Meeting FDA Standards for Medical Device Quality: *An Out-of-the-box Approach*

Swapan Jha, Vice President, PLM Segment, PTC @sjhaptcplm
David Wolf, Certified Quality Engineer & Biomedical Auditor, PTC
Jim Macdonell, Vice President, USDM Life Sciences

June 8th, 2016

SESSION AGENDA

- Introductions
- Medical Device Industry Trends & Compelling Events
- PTC's Medical Device Offering with USDM
- Stryker's "Case for Quality" discussion with Kalypso

INTRODUCTIONS

Swapan Jha

Vice President, PLM Segment, PTC

sjha@ptc.com

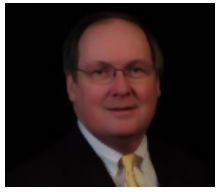
Swapan Jha is Vice President Global GTM of the Product Lifecycle Management (PLM) segment at PTC. A seasoned technology executive with broad expertise in developing and executing enterprise software sales, product and go-to-market strategies, he has 15+ years of PLM domain experience across Medical Device, Hi-Tech and Manufacturing industries. Mr. Jha joined PTC in 2015 from Oracle Corporation where he most recently served as Global Client Advisor to P&G's Key IT and business stakeholders, with responsibilities including working with cross pillar teams within Oracle and across all divisions and geographies at P&G. He previously held several leadership positions within Oracle, including Industries Business Unit, where Mr. Jha was responsible for driving growth in Oracle's supply-chain, including PLM offerings. He holds a bachelor of Engineering, and a Masters of Business Administration (M.B.A.), Finance, Entrepreneurship from the University of Chicago - Booth School of Business.

David Wolf

Certified Quality Engineer & Biomedical Auditor, PTC

dwolf@ptc.com

Prior to joining PTC, David worked for medical device manufacturing companies in a variety of roles. He has designed, patented and released several product lines for worldwide distribution. David has hands on expertise in product development, manufacturing, supply chain, regulatory and quality management. He was a catalyst that drove and managed the PTC Medical Device Value Ready Deployment (VRD), which significantly reduces the implementation time and cost for mid-market companies. He's been working with top tier medical device manufacturers while here at PTC and holds several medical device patents.



Jim Macdonell

Vice President, USDM Life Sciences

jmacdonell@ptc.com

Jim Macdonell is an experienced consulting manager with over 20 years of defining client programs and building and managing implementation teams. Experience includes compliance programs. UDI, Serialization, MES systems, laboratory systems and ERP programs. Jim has developed life sciences solutions, managed client engagements, built delivery teams and managed programs and projects. Jim is supporting the development of UDI and Commercial Practices with responsibilities for structuring and executing client programs. He holds a bachelor of Science, Industrial Engineering from the University of Notre Dame and a Masters of Business Administration from Rutgers University.

MEDICAL DEVICE INDUSTRY TRENDS & COMPELLING EVENT

WHY TRANSFORM?
ACHIEVING COMPETITIVE ADVANTAGE IN THE IOT ERA

DRIVE INNOVATION

"By 2017, **70%** of global discrete manufacturers will offer connected products."

- Heather Ashton, IDC

MANAGE COMPLEXITY

"If you went to bed last night as an industrial company, you're going to wake up today as a software and analytics company."

- Jeff Immelt, CEO GE

ENSURE QUALITY

89% of businesses say that, by 2016, *customer experience* will be their primary basis for competition.

– Gartner

BOOST PROFITABILITY

$50B devices and **$6T** in economic value projected for smart connected products by 2025.

– Cisco, McKinsey

WHAT IS THE FDA CASE FOR QUALITY?

"INCREASING THE ASSURANCE OF PRODUCT QUALITY"

RELATIONSHIP BETWEEN QUALITY AND COMPLIANCE

"Companies perceive that **the regulatory framework is misaligned with assurance of quality outcomes,** in that compliance with regulations does not ensure quality, and that current intervention practices may de-incentivize improved quality."

