

Compliance – is free!

If you start with real quality

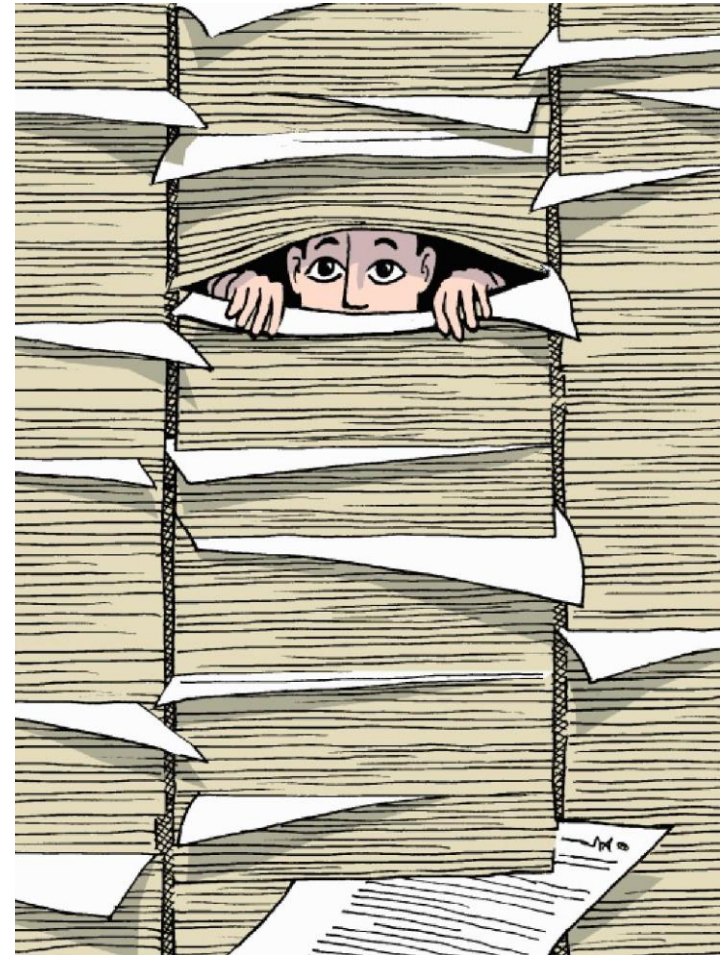
FDA is leading a movement from “Compliance” to “Quality”

It is very good news 😊

It is bringing quality, professionalism and responsibility back where it belongs.

And it saves money....

Morten Korsaa, Whitebox (Jørn Johansen, Whitebox)



Whitebox - selected references 2015-2018

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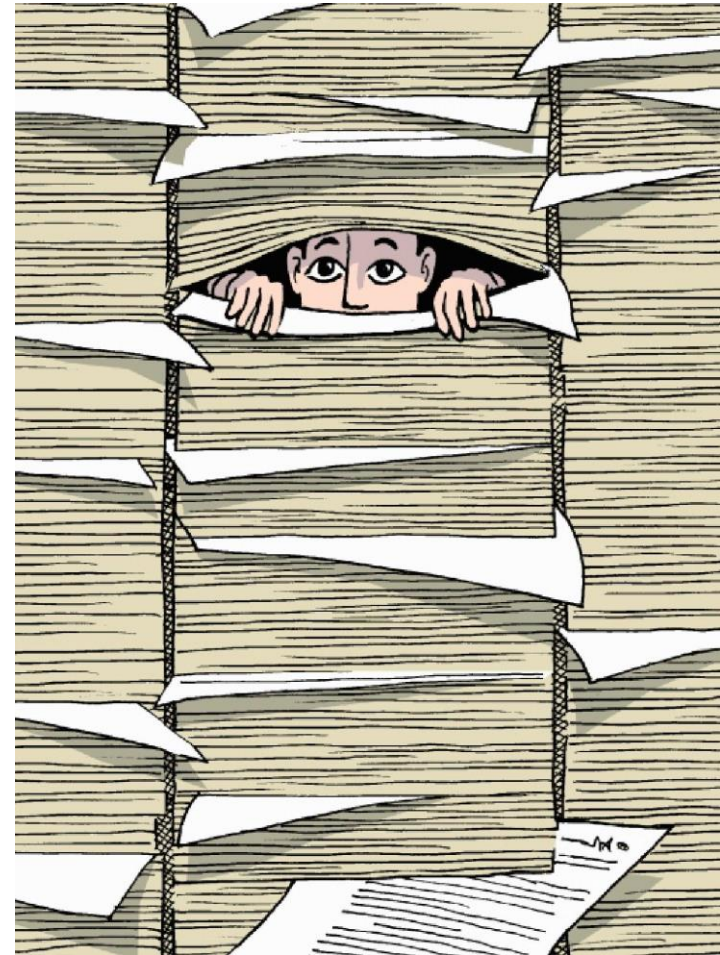
pedersen&nielsen
automobilforretning a/s
Det naturlige valg...

Agenda

- ◉ What went wrong

Workshop

- ◉ The history of Case for Quality
- ◉ The new approach
- ◉ Assessment style
- ◉ Experiences
- ◉ Plans





What went wrong?

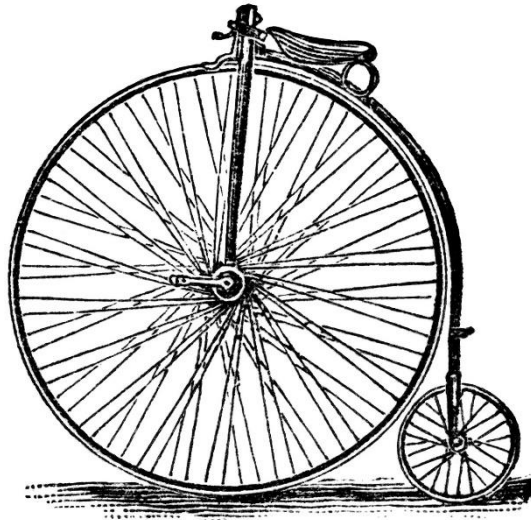
Whitebox unfiltered and subjective analysis of where the chain fell off

Important for the solution discussion

The obvious exponential increasing value of quality

Quality = Fitness for use [Juran]

Quality = Conformance with Requirements [Crosby]



Exponential increase in

- Value
- Number of parameters
- Describing difficulty
- Importance to safety
- Competence required
- Cost of bad quality

The not so obvious Quality deroute!

