

A woman with curly hair wearing a blue and white striped shirt is leaning over a desk, looking at a laptop screen. A man with dreadlocks is sitting behind her, also looking at the screen and pointing at it. The scene is dimly lit with a blue tint.

# Point of View Atryon Product Quality Excellence - Preamble

# Performance and Resilience of operations address 6 key objectives...

## FUNCTIONAL ROBUSTNESS

### • MANUF. & BUSINESS PROCESSES

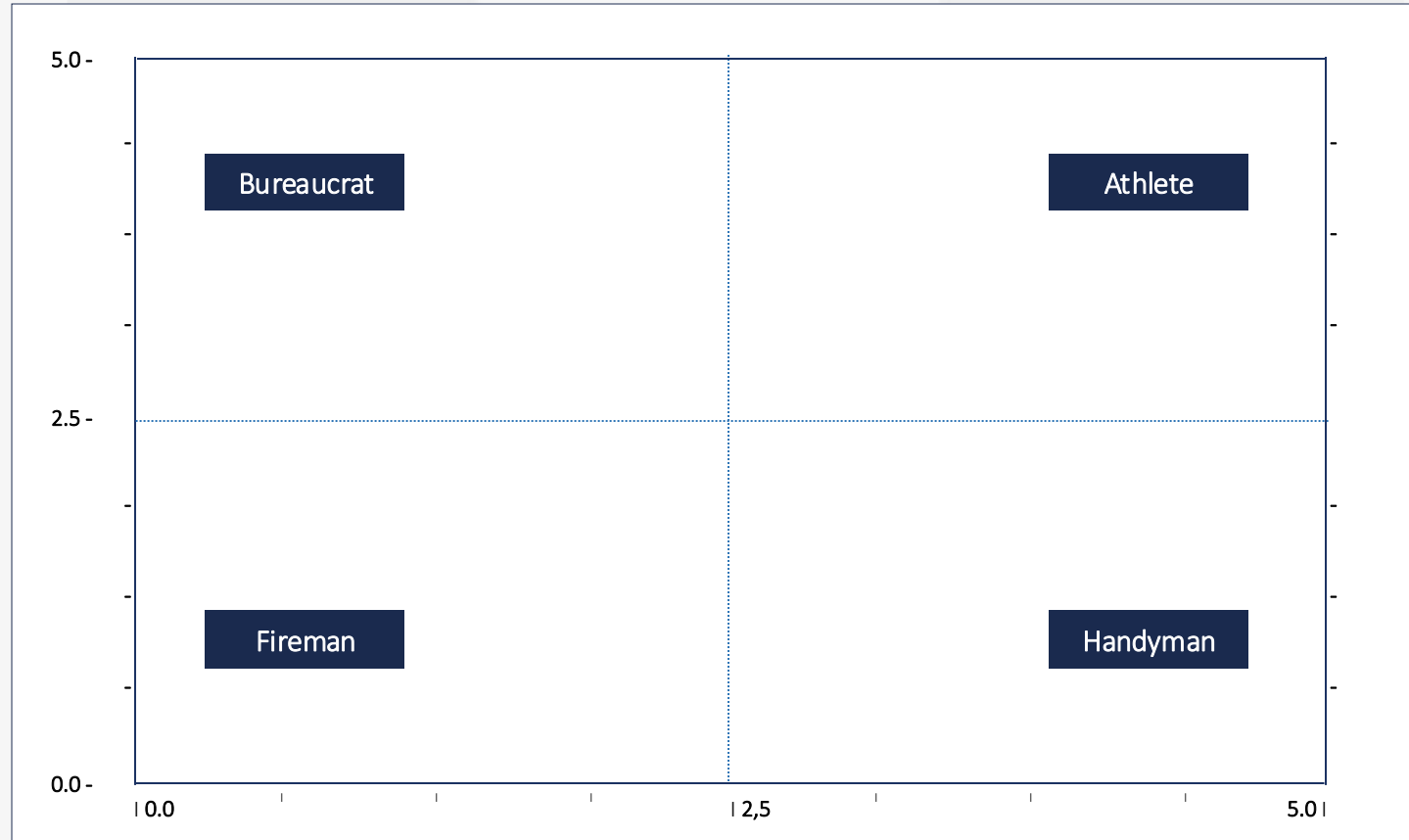
- Have manufacturing and Business Processes that integrate best practices (Lean efficiency, clear RACI, IS performance, equipment control, compliant and efficient documentation)

### • SKILLS & EXPERTISE

- Manage technical know-how and Pharma Operational Excellence expertise efficiently and sustainably

### • ORGANIZATIONAL STRUCTURE

- Implement an efficient organization, just necessary and sized with regard to regulatory constraints and a robust production plan



### • INSPIRE

- Get teams on board and make the organization's vision a shared reality on a daily basis

### • MANAGE

- Know how to master a set of interdependent technical and human parameters in order to achieve objectives aligned with the company's vision

