AGILE, CLOUD AND ERP IN VALIDATED ENVIRONMENT

Real Life Experience

12th June, 2018

Agenda

Introduction

Ulrike Kreibaum

Director Global ERP Projects

> Working in SAP environment since more than 19 years
> > 8 years as consultant
> > for more than 11 years in healthcare and life science industry

> Since 2002 as project manager in global deployments

> Since 2008 with Merck KGaA
> > Until beginning 2012 as project manager for global deployments (LA, NA and Europe)
> > Since 2012 on Program Management level e.g. responsible for project and deployment methodology
> > Since 2017 Program Management LEAN Healthcare ERP e.g. as Global Deployment Lead and Methodology responsible

Agenda

We are

MERCK

Since our founding, 350 years ago, we've become truly global with more than **52,000 employees in 66 countries** working on break-through solutions and technologies.

Merck KGaA
Darmstadt, Germany

EMD SERONO   **MilliporeSigma**   **EMD PERFORMANCE MATERIALS**

We are known as Merck internationally except for the United States and Canada, where we operate as EMD Serono in the biopharmaceutical business, MilliporeSigma in the life science business, and EMD Performance Materials in the high-tech materials business.

MERCK

To us, its to discover and develop for life in all its vibrancy, drawing our unique expertise in **health care, life science and performance materials.**
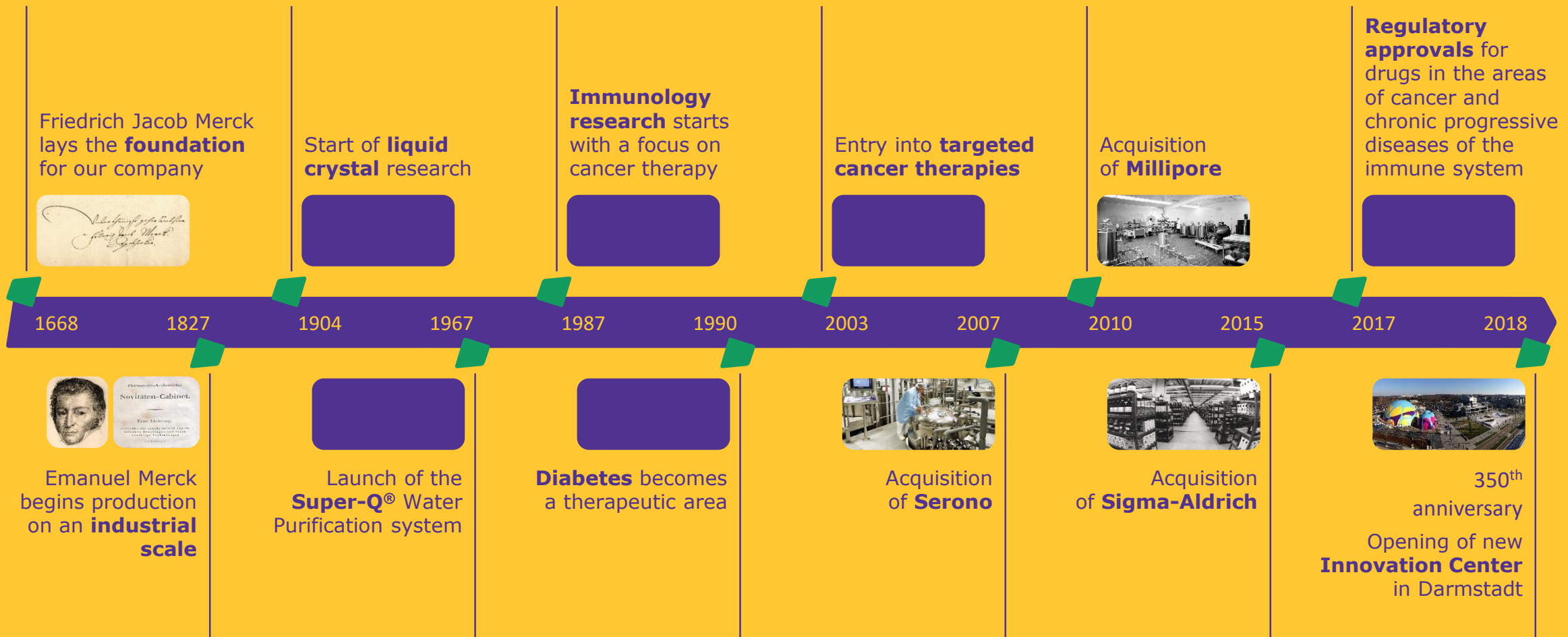
our ideas are everywhere