- ◉ Cost of quality (!)
- ◉ Quality definition
- ◉ Best practices
- ◉ Standards
- ◉ Compliance
- ◉ Audits



Cost of Quality

Wrong assumptions:

- Quality means “good-nes”, “luxury”, ...
- Quality is intangible –hence not measurable
- “Economics of Quality”
 - We can’t afford to get to good!
- The quality problems are originating from the workers
- Quality is originated in the Quality department

These assumptions left the industry with a general fear of the cost of “too much quality”!

-> Do as little as possible!

What happened on the Quality deroute implications

- ◉ The “Delegation of responsibility” trap
- ◉ The “One Size Fits All” regulation trap
- ◉ The “Cheating” trap
- ◉ Other obstacles



The “Delegation of responsibility” trap

Delegation of responsibility for quality



Quality leadership



“Quality” department



Compliance driven

- ◉ Has a manager who is “responsible” for the quality
- ◉ Maintains certificates
- ◉ Operating through a QMS
- ◉ Is checking “quality”

Quality driven

- ◉ Is driving quality
- ◉ Focus on prevention of problems
- ◉ Supporting management
- ◉ Supporting projects
- ◉ Competence focus

The “One Size Fits All” trap

Because

- The requirements for the business must be equal to all
- The requirements must fit all situations

->

- The regulation must be generic and cover everything

->

- Something will be seen as irrelevant to some businesses

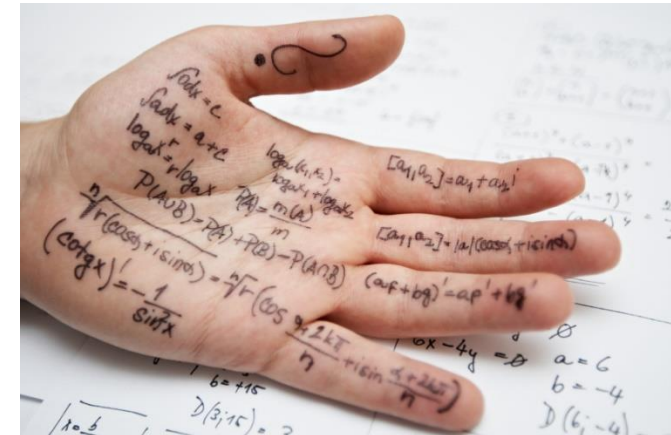


The “cheating” trap

- Quality is originally about being proud/excellent/professional/...

But the moment it was introduced as a compliance requirement to an organization

- Deep in the hearts of engineers, compliance was not recognized as true quality
- Quality became an annoying impediment of no value
- Audits was introduced to ensure compliance
- The cheating culture started
- An absolute “non quality attitude”!



Tipping point???

Jeffrey Shuren, FDA, Director CDRH:

- “We clearly were not successful in ensuring the products where high quality”
- “Compliance with FDA requirements are important, .. ,but it does not ensure that we have manufacturing and product quality”
- “What could we(FDA) do to drive a shift from a compliance mindset to a quality mindset”
- “We are applying several principles: First, we will use a maturity model(CMMI) appraisal as opposed to a compliance model. Second,”
- Proposes a review of the entire inspection process to ensure that focus is on where it is needed the most

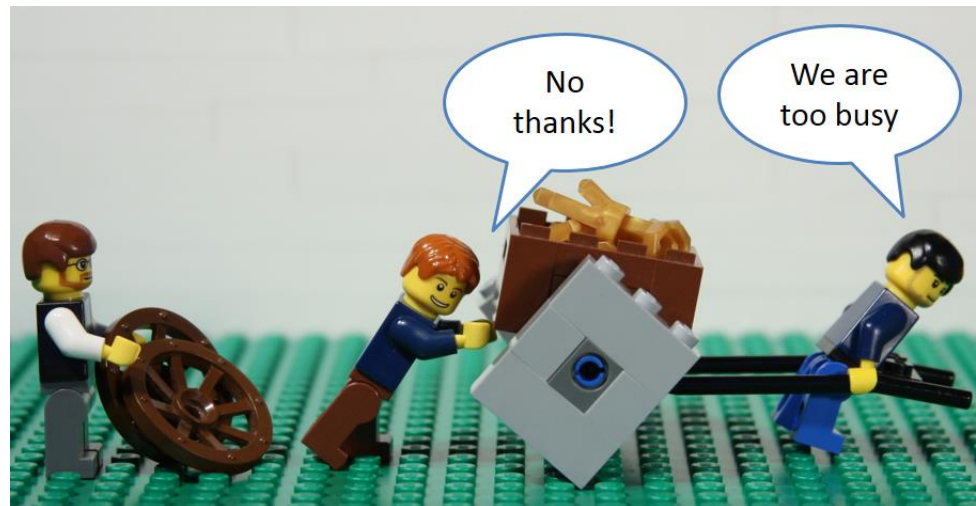


[FDA's workshop 10/10-2017]

The great quality relief

It all started with an obsession for quality. Let's get back to that.

- Step 1. Remember the intention behind the regulatory requirements.
- Step 2. Build the competences you need to deliver good quality and be proud of it.
- Step 3. Compliance will be a little (1,5%) add on to a development **COST**, (that by the way has decreased 40% due to a better performance).



Join the workshop after lunch!

- ◉ Are you interested in an alternative view on compliance and quality?
- ◉ What if compliance was for free, if achieved for the right reason??
- ◉ What is going on in FDA right now?
- ◉ What can you do to support the change?
- ◉ What is the new role of “Quality / RA / ..” ?
- ◉ What does this mean to the industry?

