

Implementation of a Pega-based SKU lifecycle process in an Agile way

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Helping people live better lives

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PLEX
Product Lifecycle Execution

FERRING
PHARMACEUTICALS

Company overview

- Privately owned, research-driven specialty biopharmaceutical group headquartered in Switzerland
- Committed to building families worldwide and helping people live better lives
- Global company with over 6,500 employees in 56 countries and distribution in 110 countries
- 2018 revenue: EUR 1.9 billion*
- 2018 R&D investment: 18%
- Founded in Malmö, Sweden, in 1950



*USD 2.3 billion – CHF 2.2 billion

2018 sales overview by therapeutic area



46% Reproductive medicine and women's health



26% Gastroenterology



17% Urology



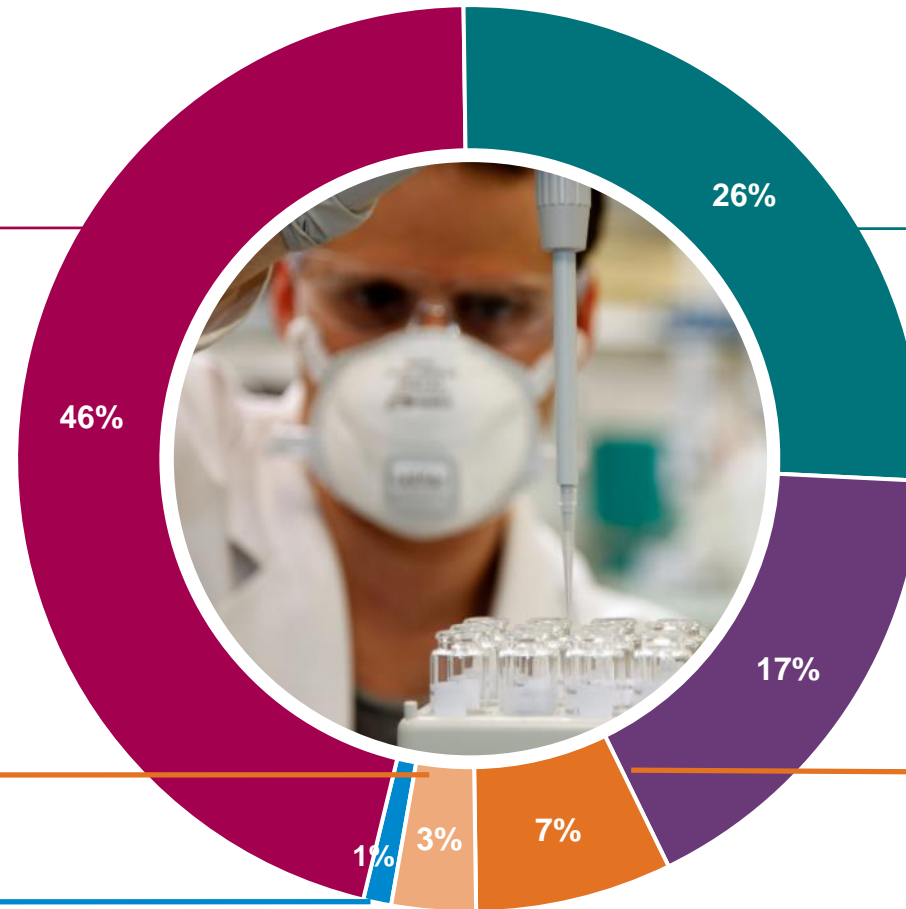
7% Orthopaedics



3% Endocrinology

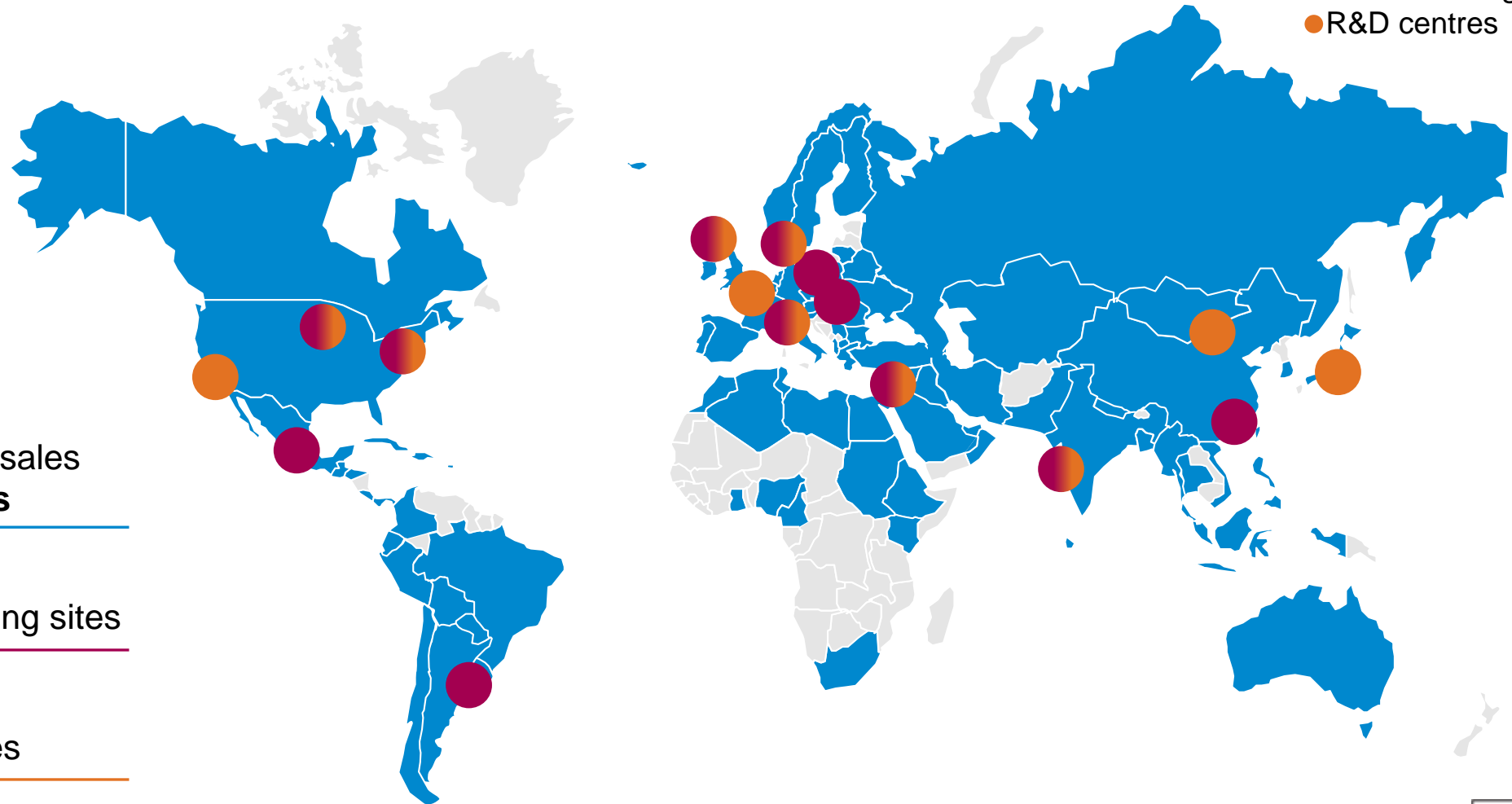


1% Other



Global presence in over 110 countries

- Marketing and sales
- Manufacturing sites
- R&D centres



Marketing and sales
in **56 countries**

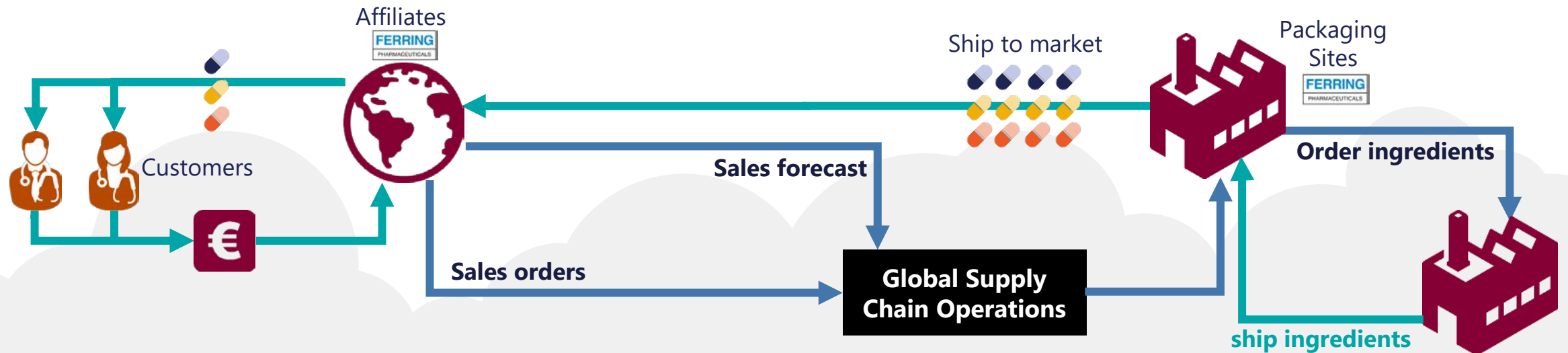


12 manufacturing sites



11 R&D centres

“Classic” Supply chain flow

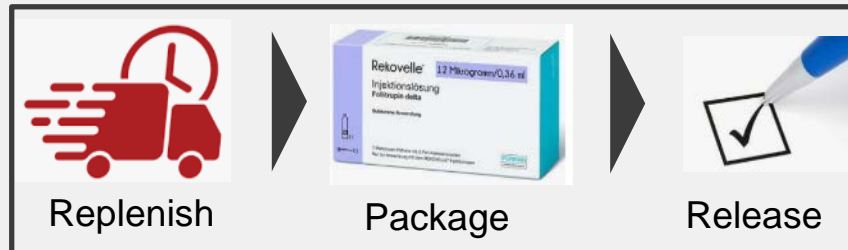


What is a Product recipe ?