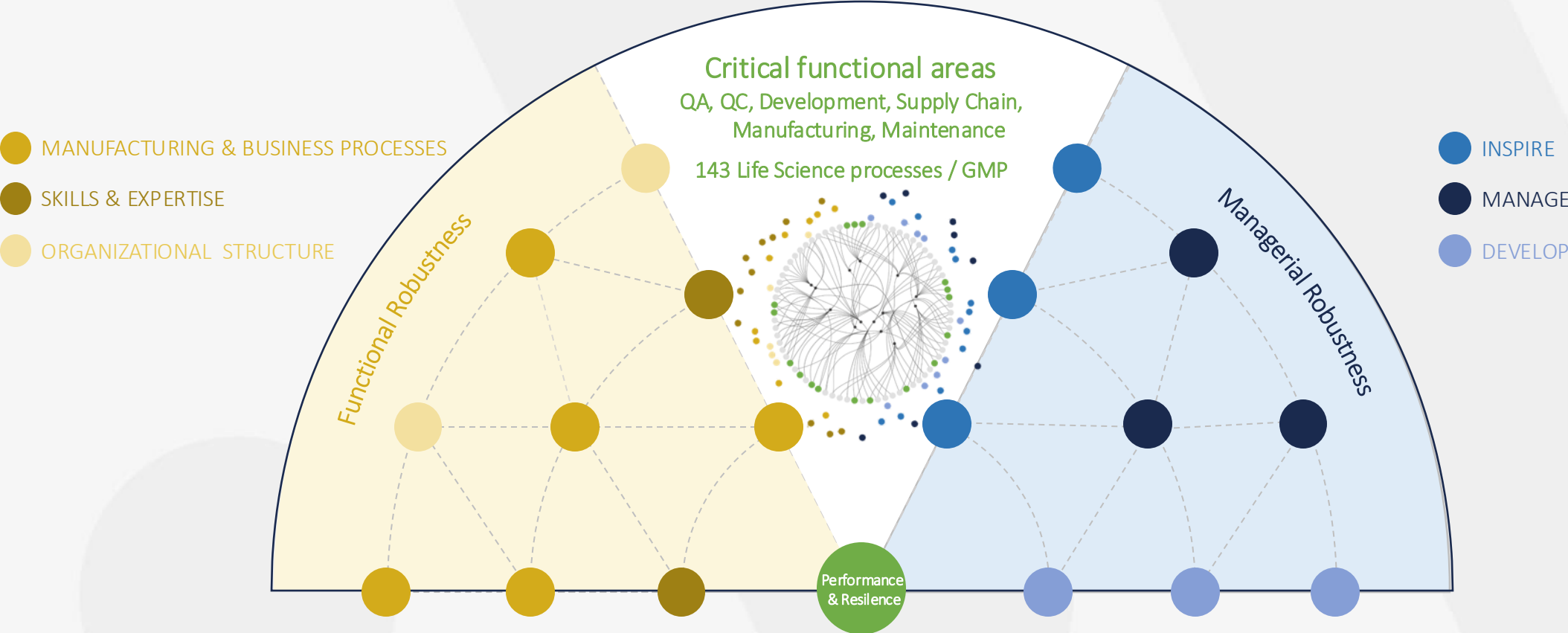
### • DEVELOP

- Set the course, facilitate change, and develop the sense of accountability

## MANAGERIAL ROBUSTNESS

...and are based on 18 functional and managerial components