from cancer therapies and laboratory tools to the display of your smartphone or the color of your car.
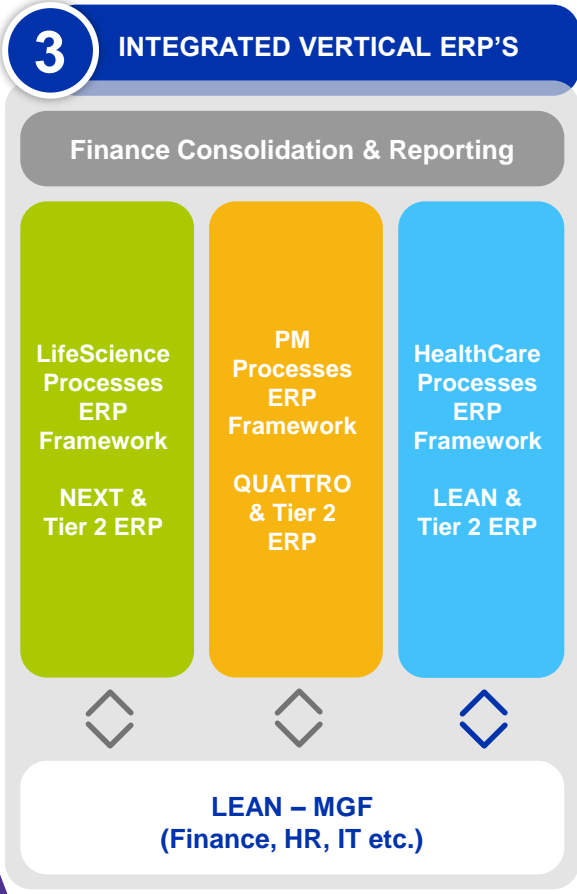
Merck

350 Years of cuRiositY

Regulatory approvals for drugs in the areas of cancer and chronic progressive diseases of the immune system

Friedrich Jacob Merck lays the **foundation** for our company

Start of **liquid crystal** research

Immunology research starts with a focus on cancer therapy

Entry into **targeted cancer therapies**

Acquisition of **Millipore**

1668	1827	1904	1967	1987	1990	2003	2007	2010	2015	2017	2018

Emanuel Merck begins production on an **industrial scale**

Launch of the **Super-Q®** Water Purification system

Diabetes becomes a therapeutic area

Acquisition of **Serono**

Acquisition of **Sigma-Aldrich**

350th anniversary

Opening of new **Innovation Center** in Darmstadt

Agenda

Background and context
Board decision for 3 ERPs gave us the opportunity to build a HC backbone of digitalization for tomorrow

3 INTEGRATED VERTICAL ERP'S

Finance Consolidation & Reporting

LifeScience Processes ERP Framework	PM Processes ERP Framework	HealthCare Processes ERP Framework
NEXT & Tier 2 ERP	QUATTRO & Tier 2 ERP	LEAN & Tier 2 ERP

LEAN – MGF
(Finance, HR, IT etc.)

