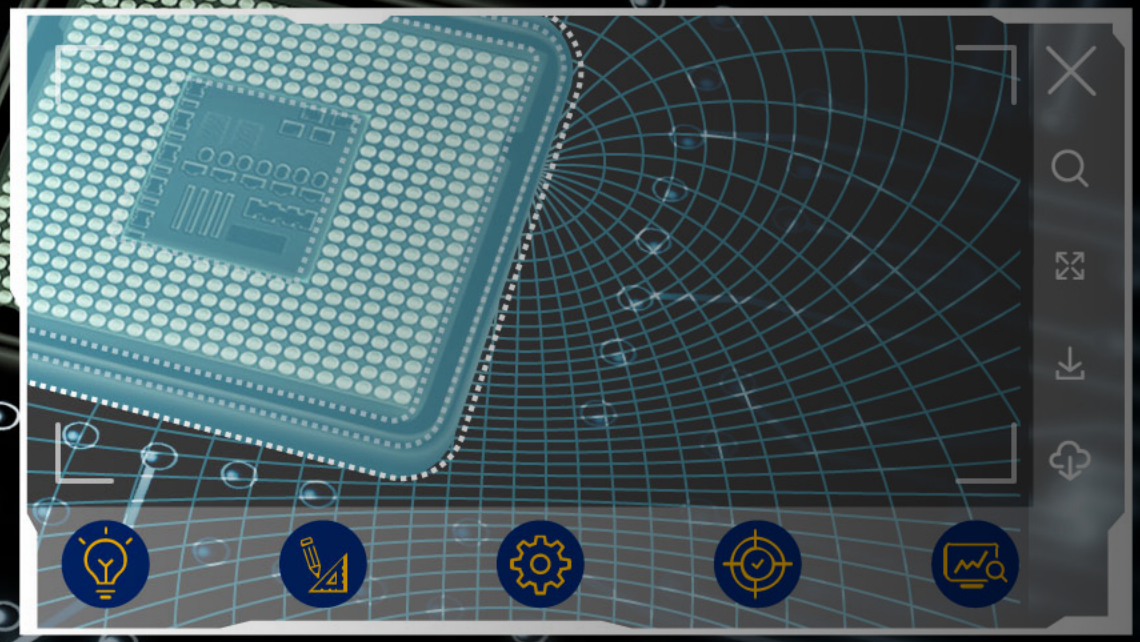
PLM AS FOUNDATION FOR A DIGITAL TRANSFORMATION IN THE MEDICAL DEVICE INDUSTRY

accenture

ISRAEL YUSTE PICON – EALA PLS LEAD @ ACCENTURE
CLAUS-PETER GAERTNER - HEAD OF OPER. & QUALITY IT @ ROCHE

MAY 2017



ABOUT ACCENTURE PLS

ACCENTURE PLS
BUILDING ON OUR SUCCESS IN INDUSTRY

Unmatched industry expertise

#1 Recognized as worldwide leader by industry analysts

25+ Years of experience in Product Lifecycle

10,000+ Product Lifecycle professionals

...plus many other partners including niche players

ACCENTURE PRODUCT ENGINEERING & LIFECYCLE SERVICES

GLOBAL PRACTICE WITH STRATEGY, CONSULTING, DIGITAL, TECHNOLOGY AND OPERATIONS SKILL SETS SUPPORTING CLIENT TRANSFORMATIONS

Recognized as worldwide **PLM Leader** by Industry analysts

2.000+ Product Lifecycle Projects

1 Integrated Global **PLS Practice**

75+ Locations
31 Countries
Innovation, R&D, Technology Delivery

25+ Years Of experience in Product Lifecycle

10.000+ PLS Professionals

Digital Product Engineering

- Innovation & Product Strategy
- R&D Control Tower
- R&D / Product Reinvention
- PLM / ALM DevOps Transformation
- Engineering Services

Manufacturing & Digital Operations

- Manufacturing Strategy
- Manufacturing Value Realization
- Manufacturing Digital Enterprise
- Manufacturing-as-a-Service

Service Operations & Optimization

- Aftermarket Service Strategy
- Service Control Tower
- Parts & Service Optimization
- Service Lifecycle Transformation
- Product Maintenance
- Service Operations

IoT & Connected Business Transformation

- Product to Service Strategy
- Connected Product & Service Innovation
- Connected Devices
- Specific Industry IoT Solutions
- Connected Product Solution Operations

«RETHINK – RESHAPE – RESTRUCTURE…FOR BETTER PATIENT OUTCOMES»

WE HELP OUR CLIENTS TO DELIVER BETTER OUTCOMES TO IMPROVE THE QUALITY OF LIFE

ACCENTURE LIFE SCIENCES INDUSTRY PRACTICE

FAST FACTS ABOUT OUR PRACTICE

15,000+ life sciences professionals in 50+ countries

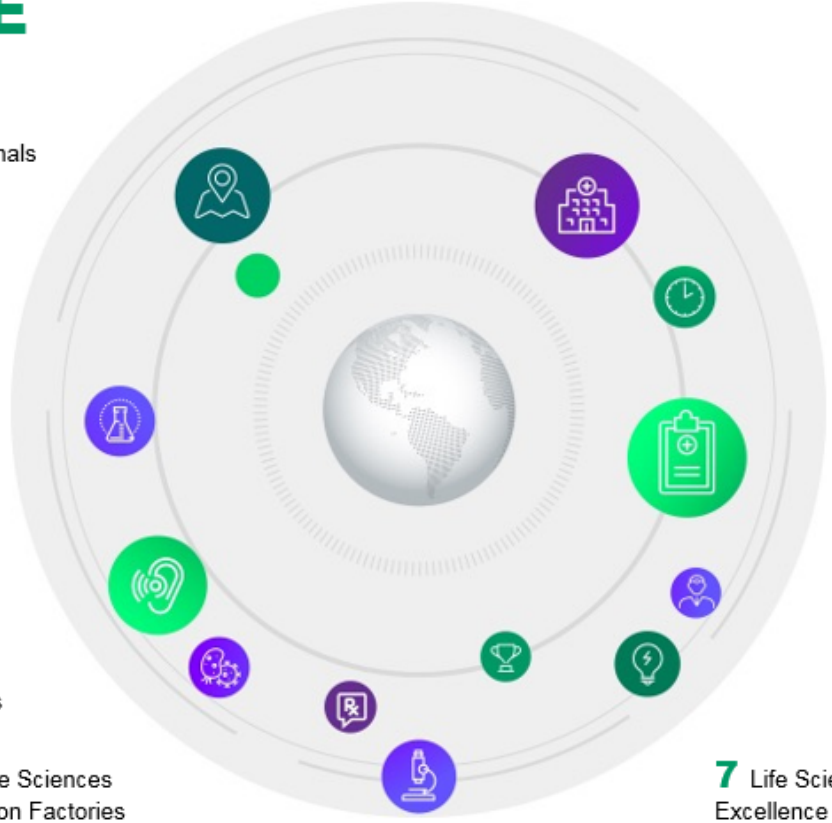
ALL of the top 10 global biopharmaceutical companies