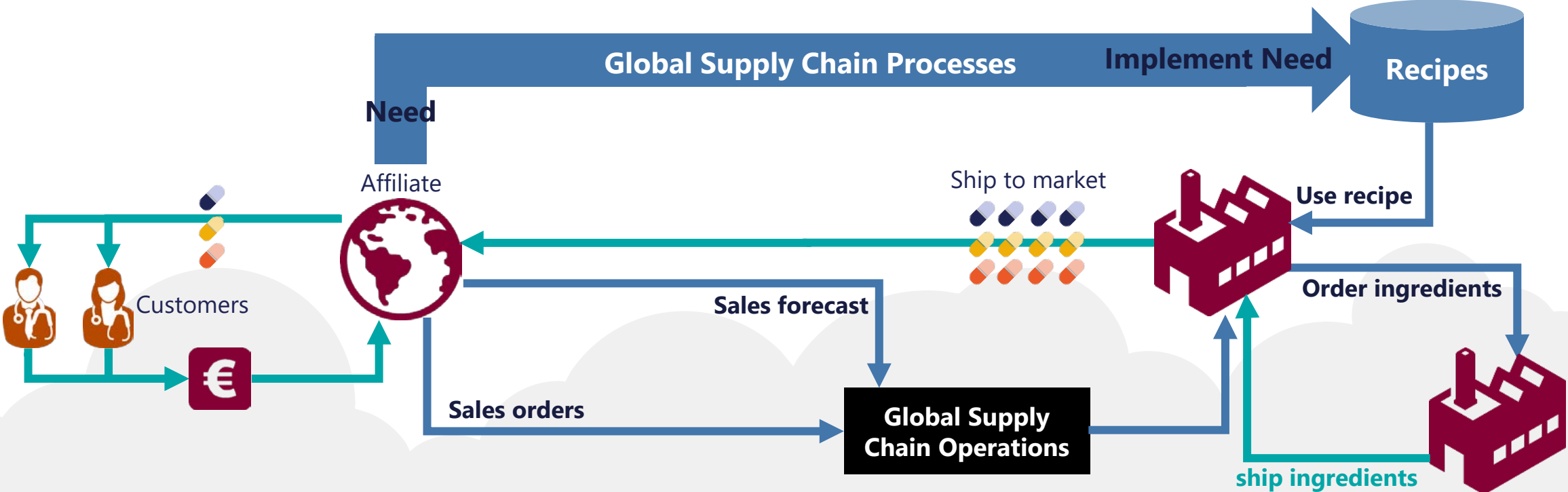
Product Specific



Country (SKU) Specific

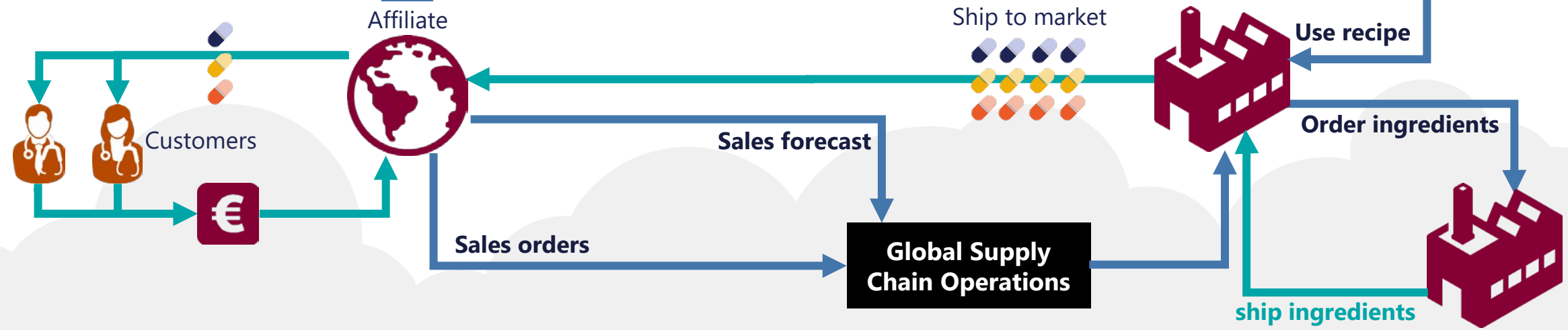
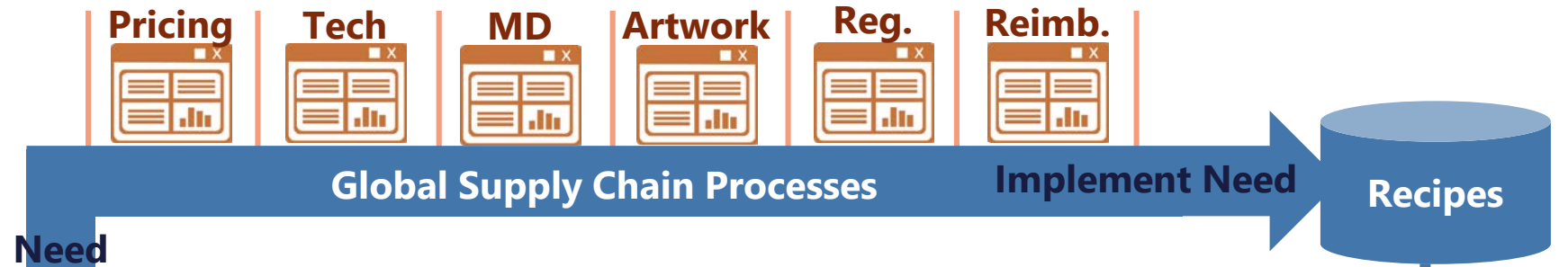
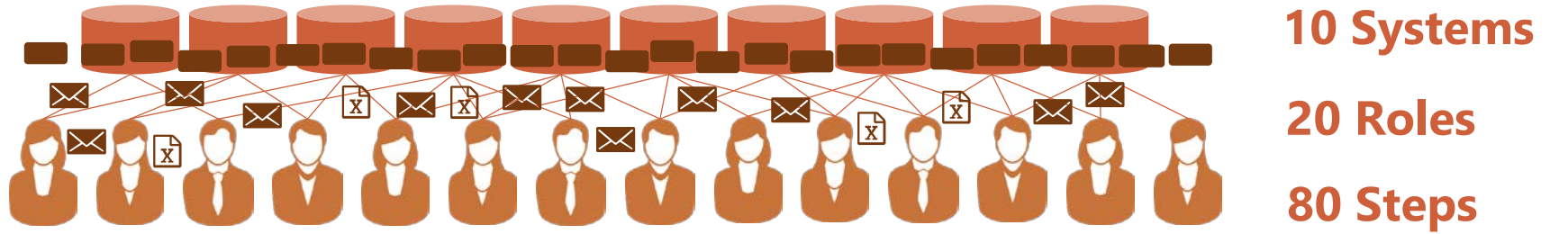


Global Supply Chain Processes



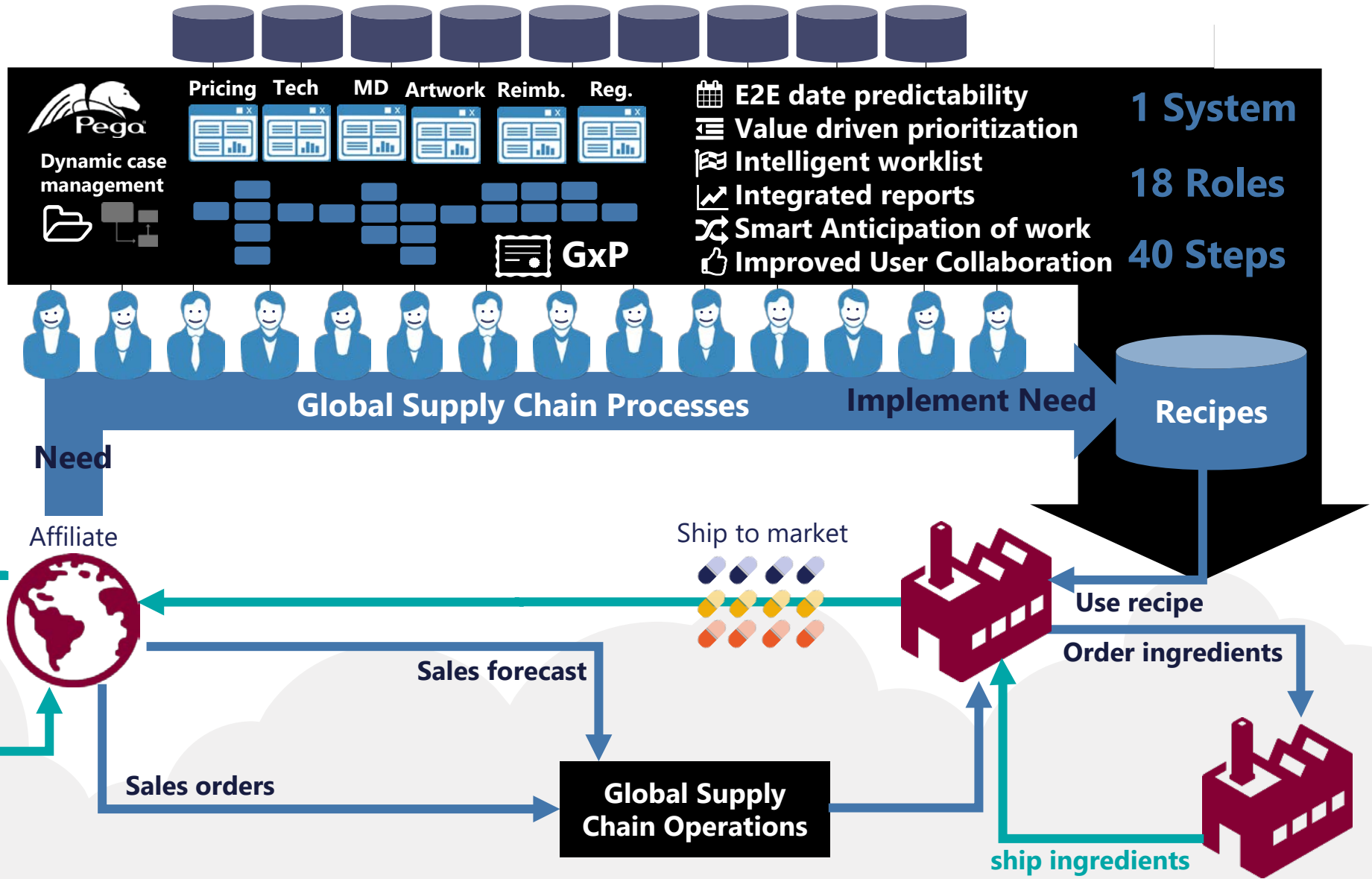
Challenges before PLEX

- Visibility
- Predictability
- Lead time/costs
- Compliance
- Automation
- Re-use & scale



New World with PLEX

- ↑ Gain Visibility E2E
- ↑ Increase Predictability
- ↓ Reduce Lead time
- 📄 GxP Compliance
- ↓ Reduce Operation Costs
- ↑ Re-use & scale



1 System
18 Roles
40 Steps

TRANSFORMING PRODUCT LAUNCH & CHANGE

Transform our organization with agile and compliant modification of product portfolio to rapidly supply patients in a dynamic world

LAUNCH & CHANGE
EXCELLENCE

↑ INCREASE VISIBILITY



Multi level case hierarchy across all systems allow full visibility on overall process status and timelines.

cost of delay is calculated and visible enabling to focus effort on most valuable work first.

Visual representation of product launch/change per country.

100%

End to end visibility



↑ INCREASE PREDICTABILITY



End to end calculation of critical path with reliable values across the sub activities.

Milestones and timeline forecasting will be made on dynamic case information.

Intelligent SLA and proactive alerts are generated to help steer actions ahead of the game.