Visibility

Customer/ Market knowledge

Patients

LEAN HC ERP develops our capabilities by providing a **backbone for digitalization**, bringing us closer to our markets and customers.
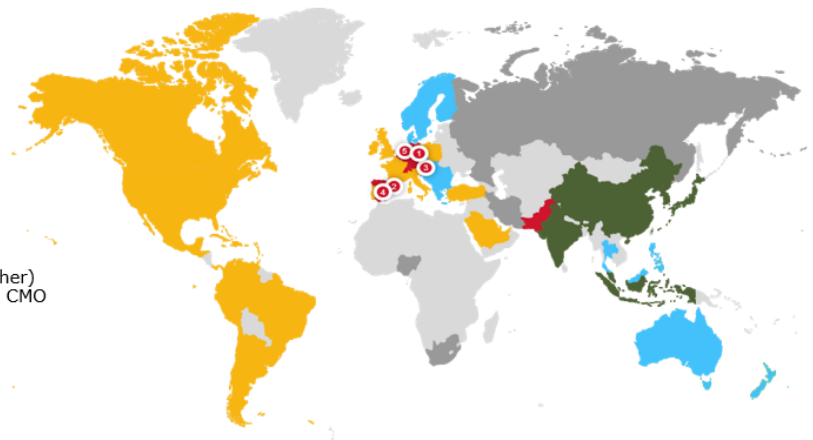
MERCK

Merck Healthcare ERP
Why LEAN was created

Today we have disparate ERP (SAP) systems that do not support our digitization strategy.

Tomorrow we will have common "state of the art" Lean ERP and fully integrated Supply Chain running complaint best practice processes and APO for all products.
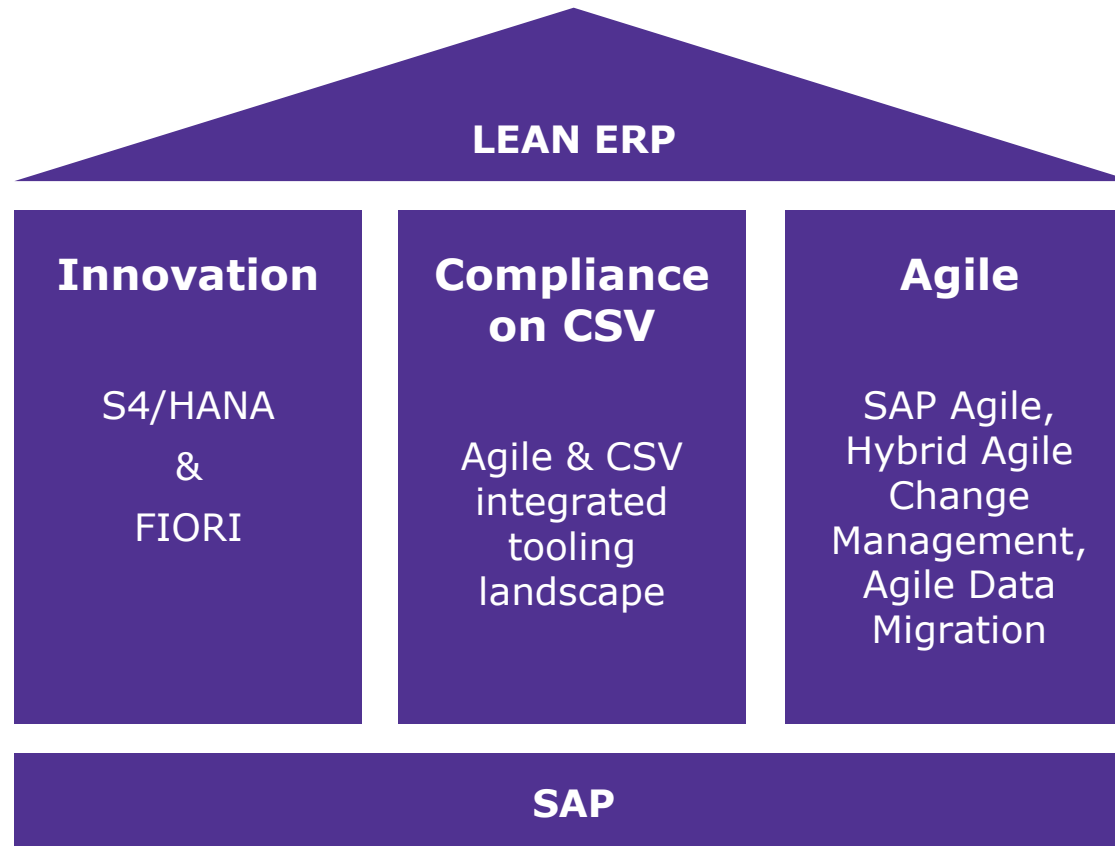
Lean SAP ERP and APO