9 of the top 10 global medical technology companies

ALL of the top 8 largest biotech companies

ALL of the top 10 global pharma markets

5 Life Sciences Solution Factories



Helping **95%** of Fortune 500 life sciences companies deliver improved outcomes for more than two decades

21+ years of business process outsourcing experience

Deep expertise in **9** of the top 10 therapeutic areas

250+ medical professionals

3 Life Sciences Innovation Centers (Dublin, Murray Hill, Sophia Antipolis)

7 Life Sciences Centers of Excellence across the globe

OUR ALLIANCE HISTORY
ACCENTURE IS A 16 YEAR STRATEGIC PARTNER WITH PTC

Strategic PTC partner since **2000**

400+ Accenture PTC professionals worldwide

PTC experience at Accenture:

- Specialized in Global, Large-Scale Enterprise Engagements
- Developed the initial Enterprise Systems Integration (ESI) to ERP solution and first large scale implementation with PTC (PTC-SAP and PTC-Oracle integration)
- Deep PTC implementation experience in both process and discrete industries
- Expertise in Windchill (PLM Platform), Creo (CAD), ProjectLink, PartsLink, MPMLink, Service Information Manager, Pro/Intralink, Pro/Engineer, Arbortext creating and utilizing project accelerators for quick configuration development and data migration
- Dedicated PTC Centers of Excellence in Montreal, Europe and India

Subset of Joint PTC Clients

EADS, AIRBUS, Raytheon, Solar Turbines A Caterpillar Company, stryker, Hasbro, PHILIPS, GENERAL ATOMICS AND AFFILIATED COMPANIES, EMC², DELL, THALES, Boston Scientific, ASTRIUM, C&A, FORCE PROTECTION, Walmart Save money. Live better., Roche

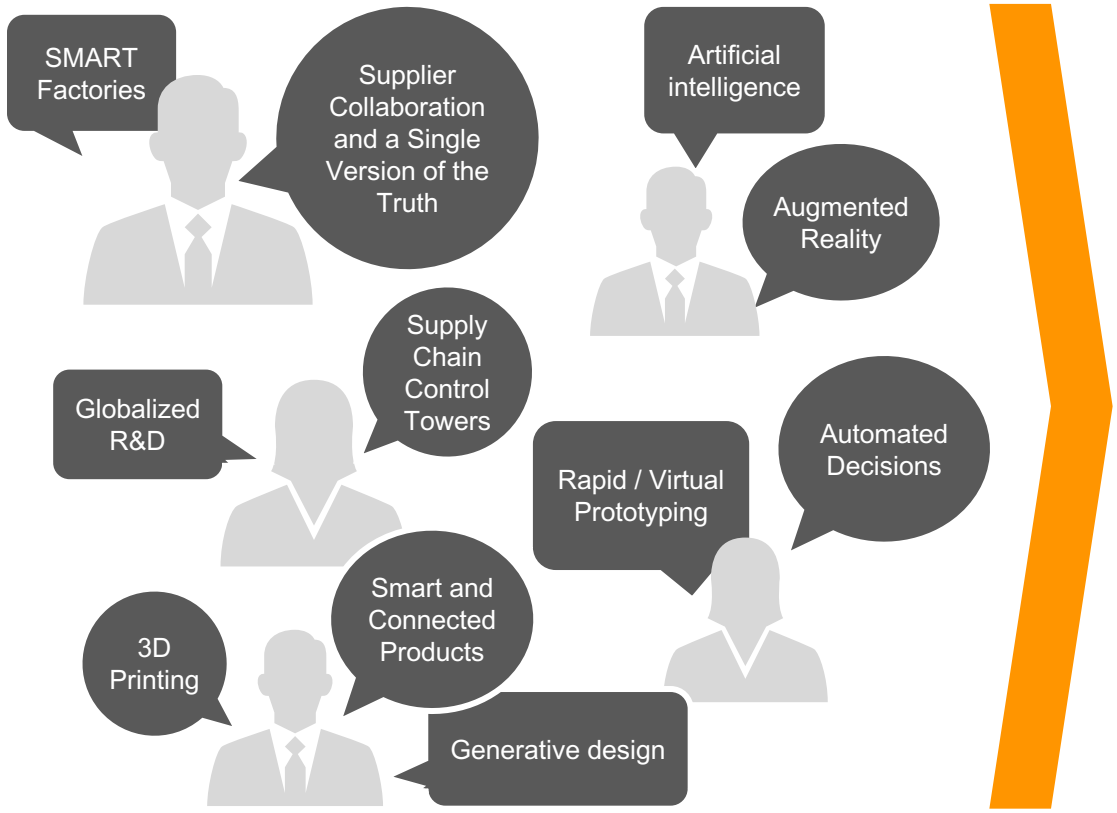
"PTC and Accenture have worked together since Windchill v1.0 and have enjoyed a strategic partnership for more than 15 years. During this journey we have jointly developed several solutions and systems for our clients in various Industry domains but also we believe have been the needed catalyst in driving needed business results. We have evolved a common process and methodology approach which incorporates our lessons learned. In addition, we periodically engage at several forums for strategic alignment. We believe it's a true model of partnership…"

Jim Heppelmann, CEO PTC

MEDICAL DEVICES INDUSTRY – CHALLENGES & SOLUTIONS

DIGITAL TECHNOLOGIES ARE CHANGING BUSINESSES
...AND UNLOCKING ADDITIONAL OPPORTUNITIES TO THE MEDICAL DEVICE INDUSTRY

Supply chain executives are determining how to deliver high performance through new technologies and capabilities...



…. While facing more challenges, workload and R&D budgets continue typically "capped"

- Higher innovation rates and more demand for shorter product lifecycles
- Increasing product complexity, driven by software-driven functionality
- Connected Products & Services and the Internet of Things (IoT) as a game changer
- New and disruptive technologies (big data, connectivity, personalization, IoT)
- Globalisation of engineering networks and integration of external partners
- Increasing cost pressure; need for standardised parts and modules and product platforms
- Complexity and cost of operating within the regulated environment

CURRENT KEY DIGITAL TRENDS WE SEE IN THE MARKET
ARE YOU READY FOR THE NEW?

Software Centric Products

- Systems Engineering
- Complexity and variants
- Convergence of Mechanical and Software Engineering
- Product Software development
- DevOps, Agile and Platform based developments

Acceleration of the Product Value Chain

- Emerging technologies for simulation and validation
- Virtualization of physical processes
- Virtual and augmented reality in manufacturing and service
- Additive – 3D / 4D Printing

Agile Manufacturing

- Product to machine communication (Cyberphysical systems)
- Closed loop integration (PLM-ERP-MES-ShopFloor)
- Mass customization and flexibility
- Data driven optimization (Supply chain, machine operations)
- Connected Industrial workers