> *"An overwhelming majority of companies interviewed believe that maintaining compliance with FDA regulations does not ensure good product quality"*

> *"An over emphasis on pure compliance versus quality outcomes"*

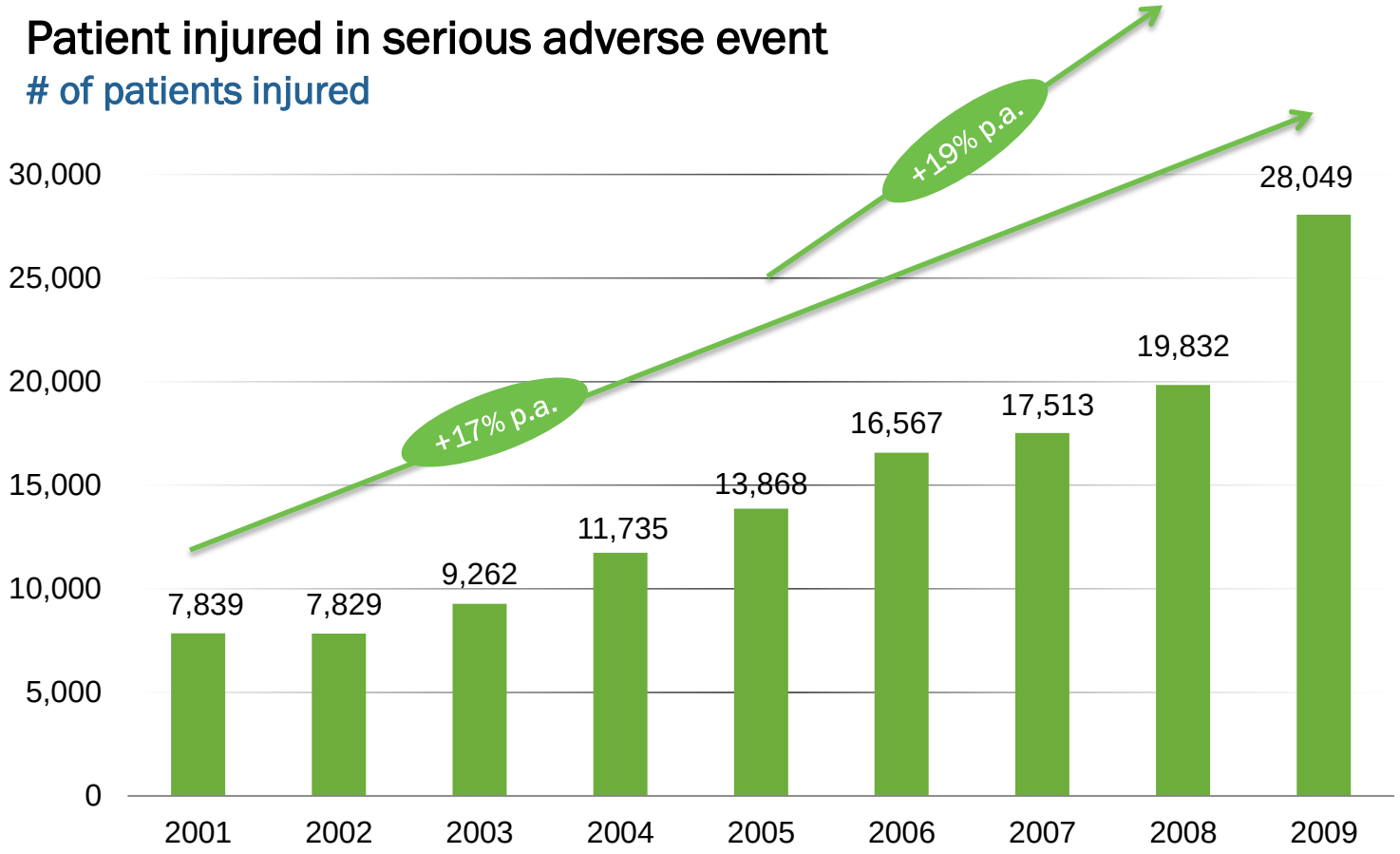
> *"It is common in medical device companies for only the quality organization to be measured on quality performance; design engineers are commonly measured on time-to-market"*

Source: FDA 2011 - Understanding Barriers to Medical Device Quality

TRENDS IN MEDICAL DEVICE ADVERSE EVENT REPORT

Key Highlights

- Number of adverse event reports has increase significantly and outpaced industry growth by a wide margin
- Several factors may contribute to the growth including reporting requirement enforcement by FDA
- Cardiovascular, IVD and general hospital/surgical devices make up most adverse event report, approx. 60%
- Radiology (diagnostic imaging) and neurology are the areas growing (~ 24% p.a.) most quickly



Source: FDA 2011 https://open.fda.gov/device/pma/

THE OPPORTUNITY TO IMPROVE THE TOTAL QUALITY COSTS

"The medical device industry is approaching a tipping point where the increasing likelihood of a quality event, the rising costs of such events, and the public nature of quality performance will force companies to focus on quality and reliability throughout product design, manufacturing, and marketing."

