MEDICAL DEVICE CATALYST

PLM World
Agenda

- Speaker and Sogeti Introduction
- Medical Devices Catalyst Overview
- Catalyst on Cloud
- QA
Speaker Introduction

Srini Datla - Sogeti USA, Practice VP – PLM & Engineering

With nearly 20 years of experience with Product Engineering, PLM and Information Technology, Srini has held several roles including PLM strategy consultant, program manager, project manager and PLM architect, CAD software developer and design engineer.

He is currently responsible for partner relations, business development, talent management, IP development and service line growth for PLM Solutions for Sogeti USA.

Srini has over 6 years of Medical Devices Industry Experience.
GET TO KNOW SOGETI

LOCAL TOUCH—GLOBAL REACH™ AT YOUR SERVICE

20,000+ SOGETI EXPERTS WORLDWIDE

45+ YEARS OF EXPERIENCE FOR DELIVERY YOU CAN COUNT ON

20+ CITIES ACROSS THE USA GIVING YOU EASY COMMUNICATION AND LOCAL ACCOUNTABILITY

15 COUNTRIES AROUND THE WORLD PROVIDING ACCESS TO GLOBAL CoEs

180,000+ EXPERTS STRONG—AS PART OF THE CAPGEMINI GROUP—

20+ GLOBAL DELIVERY CENTERS AROUND THE WORLD
SERVICES ALIGNED TO YOUR GOALS
UNLOCK THE FULL POTENTIAL OF TODAY’S LATEST TECHNOLOGIES

Business Information & Analytics
Digital Transformation
Cloud Services
Software Development & Integration
Product Lifecycle Management & Product Engineering
Testing Services

Discover & Innovate
Optimize & Build
Accelerate & Ensure
Medical Devices & Life Science Technologies: Highlights

Engaged with 12 of Top 25 Medical Device Companies
85% Repeat Business

Ranked #1 by Zinnov in 2014 in the Healthcare R&D space for 4th consecutive year
Rated as Leader by HfS in 2015 for Medical Devices & Healthcare

200+ submissions to FDA for Class II and Class III devices
40+ Class III Device FDA Submissions

1500+ Dedicated Team with 15+ years of experience

ISO 13485 Certified
Quality systems harmonized with ISO 14971 and ISO 62304

Ecosystem of Partnerships:
With Hospitals, Clinicians, Academia, Contract Manufacturers, Test Labs
SOGETI SIEMENS PARTNERSHIP
In Medical Device Industries

Medical Industry Thought Leaders

SIEMENS

SOGETI

Medical Device Catalyst

Jointly developed industry-standard solution for Regulatory Compliance

Jointly developed industry-standard solution for Regulatory Compliance

Accelerated Time-to-Value

Accelerated time-to-value for our customers by packaging best-practice business processes and corresponding configurations for rapid deployment

Accelerated Time-to-Value

Incorporated into Siemens PLM Quality by Design initiative for the Medical Device Industry.

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Smart Innovation for Medical Device Manufacturers

5 Critical-to-Quality Practices that result in “Quality by Design”

1. Systems + Model-Based Engineering
2. Integrated Design: Product / Mfg / Quality
3. Global Design Control
4. MES
5. Analytics

SOGETI CATALYST

DHF

DMR

DHR

QMS

Regulatory Mandated

Restrict © Siemens AG 2015
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Why Catalyst?