Platforms and Connected Product Operations

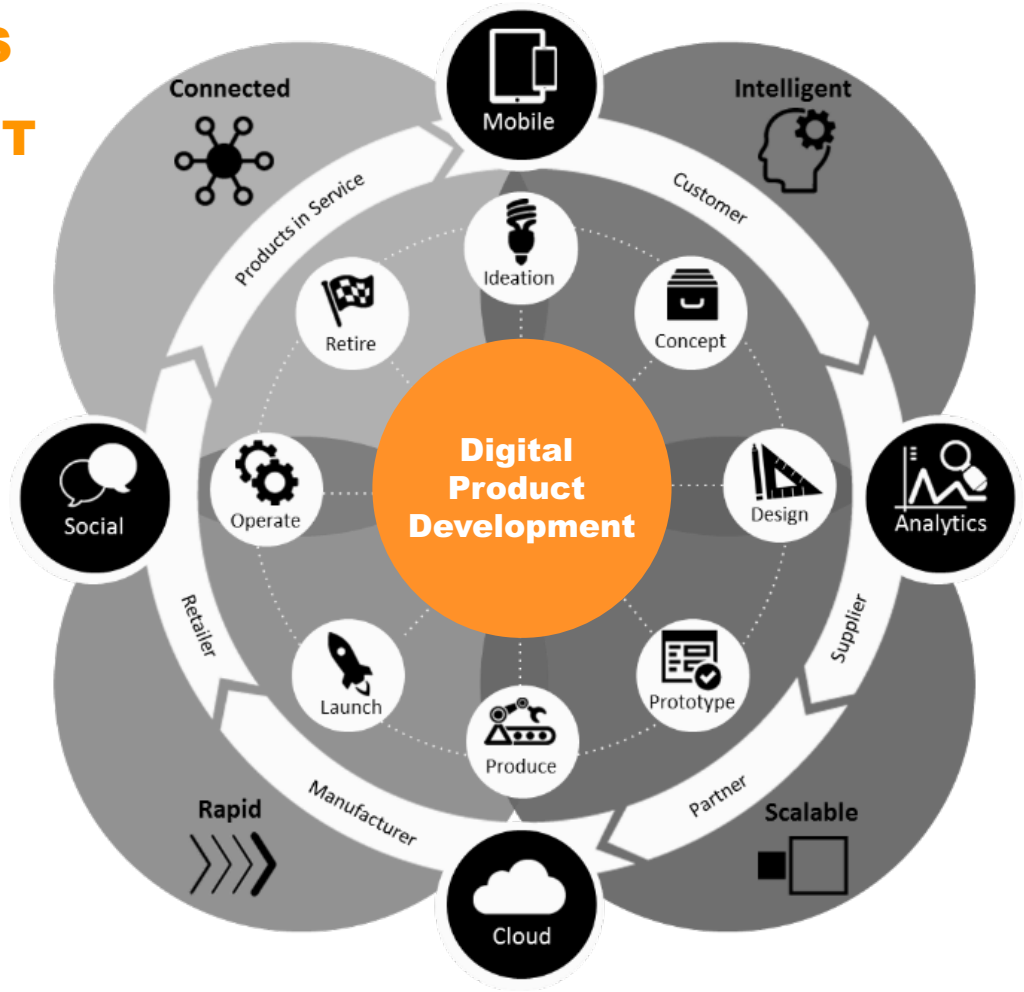
- Digital eco-systems
- Industry platforms and clouds
- Security
- Augmented product support and warranty optimization
- Software distribution and installed base management
- Data Management and Analytics

VALUE creation from connected products and services

- Innovation driven growth
- Products to Service transformation
- New business models
- Digital ecosystems and industrial platforms
- Data driven value chains
- Industrial combinatorial extensions

THE IMPACT OF THE NEW GLOBAL AND DIGITAL ECONOMIES ARE DRIVING COMPANIES TO CHANGE THEIR PRODUCT DEVELOPMENT MODEL

ACCENTURE'S PRODUCT DEVELOPMENT FRAMEWORK



- **CONNECTED PRODUCTS**
- **GLOBALISED R&D**
- **DESIGN CHAIN COLLABORATION**
- **DIGITAL PRODUCT DEVELOPMENT**
- **INSIGHT THROUGH ANALYTICS**
- **PRODUCT COST**

INDUSTRY X.0 - HELPING OUR CLIENT SHAPE THEIR PRODUCT AGENDA OF TOMORROW

Smart Experiences	Hyper-Personalization & New Experiences	• Designing, creating experiences and business models
Smart Products & Services	Ecosystems & Smart Services	• Help our clients innovate their own ecosystems, digital portfolio and aftermarket services
	Platforms & Analytics	• Help our clients leverage/optimize IoT with aaS solutions
	Smart Products	• Help our clients “cognify” their products with embedded software and connectivity
Engineering & Production	Digital PLM and Engineering	• Enable next generation Digital Product Lifecycle Management
	Manufacturing and Production	• Help clients transform their production for greater efficiency

ENABLING PLM TRANSFORMATION – CPLS ACCELERATOR

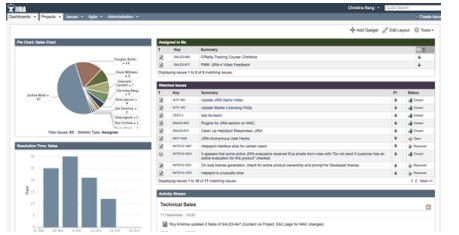
A PLM TRANSFORMATION AS STARTING POINT TO MOVE INTO THE "NEW"

CPLS ACCELERATOR IS THE FIRST STEP INTO DIGITALIZATION

1 PLM Transformation – cPLS Accelerator

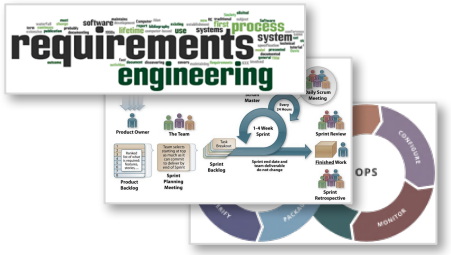
2 New Business Models – Connected health