■ Burning ERP Platforms (SAP and other)
■ No full solution existing e.g. Russia CMO
■ Tempo countries requiring upgrade
■ Scala countries
■ Emerald countries

Priority:
1 Darmstadt
2 Mollet
3 Spittal
4 Tres Cantos

1 **Operations and Supply at risk due to some key manufacturing sites running on "burning platforms" (out of maintenance)**

2 **Legacy Supply Chain processes restricting business agility and visibility leading to operational complexity & inefficiency**

3 **Inability to adopt "next generation" technologies like advanced analytics and mobility to drive competitive business advantage**

MERCK

Introduction to Business and Strategic objectives
Key strategic principles

- Lovable User Interface
- More advanced real-time management reporting
- More agile platform to support inorganic and organic growth

LEAN ERP

Innovation	**Compliance on CSV**	**Agile**
S4/HANA & FIORI	Agile & CSV integrated tooling landscape	SAP Agile, Hybrid Agile Change Management, Agile Data Migration

SAP

- Flexibility for scope corrections
- Business integration and adherence to business requirements
- Faster delivery
- Assuring real-time results and transparency

MERCK

LEAN is supporting the MERCK digitalization journey...

To find out more about the LEAN topics and technologies, please have a look at the digital infographic published in the LEAN EVA room: "About" section under "LEAN Infographic".

Latest technology based on SAPs S/4HANA will help to harmonize business processes and enable improved Analytics and Reporting. This will bring efficient Operations and more effective decision making along the entire Supply Chain - from Planning to Production and Distribution.

LEAN is hosted in the cloud and is accessible via a new intuitive, collaborative user interface, applying SAP Fiori technology.

MERCK

SAP S/4 HANA — Speed to manage complexity

SAP — Mobility through responsive interface

SAP Cloud — Accessibility any time anywhere

Real time Reporting & Analytics

Forecast-to-Plan (F2P)

IBP — Demand Planning with Integrated Business Planning (IBP)

Global Supply Planning

Local Supply Planning

Development of strategic, tactical, and operational supply chain plans as starting point for Production Planning and Manufacturing.

Account-to-Report (A2R)

Financial planning and forecasting, operations accounting and controlling as well as period end closing and reporting.

Fiori Apps and Financial Framework

Plan-to-Produce (Pl2P)

PAS|X WERUM — Manufacturing Execution System

SAP EWM — Extended Warehouse Management

Production

Materials Movement

Quality Management

Batch Management

Planning and Manufacturing of finished products including assembly of goods, quality control and final release.

Purchase-to-Pay (P2P)

Monitoring purchase orders, including receiving and verifying of products and services, and managing payments of suppliers.

Purchase Order

Fiori Apps for Procurement, eForms and Output Management

Project-to-Decommission (P2D)

SAP PPM — Portfolio and Project Management

Mobile Maintenance Request Management

Managing enterprise assets such as production equipment including projects, construction, maintenance as well as asset analytics.

Order-to-Cash (O2C)

Setting up and processing of sales orders, including outbound warehouse management and transportation, as well as handling of customer service.

SALES ORDER

Global Trade Service

Transport Mangement

End to end...

Supplier

Production

Warehouse

Customer

Transport

LEAN
Global ERP for Health Care

Manage-to-Activate (M2A)

Creation, maintenance and activation of all master data objects (e.g. materials, vendors, Finance) on global and/or organization specific level (e.g. plant, legal entity). Supporting processes to ensure data quality.