Workshop Community 9: Trends & Challenges in Medical Device Industry

Working on the “EuroSPI 2019 – Medical device workshop’s” take on:

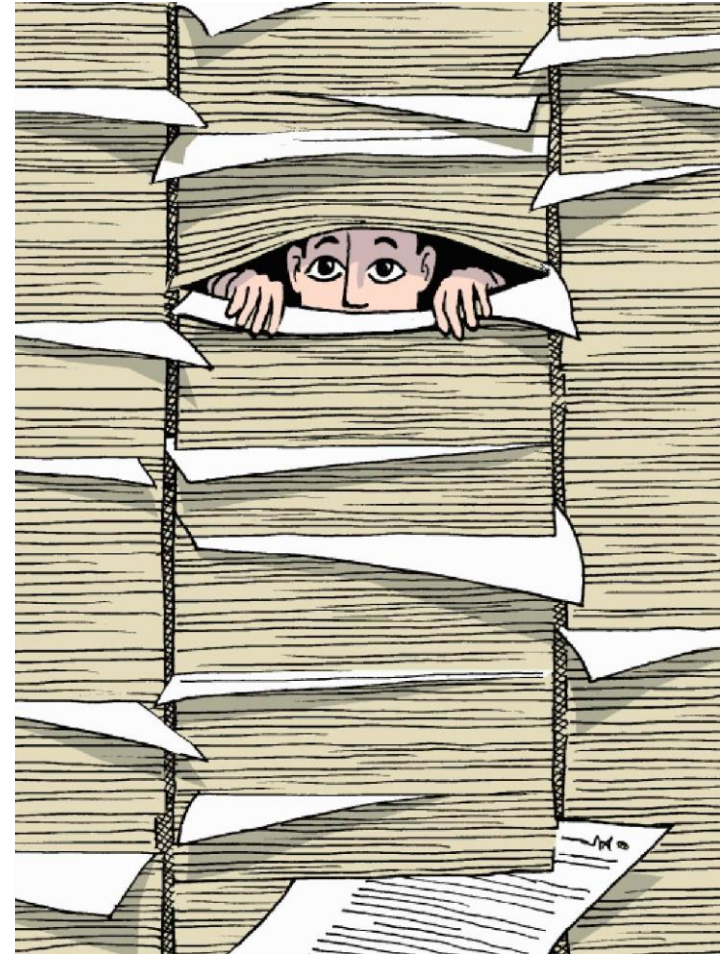
- Is “Case for Quality” good or bad ?
- What is the expected implications for
 - The industry?
 - Medical device professionals?

Agenda

- ◉ What went wrong

Workshop

- ◉ The history of Case for Quality
- ◉ The new approach
- ◉ Assessment style
- ◉ Experiences
- ◉ Plans



The FDA's Case for Quality: Enabling Improvement in the Medical Device Industry

The history – so far

CASE FOR QUALITY

FDA, 2010'ish: Hmmmm.....

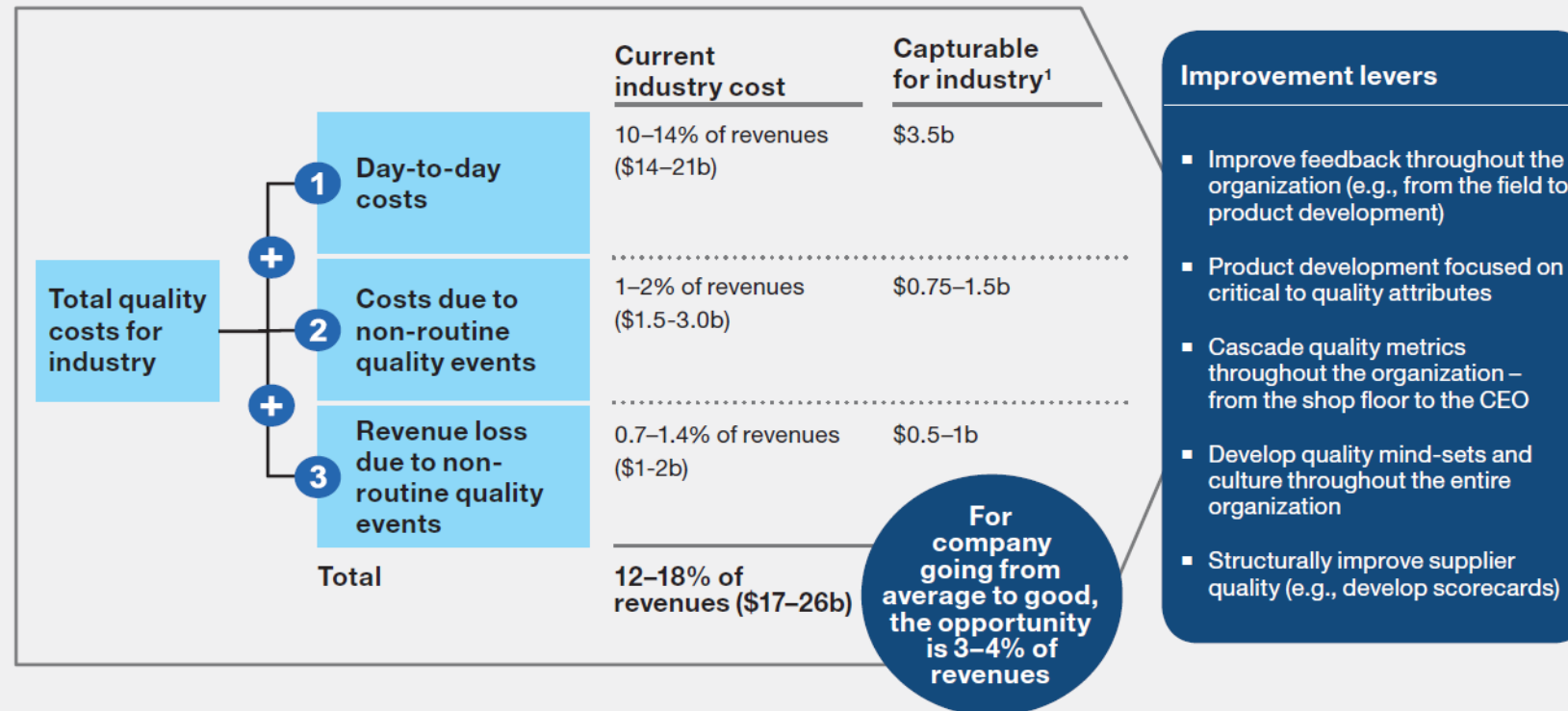
- ◉ We have manufactures who have no regulation issues, but do have quality issues!
- ◉ We have manufactures who have regulation issues, but no quality issues!
- ◉ Are we driving the right attitude?