- McKinsey, The Business Case for Medical Device Quality , 2013

"The Financial Benefit Opportunity Is $4.75-$6.0b For The Medical Device Industry" - McKinsey

RECALL CASE CODES BY ROOT CAUSE

"Nearly one-third of recalls are due to design flaws and almost another quarter are due to issues with manufacturing"

	Design	Suppliers	Manufacturing	Post Production & Change Control	Other	Unknown	Total by Product Attribute
Hardware	15%	12%		2%			29%
Software	8%			7%			15%
Labeling	4%		3%	1%			8%
Packaging	1%		3%				5%
Process	3%	2%	18%	1%			24%
Regulations					1%		1%
Other					9%		9%
Unknown						9%	9%
Total By value Stream	31%	14%	24%	12%	10%	9%	100%

>=15% 5-14% 1-5%

Source: Data from RECS database

PTC'S MEDICAL DEVICE INDUSTRY OFFERING

END-TO-END TRACEABILITY: MECHANICS OF A SINGLE SOURCE OF TRUTH

Benefits of PTC PLM

- Creates a single source of truth
- Shifts from Corrective to Preventive
- Enables quality-driven change
- Closes the loop

PTC PLM Product Lifecycle Management Backbone

Documents Backbone

Manage & Control all key documents / Document Control

Products Backbone

Manage and control product information / CAD, BoM, BOO, Change Control, Processes / Workflows…

Quality Backbone

Quality, reliability, and risk management is harmonized with engineering & suppliers, across products & processes

Product-Based Information: *Design, CAD / Visualization, BoM, Parts, Variants, Change, Workflows*

Document-Based Information: *SOPs, Policies, Quality Manual*

Quality Records associated to products & documents: *CAPAs, NCs, Complaints, Audits, Training…*

Concept
Portfolio Mgmt
Prod. Requirements
Design Inputs
Quality History
CAPAs
DHF

Design
CAD
Risk & Hazards
FMEA
Design Validation
Design Reviews
CAPAs
DHF / DMR

Launch
PMA / 510K
UDI

Manufacturing
Mfg Process Plans
Nonconformances CAPAs
Mfg BoM Instructions
Supplier Mgmt

Service
Service Ticketing
Warranty
Inventory Mgmt
Complaints
CAPAs

PTC BEST PRACTICES FOR ISO 13485 MEDICAL DEVICE MANUFACTURERS

Mandatory Compulsory Processes of ISO 13485:

- Document Control
- Design Control
- Internal Audits
- Control of Nonconforming Product / Service – Internal & External
- Customer Experience
- Corrective and Preventive Action
- UDI
- Risk and Reliability

Benefits:

- ISO 9001 provides basis for all derivative Standards (i.e. ISO 13485, AS9100, ISO 16949)
- Provides a uniform approach
- Provides baseline PTC perspective on these key processes and their integration
- Speeds implementations – reduces customer costs
- Allows for base validation packages to be assembled by partners
- Allows for baseline training packages to be developed by partners
- Provides immediate value in SMB implementations

PTC MEDICAL DEVICE INDUSTRY **VALUE-READY DEPLOYMENT ™**

A ready-to-deploy services offering to implement proven industry best-practices

- **Proven**
  - Developed with leading Medical Devices Companies
- **Industry Specific and Comprehensive**
  - Based on PTC perspective of ISO 13485 / 820 CFR for Document Control, Product Realization, Nonconformance, Customer Feedback, CAPA, Audits, UDI
- **Rapid Time-to-Value**
  - Pre-defined PTC Windchill deployment methodology, baseline configurations, validation scripts and adoption program for Medical Device industry

Rapid Time-to-Value	Lower Risk	Lower TCO

WHAT MAKES UP A VRD?