For more information about the **Lean Project** access our page on EVA:
https://evarooms.merckgroup.com/Project/LEAN

Powered by BT

Merck Healthcare ERP

LEAN Journey
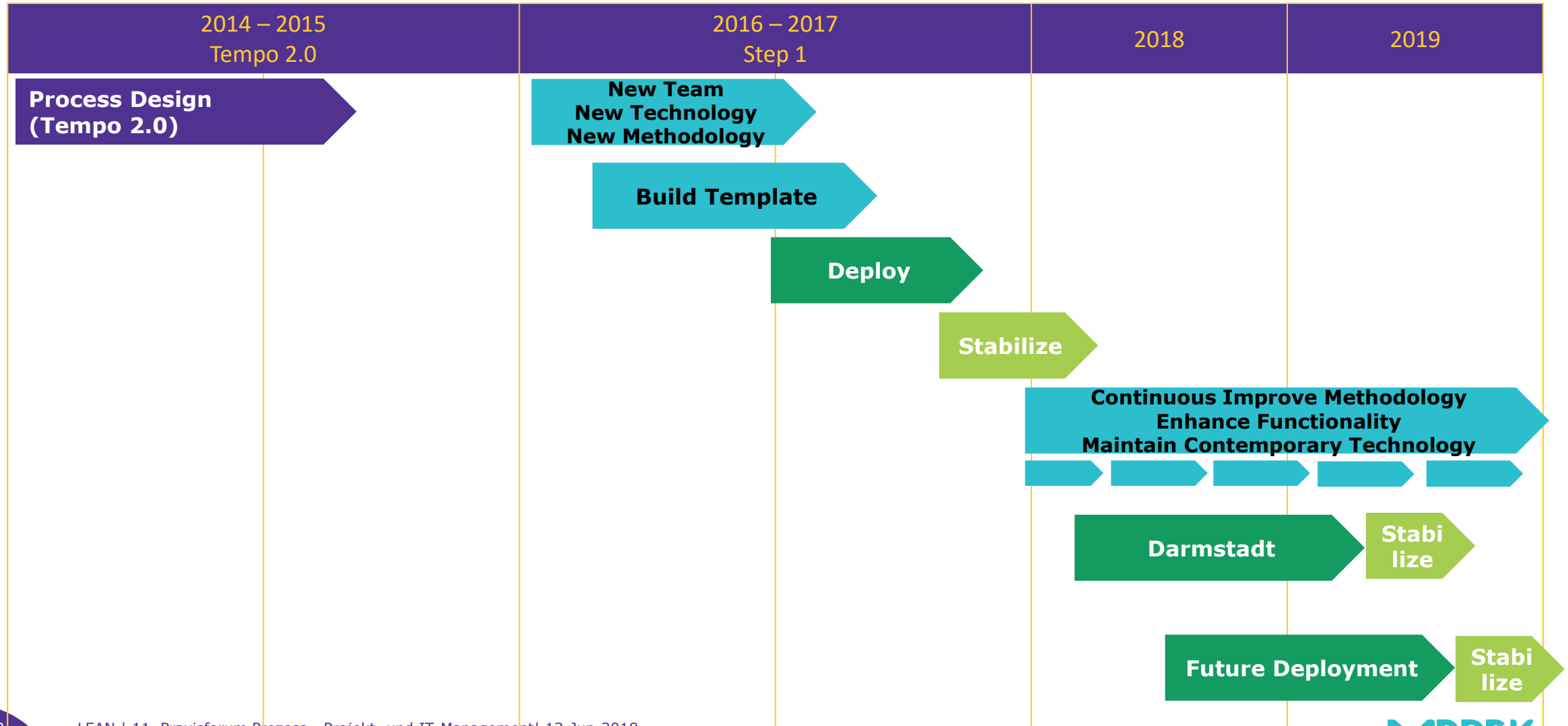
2014 – 2015 Tempo 2.0	2016 – 2017 Step 1	2018	2019

Process Design (Tempo 2.0)