Is quality good business??

2013 - McKinsey report:

Exhibit 5 | The opportunity to improve the total quality costs for the industry is \$4.75–\$6b



Looking for a framework to support quality

June 2015



Recommendations

Maturity Model Research Report

It is recommended that CMMI be leveraged as the basis for the development of a quality system maturity model for Medical Devices. CMMI has been successfully implemented in multiple regulated industries and includes a significant number of elements that are applicable to Medical Devices. Other industries have

Page 5 of 37

This research analysis was prepared for MDIC's use and consideration; this report has been developed for informational and educational purposes.

March 2017

FDA Business Investments

OIM-10- DOS-ELMS- AWQA-110	Agency Wide Quality Assurance Support Contract to provide Division of System under FDA's OIM ability to define, create, standardize Quality Assurance and related practices for critical project leading to an improved overall application quality. Implementation strategies and plans for a comprehensive CMMi and overall Metrics plan	60 months	\$5-\$10M	Q3
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<https://www.fda.gov/AboutFDA/business/ucm1157439.htm>



Oktober 2017

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Strengthen Product and Manufacturing Quality within the Medical Device Ecosystem

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Description: CDRH 2016-2017 Strategic Priority: Promote a Culture of Quality and Organizational Excellence

Definition: Goal: Strengthen Product and Manufacturing Quality within the Medical Device Ecosystem

Briefing Status: ON TRACK

Prior Briefing Status: ON TRACK

Milestone Description	Milestone Date	Milestone Status	Milestone Completion Date
A. By September 30, 2016, develop metrics, successful industry practices, standards, and tools that manufacturers can use to evaluate product and manufacturing quality beyond compliance with regulatory requirements.	9/30/2016	Completed	9/30/2016-Partnered with MDIC to develop metrics and best practices to assess quality system performance, and analytical tools to assess device quality by hospital value analysis committees.
B. By December 31, 2016, pilot voluntary use of product and manufacturing quality metrics and evaluation tools.	12/31/2016	Completed	12/31/2016-Partnered with MDIC and Capability Maturity Model Integration (CMMI) Institute on a proof-of-concept and pilot with three device manufacturers, to evaluate use of the CMMI appraisal process as a foundation for a future third party program.
C. By December 31, 2017, propose a voluntary program to recognize independent evaluation of product and manufacturing quality.	12/31/2017	ON TRACK	

Highlights from FDA's workshop 10/10-2017

Jeffrey Shuren, FDA, Director CDRH:

- “We clearly were not successful in ensuring the products were high quality”
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Highlights from FDA's workshop 10/10-2017

Stephanie Christopher – MDIC Medical Device Innovation Consortium

- "It's a movement"
- "..not just another checkbox activity"

About MDIC

MDIC is the first-ever public-private partnership (PPP) created with the sole objective of advancing medical device regulatory science.

• We are a nonprofit 501(c)(3) organization that operates in partnership with the FDA to improve the medical



Workshop topic 1







- ◉ Is the intentions behind “Case for Quality”
 - Valid ?
 - Pointing in the right direction?



The new approach

MDDAP: Medical Device Discovery Appraisal Program

MDDAP: WHO ARE THE STAKEHOLDERS?

Organization	High Level Roles for Pilot	
	Pilot Steering Committee	Provides leadership, direction and pilot process input
	FDA	Provides regulatory modifications, verifies participants, reviews detailed findings and improvement, provides pilot process input
	MDIC	Coordinates working groups of enrollment, appraisal, metrics, communications and program oversight; provides pilot process input
	Appraisers	Execute appraisals, provide findings to participants, executes checkpoints, provides full datasets to coordinating center, provides pilot process input
	Participating Device Manufacturers	Receives appraisals, drives improvements within business, participates in checkpoints to report progress, provides pilot process input
	CMMI® Institute Program Management Office	Provides model, manages enrollment/de-enrollment, provides playbook for appraisers, provides appraiser training, connects appraisers to participants, adjusts appraisal scope as necessary, assures appropriate appraisal and appraiser consistency, collects appraisal data, trends data, provides deidentified data to participants / steering committee, manages appraisal issues, adjust approach based on feedback from steering committee and stakeholders

Regulatory benefits:

Medical Device Manufacturers in this program will receive regulatory benefits:

Inspections



- Facility is removed from routine inspection
- Facility is removed from risk-based work plan

30-Day Change Notices



- Streamlined submission
- Bundle multiple products & changes
- Accelerated approval – 48 hours