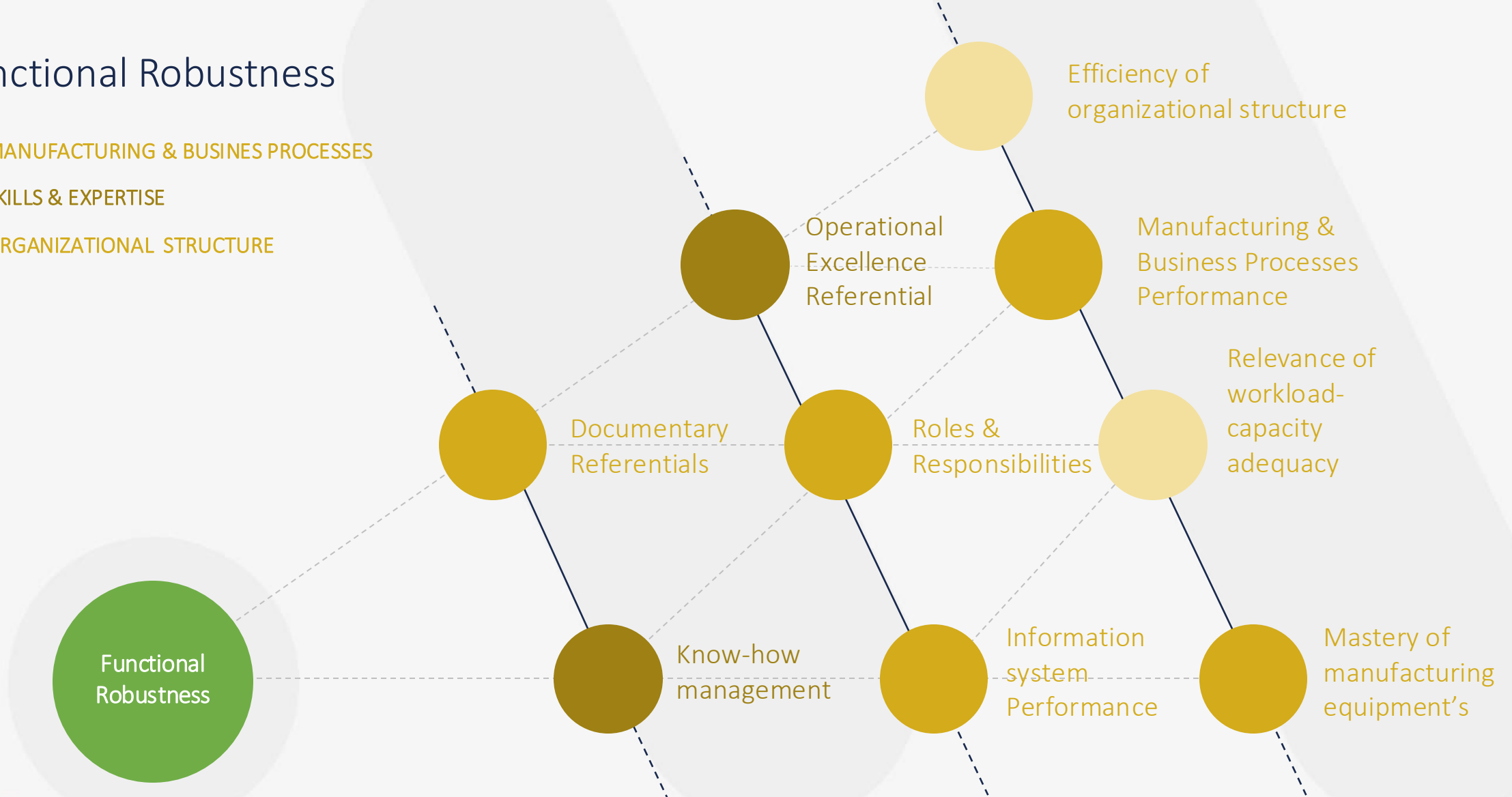
18 inter-related components



# 9 Functional components

## Functional Robustness

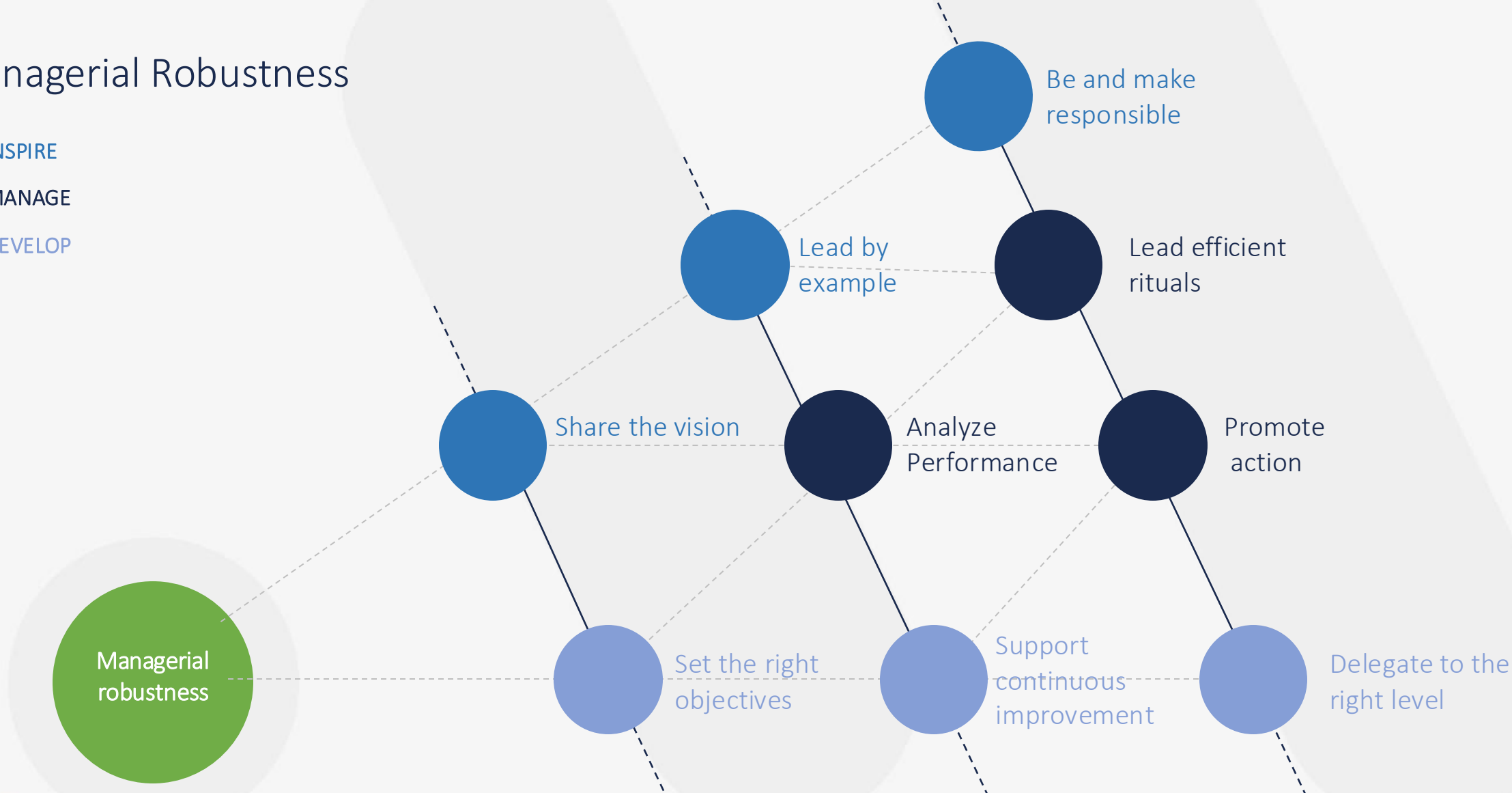
- MANUFACTURING & BUSINESS PROCESSES
- SKILLS & EXPERTISE
- ORGANIZATIONAL STRUCTURE