3 New Eco Systems – Intelligent platforms

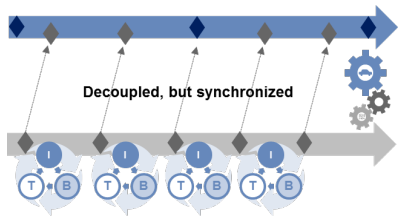


PLM DITIGAL TRANSFORMATION

4 Software Development Operational Excellence



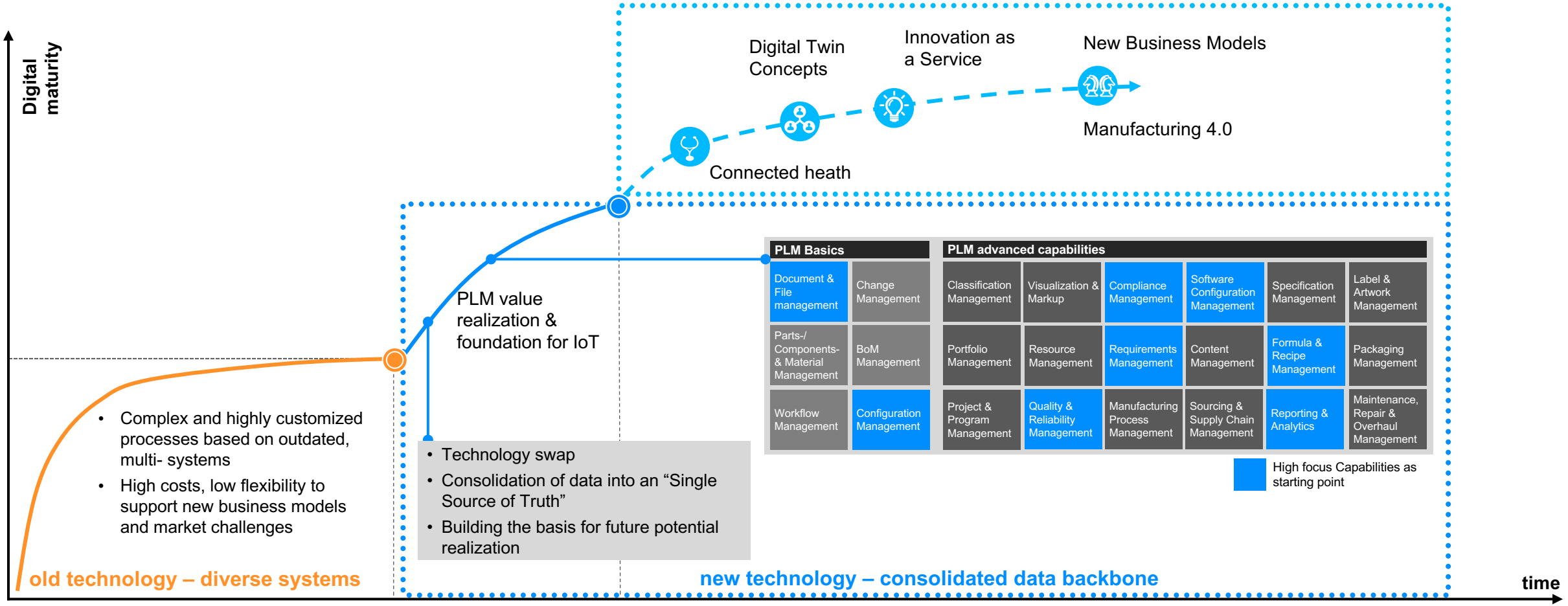
5 Smart Manufacturing



6 Service Operational Excellence

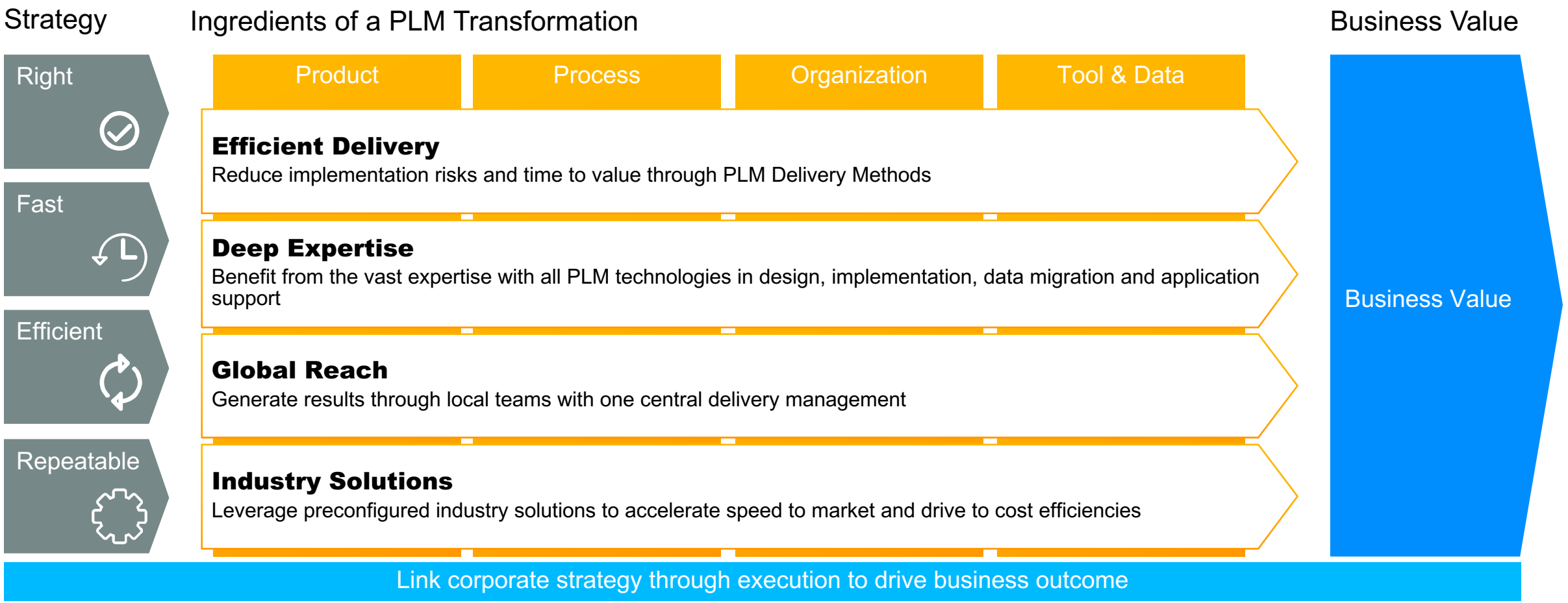
WE UNDERSTAND PLM AS A STARTING POINT FOR A LARGE DIGITAL TRANSFORMATION JOURNEY AND FOUNDATION FOR IOT

WHERE WOULD YOU START YOUR DIGITAL TRANSFORMATION?



DEFINING PLM AS AN STRATEGIC BUSINESS TRANSFORMATION GENERATING BUSINESS VALUE

A TRANSFORMATION APPROACH



AN SOLID STRATEGY APPROACH AS KEY TO SUCCEED
HOW STRONG IS THE CASE?

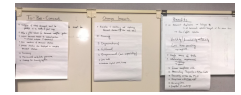
CAPABILITY DEFINITION & SCOPING
PLM Capabilities assessment

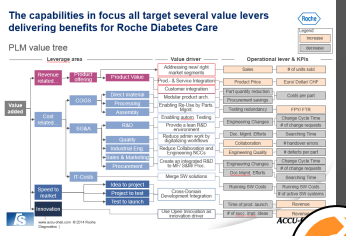
- Capabilities maturity checked in assessment
- Importance of capabilities for the business determined

BENEFIT ESTIMATION
to quantify the value of each capability

COST EVALUATION
developed from current figures

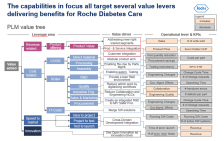
- Client input
- Assumptions based on experiences, related projects
- Workshop Results

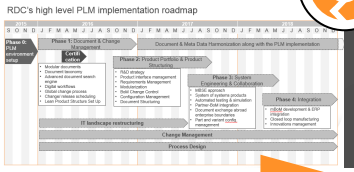




BUSINESS CASE
to calculate and visualize the value of the PLM Foundation

- Rough business case structure
- Quantification of qualitative figures → input is the benefit and cost estimation
- Calculation of overall benefits and costs