Best Practice Baseline Configuration	☑ PTC baseline configurations to match industry best practices for ISO 13485 Compulsory Processes – configurations include updated attributes, types, layouts, workflows, lifecycles, queries and dashboard reports
Getting Started Guide	☑ Guide shows how to get started with each module and follow the simple steps to utilize the various best practice functions
Web-based Training for Administrative Users	☑ Standard Web-based training for administrative users
Web-based Training for End Users	☑ Standard Web-based training course for end users with one course for each process
PTC Validation Accelerator Package	☑ PTC provides a complete set of pre-configured validation ready regulatory templates
Pricing	☑ Modular by process

"**PTC** Partners with **USDM Life Sciences** to Deliver Windchill Validation Accelerator Pack (VAP) for PTC Medical Device VRD."

VALIDATION ACCELERATOR PACKAGE (VAP) FOR PTC® WINDCHILL®

The VAP offers a complete set of pre-configured validation ready regulatory templates

- ☑ Computer System Validation Plan
- ☑ System Requirements Specification (SRS)
- ☑ IQ, OQ and PQ Protocols
- ☑ Risk Assessment
- ☑ Validation Test Scrips
- ☑ Requirements to Test Traceability Matrix
- ☐ Software Validation Summary Report
- ☐ Annual Vendor Audit
- ☐ Subscriptions to maintain validated state