New Team New Technology New Methodology

Build Template

Deploy

Stabilize

Continuous Improve Methodology Enhance Functionality Maintain Contemporary Technology

Darmstadt

Stabilize

Future Deployment

Stabilize

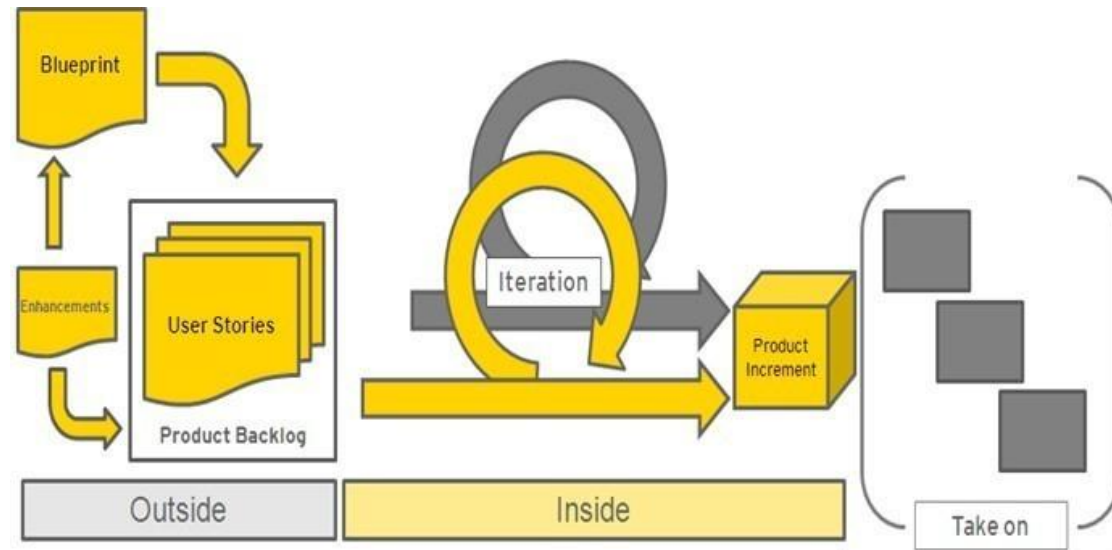# SAP projects require an overall frame of reference for Agile to work within

Outside

ARIS Blueprint

Business Blueprint for the Strategic solution.

The business **processes** detail "how" Merck executes or would like to execute its capabilities

Translate these 'requirements' in form of user stories

Take On - Outside

The sum of all the work completed during the iterations and all previous iterations into a Release

Additional **Business Acceptance Test (non-validated)** is executed here.