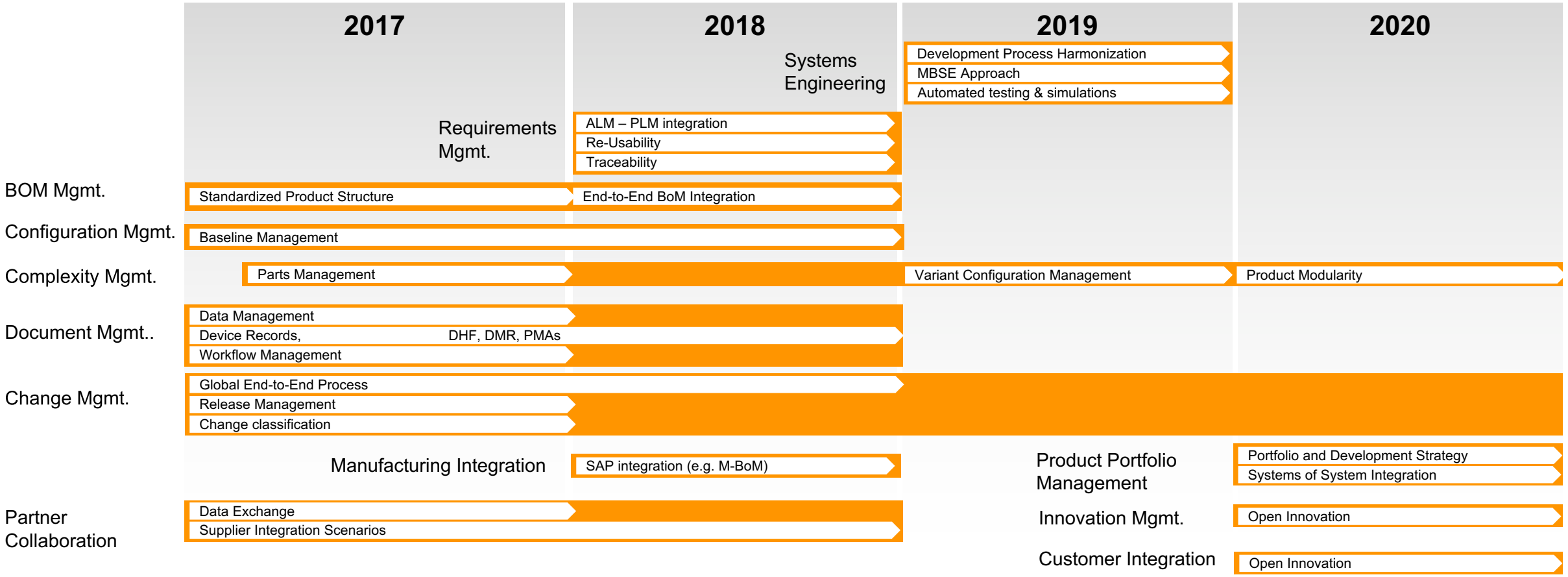
IMPLEMENTATION ROADMAP

- Implementation Sequence is partly predetermined by functional dependencies
- Client requirements/ preferences are considered

BUSINESS CASE SUMMARY
Cost and Benefit development and Break Even (NPV Calculation)

- Matching Costs and Benefits to determined roadmap
- Visualization of the break even
- NPV Calculation

SAMPLE OF A CAPABILITY ROADMAP FOR A PLM TRANSFORMATION



KEY GUIDING PRINCIPLES TO ENSURE A SUCCESSFUL TRANSFORMATION

GUIDING PRINCIPLES FOR PLM PROGRAMS

Value Driven	 **Value**	Reliable values concerning benefits and costs in early stages of the project to derive a robust decision basis for future investments and rollout sequences.
Process Improvement	 **Value**	Consistent improvement and standardization of core processes and organizations as an essential part of the project scope.
Focus and Pace	 **Risk, Cost**	Focus on essential capabilities, professional project management, reuse of proven approaches, predefined business processes and standardized IT systems.
Integration	 **Value**	Tight integration of downstream business processes and applications cross sites and cross the extended company network.
Change Management	 **Risk**	Achieve commitment and buy-in on the organizational and the individual level through an integrated set of tailored change management actions.

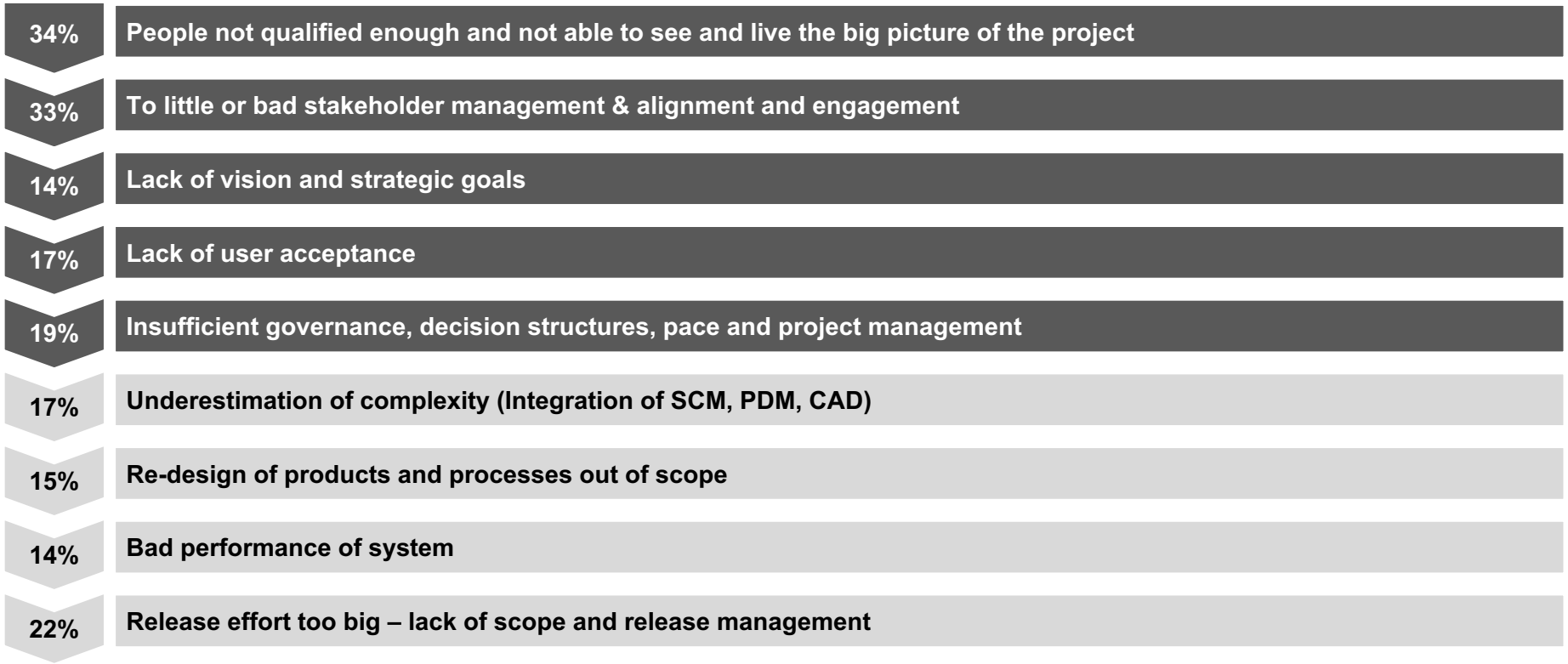
KEY ROOT CAUSES OF PLM FAILURE ARE ALSO CHANGING UNDER THE NEW DIGITALIZATION ERA
ARE YOU PREPARED?