**Business Benefits**

- Accelerate product development with reuse of existing DHF/DMR and product deliverables
- Reduce the risk of non-compliance and potential penalties with standardization and quality gates in product development.
- Improved quality with continuous monitoring of product development progress
- Accelerated Time to Regulatory Agency Approval with electronic DHF/DMR and eSignatures
- Reduce audit times by up to 60% with easy to use reporting and visual navigation

**IT Benefits**

- Reduced time for business alignment with pre-defined business process templates
- Reduced Implementation time and effort with pre-configured system.
- Reduced IT system validation with ready to deploy Computer System Validation (CSV) templates
PRODUCT FEATURES

Medical Device Catalyst

Pre-Configured Teamcenter Template

- DHF/DMR Management
- Requirements Traceability Matrix
- Pre-Defined Security Model

Deployment Accelerator

- Validation Ready Regulatory Template
- Solution Guide
- Deployment Guideline

21 CFR Part 11 & 820 Compliance

Pre-Configured Workflow
The catalyst provides an intuitive interface to quickly find and access design history file and device master record whether it is for a design review or for a regulatory inspection. Product engineers can reduce the time to track, manage and reuse product information.
DHF/DMR MANAGEMENT

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DMR-000065/A4-Laparoscopic-stapler

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DHF/DMR TEMPLATE MANAGEMENT

Based on FDA guidelines, predefined templates for DHF and DMR’s ensuring consistency in regulatory submissions and avoids compliance gaps. An administrator can quickly configure structures for use in new product lines or new geographies.
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The catalyst comes preconfigured workflows representing leading design control practices including CFR 820 guidelines. Built in electronic signatures enable compliance to CFR part 11 with simple audit trail and reporting.

These workflows support: dynamic participants; a fast-track option; an easy-to-understand change history and friendly e-mail notifications. Auto generated PDF’s for MsOffice deliverables provide quick access to approved deliverables.
Program leads can easily generate detailed requirements traceability reports which can be used tracking completeness of the design and ensure compliance to CFR 820.

These reports and document exports are generated in clicks rather than the weeks required with isolated “silod” engineering and desktop tools and readily available regulatory inspection.

Complete traceability coverage enables teams to quickly identify the impact of any change, while ensuring that integrity of all downstream artifacts and activities.
The catalyst provides predefined industry standard roles, organizations and groups. Project based security model is defined and aligned with business process and organization best practices.
Medical Devices Catalyst Roadmap

2016

In Flight

• Design Controls (DHF management)
• Document Control (DMR Management - preliminary)
• Requirements Traceability Matrix
• Cloud Ready

2016

Scheduled

• Stage Gate Processes (Project and Program Management)
• Quality Records Management
• DMR (PLM-ERP integration)

2017

Planned

• Risk Management
• Doors integration
• ALM integration
• Systems Engineering
• eQMS integration
• eMDR (HL7) integration
• UDI and label Management
• Product Catalogues, IFU Service manuals
• Camstar integration
Medical Devices Catalyst on CLOUD

Sogeti Cloud Complete
Leveraging the advantages of Cloud in five key ways ...

1. To improve business performance
   - Competitive advantage through access to leading edge and best of breed business applications and Business Technology solutions (e.g., marketing, analytics, retail). Increase innovation, experiment with fail fast approach.

2. To improve business agility
   - Competitive advantage through ability to provision and change custom IT services quickly and reliably at low risk and cost. Increase speed to deploy.

3. To rationalize a legacy application estate
   - Use the standardization provided by the cloud as an opportunity for rationalize applications, through consolidation onto cloud standard technologies.

4. To improve quality of application services
   - Use cloud infrastructure to overcome limitations of hosted services. Performance, scalability, and resilience are the qualities most often sought after. Flexible & Scalable.

5. To lower the IT Cost base
   - Use the economies of scale provided by the cloud to realize sustainable lower infrastructure and ITSM costs.
   - Move Capex to Opex.
Amazon AWS

Today the benefits are known...

Move from operational to variable cost

Lower variable cost than most companies can achieve

No need to guess capacity

Agility, speed & innovation

Remove undifferentiated heavy lifting

Go global in minutes
Why AWS?

