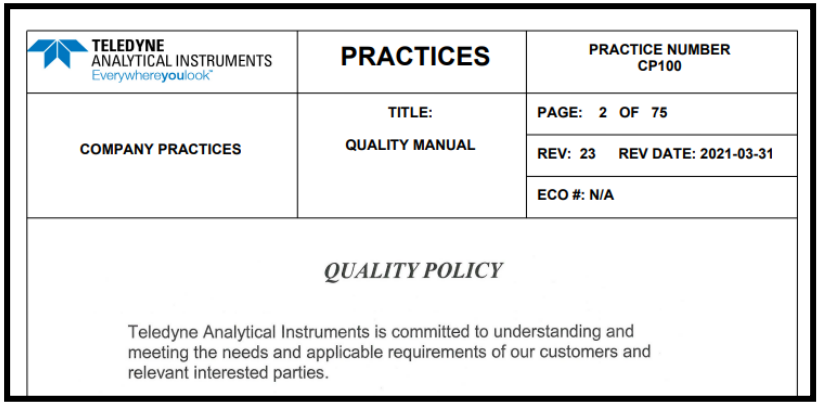
***Maintaining an effective Quality Management System***

***Providing courteous, knowledgeable, and timely support***

***We are a biotechnology organization that continuously improves our processes to ensure our name is synonymous with the highest standards for customer satisfaction and loyalty.***

*Rev. 0.2*

# ISO 13485 Quality Manual Examples



TELEDYNE ANALYTICAL INSTRUMENTS
Everywhereyoulook™

| | | |
|---|---|---|
| | **PRACTICES** | **PRACTICE NUMBER** CP100 |
| **COMPANY PRACTICES** | **TITLE:** **QUALITY MANUAL** | **PAGE: 2 OF 75** |
| | | **REV: 23 REV DATE: 2021-03-31** |
| | | **ECO #: N/A** |

***QUALITY POLICY***

Teledyne Analytical Instruments is committed to understanding and meeting the needs and applicable requirements of our customers and relevant interested parties.

exsurco® medical

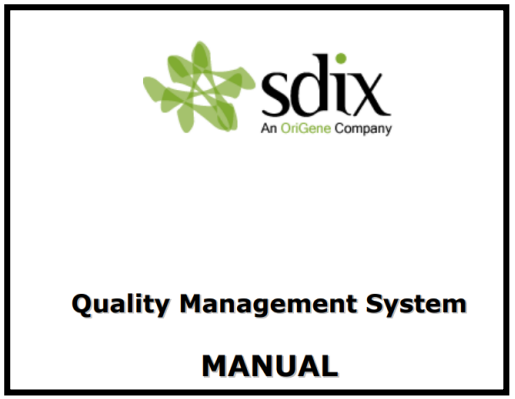
QUALITY SYSTEM MANUAL

ISO 13485 U.S. QSR (21 CFR 820)

***JADE PRECISION MEDICAL COMPONENTS, LLC***
*105A James Way*
*Southampton, PA 18966*

PRODUCT RESOURCES
DESIGN – BUILD – SERVICE

**Quality Management**
**System Manual**
**for ISO 13485:2016**



sdix
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**Quality Management System**

**MANUAL**