USDM Life Sciences

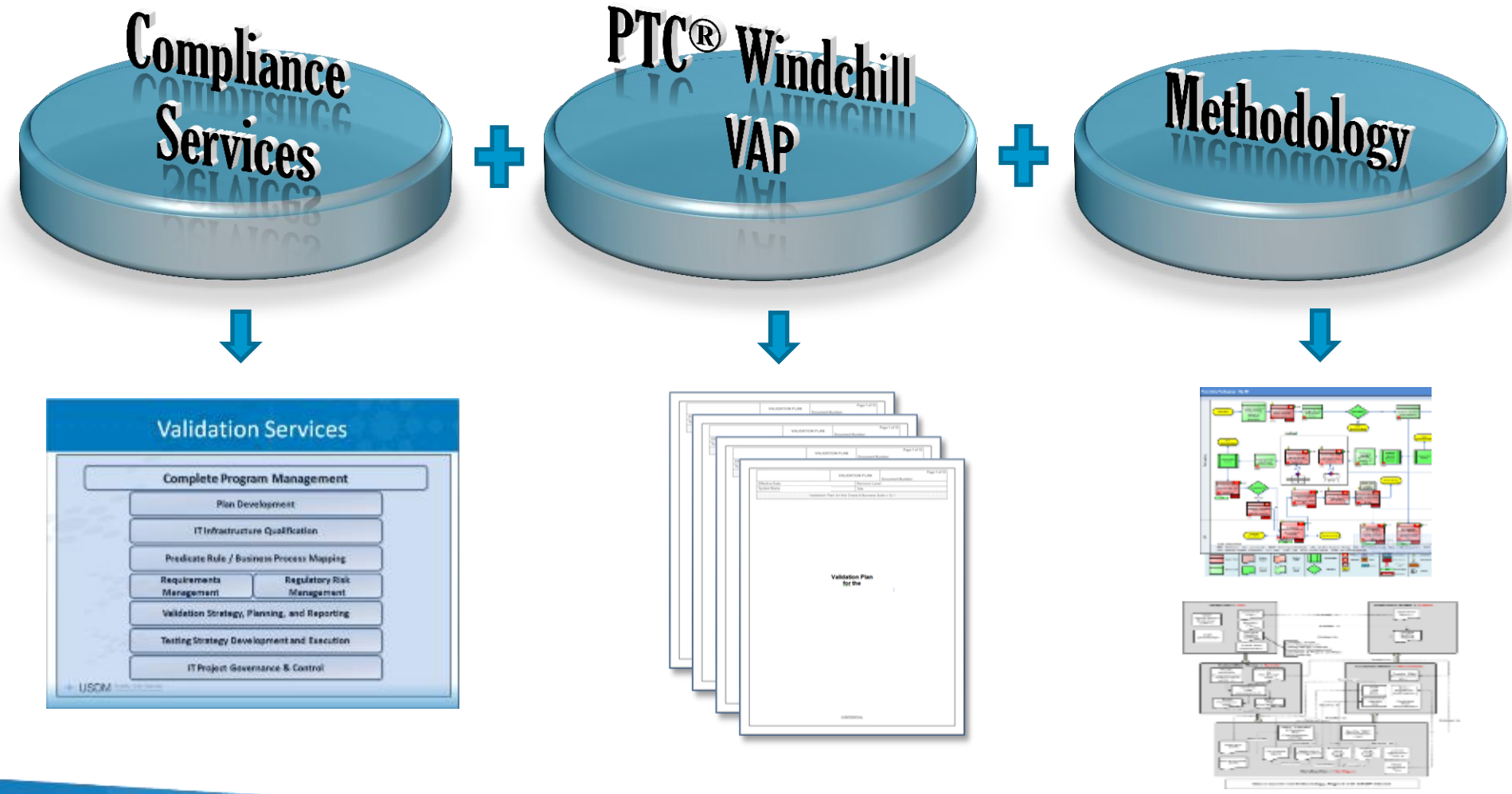
Cloud Compliance

UDI Industry Leadership

DSCSA Industry Leadership

Global System and Supplier Auditing

USDM Life Sciences Provides a Complete Compliance Offering



WHY GHX AND PTC?

Supports Both GUDID and GDSN Requirements!

Together, PTC and GHX offer a solution to help medical-surgical manufacturers meet both ***commercial and regulatory compliance*** needs, including the submission requirements of the FDA's new Unique Device Identification (UDI) rule.

- September 24, 2016 Deadline - Data for class II devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.
- September 24, 2016 Deadline - The labels and packages of class II medical devices must bear a UDI. § 801.20.

GHX + ptc

Source: FDA Compliance Dates for UDI Requirements

LIVEWORX 16™

KALYPSO

stryker®

CASE FOR QUALITY: PLM JOURNEY BRIEFING

Rod Walters, Kalypso
Toniel Speidel, Stryker

Wednesday, June 9

AGENDA TOPICS

- **Introductions**
  - Case for Quality: A Transformational Journey
  - Capabilities Framework & Solution Scope

- **Stryker Case for Quality**
  - Program Challenges
  - Executive Alignment
  - Business Case for Change
  - Q&A

INTRODUCTIONS

Rod Walters

Partner, Kalypso

rod.walters@kalypso.com

Leader in Kalypso's global PLM solutions practice and responsible for PTC PLM & Thingworx practice. Serving clients with innovation and transformational PLM engagements in medical, industrial, high tech and retail industries.

Experience:

- 25+ years of enterprise solution and PLM experience with focus on Innovation, PLM and IoT strategy, solution selection, planning and implementation delivery
- Deep PLM experience from 10+ year tenure in PLM market as a Sr. Vice President at PTC
- Held executive management roles at leading enterprise software companies Oracle and PeopleSoft

Credentials:

- BA degree in Economics from Harvard University
- Certified in Production and Inventory Management

Toniel Speidel

Senior Manager, Product Engineering Stryker

Toniel.speidel@stryker.com

Toniel is an experienced business leader driving Stryker's global PLM initiative to over 20,000 users across 9 Divisions, 31 manufacturing sites, and selling organizations in over 100 countries around the world. She has 17 years of experience in the medical device industry in various capacities and functions including design controls, risk management, new product development, quality management systems, sales & operations planning, inventory and logistics, lean manufacturing and materials planning. She holds a BS in Chemical Engineering and an MBA in Management of Technology from Syracuse University.

KALYPSO

+

ptc

ACCEL FOR MEDICAL DEVICE DEPLOYED ON Windchill A PTC Product POWERED BY ThingWorx A PTC Business

PTC ServiceAdvantage

Dedicated
PTC Service Advantage Partner with
Proven Medical Device Industry Successes

Medtronic

Alcon

Johnson & Johnson

stryker

JABIL

70+ PTC implementation practitioners on three continents

Leading practice
Windchill PLM accelerators for highly regulated industries

Access to all levels of PTC product, service and technical support

Smart, Connected Product & Digital market alignment

On Demand Offerings
SaaS and Cloud offering covering the full stack of software, infrastructure and managed services

Transformational Services
Strategy, Change Enablement, Leading Practice Adoption, Continuous Improvement and Value Realization

PLM MEDICAL DEVICE INDUSTRY CAPABILITIES FRAMEWORK

Strategic Capabilities

- Product Strategy and Roadmaps
- Ideation & Idea Management
- Phase Gate Decision Making
- Portfolio Management
- Resource Management
- Project Management
- Trending and Analytics

Design Capabilities

- Research Management
- Engineering/CAD Management
- Software Development
- Requirements & Traceability
- Specification Management
- Verification & Validation

Data Management Capabilities

- Configuration Management
- Device Master Record
- Environment & Material Compliance
- IP & Asset Management
- Product Registration
- Content Management
- Router
- eIFU
- Tooling Management
- Packaging & Labeling Management
- UDI/Master Data

Quality Management Capabilities

- NCR
- CAPA
- Audit Management
- Complaints / PMS
- Management Review
- Training Management (ComplianceWire Integ.)