AWS positioned as the “Leader” in the IaaS Magic Quadrant for the 5th consecutive year

- AWS is the only “Leader” recommended for Enterprise Workloads
- Gartner increased predictions about AWS market share and customer adoption from 5x the other 14 providers combined to 10x the other 14 providers combined
- Gartner calls AWS the provider most commonly chosen for strategic adoption.
- Gartner concludes AWS has the richest array of IaaS features and PaaS-like capabilities in the market
- Gartner calls AWS the safe choice
- Gartner proclaims AWS has a multi-year competitive advantage

AWS named as a leader in the 2015 Gartner Public Cloud Storage Services Magic Quadrant

- AWS is the coherent “Leader” recommended for Public Cloud Storage Services
- Gartner rated AWS as having both the furthest completeness of vision and the highest ability to execute
- Gartner concludes AWS continues to be an innovative and agile cloud storage provider with a steady cadence of new products and functionalities that is helping it sustain its market leadership
- Gartner says AWS’s storage portfolio continues to evolve to meet growing customer needs across a wide set of use cases.

Source: Gartner Magic Quadrant for Cloud Infrastructure as a Service, Worldwide (May 2015)
Sogeti Cloud services portfolio

We leverage an ECOSYSTEM of partners to deliver our CLOUD services.

Cloud Choice

Cloud Advisory
- Cloud Strategy
- Cloud Business Vision
- Cloud Roadmap

Cloud Migration
- Legacy apps/workloads assessment & migration
- New cloud native apps

Cloud Operations
- Cloud service integration (Infra+ apps) & cloud management (COMPLETE)

Transforming the applications portfolio

Infra & Apps together
Optimal workload allocation to public and private IaaS - safely and in control

Helping our clients define, plan and deliver their journey to the Cloud
Services that bring Cloud benefits alive to our customers e.g. “provisioning, orchestrating, managing and governance and control”.

- Cloud Ops. provisions the platforms that add most value to the client in terms of performance, economics, business case and security.
- Typically, our clients are migrating to a hybrid estate that includes SaaS, public cloud – PaaS and IaaS – private cloud, dedicated cloud – and still some upgraded conventional infrastructure.
- Cloud Ops. then orchestrates those platforms to work together within the overall enterprise architecture.
- Crucially, Cloud Ops. provides the management and governance of the service clients consume.

Press enter to continue...
# Cloud Operations (Complete) end to end Management

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<th>Decide</th>
<th>Design</th>
<th>Build</th>
<th>Integrate</th>
<th>Migrate</th>
<th>Run</th>
<th>Support</th>
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<td>Usage and Accounting</td>
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<td>High Availability</td>
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<td>Server, Storage, Network Management</td>
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**Cloud Infrastructure Abstraction & Aggregation Layer**
Teamcenter Infrastructure Typical Process

- Project Kickoff
- Sizing
- Procure Hardware
- Install/Test / Cutover
- Tuning
- Monitor

- OS Patch / Upgrade
- Hardware Failure
- Storage changes
- New Facility
- New Project

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Medical Devices Catalyst on AWS

Sogeti Medical Devices Catalyst AWS Machine Image / Cloud Formation Script
Teamcenter AWS Machine image from Siemens

Global Rollout on demand

Deploy on Demand

Client 1 VPC
Client 1 Corporate Network

Client 2 VPC
Client 2 Corporate Network

Client 3 VPC
Client 3 Corporate Network

Scale on Demand
Managed by Sogeti Cloud Complete

Managed by Sogeti Cloud Complete
Why Catalyst on Amazon AWS & Sogeti Cloud Complete

• ‘I want a solution quickly’
  ✓ Teamcenter Application plus infrastructure as a package

• ‘Get me out of my datacenter – It is too slow’
  ✓ Migrating workloads to cloud infrastructure

• ‘I do not have Capex but need to start project NOW’
  ✓ Pay as you go. Siemens licenses, Sogeti services and AWS on a monthly subscription.

• ‘I do not have trained staff to support Teamcenter’
  ✓ Setup, monitoring and management by Sogeti Cloud Complete
Thank You