History of failure

Only **16%** of PLM projects are successful.

41% fail.

43% end up with time and budget overrun.



Way to success

Guidance principals enabling leaders, project- team and staff

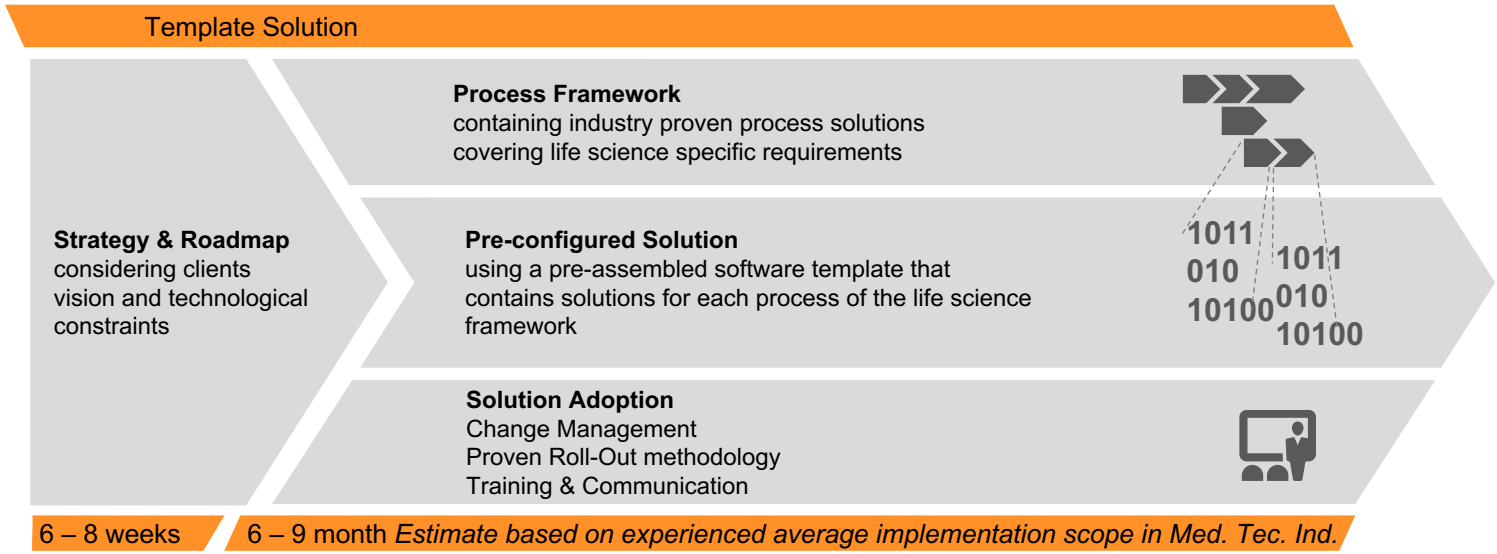
Additional challenges associated to new digital technologies are also becoming challenges and root causes of failure (e.g.: Technology challenges, IT Infrastructure, etc…)

Failure based on people issue

* Accenture Analysis of PLM projects of Accenture plus Benchmark

A PROVEN AND EFFECTIVE SOLUTION APPROACH

WE SUPPORT OUR CLIENTS FROM DAY 0 WITH THE RIGHT STRATEGY AND A TEMPLATE SOLUTION…



Why using a template solution instead of following a "greenfield" transformation approach?

1. **Significant Cost reduction** — up to 40%
2. **Faster implementation** — 40% faster
3. **Proven solution** — 30% less customizations

Key Elements

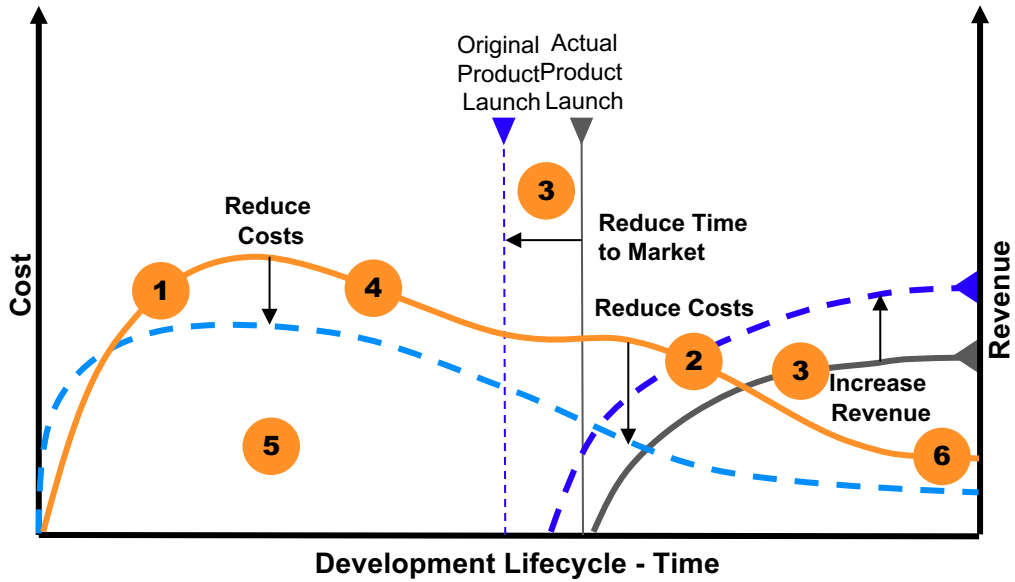
- One initial transformation initiation to identify key capabilities and confirm the IoT Vision – **Value Driven Approach**
- **Consolidated process** data base and **framework** based on industry proven practices and technological possibilities
- **Continuous assessment of continuity** from strategy to solution
- **Full traceability** from strategy through processes to solution components to address strategic targets with operational levers in real time
- Solution packages prepared as a pre-configured **Life Science solution template**
- Release stacking based on technological & capability constraints - **fast quick wins** & enablement for digitized business models

WHAT KIND OF CHALLENGES CAN BE SOLVED IN THE MEDICAL DEVICE INDUSTRY WITH A PLM TRANSFORMATION*

DO THESE CHALLENGES AFFECT YOUR BUSINESS TODAY?