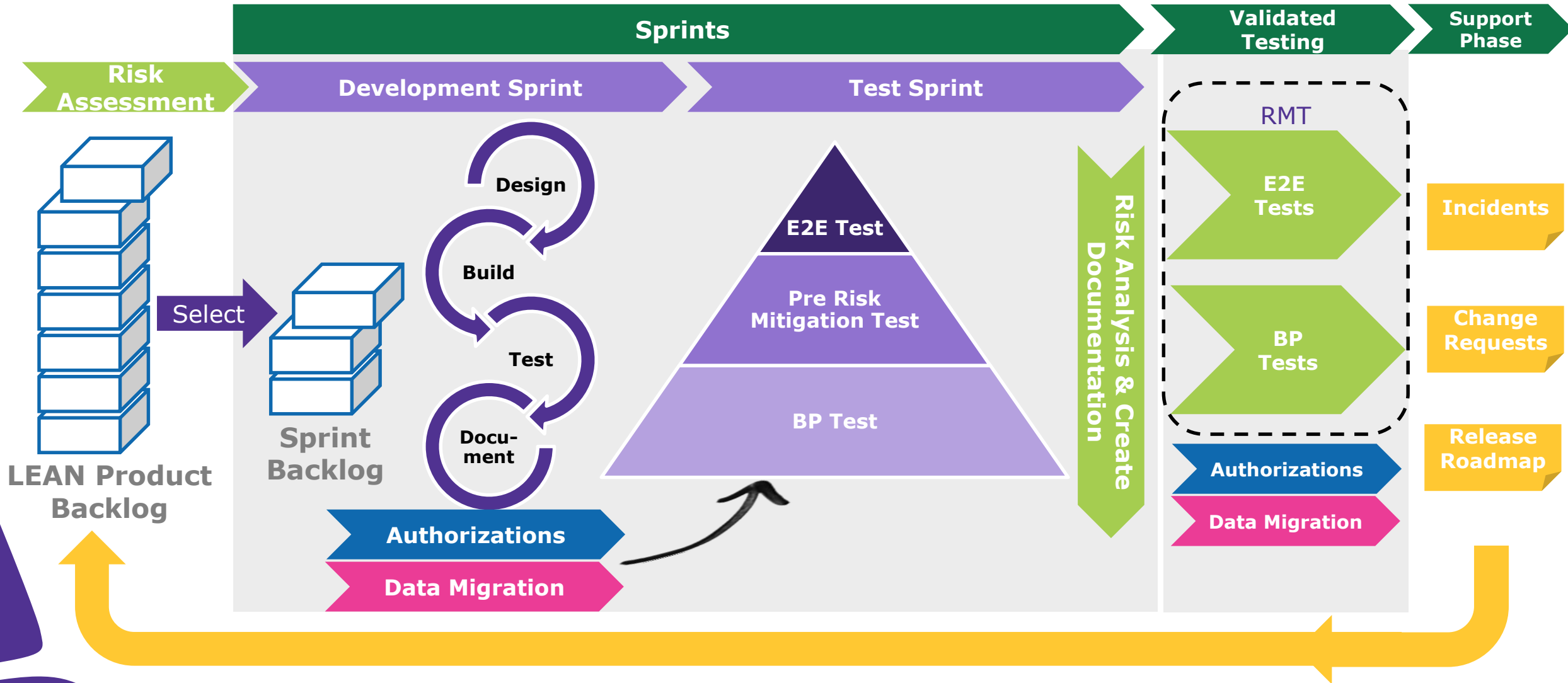**Validated Testing** happens here

Inside

Multiple iterations of the **time-boxed sprints** during which a "done", useable, and potentially releasable product Increment is created