Collaborative Capabilities

- eProcurement/ Data Pools
- Supplier Quality & Collaboration
- Sourcing & Cost Management
- Design Collaboration
- Sales
- Service

Foundational Capabilities

- Document Management
- Change Management
- Design History File
- Risk Management
- Bill of Materials Management

Technical Infrastructure

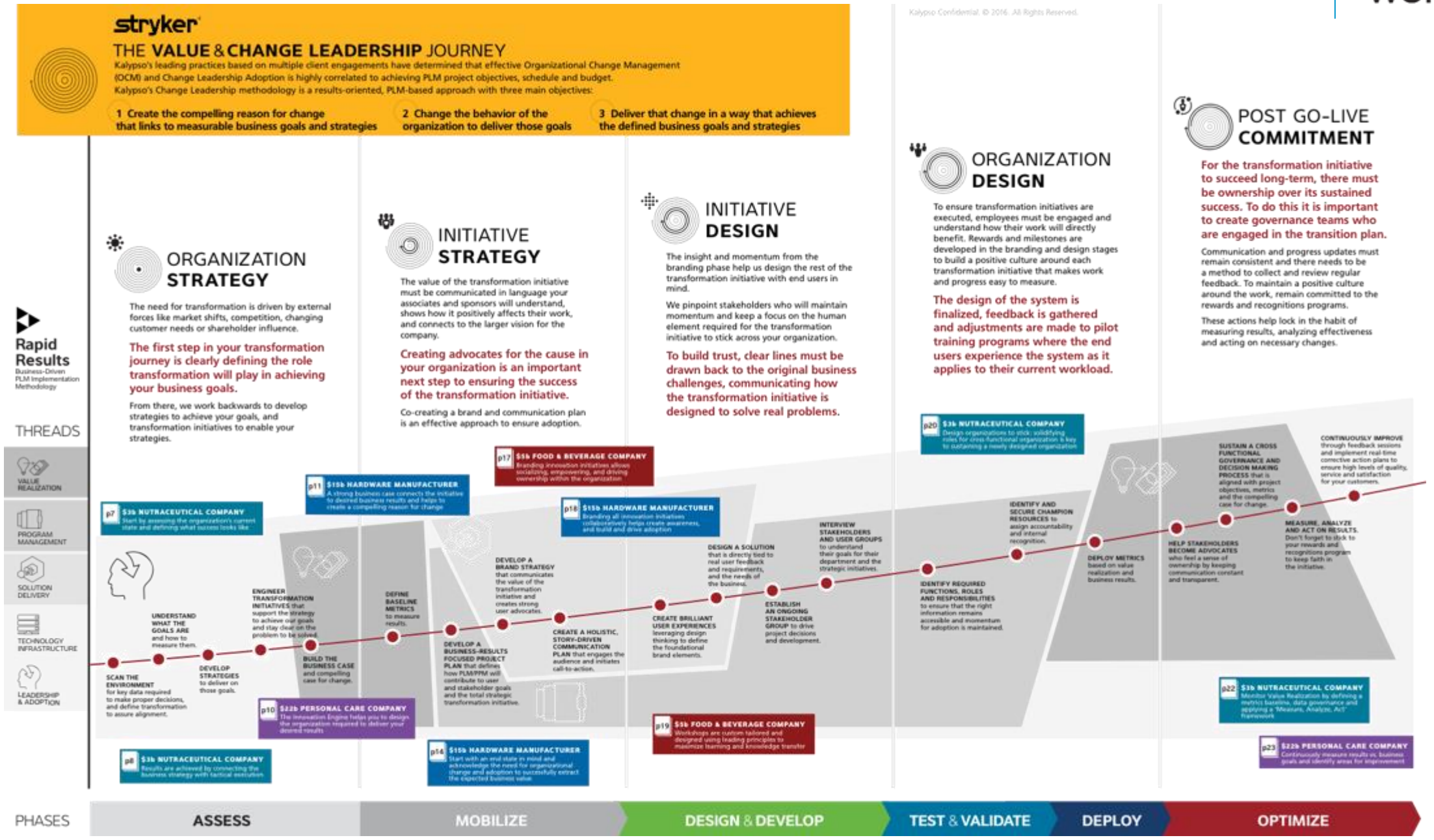
KALYPSO MEDICAL DEVICE INDUSTRY SOLUTION