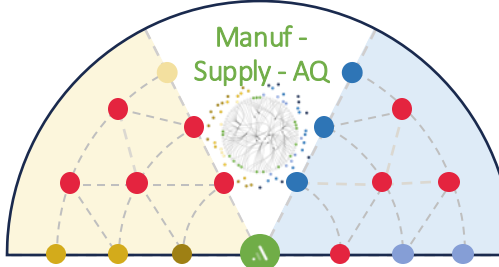
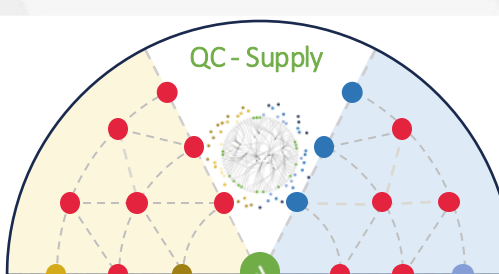
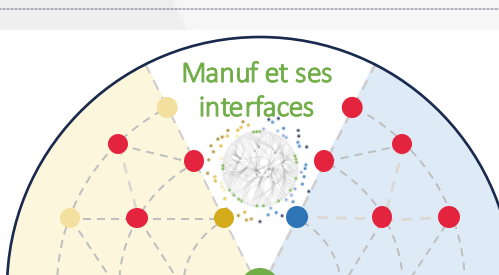
# 9 Managerial components

## Managerial Robustness

- INSPIRE
- MANAGE
- DEVELOP



# Depending on the measured level of resilience and the targeted savings, the atryon solutions integrate some of the components...

Context	Approach	Components	Results
<ul style="list-style-type: none"> <li>• <b>Middle Pharma / Injectable</b> : Strengthen the site's planning adherence in the context of “permanent” crisis management linked to a lack of managers (Site Head, Manuf Head, QA Ops head), a silo logic reinforced by shop floor management practices and processes that do not allow for a 40% increase in volumes</li> </ul>	<ul style="list-style-type: none"> <li>• Jointly develop Manufacturing / Maintenance managerial skills, focusing on Tier meetings management</li> <li>• Set up a Supply / QA task force to accelerate return to planning adherence</li> </ul>	 <p>The diagram shows a semi-circular structure with a central grey gear icon. It is divided into three colored regions: yellow on the left, blue on the right, and green at the bottom. A central green circle is labeled 'Manuf - Supply - AQ'. Red dots are scattered throughout the structure, representing targeted components.</p>	<p><b>+28%</b> of planning adherence in 6 months, generating a drastic reduction in penalties linked to the risk of market failure</p>
<ul style="list-style-type: none"> <li>• <b>Middle Pharma / Dermatology</b> : As part of a plan to improve the productivity of a QC lab by 20% over 3 years (automation, process optimization, organization, methods, planning, etc.), design and implement an integrated solution</li> </ul>	<ul style="list-style-type: none"> <li>• Analysis planning and scheduling processes redesigned</li> <li>• Implementation of an “Analytical Excellence” dynamic (robustness of methods, efficiency of organization, rationalization of documentation (digital) and of the QC Management Operating System)</li> </ul>	 <p>The diagram is similar to the first one, but the central green circle is labeled 'QC - Supply'. The structure and color regions (yellow, blue, green) are the same.</p>	<p><b>+20%</b> productivity in 3 months, including re-synchronization of Supply - QC flows and implementation of a Supply - QC SLA</p>
<ul style="list-style-type: none"> <li>• <b>Big Pharma / Pharma Solid Forms:</b> Following a far-reaching structural transformation, which involved the entire French General Management and its three sites, to improve industrial performance, which was absent despite the “organizational” transformation carried out upstream on the basis of this promise</li> </ul>	<ul style="list-style-type: none"> <li>• Complete transformation of the Management Operating System</li> <li>• Implementation of new managerial practices on the shop floor (Coach the Coach approach) and implementation of targeted solutions to bring several manufacturing lines back up to nominal output..</li> </ul>	 <p>The diagram is similar to the previous ones, but the central green circle is labeled 'Manuf et ses interfaces'. The structure and color regions are consistent.</p>	<p><b>+26%</b> productivity in 5 months and <b>+17%</b> of OEE on targeted lines (3 sites)</p>

