

# FDA Case for Quality MDDA Pilot

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Edwards Lifesciences



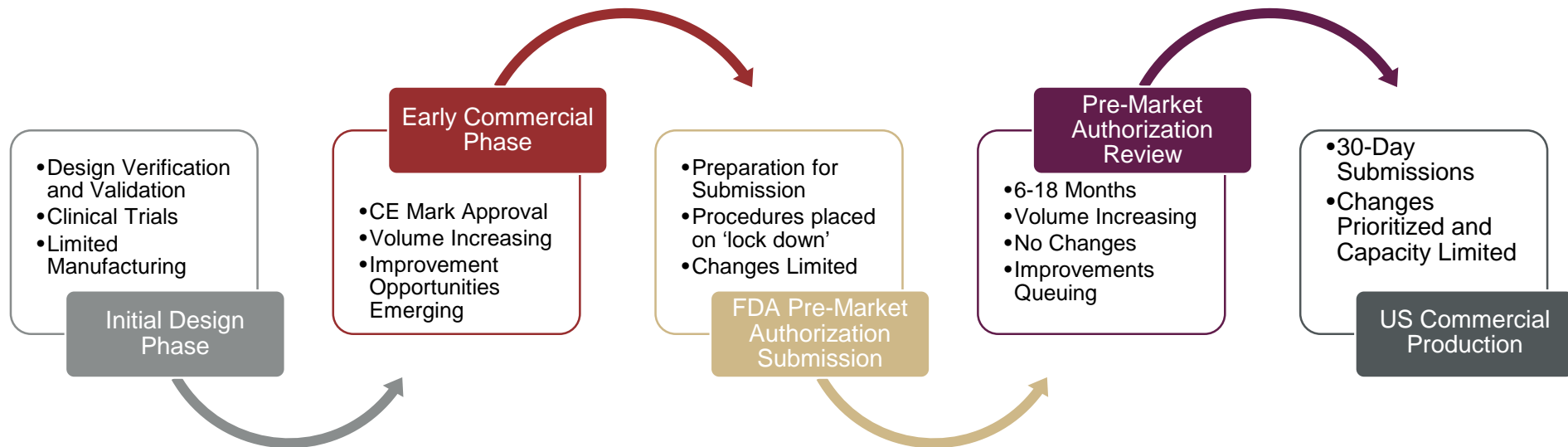
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# Why participate in the MDDA pilot?

- FDA & Edwards Lifesciences Mission
  - Patients should have access to safe, effective, high quality medical devices
- Benefits Support Mission
  - Improved Compliance
  - Higher Quality
  - Positive Economics



# Lifecycle for a PMA device



Streamlined Submission Promotes Device Quality

# 30-Day Process Limits Continuous Improvement

- Edwards Lifesciences Draper
  - Multiple PMA devices
  - Multiple Generations
- 30-Day Notice Process is Restrictive
  - Single change per Notice
  - One 30-Day per week
  - November 14<sup>th</sup> – Last 2017 30-Day
- Compliance and Quality Impacts
  - Changes Prioritized, Delayed
  - Sub-optimal Changes
  - Reactive Only



# Benefits are Impactful

- Edwards Draper CAPA Q3 2017

510k Devices	PMA Devices
54 Open CAPA	60 Open CAPA
0 Extensions Due to Submissions	13 Extensions Due to Submissions

- 30-Day Process is Internally Complex
  - Additional Information Requirements
  - Complex Communications and Coordination
  - Missed Opportunities Due to Delays