Site Changes



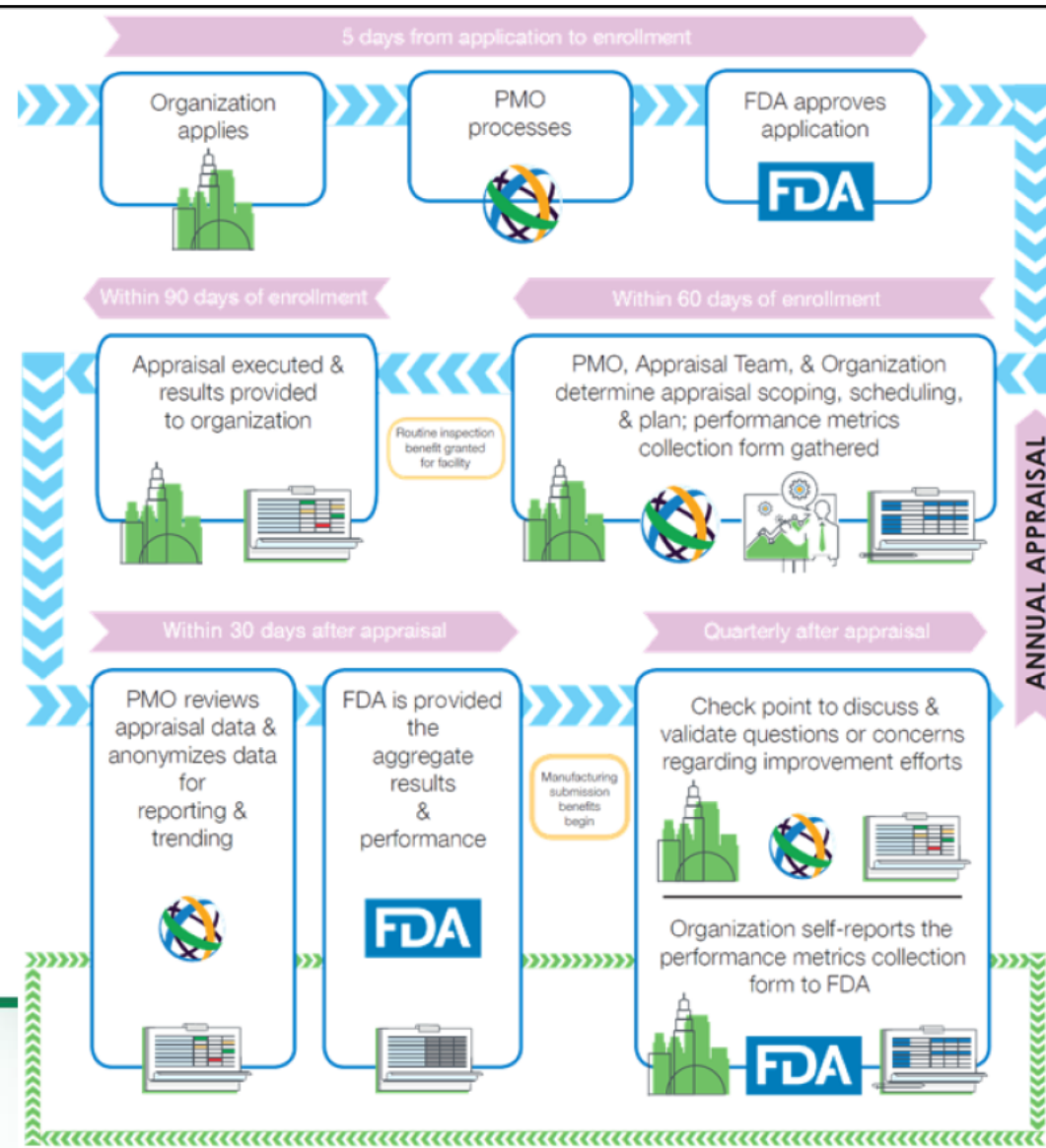
- Streamlined submission
- Accelerated approval – 1 week

PMA Manufacturing Section



- Streamlined submission
- Waive pre-approval inspection

These benefits reduce the burden and disruption of audits, accelerate the review and approval process for changes, and shift resources to innovation and improvement.



Pilot programs – so far (June 2019):

Program Adoption



Appraisals Executed

44 all time
9 YTD



Appraisers in Program

20 current, 20 pending

Facilities Enrolled

45 actively enrolled
over 22 Companies



Time from Enrollment to Appraisal

116 days (Y2 – 369 days)



Trained Embedded ATMs

37 participants
9 FDA



Pilot programs – so far (June 2019):

Program Effectiveness – Baseline Appraisals

(199 survey respondents)



**Value to
product quality**
yes: 85.4%



**Appraisal has
value add**
yes: 94%

**Experience
with appraisal**
91% positive
9% neutral



**Conflict with
compliance**
no: 98%



Recommend pilot
NPS +54
(n = 46)



MEDICAL DEVICE
DISCOVERY APPRAISAL
PROGRAM

Pilot programs – so far (June 2019):

Program Effectiveness - Reappraisals

(37 survey respondents)

Experience with appraisal

96% positive

4% neutral



Impact to product quality

- Better knowledge of what product quality is and how to produce it
- Common language across teams, improved communication
- Better process improvement, different perspective = new ideas
- Pathway towards risk mitigation of nonconforming products
- Increased customer satisfaction, reduction in waste (time/product)
- Increased rigor and predictability in new product development
- Greater focus and understanding of measurement systems

Recommend pilot


NPS +70


(n = 37)




MEDICAL DEVICE
DISCOVERY APPRAISAL
PROGRAM

Pilot programs – so far (June 20 2019):

June 20 Case for Quality Forum: Update from CDRH

Watch later Share

CDRH Pilot Details To Date



Current Pilot Statistics

- 51 Accepted sites
 - 45 Active Sites/23 Companies
 - 5 Multi-site appraisals
 - FDA recognized small businesses
 - All types of product risk classifications at site
- Additional enrollments
 - Non-regulated site
 - Pharmaceutical only sites

Inspection Metrics

- Routine Inspections Waived: 46
- Pre-Approval Inspections Waived: 5
 - For causes that occurred: 4
 - No observations
- Foreign sites: 16

Observations

- Increased industry investment
- Cross-training and collaboration
 - Practice sharing
- Focus on culture
- Issue resolution and patient safety focus

MORE VIDEOS

Pilot programs – so far (June 20 2019):

CDRH Pilot metrics to date

FDA



CDRH Metrics

- 60+ Modified change notices reviewed
- 73% Reviewed in 5 days or less
 - Average review time (3.2 days)
- Issues observed
 - Some submissions needed extra expert consults
 - Expanding product areas
 - Submission tracking/visibility
 - Variability in review focus
 - Training
 - Communication

Site transfer

Streamlined site transfer submission developed by CDRH reviewers

- Target: 180 days → 10 business day review
- First site change
 - 95 Days
 - Internal communication
 - Resource
 - Training
- Second site change
 - 13 Days


Improvement Activities at CDRH

- Improving training on pilot
- Improve clarity and expectations
- Increasing engagement with review teams
- Improving incoming submission tracking/communication
- Improving results sharing across review teams


Pause (k)

Communicate: CaseforQuality@fda.hhs.gov

Pilot programs – so far (June 20 2019):




June 20 Case for Quality Forum: Update from CDRH




What's Important to You?