● Targeted components

# ... either all key components and functional areas for a full scope operations transformation

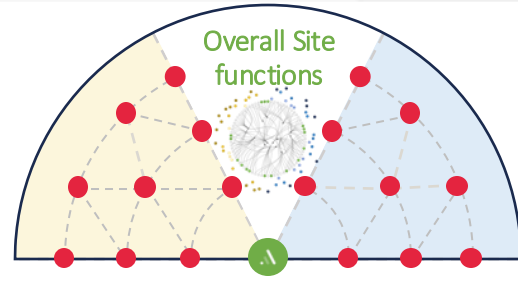
## Context

- **Middle Pharma / Aseptic Medical Device :** Following a major LBO and growth prospects of around 30%, drastically improve a site's EBITDA

## Approach

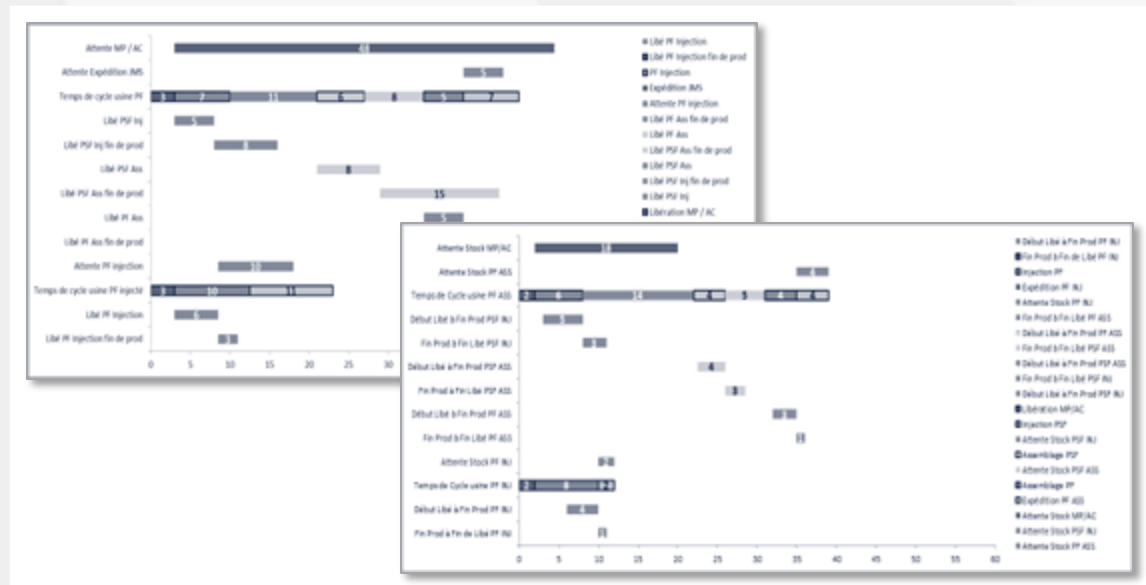
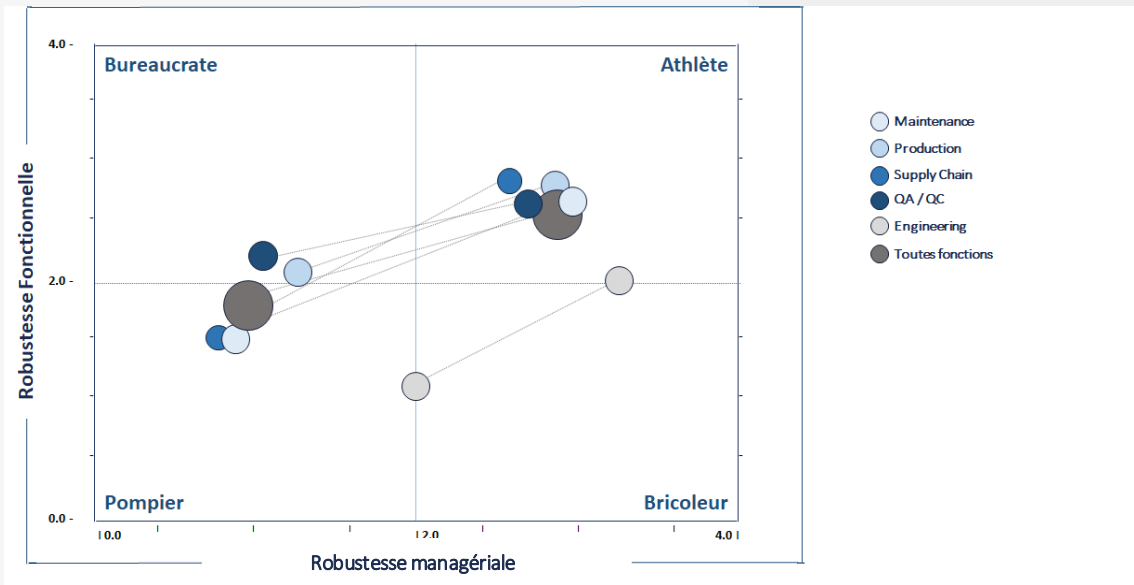
- Diagnosis and design of a Site roadmap
- Implementation of a site vision and operational objectives
- Complete overhaul of the Management Operating System and major changes to Site processes and organization (across all functional areas).