20%-40%

Actual vs. Promised Date Variability Reduction



↗ MAXIMIZE FINANCIAL BENEFITS



Activities are intelligently run in parallel and cost of delay is used to prioritize work and get most valuable work done first.

Complexity is managed and common packs creation is a rational decision based on business value on creation and economies of scale.

Overdue cases number are reduced by proactive planning and decision making on the overall process.

20%, 10%

Overall Lead Time from change & launch decision to last shipment reduction



 **GXP COMPLIANCE**



System allow to anticipate the start of some tasks at risk with full digital audit of approvals.

Stock management is manage to avoid product recall because of wrong SKU being shipped.

System ensure that all approved LU are carried over for implementation diligently and otherwise notify the MU creator.

100%

GxP Compliance



↘ REDUCE OPERATIONAL COSTS



Automate manual steps and removing system switching needed by auto populating data and propagating data automatically to backend systems.

personal worklist with assignments created by the system based on finer statuses definition and SLAs eliminate the need for local excel spreadsheet.

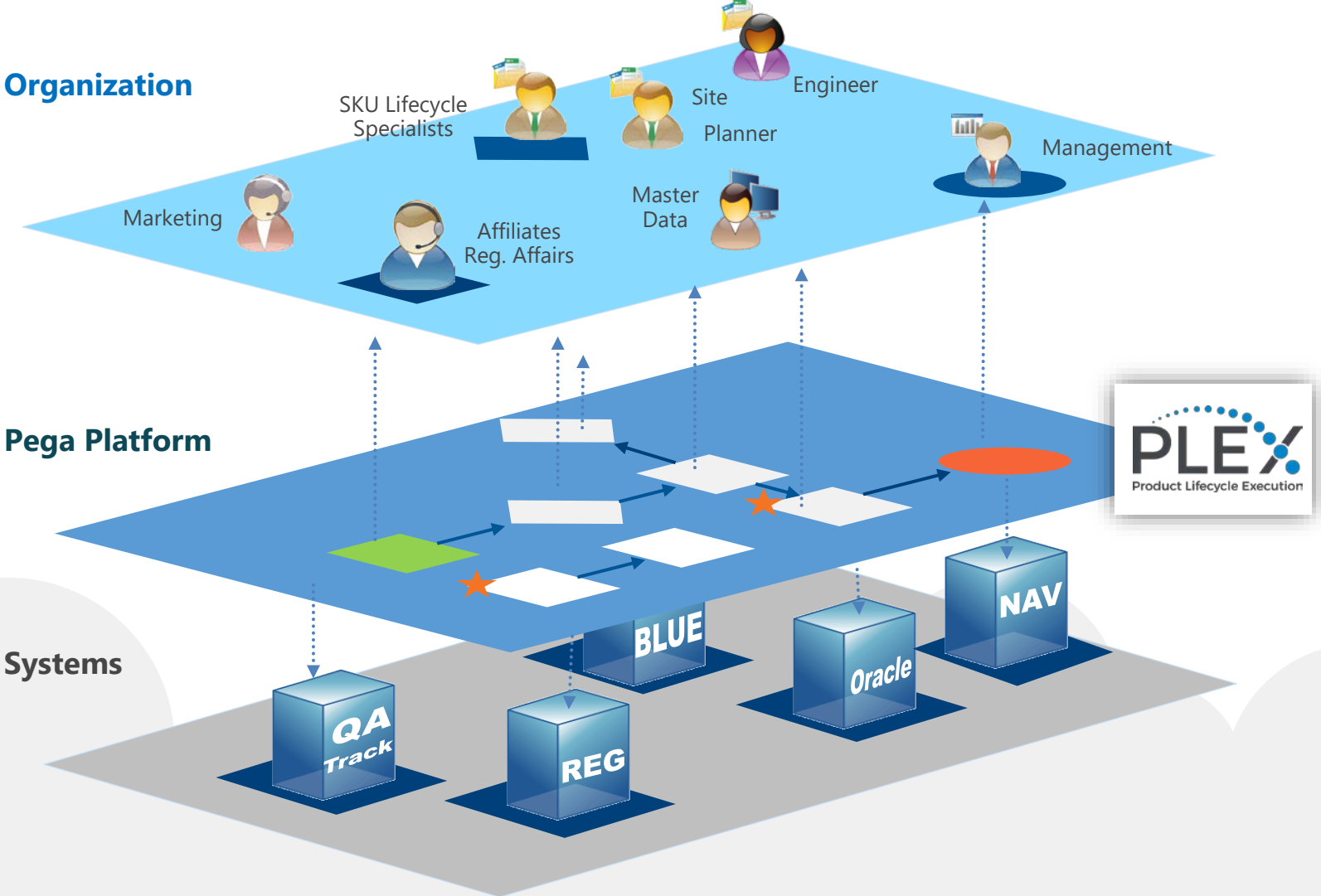
Improved user experience and productivity with intent driven screens and intelligent wizards.