Key Challenges	How PLM helps
1 Significant cost pressure "Our development process is too ✸ expensive – all this rework…"	Overall costs, from development to operations, need to be optimized to remain competitive
2 Industrialization of healthcare "We invented a new housing even though we did not intend to do so…"	Provide tools to obtain full part management capabilities to drive re-use of parts and requirements
3 Too long time-to-market "Our product is missing its market launch – again."	Increase efficiency in development to hold launch dates and leverage full revenues
4 Regulatory environment "Pulling together the materials for a milestone approval takes far too long"	Provide tools to automate compliance reporting and audit trail in order to reduce administrative costs
5 Strategic Make vs Buy decisions "Our SW development delivery is not efficient and we miss key skills"	Reduce required R&D FTEs through efficiency gains and review partnering with key players for non-core work
6 Applying new service models "We cannot deploy system changes online, we always need the field technicians to do it"	Evolve to Connected products and obtain full management capabilities

*) Non exhaustive

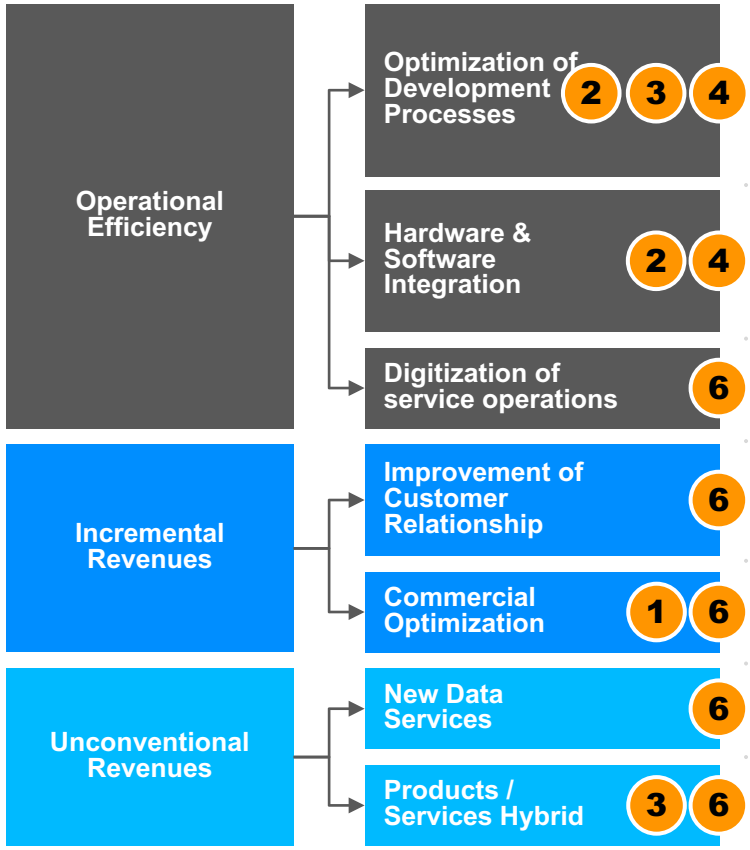


Key challenges mapped to an exemplary product lifecycle identify real pain points in the everyday work.

✸ Recurring quotes collected during PLM assessments in the medical technology industry

Actual Cost
Original Cost
Actual Revenue
Original Revenue

PLM CAN LEVERAGE POTENTIAL VALUE IN DIFFERENT AREAS
… AND HOW?



Illustrative Benefits

- **Reduce engineering costs** and administrative effort during development through automated PMA and FDA reporting capabilities for DHF, DMR or technical file creation
- **Increase Speed-to-Market** by **driving the re-use** of software and hardware components by having full transparency of product data in one single source of truth
- **Increase engineering efficiency** by improving transparency & collaboration with partners (e.g. simultaneous engineering)

- **Shorten development projects** by PLM & ALM Integration, which enables full traceability of hardware and software components to initial requirements
- **Improve system compatibility** through System Engineering capabilities to drive the interconnectivity of products
- **Manage growing complexity** with configurable BoMs and **minimized effort**

- **Reduced service costs** with as-maintained BoM views that allow for **remote maintenance** of devices in the field
- **Increase market fit** of new products with surveillance of used functionalities on devices

- **Reduce Lead Time from** order to delivery of medical devices allows customers an earlier usage of the equipment
- **Improve market acceptance** by developing customer solutions rather than products
- **Leverage new channels of customer feedback** through service data conversion into requirements for new products

- Access to certain software features is provided against an **annual license fee → Continuous remote software updates** or access to anonymized data bases supporting diagnoses as business model

- **New revenues** based on new business models (e.g. Connected Healthcare) and digital services
- **Reduce service costs** by leveraging remote software updates

- **Drive innovation** by using information about feature usage as direct input for the new product development

ILLUSTRATIVE EXAMPLE OF BENEFITS AFTER A PLM TRANSFORMATION

Increase Revenue	**10 - 20%** New product success rate	**15 - 25%** New product output	**2 - 4%** Revenue lift due to better product mix, faster time to shelf
Accelerating Time to Market	**4 - 55%** Faster product launch	**10 - 60%** Improve product development	
Decrease Cost	**5 - 15%** Direct Materials cost	**10 - 30%** Operational and development / engineering expense	
Decrease Cycle Time	**10 - 75%** Change control cycles	**5 - 35%** Design cycles	**10 - 15%** Time-to-volume

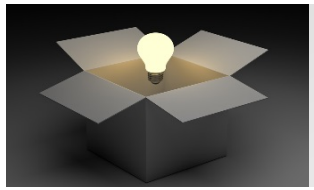
* Based on Accenture experience, illustrative examples only

ROCHE DC – PLM TRANSFORMATION

ROCHE DIABETES CARE
PLM TRANSFORMATION

Our current landscape is **highly fragmented** and **cannot support** our increasingly **complexity** or our highly-connected products

The proposed **roadmap** is laid out in 4 phases, with the goal to address **strategic business needs** first and lay the foundation for subsequent **business value-driven capability** phases, with value realization associated with each phase



Proposed Solution should be comprehensive to include **PLM and Document Management** functions and adopt **industry proven/certified solutions** to minimize the overall implementation efforts and associated risks of building a custom solution

Proposed PLM transformation to introduce PLM information management **to save the business bottom line costs** by reducing non-value added R&D efforts, promoting re-use, facilitating traceability and complexity management, and improving quality. Furthermore, use PLM as enabler to adapt the organization from functional to product centric

STARTING SITUATION

ROCHE DIABETES CARE WAS FACING NEW MARKET CHALLENGES WHILE SUFFERING PAINS IN SEVERAL AREAS

Pain Points

PROCESSES
- Time consuming manual data exchange between IT-Systems
- Error prone manual configuration management
- Paper based workflows

EXTRACT

DATA
- Missing holistic product view
- Lack of integration with partners
- Lack of a single source of truth

IT COSTS
- Lack of transparency of IT costs due to historically grown IT-landscape

