Tame the Metrics

Innovate and Integrate for Strategic Growth

Meetu Arya
IESD - Product Development
# St. Jude Medical at a Glance

<table>
<thead>
<tr>
<th>Founded:</th>
<th>1976</th>
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<tbody>
<tr>
<td>Global Headquarters:</td>
<td>St. Paul, Minnesota, USA</td>
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<tr>
<td>First Product:</td>
<td>Mechanical Heart Valve</td>
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<td>Global Reach:</td>
<td>Products sold in 100+ countries</td>
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<td>More than 20 principal operations and manufacturing facilities worldwide</td>
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<td>Employees:</td>
<td>15,000+</td>
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<td>2010 Net Sales:</td>
<td>$5.165 billion</td>
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<td>Technology Platforms:</td>
<td>Cardiovascular and Ablation Technologies</td>
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<td></td>
<td>Atrial Fibrillation</td>
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<td>Cardiovascular</td>
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<td>Implantable Electronic Systems (IESD)</td>
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<td>Cardiac Rhythm Management</td>
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<td>Neuromodulation</td>
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Global Presence

Corporate Headquarters
St. Paul, MN

Technology Platforms

Cardiovascular
St. Paul, MN

Atrial Fibrillation
St. Paul, MN

Cardiac Rhythm Management
Sylmar, CA

Neuromodulation
Plano, TX

United States Manufacturing
- Arizona
- California
- Minnesota
- New Jersey
- Oregon
- Puerto Rico
- South Carolina
- Texas

International Manufacturing
- Brazil
- Israel
- Maylasia
- Thailand
- Costa Rica

Geographic Divisions
Regional Headquarters

Asia Pacific
Hong Kong

Europe, Middle East, Africa, Canada
Brussels, Belgium

Japan
Tokyo, Japan

Latin America

United States
Austin, Texas

United States Manufacturing
- Arizona
- California
- Minnesota
- New Jersey
- Oregon
- Puerto Rico
- South Carolina
- Texas
Overview of IESD Product Development

- **Demographics**
  - Located in 4 US sites; Europe and Asia across multiple different time zones
  - Just under 1000 people
  - Consisting of:
    - Clinical Systems Engineering
    - Firmware Development
    - Hardware Development
    - Software Development
    - Operations
    - Strategic Planning

- **Products**
  - Implantable Class III Devices – ICD’s, Pacers, IPG’s, Leads etc. (Heart and Neuro devices)
  - Remote Monitoring devices

- **Regulations**
  - FDA, TUV, Japan, Canada…
  - Class III medical devices have the most stringent regulatory controls. Class III devices usually support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury to the patient.
Challenges in Medical Device Development

Safety…Reliability…Compliance

Reducing cost and time to market in a highly regulated industry and interconnected life sustaining technology in today’s economic environment while maintaining highest Quality.

High Quality & Strategic Growth

What to Measure

How to Collect

Multiple Products

Multiple Sites

Multiple Processes

Decision Making

Regulations

Behavioral Impact

Multiple Models

Multiple Models

How to Integrate

Multiple Models

St. Jude Medical

More control. Less risk.
Need of the Hour

An innovative infrastructure to assess our progress towards our goal

- **Key considerations**
  - A unified end-to-end Measurement system to take data-driven informed business decisions that drive right behavior.
    
    MA-SG1; SG2; OPP-SG1; OPM-SG1; QPM-SG1

  - To measure, monitor and thus bring change for increased agility, optimized project performance and attainment of business objectives
    
    MA-SG1; SG2; OPP-SG2; OPM-SG3; QPM-SG2

  - Data integrity at highest priority
    
    MA-SG2

  - Focus on minimal overhead for all stakeholders including, data providers
    
    MA-SG2
Product Development Dashboard

- Defined
- Automated
- Controlled
- Documented

- Online
- Navigable
- Reproducible

KPI *

Action

Process

Access

Scorecards

* Key Performance Indicators

1st business day of month

6th business day of month

9th business day of month

11th business day of month

14th business day of month

Data collection for period = previous month
Cutoff date = last day of the previous manufacturing month

Current Month

5 business days

3 business days

2 business days

3 business days

Update and analyze Dashboard

Dashboard review

Refine based on feedback from management

Publish Dashboard for internal review

Quality

Efficiency

Cost

Operations

Resources
Dashboard – Sneak Peek

- Vehicle to drive positive behavior
  - Provide business insight and progress updates
  - Monitor and adjust execution strategy
  - Clarify and align goals and improvements across the organization

- Highlights
  - Consolidated summary and detailed view
  - Quality Targets for higher quality – *statistically controlled*
  - Metrics correlation and analysis – *multiple dimensions (departments/projects/trends)*
    - Quarterly and Yearly analysis; accumulative reflection; variance; root cause
  - Actionable Inferences - *decision making*
  - Metrics suite *(examples)*:
    - **Quality**: Field Issues; Defect Density; Bug Fixes; Incoming Tickets; SLA
    - **Efficiency**: SW Productivity; Scrap; First Pass Yield; Test Time
    - **Cost**: Operating Expense; Capital Expense; R&D expense as a % of Sales
    - **Operations**: Cost/Unit; Scrap $/Unit; Delivery
    - **Resource**: Headcount; Attrition
Dashboard – Sneak Peek…contd.

Dummy Data
Success Stories

- **Key improvements**
  - Development cost
    - 15% reduced
  - Tech Services complaints
    - 25% reduced
  - Remote Monitoring Product Returns
    - 14% reduced
  - Product Development Efficiency
    - 30% increase in product deliveries to market
  - Greater sustaining support
  - Regulatory submission prep. time
    - 20% reduced
  - Cross functional process initiatives
    - 40% increases

Potential Expansions

- **Miles to go…**
  - Continuous improvement in meeting goals
  - Continuous evaluation of goals and techniques
  - Accelerate automation
  - Create Process Performance models
  - Introduce real time business intelligence
  - Further amalgamation of Leading and Lagging Indicators
Take Aways

- Tame your metrics…don’t get tamed!
  - Know the business objectives
  - Start slow but never with a single metric → holistic approach
  - Integrate teams to function collaboratively towards a common strategic goal
- Define your process
- Gear up to face the resistance → overcome by sharing mutual benefits (win-win!)
- Circle back with primary customers → perform VOC to stay on track
- Adopt industry proven techniques and practices
- Do NOT give up!!!
Questions?

Thank You!

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