50%-70%

Manual steps in and outside systems removed on the overall process



Case & Process Management for Digital Process Automation



QA track = Change control System
Blue = Artwork Management System

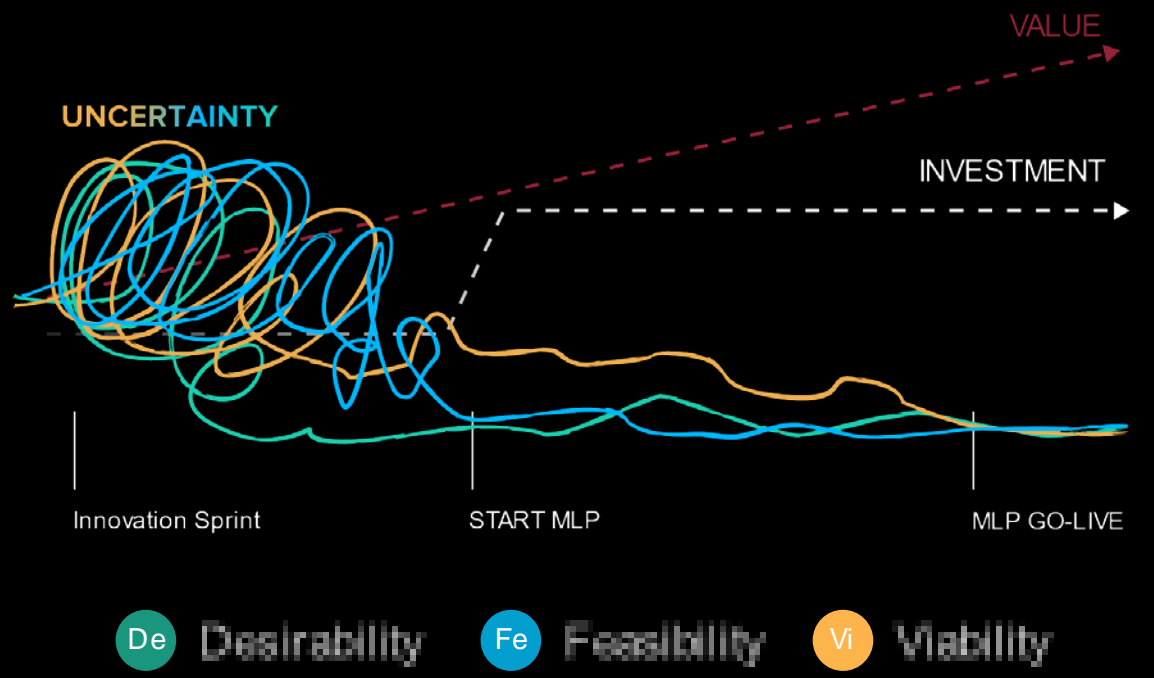
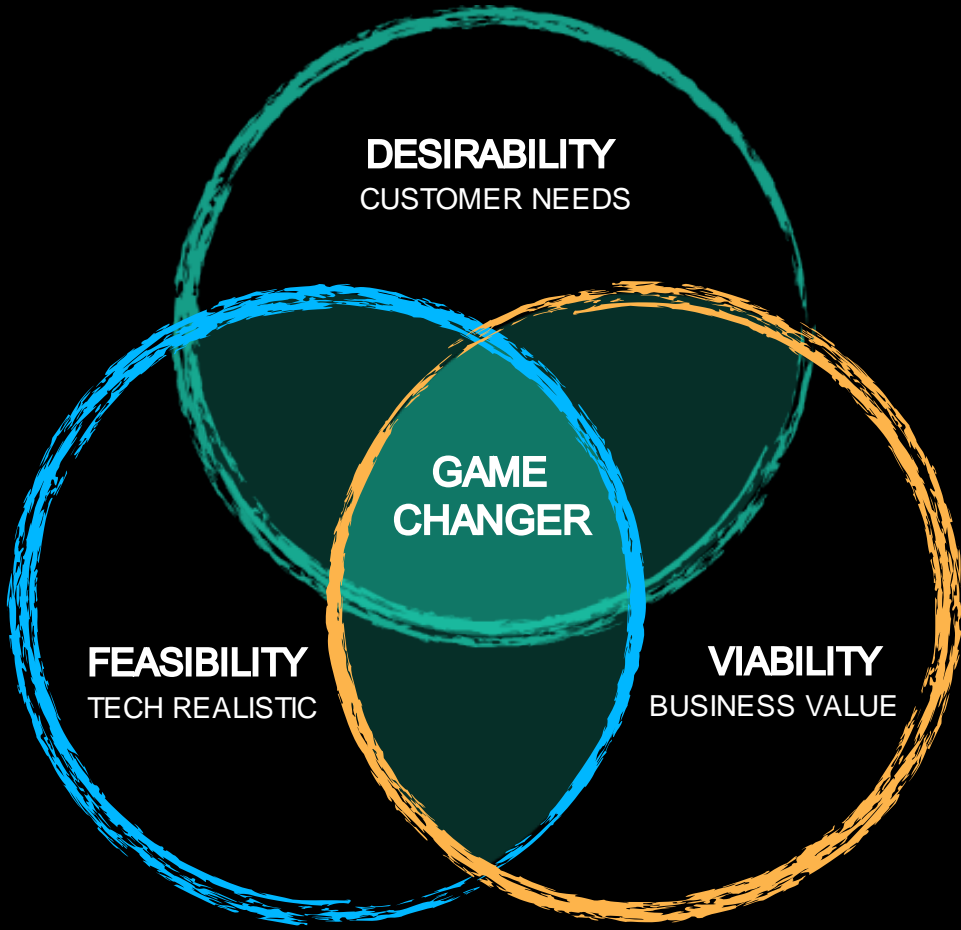
Oracle = ERP plants
NAV = ERP distribution

Traditional approach does
not work anymore





We need a new way of working that provides faster feedback cycle, engage the user more into the process yet retain uncompromised quality.