Business Impact

Long time-to-market

High development costs

Lost innovation leadership

Dissatisfaction with business processes

Challenges

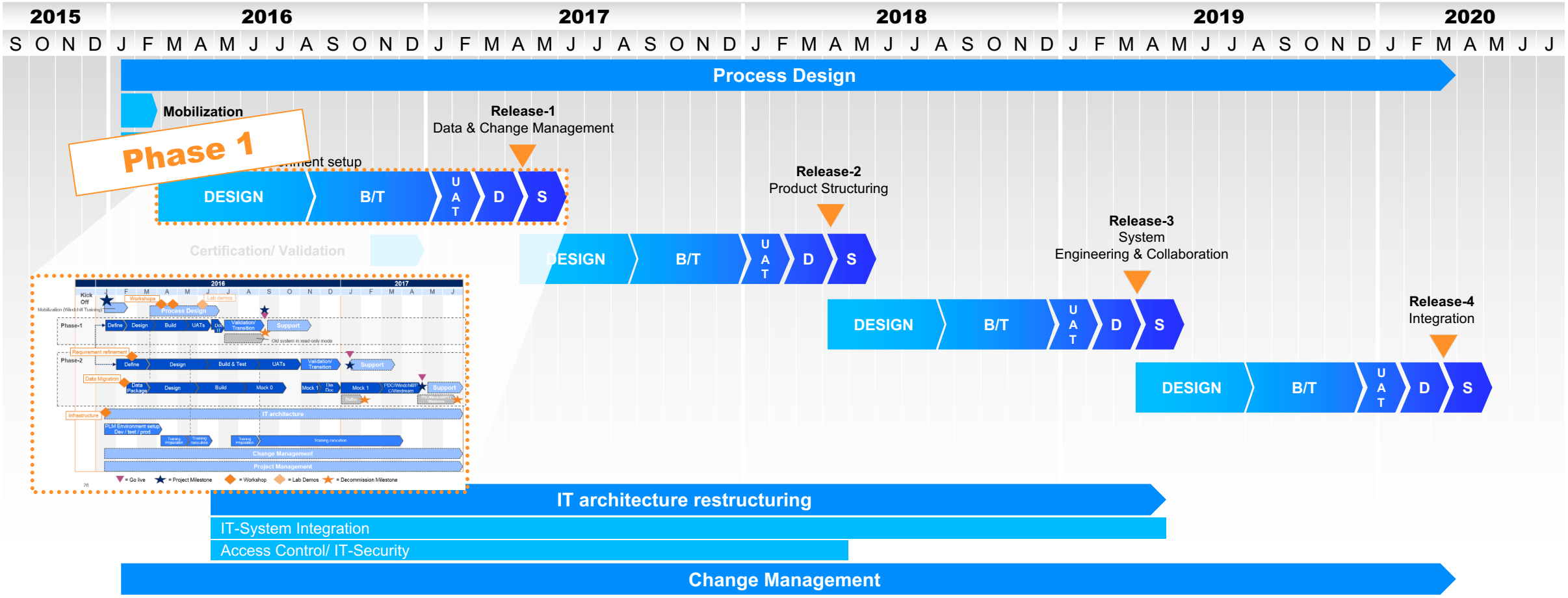
PRODUCT
- Increasing **complexity** due to more **connected** portfolio
- Customer solutions focus creates product **dependencies**
- **Smart** technologies (IoT)

MARKET
- Business **flexibility** to adapt to changing market demands
- Growing **cost** and regulatory pressures

BUSINESS
- Increasing **collaborations** with external partners
- Emergence of PMA products for DC

WE ARE FINISHING UP THE PHASE 1 OF THE OVERALL ROADMAP

SETTING THE SCENE ON THE ROADMAP



HIGH-LEVEL GOALS FOR THE BUSINESS & PLM

THE PLM VISION HAS BEEN DERIVED FROM BUSINESS GOALS

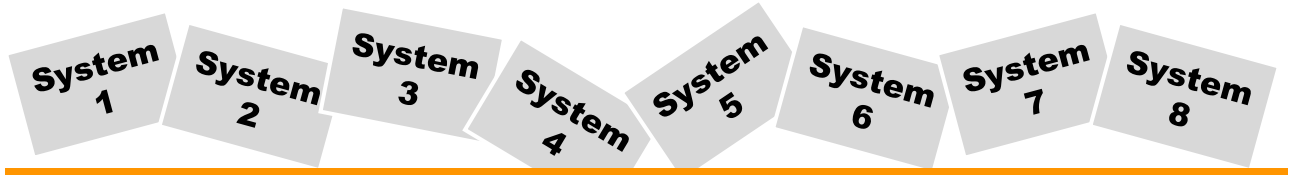
Business goals

- **Reduce Cost**
- **Increase Speed to Market**
- **Accelerate Innovation**
- **Enable Greater Business Flexibility**
- **Reduce Regulatory Compliance Risk**

Cornerstones of PLM vision

- **Simplify IT Landscape…**
- **Improve internal and external collaboration…**
- **Introduce a product centric data & document management …**
- **Improve reuse of technical assets…**
- **Introduce single source of truth…**

CURRENT STATUS
PHASE 1 IS 75% COMPLETE; PHASE 2 FUNDED AND RAMPING UP



8 systems consolidated into a single source of truth

Process Harmonization achieved in one year

- Globally harmonized doc. & change management, including records management
- Lean Process established for records, IT documents or prototyping needs
- Centralization of Document Control / Change Management
- Baseline Reporting functionality globally rolled out
- Templates / Data Governance models established to ensure sustainability

General Improvements | Topics to be addressed in future phases | Process Improvements

- Training integration. Manual workarounds established until WT can integrate with new system
- Robust SAP integration (driven by effort to not recreate data in Windchill which exists already in SAP)
- PLM-level governance established
- System-driven product structure hardcoded
- Validation documentation harmonization planning
- End-to-end traceability (Requirements – Specifications – Design – BOMs)

DESIGN & PROCESS HIGHLIGHTS 1/2

Changes	Description
1 Single Source of Truth	• 5 core / hub sites in one system • All sites will be able to access each other's content, except confidential information • Data from 8 doc management and department drives moved to WT • All R&D mechanical design authoring consolidated to one tool • Across site nomenclature harmonization
2 Digitized Records Management	• Product & Process-centric organization of data: Quality Management, Product & Business Branches • Records Management fully digitized: Not applicable to raw data • Records linked directly to products / multiple products
3 Flexible Change Processes	• Lean Version Control vs. Fast Track vs. Full Track Changes • Inclusion of PMA attributes and triage for PMA-relevant changes • All Changes will begin & end in Windchill in an effort to drive consistency and transparency

DESIGN & PROCESS HIGHLIGHTS 2/2

Changes	Description
4 Single Information Sharing Point	• Solution to provide access for affiliates not at hub sites • Will provide Product-specific content (e.g. labelling) • Will provide 'pre-built' searches to access process-specific content • Will not create a copy of any documents outside Windchill
5 Labeling in Windchill	• Decision with Labeling & Product Management to begin and end all labeling creation / update requests in Windchill • Harmonized between sites to support a move towards global projects • This should allow for more transparent & accurate baselining of labeling process times
6 Baseline Reporting – eDHFs, Milestones, etc.	• Project milestones and design control readiness states reviews moved into WT • Operations launch distribution to be moved into WT • DMRs, DHFs, etc. to be electronically built as baselines • PMA reporting built-in

ABOUT ACCENTURE

Accenture is a leading global professional services company, providing a broad range of services and solutions in strategy, consulting, digital, technology and operations. Combining unmatched experience and specialized skills across more than 40 industries and all business functions – underpinned by the world's largest delivery network – Accenture works at the intersection of business and technology to help clients improve their performance and create sustainable value for their stakeholders. With approximately 401,000 people serving clients in more than 120 countries, Accenture drives innovation to improve the way the world works and lives.

Visit us at www.accenture.com.

CONTACT INFORMATION

ACCENTURE:
Israel Yuste Picon
T: +49 175 57 68 042
E: israel.yuste-picon@accenture.com

ROCHE:
Claus-Peter Gaertner
T:+41 61 687 88 91
E: claus_peter.gaertner@roche.com

ADDITIONAL INFORMATION

For more information on the Accenture Product Lifecycle Services, please click on the link to **www.accenture.com/PLS**