It includes **detailed design, build and test**, documentation

Multiple solution based scrum teams work in parallel integrating the cross stream teams where required (data, analytics, security, change management etc.)
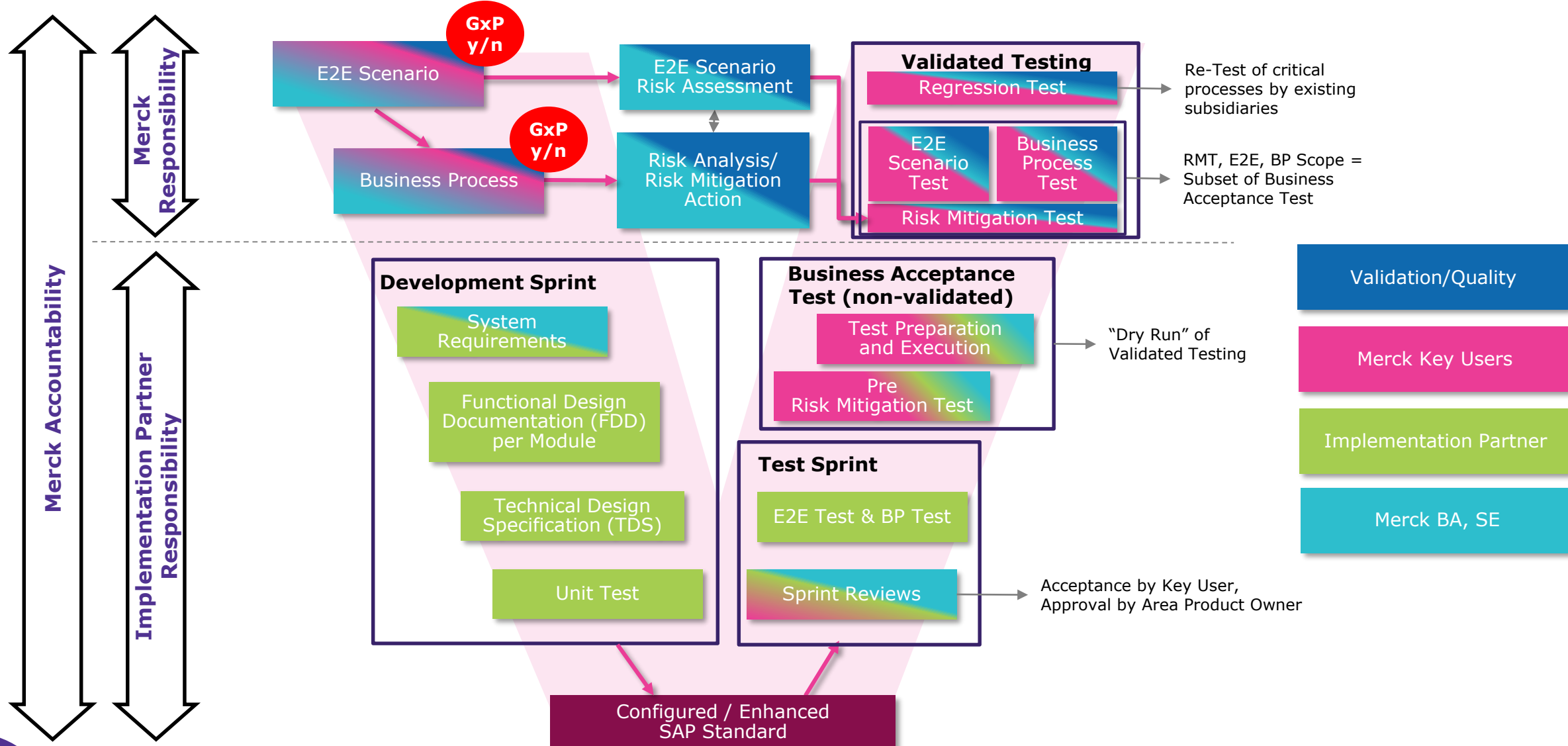
Introduction to LEAN methodology
High-Level Plan on LEAN Strategies

LEAN | 11. Praxisforum Prozess-, Projekt- und IT-Management| 12-Jun-2018

Mapping of Validation Requirements to LEAN

Merck Responsibility

Merck Accountability

Implementation Partner Responsibility

GxP y/n

E2E Scenario

GxP y/n

Business Process

E2E Scenario Risk Assessment

Risk Analysis/ Risk Mitigation Action

Validated Testing

Regression Test → Re-Test of critical processes by existing subsidiaries

E2E Scenario Test | Business Process Test → RMT, E2E, BP Scope = Subset of Business Acceptance Test

Risk Mitigation Test

Development Sprint

System Requirements

Functional Design Documentation (FDD) per Module

Technical Design Specification (TDS)

Unit Test

Business Acceptance Test (non-validated)

Test Preparation and Execution → "Dry Run" of Validated Testing

Pre Risk Mitigation Test

Test Sprint

E2E Test & BP Test

Sprint Reviews → Acceptance by Key User, Approval by Area Product Owner

Configured / Enhanced SAP Standard

Validation/Quality

Merck Key Users

Implementation Partner

Merck BA, SE

MERCK

Introduction to LEAN specific Agile implementation
Main implemented concessions due to antipoles within SAP, CSV and Agile

Adjustment of Definition of DONE

Creation of X-Scrum Teams

Agile Project Management needs to be substituted by document management tool

Extension of the classical 3 Scrum roles, to more roles

Key User specify and Test the new system

Higher efforts in documentation and testing

3 week *Sprint*

Any
Questions?

Many Thanks