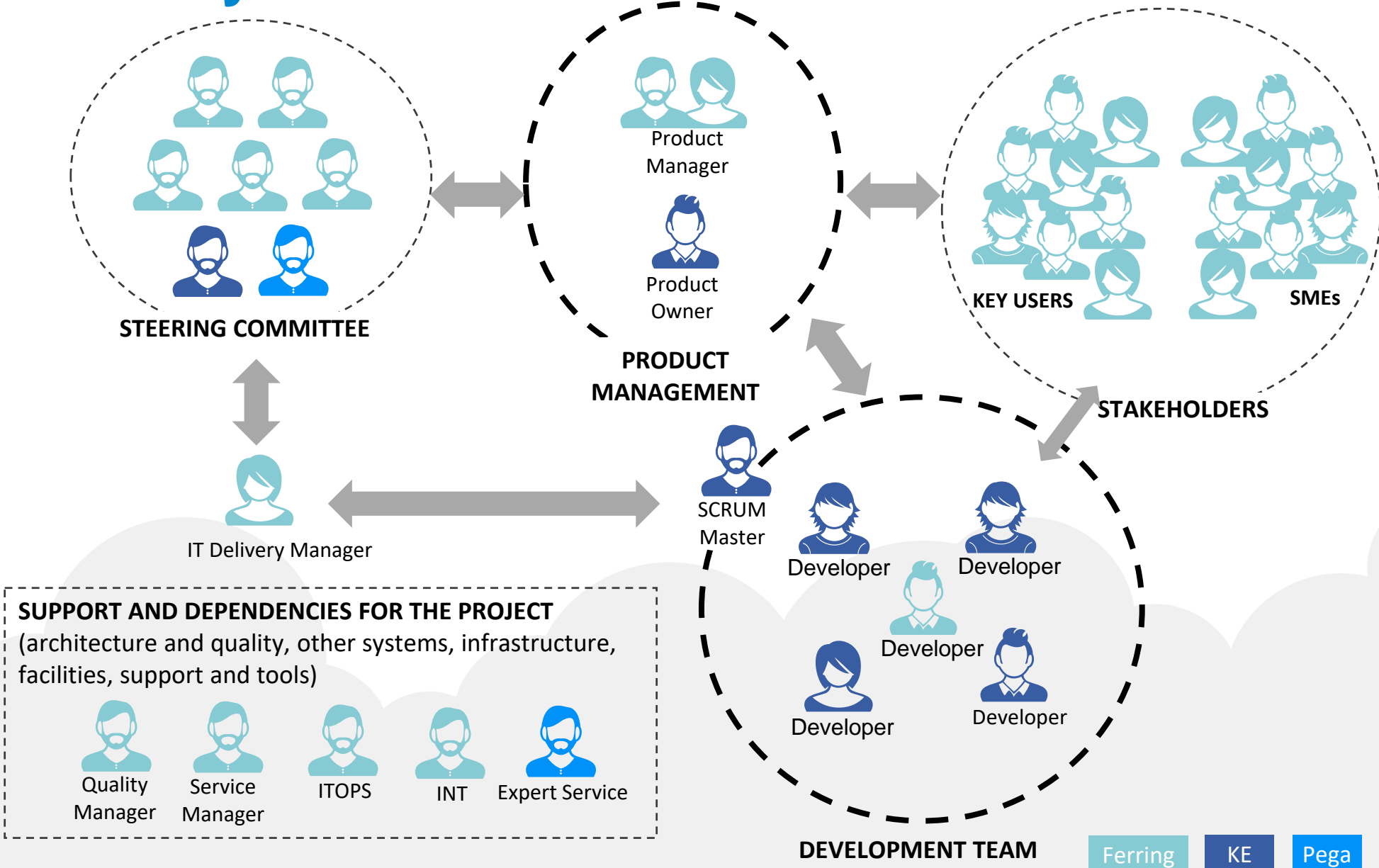




Leap of faith

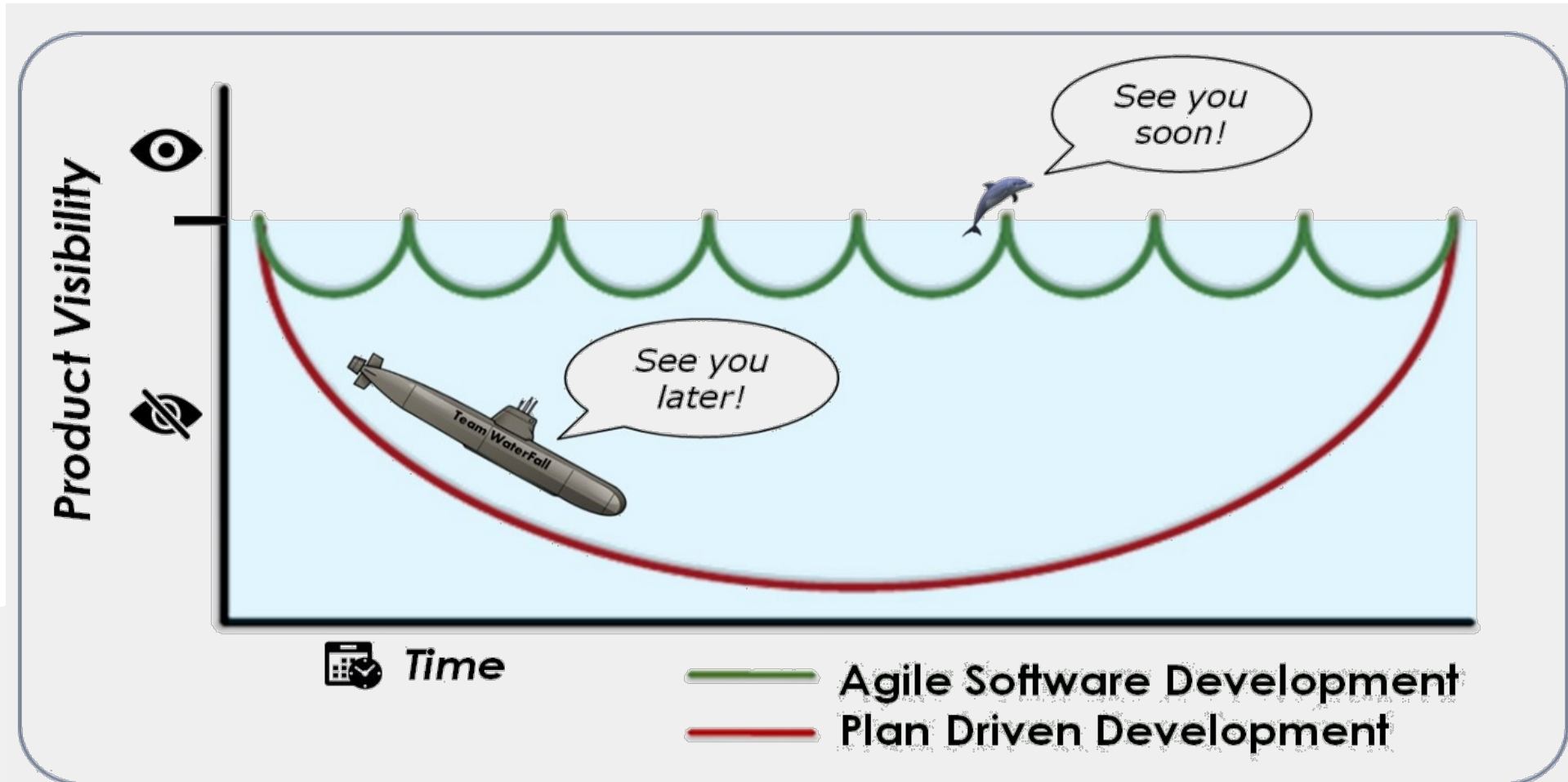
Invest in the solution, but also in the methodology

Agile Delivery Model

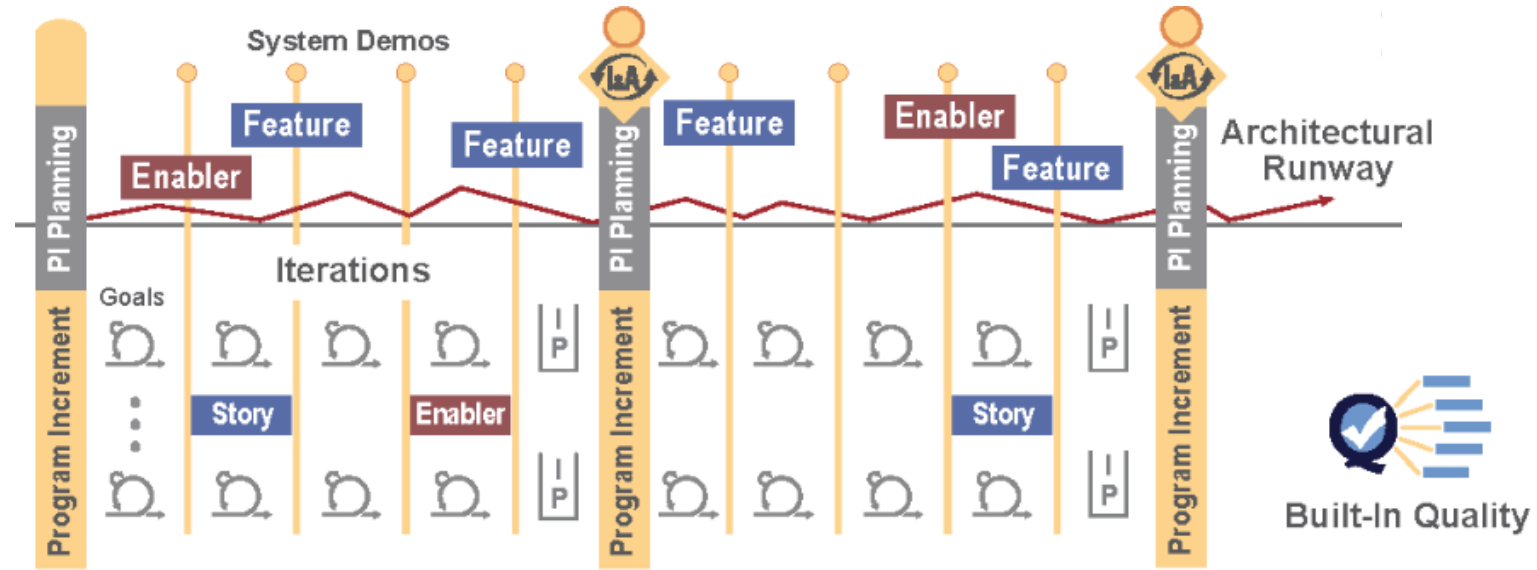


Ferring KE Pega

Change of Paradigm requires Training and Preparation



Agile Delivery Cadence



The timeline tracks key milestones from January to December:

- JANUARY:** KICKOFF, PI 1 INNOVATION & PLANNING
- FEBRUARY:** APAC DEMO
- MAY:** SOFT GO-LIVE CHANGES
- JUNE:** DEMO LAUNCH COMMITTEE, PI 3 INNOVATION & PLANNING
- JULY:** CHANGES RAMP-UP
- AUGUST:** SOFT GO-LIVE LAUNCH, PI 4 INNOVATION & PLANNING
- NOVEMBER:** FULL GO-LIVE CHANGES
- DECEMBER:** FULL GO-LIVE LAUNCHES