Simplified & Bundled Notifications Promote Device Quality and Compliance

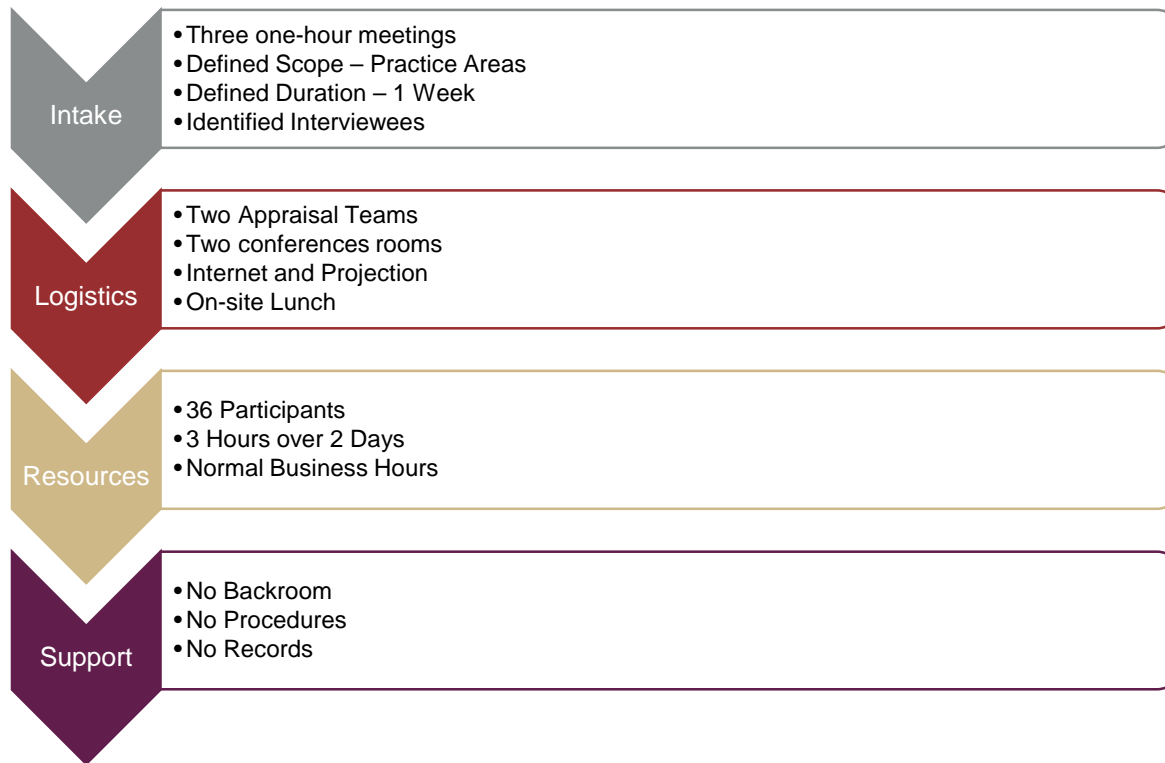
# MDDA Experience

Completed at Edwards Lifesciences  
Draper Facility 11/06/17 to 11/10/17



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# MDDA Preparation



# 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, 8 - Walk Thr	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 Qu Assurance (S SLC Capital R	10:30 – 12:30 MDDA Appraisal - Requireme nts 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 scope

## Appraisal Practice Areas – Level 2

Requirements Development and Maintenance (RDM)

Planning (PLAN)

Monitor & Control (MC)

Managing Performance and Measurement (MPM)

Configuration Management (CM)

Process Quality Assurance (PQA)

Technical Solution (TS)

Product Integration (PI)

Estimating (EST)

Governance (GOV)

Implementation Infrastructure (II)

## Out of Scope

Supplier Agreement Management (SAM)

Risk Management (RSKM)

Decision Analysis and Resolution (DAR)

Causal Analysis & Resolution (CAR)

Process Management (PM)

Process Asset Development (PAD)

Verification and Validation (VV)

Organizational Training (OT)

Peer Reviews (PR)

**Inclusion of SAM and RSKM  
aligns with site activities**

# 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

# Initial MDDA Impressions



## Positives

- Structured & Organized
- 2 Appraisers per Practice Area
- Scheduled Work Time
- Sensitive to Reporting Structures
- Validation – Feedback and Learning
- Active Communication
- Open Engaging Environment



## Improvements

- CMMI Services Agreement
- Terminology
- Practice Area Purpose and Roles Unclear
- Facility Tour First
- System Expertise not Product Knowledge
- 4-6 Interviewees per Practice Area
- Missing “Front Line” Employees



## MDDA Structure

- MDDA Scope Flexible Over Annual Cycles
- Create Practice Area for “Front Line” Employees
- Device Classification Alignment with MDDA Practice Areas

# Feedback from Participants

## MDDA Process

- Responding to open ended questions challenging, ambiguity hard to deal with, did we get it right?
- Clarification or examples of what the model is looking needed to better understand the question
- Terminology confusing, difficult to get aligned (Configuration Management, Requirements, Development)
- Results reflected weaknesses that are actionable and make us better
- Discussion did not allow enough focus on all strengths
- Better introduction to practice areas prior to interviews helpful
- Positive discussion oriented approach was engaging with low stress

## Appraisal Process

- Keep validation sessions small, don't mix practice areas
- Small teams make sure everyone speaks up
- Validation sessions are key to good results
- Approach allowed unbiased discussion
- Appraisers were respectful of people's time and the experience was very smooth
- Appraisers effectively asked for detail and clarification

# Essential Elements of Product Quality



## Annual Touchpoints

- Compliance – MDSAP
- Site Management – MDDA

## Additional Focus Needed

- Workforce Engagement

# MDDA Next Steps for Edwards Lifesciences

- Receive Final Report
- Internalize Results – Identify Targets
- Determine Frequency of Checkpoints with CMMI
- Additional Benefits – Understand Process
- Operator Input – Seeking Ideas



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Helping Patients is Our Life's Work, and

*life is now*