ACCEL FOR MEDICAL DEVICE DEPLOYED ON Windchill POWERED BY ThingWorx | LIVEWORX 16

Document Management DHF/DMR	Part Management	CAx Management	Promotion Request
Change Management	Electronic Signature	Roles and Access Control	Validation Documentation
Design Control Utility	Design History File Checklist	Project Management Dashboard	Requirements Management
CAPA / Complaints / Non-Conformance	Risk Management	Regulatory Submission	Learning Management

TRANSFORMATION APPROACH

KALYPSO | LIVEWORX 16



stryker

ProjectSAPPHIRE

#onePLM

BUSINESS CASE FOR CHANGE

Toniel Spiedel, Senior Manager – Stryker

INTRODUCTION

Product Lifecycle Management (PLM) is comprised of **standard processes, people interactions and an enterprise information system** that enables and integrates across the product lifecycle.

SAPPHIRE is Stryker's program to deliver mature PLM capabilities across the enterprise

CLIMATE & PROGRAM CHALLENGES

Multiple Global PLM Program Attempts	Centralized IT with Shared Services Model	Pent Up Demand in Business
Organization in Transition	14 different independent environments vying for IT resources	Competing Program Priorities
Two Competing PLM Platforms	Continuous flow of acquisitions	Two Competing PLM Platforms

“Need: A compelling case for Change”

STRYKER APPROACH

Partner with Business	Develop Credibility and Champions for Change
Resolve Platform Direction	Implement Governance & Executive Sponsors
Define Scope and PLM Capabilities Roadmap	Build Leading Practice Approach Capabilities Roadmap

"Given short time frame, lack of internal experience, shortage of resources, and need for industry validation, Stryker looked outside for support."

GLOBAL PLM STRENGTHENS

Four Strategic Platforms

PLCM

We must reduce the number of unnecessary SKUs and eliminate the costs of complexity throughout the organization.

Regulatory Compliance

We must simultaneously improve regulatory control and execute our processes faster.

Innovation Volume & Velocity

We must increase our ability to innovate and enable divisions to collaborate.

Globally Integrated Company

We must learn to ‘speak the same language’ and operate as a globally integrated company.

“PAINSTORMING”

To better understand the barriers to fulfilling strategic objectives, we facilitated a course of “painstorming” interviews with 40+ leaders across business units and functions with the purpose of identifying business “pain points.”

PLCM
- Product Obsolescence
- Change Management
- Impact Analysis
- Costs of Complexity
- Component/Part Introduction

Regulatory Compliance
- Product Registration
- Change Management
- Document Management *(DHF, DMR, Tech Files, etc.)*
- Collateral Material
- Design Transfer
- Audits

Innovation Volume & Velocity
- Cross Divisional Innovation
- Stage Gate/NPD Process
- Design Control
- CAD Tools
- Electronic Instructions for Use
- Configuration & Change Management
- Internet of Things/ Connected Products

Globally Integrated Company
- Acquisition Integration Process
- M&A Strategy
- Commodity Rationalization
- Supplier Management
- Centers of Excellence