ONE TEAM



Agile Program Metrics



PEGA COMPLIANCE SCORE



82%

COMPLIANT RULES

1485

TOTAL RULES

274

RULES WITH WARNINGS

36

UNJUSTIFIED WARNINGS

Allure

ALLURE REPORT 7/6/2019
1:38:29 - 6:04:29 (4h 25m)

166 test cases

98.79%

SUITES 36 items total

- PLEX-231: RPP - Manual Initiation (1 failed, 10 passed)
- PLEX-570: Review My Request (1 failed, 1 passed)
- PLEX-213: Manage regulatory labeling changes (17 passed)
- PLEX-244: Authorisation Configuration (16 passed)
- PLEX-414: Anticipate At Risk - Validation (11 passed)
- PLEX-508: Start a new launch (10 passed)
- PLEX-519: Capture Volume And Price for New Product Launch (10 passed)
- PLEX-524: Capture Launch Information (8 passed)

TREND

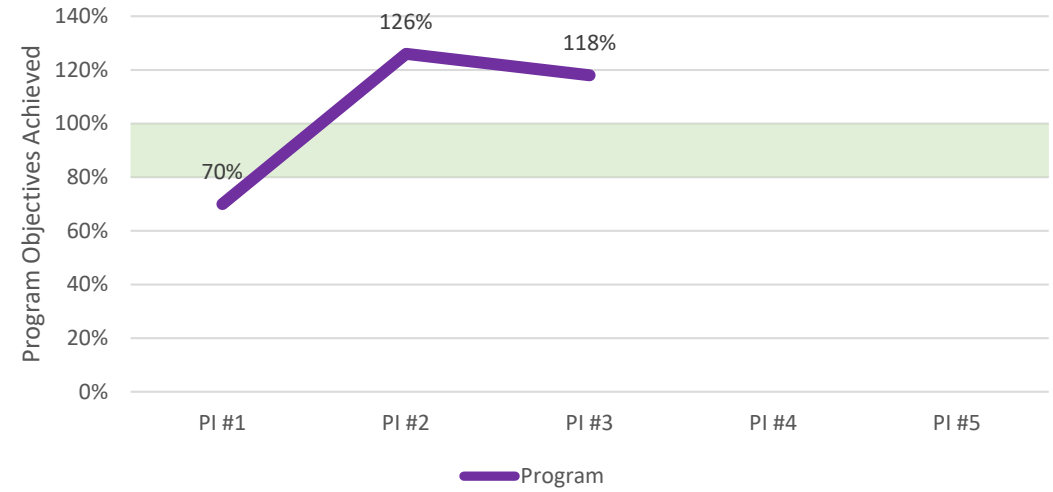
CATEGORIES 1 item total

- Product defects (2)