Pilot impact metrics

Value analysis was based on data provided based on comparison to traditional compliance audits and an average manufacturing change implementation improvement of 21 days for pilot sites as compared to non-pilot sites



FDA



Manufacturers

Patients/Providers

- 37% of manufacturing changes were to improve product quality and were implemented 21 days faster
- Increase in manufacturer improvement submissions, including changes to reduce manufacturing defects
- 882 High-risk patients received treatment due the 21 day difference → Greater than \$10 Million dollar savings in annual healthcare costs
- Increase implementation of manufacturing automation to improve traceability and error-proofing (18%) of changes
- Defect reductions (99 PPM → 19 ppm)

FDA

- Increase in submissions to improve product quality
- Increased engagement on process improvement
- Improved submission decision consistency
- Increased sponsor engagement
- Increased resource visibility and allocation for inspections and reviews
- Improved impact traceability
- Improved data-analytics on changes, products, and sites
- Best practice sharing among manufacturers
- 11 – 46% Improvement in performance over 1 year

Manufacturers

- **Assessment costs**
 - FDA/ MDSAP: \$140-350K – Site operations disrupted
 - Pilot appraisal: Less than \$80K – No operation disruptions
- **Reported change notice value examples**
 - \$286 K Annual savings
 - 10 Dedicated inspection employees reallocated to higher value operations due to improvement
 - 11% Production capacity increase → Greater than \$15 million in product sales
- **Strategic/systemic improvement implementation vs compliance resolution**

MORE VIDEOS

www.fda.gov 14:01 / 37:14

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Pilot programs - experience

MDDAP: PROGRAM EFFECTIVENESS METRICS (05APR2018)

- **Did the appraisal identify areas or processes that could improve how work is performed to increase product quality?**
91% YES | 9% NO
- **Did the appraisal practice areas conflict with any regulatory compliance assessment areas?**
98% NO | 2% YES
- **Did you find the appraisal to be of value?**
100% YES | 0% NO
- **Would you recommend this program?**
100% YES | 0% NO

Workshop topic 2

- ◉ Will the benefits from joining “Case for Quality” be worth the effort?
- ◉ What would be the major obstacle to join?

	1.1	1.2	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	66%
Estimating (EST)	S		S	S	P	S					92%
Planning (PLAN)	S	S	P	P	P	P	S	S	P	D	98%
Monitor and Control (MC)	S	S	P	P	P	P					57%
Configuration Management (CM)	P		P	S	S	S	D	S			62%
Managing Performance and Measurement (MPM)	S	S	S	S	S	S	S	P	S		80%
Requirements Development and Maintenance (RDM)	P		S	D	P	P	P	D			38%
Process Quality Assurance (PQA)	P		P	P	S	S					60%
Governance (GOV)	S		S	S	P	P					72%
Implementation Infrastructure (II)	S		S	S							90%
Product Integration (PI)	S		D	P	P	S	S	S			62%
Technical Solution (TS)	P		P	S	S						65%

S Detailed
 P Partial
 D Deficient

Assessment style

MDDAP: WHAT DOES THE PROGRAM LOOK LIKE?

Onboarding and Scoping

- Kick-Off Call with PMO
- Intake Call & Follow-up Scoping Calls
- Sampling method for devices
- Identifying Appraisal Participants
- Determining Appraisal Schedule
- Plan reviewed with Org and PMO
- Submission of Quality Metrics to FDA

Lessons Learned: Inspection benefit moved until after appraisal is scheduled, allows FDA time to implement & ensures org engagement
Program kick-off meeting
Training created to expand appraiser bench

Appraisal Execution

- 5 days, 2+ appraisal team members
- CMMI and Medical Device Experience
- Includes tour of the facility for context
- Interview-based, limited doc review
- Conversations with those who do work
- Validation sessions
- Final results belong to organization
- Org identifies weaknesses to focus on

Lessons Learned: Intake/scoping templates, standardized heatmap tool, post-appraisal survey, unique individual journey, mentorship

Process scope and what the organization see

MDDAP: DATA SHARING (ORGANIZATION VIEW)

Full scorecard and specific results against model

	1.1	1.2	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	66%
Estimating (EST)	S		S	S	P	S					80%
Planning (PLAN)	S	S	P	P	P	P	S	S	P	D	56%
Monitor and Control (MC)	S	S	P	P	P	P					57%
Configuration Management (CM)	P		P	S	S	S	D	S			63%
Managing Performance and Measurement (MPM)	S	S	S	S	S	S	S	P	S		84%
Requirements Development and Maintenance (RDM)	P		S	D	P	P	P	D			36%
Process Quality Assurance (PQA)	P		P	P	S	S					60%
Governance (GOV)	S		S	S	P	P					70%
Implementation Infrastructure (II)	S		S	S							90%
Product Integration (PI)	S		D	P	P	S	S	S			63%
Technical Solution (TS)	P		P	S	S						65%