## Components



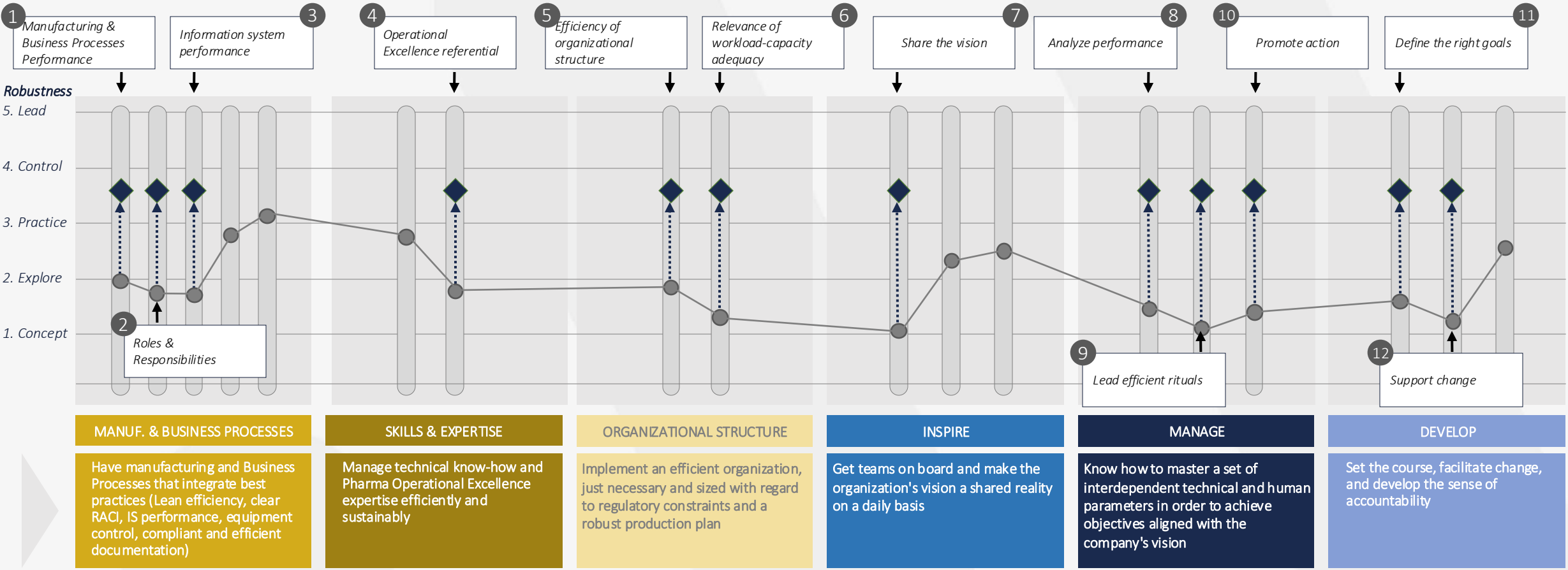
## Results

**+93%** EBITDA in 18 months,  
including a reduction of **16%** of plant cycle time



● Targeted Components

# For the jointly agreed scope, we target the functional and managerial components to be developed



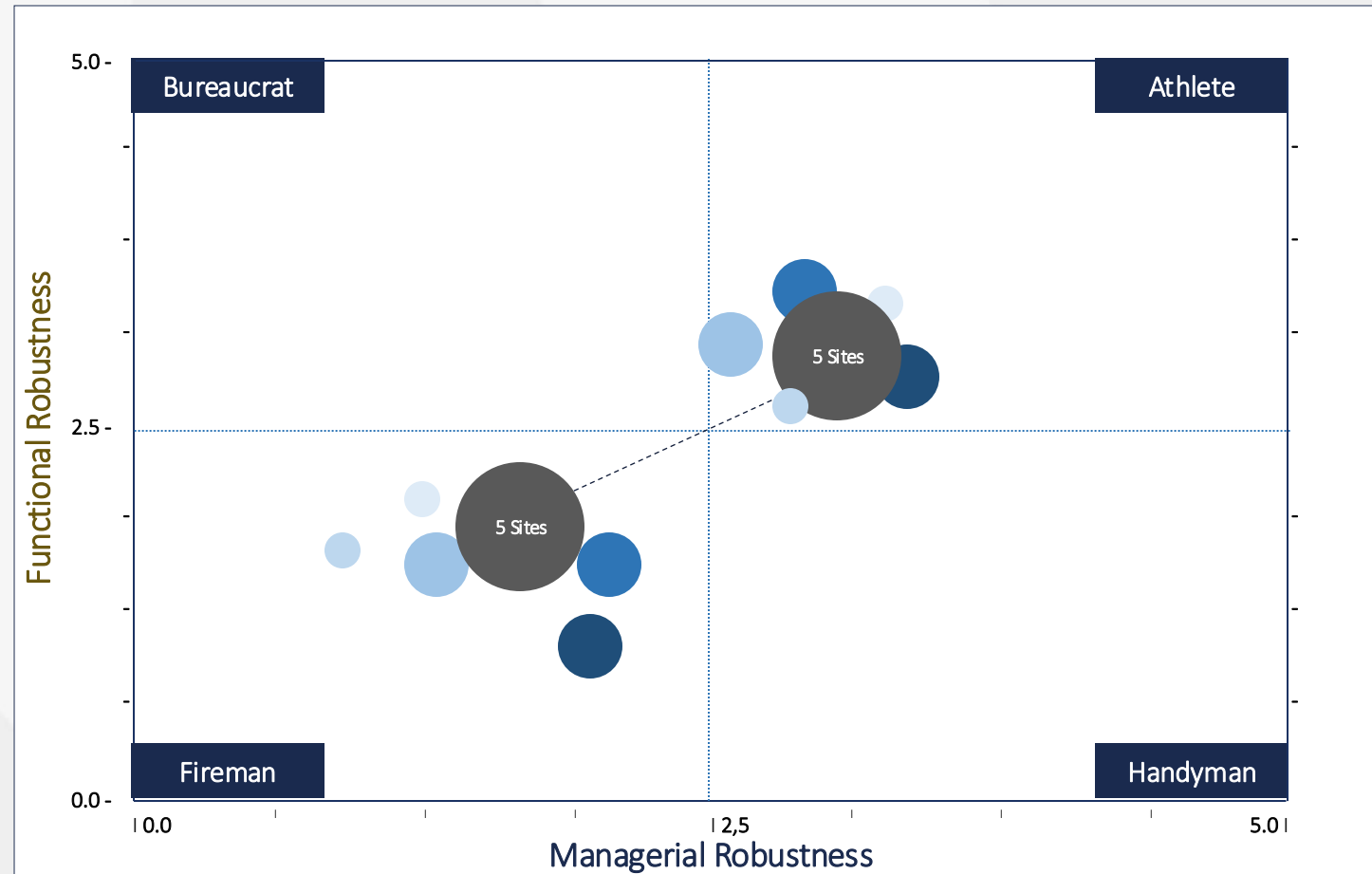
MANUF. & BUSINESS PROCESSES	SKILLS & EXPERTISE	ORGANIZATIONAL STRUCTURE	INSPIRE	MANAGE	DEVELOP
Have manufacturing and Business Processes that integrate best practices (Lean efficiency, clear RACI, IS performance, equipment control, compliant and efficient documentation)	Manage technical know-how and Pharma Operational Excellence expertise efficiently and sustainably	Implement an efficient organization, just necessary and sized with regard to regulatory constraints and a robust production plan	Get teams on board and make the organization's vision a shared reality on a daily basis	Know how to master a set of interdependent technical and human parameters in order to achieve objectives aligned with the company's vision	Set the course, facilitate change, and develop the sense of accountability