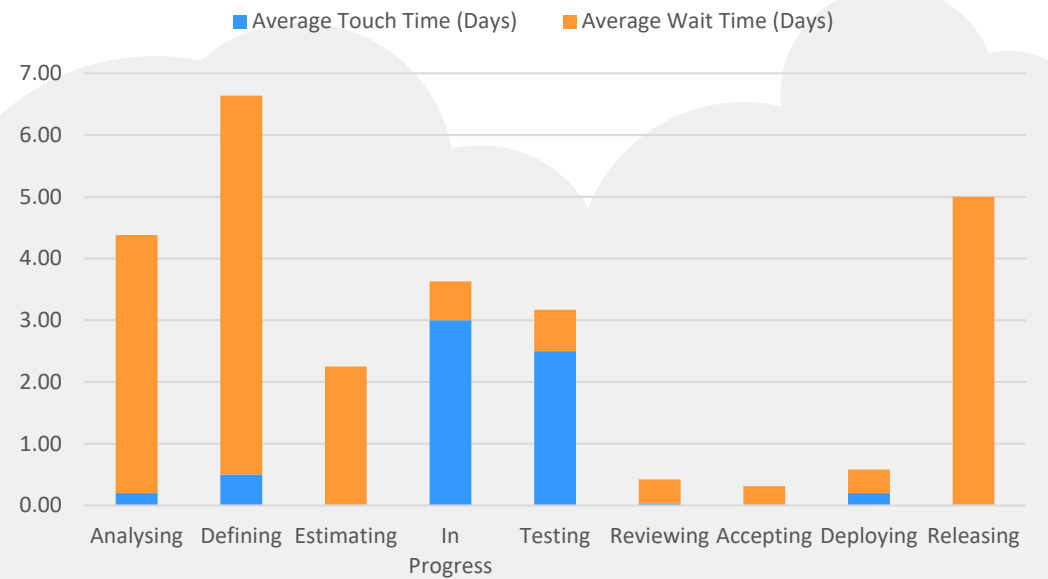
EXECUTORS

- Jenkins
- Automated Regression Test (DT1) #116

Program Predictability Measure

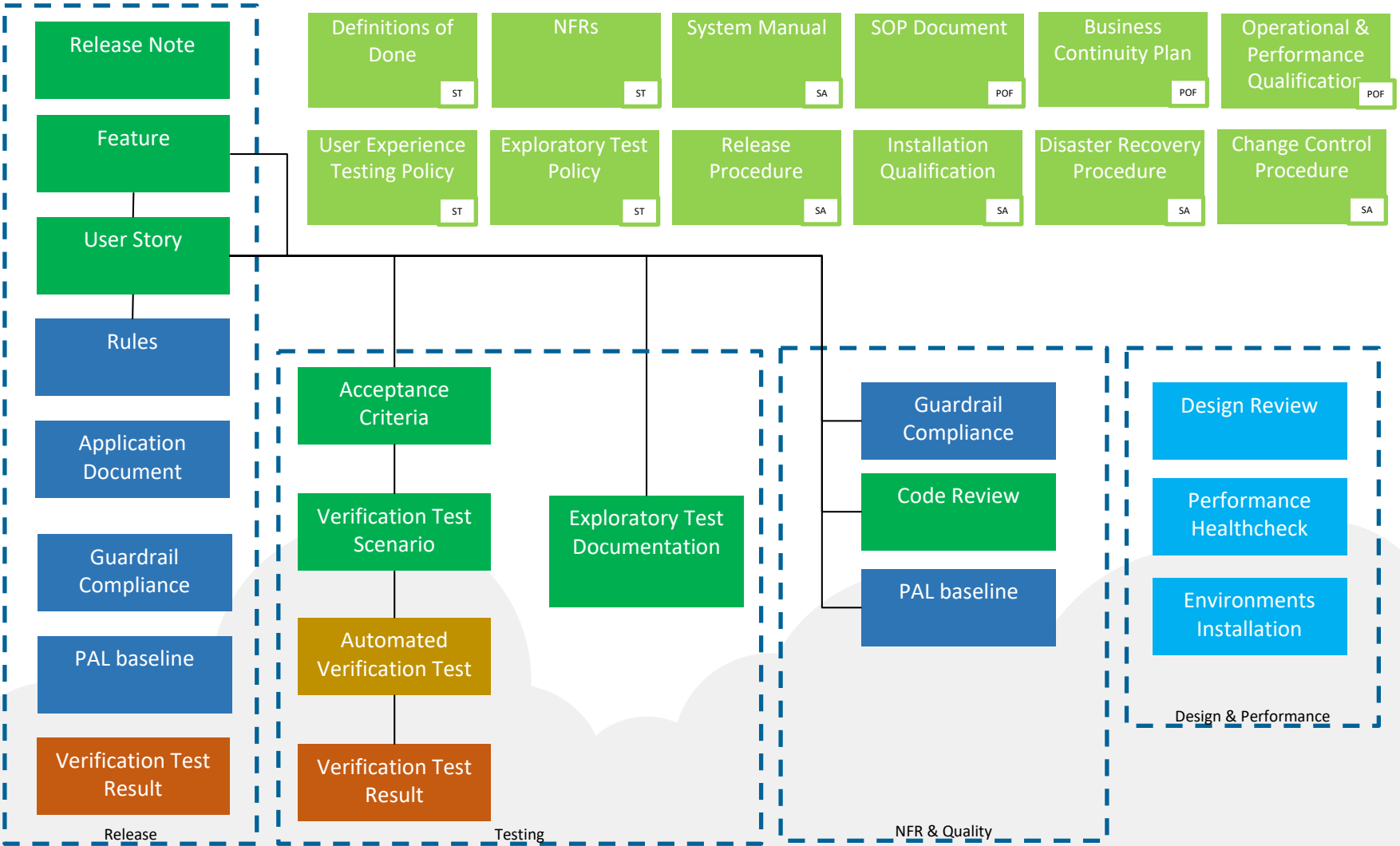


Pipeline Efficiency Stories

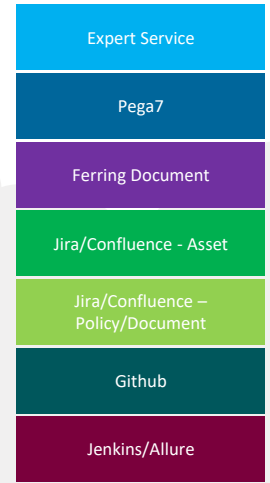
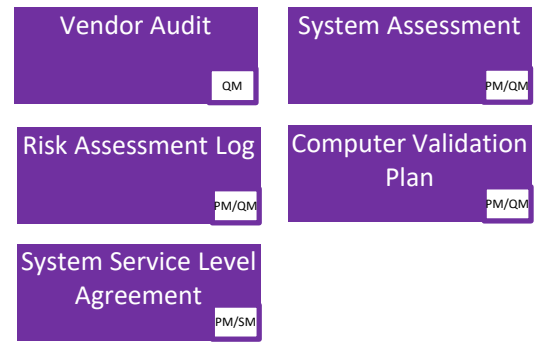


Agile in Pharma? Documentation and GxP Aspects

Project lifecycle artefacts



Pre-project artefacts



This slide shows the exhaustive set of artefacts used for system GxP validation. All artefacts on this slide are sufficient to satisfy the full set of activities/deliverables required for a GxP compliant system. It is to note that one of the product principles is that "user training is embedded in application user experience" and as such no classroom or formal training should be needed.

Primary owner for documents:

PM = Project Manager (Ferring)	POF = Product Owner (Ferring)
SA = System Architect (Ferring)	SM = Service Manager (Ferring)
ST = Scrum Team	QM = Quality Manager (Ferring)

DESIGN SPRINT



Agile development example: Invest on user-adoption 1/2

1. Before change: fully manual system

Finished Product description table		Requested Quantity	Current item number	New item number (if known)	Semi-finished item number	Material Specification	Supplier
Ingredient type	<input checked="" type="checkbox"/>	1	5007000177			F-MS-2056	
Carton	<input type="checkbox"/>						
Collection carton	<input type="checkbox"/>						
Collection carton label	<input type="checkbox"/>						
Substance label	<input checked="" type="checkbox"/>	1	5008000166			F-MS-1103	
Solvent label	<input type="checkbox"/>						
Reimbursement label	<input type="checkbox"/>						
Leaflet 1	<input checked="" type="checkbox"/>	1	5009000697			F-MS-3040	

2. PLEX: addition of 2 complex interfaces: bring transparency about BoM content + current artwork

Parent Case for Change (R-17)
Change (C-49) **NEW** 8301000022 - MENOPUR MULTIDOSE powd and solv for sol for inj vial 1x 600IU SG - SG

Item Name	Item Number	Item description	View Artwork	Change	Delete
Bulk Product	I-3006000532	D powd for sol for inj 600IU vial		<input type="checkbox"/>	<input type="checkbox"/>
Label	I-2008054079	Label wvd for sol for inj vial 1x 600IU SG		<input type="checkbox"/>	<input type="checkbox"/>
Bulk Solvent Labelled	I-3006000073	D solv for sol for inj syr 1ml		<input type="checkbox"/>	<input type="checkbox"/>
Label	I-2008054080	Label iv for sol for inj syr 1x 1ml (600IU) SG		<input type="checkbox"/>	<input type="checkbox"/>
Medical Device	I-2011050071	Plunger Rod for Syringe barrels 1ml		<input type="checkbox"/>	<input type="checkbox"/>
Medical Device	I-2011050252	Needle 25Gx5/8 - 0.5x16mm Orange		<input type="checkbox"/>	<input type="checkbox"/>
Medical Device ⓘ	I-2001053054	IT of 9 pcs syringes / alcohol pads rope N.V.		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Carton	I-2007055837	Carton wvd and solv for sol for inj vial 1x 600IU SG		<input type="checkbox"/>	<input type="checkbox"/>
Leaflet	I-2009054558	Leaflet MENOPUR powd and solv for sol for inj vial SG		<input type="checkbox"/>	<input type="checkbox"/>
Medical Device ⓘ	2001053976				<input checked="" type="checkbox"/>

For a new active or solvent, is it added or replaced?

Agile development example: Invest on user-adoption 2/2

3. PLEX: Second version following end-user feedback and UX experience workshop.

Change (CH-583) NEW 5001800604 - [redacted] - [redacted] - Low Actions

✓ 1. Capture Context ✓ 2. Validate Product Data **3. Assess Bill of Material Impact** 4. Capture Country Timelines Constraints 5. Review My Request

Bill of Material

Below is the list of ingredients linked to this SKU. Please assess the impact on any of the components in the list by clicking on it and deciding on the action to be taken. The impacted component(s) may be preselected from the parent change.

Action: Add Change Remove

Item type:

Item Description:

Comment:

Add

Materials Affected

Show

BP ✓ BPSOL CART ✓ LABE ✓ LEAF ✓ SPM

Item	Version	Comment	Action
----- powd for sol for inj 3.2mg vial F powd for sol for inj 0.8mg vial BP 3006000444 3006000445	1		Replace
Carton powd and solv for sol for inj vial 1x 3.2mg FR CART 5007001094	1		No Change
Label ----- F powd for sol for inj vial 3.2mg FR LABE 5008000770	1	Remove this label	Remove
Label ----- solv for sol for inj vial 10ml FR LABE 5008000771	1		No Change
Leaflet powd and solv for sol for inj vial 1x 3.2mg FR LEAF 5009000739	1	Change leaflet text	Change
Add a new leaflet for Doctors LEAF			Add



Key Success Factors

1

Customer Centricity

2

Lean-Agile
Approach

3

DevOps Culture

Thank you



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