S	Satisfied
P	Partial
D	Deficient

... and what FDA see

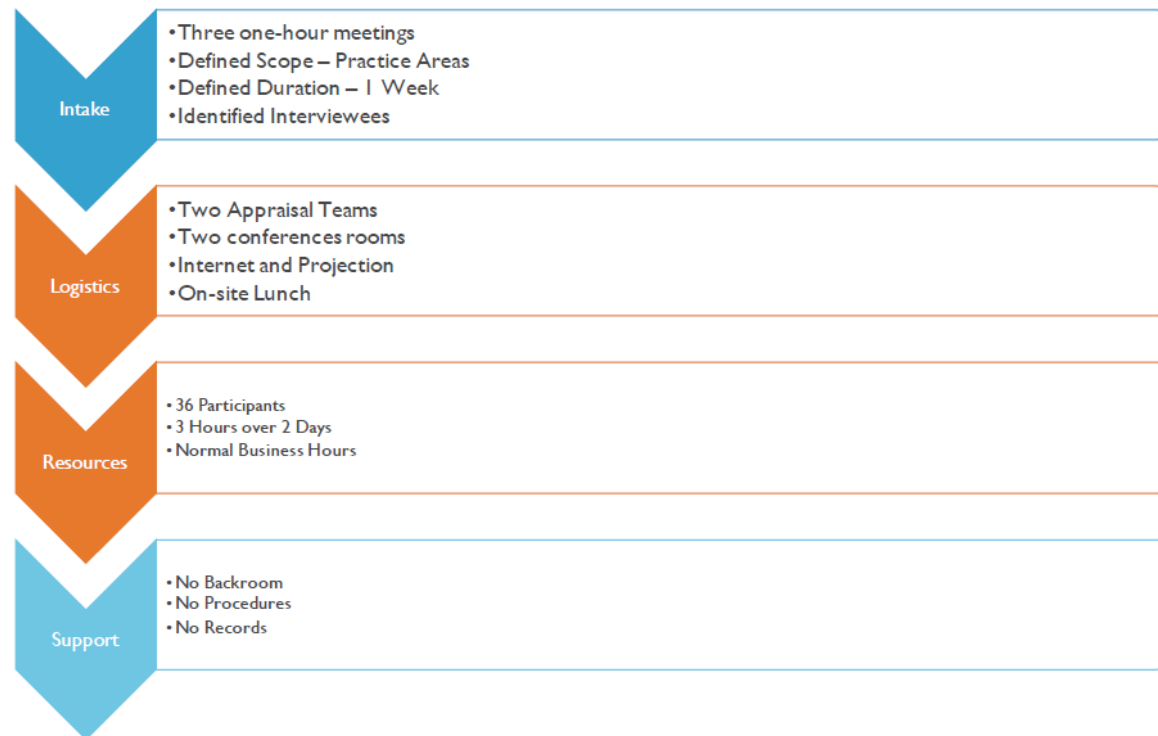
MDDAP: DATA SHARING (FDA VIEW)

Process area results and overall score for an organization

Company Name	# Practices	66%
Estimating (EST)	5	80%
Planning (PLAN)	10	56%
Monitor and Control (MC)	6	57%
Configuration Management (CM)	7	63%
Managing Performance and Measurement (MPM)	9	84%
Requirements Development and Maintenance (RDM)	7	36%
Process Quality Assurance (PQA)	5	60%
Governance (GOV)	5	70%
Implementation Infrastructure (II)	3	90%
Product Integration (PI)	7	63%
Technical Solution (TS)	4	65%
	68	

Considerably less preparation than usual

MDDA SITE PREPARATION



Done in one week

MDDA WEEK

GMT-07	Mon 11/6	Tue 11/7	Wed 11/8	Thu 11/9	Fri 11/10
8am	8 – 9 MDDA Appraisal Team 12050 Lone Peak Pkwy	8 – 9 MDDA Appraisal Team Edwards Lifesciences, 12050	8 – 9 MDDA Appraisal Team Edwards Lifesciences, 12050	8 – 9 MDDA Appraisal Team Edwards Lifesciences, 12050	8 – 9 MDDA Appraisal Team Edwards Lifesciences, 12050
9am	9 – 10 MDDA Kick Off SLC East Assembly Room	9 – 11 MDDA Appraisal - Planning (PLAN): Monitoring & Control (MC); Estimating (EST) SLC Golden Spike	9 – 10 MDIC Combined Team GoTo_DT		
10am			10 – 11 Follow Up Interviews Conference Room <please	10 – 11 Follow-up -Validation of SLC Golden Spike	
11am	10:30 – 12:30 MDDA Appr. Process Quc Assurance (S SLC Capital R	10:30 – 12:30 MDDA Appraisal - Requirements SLC Golden Spike			
12pm					
1pm		12:30p – 2p Governance (GOV) Ken and Walt SLC Golden Spike		1p – 2p Follow-up - Validation SLC Golden Spike	
2pm	1:30p – 3:30p MDDA Appr. Configuratio Managemen SLC Capital R	1:30p – 3:30p MDDA Appraisal - Technical Solutions/P SLC Golden Spike			
3pm		3p – 5p MDDA Appraisal - Managing Performance and Measurement (MPM) SLC Golden Spike	3p – 4p Validation for RDM/PQA Interviews		3p – 5p MDDA Appraisal Results Read out SLC East Assembly Room
4pm			4p – 5p Governance - Follow-up SLC Golden Spike		
5pm	5p – 6p Appraisal Team Daily Wrap	5p – 6p Appraisal Team Daily Wrap	5p – 6p Appraisal Team Daily Wrap	5p – 6p Appraisal Team Daily Wrap	5p – 6p Appraisal Team Daily Wrap
6pm					

- Site wide sessions in green
- Interview sessions in blue
- Validation sessions in red


MDDA Execution Summary

MDDA VS COMPLIANCE AUDIT

	MDDA	Compliance Audit
Dedicated Resources	1	10
Duration	1 week	2 weeks
Personnel	~ 240 person hours	~ 1500 person hours
Total Cost	\$74,000	\$140,000

- Defined Duration
- Pre-planned Events
- Minimal Business Interruption
- Organized
- Less Expensive

Another comparison



How are manufacturers perceiving the difference in the 2 processes?