PLM STRATEGY & PLANNING

Define Requirements & Business Case

Focus on Harmonized Business Process

Link Case to Strategic Platforms

Pain Storming with Business Executives

Work with R&D & Quality Equally

Assess Competitive Landscape

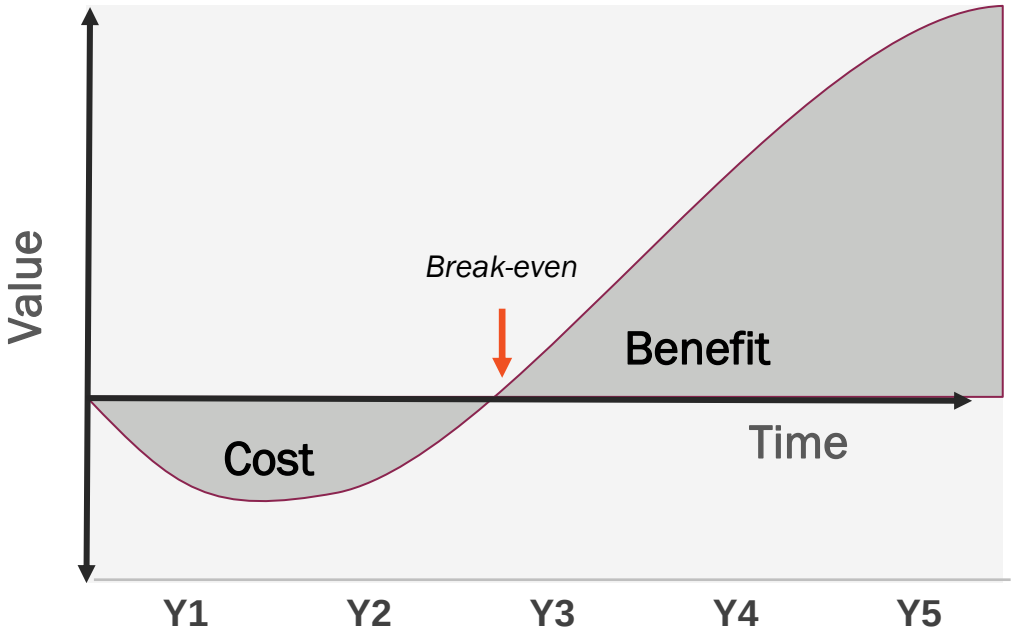
Align with Finance on ROI and Business Case

Think Top Down

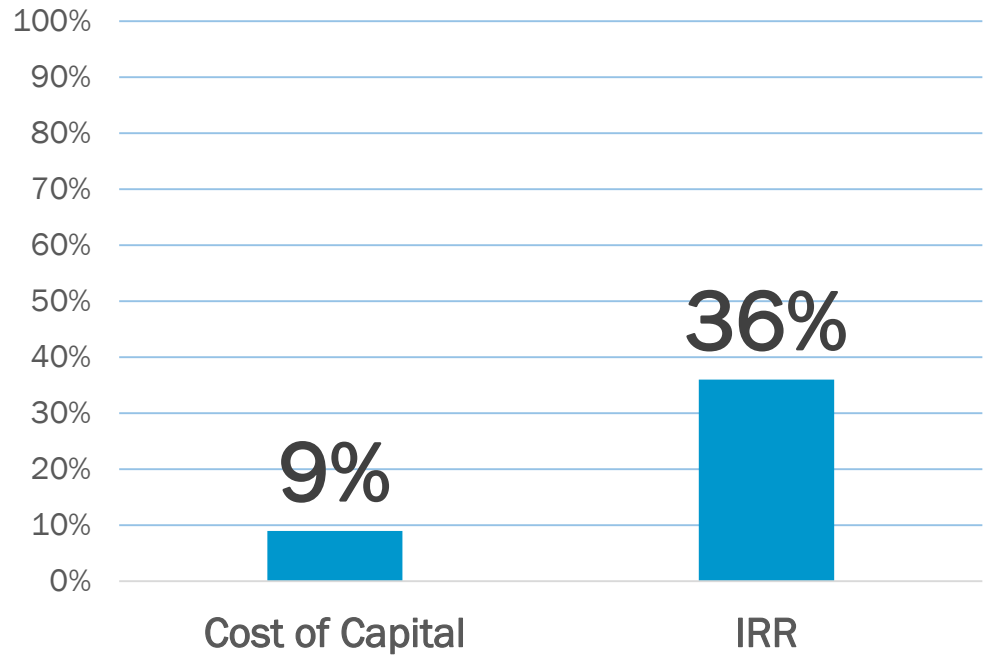
COMMERCIAL SUMMARY

The Sapphire program enables operational measures that will **positively impact EBITDA** while creating **longer term strategic value for the company**.

Payback Trajectory



IRR vs Cost of Capital



20 month Payback*, $28M NPV, 36% IRR

* Payback excluding non-quantifiable financial benefits

SUMMARY

Global Program

Governance and 3 Year Funding Established

Platform Decision Complete

Resources Committed

Global Design in Process

Foundational for Stryker Future Success


LIVE
WORX16™
TAKE A FRESH LOOK AT THINGS
liveworx.com