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

- **Initial Design Phase**
  - Design Verification and Validation
  - Clinical Trials
  - Limited Manufacturing

- **Early Commercial Phase**
  - CE Mark Approval
  - Volume Increasing
  - Improvement Opportunities Emerging

- **Pre-Market Authorization Review**
  - Preparation for Submission
  - Procedures placed on "lock down"
  - Changes Limited
  - 6-18 Months
  - Volume Increasing
  - No Changes
  - Improvements Queuing

- **US Commercial Production**
  - 30-Day Submissions
  - Changes Prioritized and Capacity Limited

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 14th – Last 2017 30-Day

- Compliance and Quality Impacts
  - Changes Prioritized, Delayed
  - Sub-optimal Changes
  - Reactive Only
Benefits are Impactful

- Edwards Draper CAPA Q3 2017

<table>
<thead>
<tr>
<th>510k Devices</th>
<th>PMA Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>54 Open CAPA</td>
<td>60 Open CAPA</td>
</tr>
<tr>
<td>0 Extensions Due to Submissions</td>
<td>13 Extensions Due to Submissions</td>
</tr>
</tbody>
</table>

- 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
MDDA Preparation

Intake
• Three one-hour meetings
• Defined Scope – Practice Areas
• Defined Duration – 1 Week
• Identified Interviewees

Logistics
• Two Appraisal Teams
• Two conferences rooms
• Internet and Projection
• On-site Lunch

Resources
• 36 Participants
• 3 Hours over 2 Days
• Normal Business Hours

Support
• No Backroom
• No Procedures
• No Records
# MDDA Week

<table>
<thead>
<tr>
<th>Mon 11/6</th>
<th>Tue 11/7</th>
<th>Wed 11/8</th>
<th>Thu 11/9</th>
<th>Fri 11/10</th>
</tr>
</thead>
<tbody>
<tr>
<td>8am</td>
<td>8am</td>
<td>8am</td>
<td>8am</td>
<td>8am</td>
</tr>
<tr>
<td>MDDA Appraisal Team</td>
<td>MDDA Appraisal Team</td>
<td>MDDA Appraisal Team</td>
<td>MDDA Appraisal Team</td>
<td>MDDA Appraisal Team</td>
</tr>
<tr>
<td>10am</td>
<td>10am</td>
<td>10am</td>
<td>10am</td>
<td>10am</td>
</tr>
<tr>
<td>MDDA Kick Off</td>
<td>MDDA Appraisal - Planning (PLAN) Monitoring &amp; Control (MC) Estimating (EST) SLC Golden Spike</td>
<td>Follow Up Interviews Conference Room &lt;please&gt;</td>
<td>Follow up - Validation of SLC Golden Spike</td>
<td></td>
</tr>
<tr>
<td>1pm</td>
<td>1pm</td>
<td>1pm</td>
<td>1pm</td>
<td>1pm</td>
</tr>
<tr>
<td>2pm</td>
<td>2pm</td>
<td>2pm</td>
<td>2pm</td>
<td>2pm</td>
</tr>
<tr>
<td>MDDA Appraisal Management SLC Capital R</td>
<td>MDDA Appraisal - Performance and Measurement (PnP) SLC Golden Spike</td>
<td>Validation for RDM/PQA Interviews SLC Golden Spike</td>
<td>MDDA Appraisal Results Read out SLC East Assembly Room</td>
<td></td>
</tr>
<tr>
<td>3pm</td>
<td>3pm</td>
<td>3pm</td>
<td>3pm</td>
<td>3pm</td>
</tr>
<tr>
<td>4pm</td>
<td>4pm</td>
<td>4pm</td>
<td>4pm</td>
<td>4pm</td>
</tr>
<tr>
<td>MDDA Appraisal Team Daily Wrap</td>
<td>MDDA Appraisal Team Daily Wrap</td>
<td>MDDA Appraisal Team Daily Wrap</td>
<td>MDDA Appraisal Team Daily Wrap</td>
<td>MDDA Appraisal Team Daily Wrap</td>
</tr>
</tbody>
</table>

- Site wide sessions in green
- Interview sessions in blue
- Validation sessions in red
# MDDA scope

<table>
<thead>
<tr>
<th>Appraisal Practice Areas – Level 2</th>
<th>Out of Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements Development and Maintenance (RDM)</td>
<td>Supplier Agreement Management (SAM)</td>
</tr>
<tr>
<td>Planning (PLAN)</td>
<td>Risk Management (RSKM)</td>
</tr>
<tr>
<td>Monitor &amp; Control (MC)</td>
<td>Decision Analysis and Resolution (DAR)</td>
</tr>
<tr>
<td>Managing Performance and Measurement (MPM)</td>
<td>Causal Analysis &amp; Resolution (CAR)</td>
</tr>
<tr>
<td>Configuration Management (CM)</td>
<td>Process Management (PM)</td>
</tr>
<tr>
<td>Process Quality Assurance (PQA)</td>
<td>Process Asset Development (PAD)</td>
</tr>
<tr>
<td>Technical Solution (TS)</td>
<td>Verification and Validation (VV)</td>
</tr>
<tr>
<td>Product Integration (PI)</td>
<td>Organizational Training (OT)</td>
</tr>
<tr>
<td>Estimating (EST)</td>
<td>Peer Reviews (PR)</td>
</tr>
<tr>
<td>Governance (GOV)</td>
<td></td>
</tr>
<tr>
<td>Implementation Infrastructure (II)</td>
<td></td>
</tr>
</tbody>
</table>

Inclusion of SAM and RSKM aligns with site activities
MDDA vs. Compliance Audit

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

<table>
<thead>
<tr>
<th></th>
<th>MDDA</th>
<th>Compliance Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dedicated Resources</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Duration</td>
<td>1 week</td>
<td>2 weeks</td>
</tr>
<tr>
<td>Personnel</td>
<td>~ 240 person hours</td>
<td>~ 1500 person hours</td>
</tr>
<tr>
<td>Total Cost</td>
<td>$74,000</td>
<td>$140,000</td>
</tr>
</tbody>
</table>
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
Edwards

Helping Patients is Our Life’s Work, and life is now