FDA

	FDA inspection	CMMI appraisal
Mind-sets	<ul style="list-style-type: none">Only answer questions asked	<ul style="list-style-type: none">Be open in answering questions
Discussion	<ul style="list-style-type: none">Do not discuss improvement opportunities or future plans	<ul style="list-style-type: none">Weaknesses are opportunities to improve business processesTalk about improvements made over time and where we are going
Interaction	<ul style="list-style-type: none">Inspectors interrogate quality leaders, process experts, and record ownersInspectors look for evidence of noncompliance to regulations	<ul style="list-style-type: none">Appraisers conduct group interviews of “doers” responsible for work productsAppraisers engage in discussions to truly understand how the business operates relative to best practices
Time investment	<ul style="list-style-type: none">Large support team with backroom/ front room, streams, scribes, etc.2-day inspection, 1,370 hours	<ul style="list-style-type: none">Minimal disruption to site resources and no need for backroom/front room5-day appraisal, 340 hours

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Workshop topic 3

◉ The assessment style

- Pros?
- Cons?

◉ Will the industry be ready?



Experiences so far

The mindset seems to be the greatest challenge

Testimonial - benefit for the business

Camera and Voice (1)

MS 20
10:51

Share - CRMAC2



CRMAC2

A Paradigm Shift – The Impact

Metric	Pre	Post	Impact
Process Validation Time	38 day Average	7 day Average	83% reduction
Service Defect Tracking (Camstar customization)	PQ = 22 runs, 35 days	PQ = 1 run, 3 days	91% reduction
Validation System Change Backlog (Camstar & Epicor)	90 changes in backlog (Extreme Frustration / low morale)	0 Changes in backlog!	<ul style="list-style-type: none">• High morale• More value from technology• Higher quality and productivity
Camstar SU13 Upgrade Timeline	Feb '18	Nov '17	<ul style="list-style-type: none">• Utilize system improvement upgrades
CSV 589 – Sublevel monitor work flow configuration update	18 days	3 days	<ul style="list-style-type: none">• 84% reduction.
CSV 501 – ECG BOM Filter Improvements	Modeled Apr '17 Scheduled Oct '17 Due to resources and backlog	Aug '17 – Performed Validation 1 day Validation	<ul style="list-style-type: none">• More real time implementation of system improvements.

LifeVest®

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Additional observations

- ◉ New concept – trust!
 - Don't underestimate the impact of moving from a dis-trust based system to a trust based system.
- ◉ QA staff – don't expect they can change fast
 - However tempting, don't make an experienced QA/RA person in charge of the site
- ◉ New requirements for top management
 - Before: Be compliant, and your ok. <Top management don't need to know the quality details, and detailed quality management can be delegated>
 - Now: Responsibility to know what quality details to improve, and act. Top management must have detailed quality insight lead.
 - Delegation **not** possible!
 - (Same attitude in MDR ?!?)

Additional observations

- ◉ FDA: “Promise that you come early to us, and we promise that we will work with you” , -- and it is working!!

Plans

What happens next?

Can I join?

What can we expect

- ◉ A movement from compliance to quality is inevitable
- ◉ The perception of "quality" will change back
- ◉ The required skills will change
 - Bean-counter management -> Quality leadership
 - Compliance audits -> quality support
 - Compliance requirements -> professional skills
- ◉ The speed will be annoyingly slow
- ◉

How can we prepare

- ◉ If you appreciate the change – be a leader of it
- ◉ Make your own analysis of why “quality” died, or became synonymous with compliance
- ◉ Train your own rethoric and always distinguish clearly between compliance and quality
- ◉ Always look for the motivation behind a “quality assurance activity”
- ◉ Watch out for excessive “quality control”
- ◉ Always aim for the higher target: Quality – then compliance will follow for free (well, almost)

Who can join?

Enrollment Requirements

Must be a U.S. based company/site or global company that distributes medical devices in the U.S. (Class I, II, III).

Facilities must be those responsible for the manufacture and processing of medical devices. ^

- Facilities must not be under Official Action Indicated (OAI) status or subject to a judicial action.
- Companies with OAI can become eligible for benefits when they have provided the FDA with confirmation that appropriate corrective action has been implemented, and those actions have been verified by the FDA during a follow up inspection.

Companies must have a [1] prior history or compliance profile, [2] site registration, and [3] listing with the FDA. ^

- Examples of ineligibility include: new manufacturers, start-up companies, no FDA inspections, no marketed products in the U.S., etc.

What you need to do

Participation Requirements

Annual program fee to be paid once you are accepted into the pilot program.

Participation in a Medical Device Discovery Appraisal within the 90-day target and payment of the associated costs.

Check points at defined frequencies to confirm progress and improvement from initial appraisal results.

Sustained favorable compliance profile/history as defined in the enrollment requirements.

Benefits

Regulatory Modifications

Upon signing the Discovery Appraisal SOW, your facility will be removed from the FDA's routine inspection list.

Upon completion of a Discovery Appraisal, your manufactured medical devices will be eligible for:

- Streamlined 30-Day Change Notices, bundling multiple products and changes, with accelerated approval.
- Streamlined site change submission with accelerated approval.
- Streamlined PMA submission & waived pre-approval inspection.

Workshop topic 4

- ◉ What does this mean to you as a medical device professional?
- ◉ How will Case for Quality affect the industry?

More info....

- <http://mdic.org/cfq/case-for-quality-public-forum-presentations/>

Reserve

Watch out for the different attitudes

When a person is presented with a quality/capability/standard/.. requirement, analyze carefully at the response:

How little can I get away with and still comply with the standard



VS

What do I need to do to get the benefits



Where to look for quality

- ◉ Final product
 - Important,
 - but too late
- ◉ All “handovers”
 - Study all the sub-processes and artefacts
 - Where did the problem come from?
 - Was anyone passing on a problem?
 - Enables proactivity



What is quality ??

Our definition of medical device quality consists of seven domains

1 Safety: Device does not compromise the clinical condition or the safety of patients, or the safety and health of users.

2 Effectiveness: Device produces the effect intended by the manufacturer relative to the medical condition(s).

3 Reliability: Device system or component is able to function under stated conditions for a specified period of time.

4 Patient Satisfaction: Device was perceived to meet or exceed patient expectations of usability and outcome.

5 Usability: Device minimizes the risk of user errors by patients or clinicians.

6 Availability: Device is available to fill first request orders.

7 Compatibility: Device is compatible with related devices or drugs, the use environment or relevant standards.