Robustness  Actual  Target

# ... and design the roadmap to achieve the targeted operational objectives (Group / Site / BU / Functions )

## As Is

- Weak process robustness: QC planning/scheduling and sample flow management
- Lack of analytical standards and heterogeneous LIMS functional coverage across sites
- Opportunity to merge several labs and review each lab's span of control with redefinition of roles and responsibilities
- Very limited QC / Supply Chain integration (heterogeneous between sites)
- Lack of performance management (kPI's, visual management) and embolization of labs by emergencies
- Weak managerial maturity, heterogeneous rituals



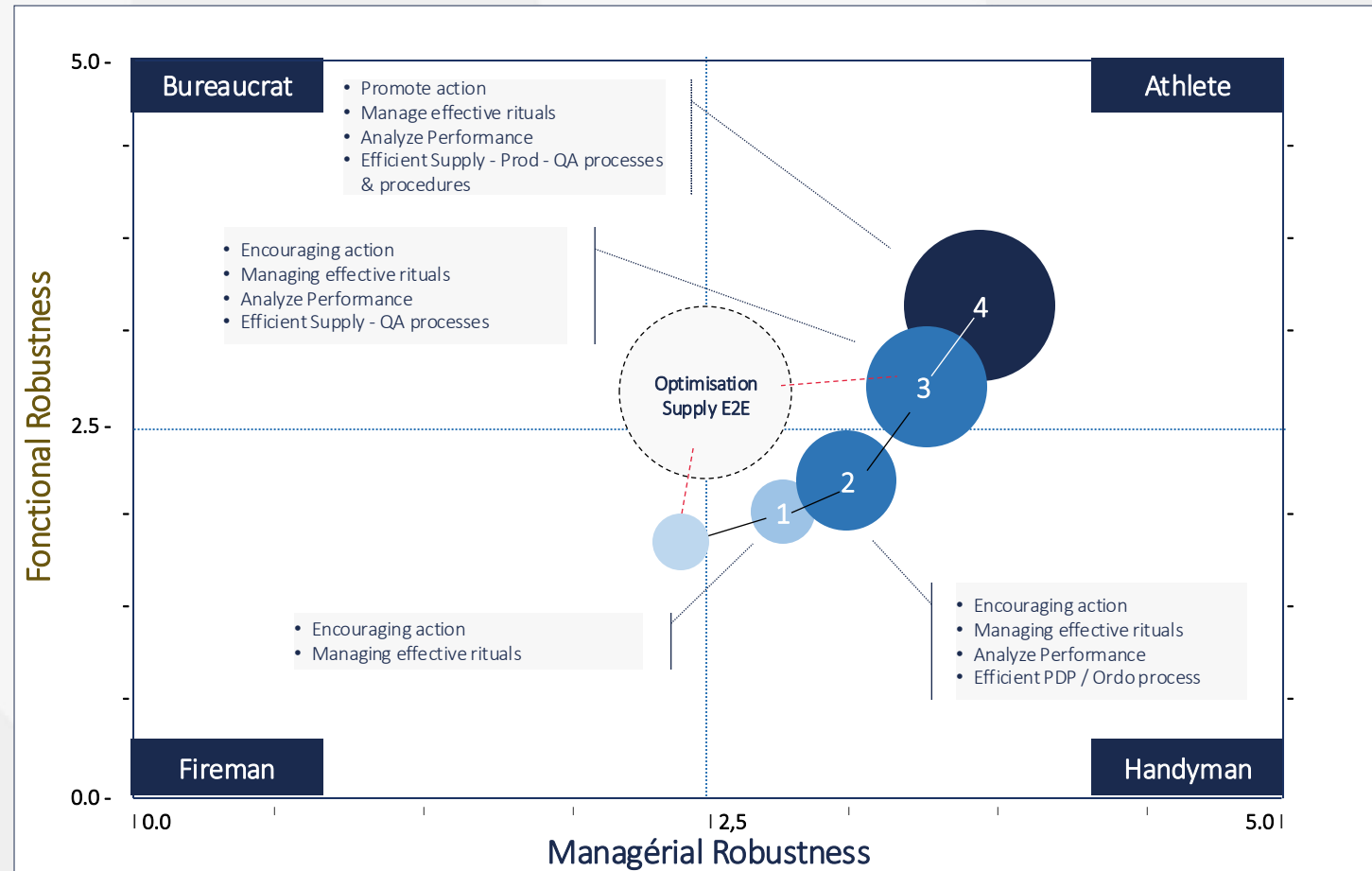
## To Be

- Design and implementation of a complete QC-Supply Target Operating Model (Organizational structure, job description referential, technical and managerial skills, governance and KPI's linked to operational objectives)
- Best practices integrated in QC planning/scheduling and sample flow management
- Integration / SLA S&OP - QC
- LIMS scoping and IS roadmap with solutions benchmark
- Coaching on the shop floor to implement a pilot, then full scope deployment using the internal coach's trained and coached during the pilot (Lab & Scope Atryon approach)

# When a solution includes different scenario's, the modeling takes into account the impact and effort of implementation, becoming a decision support

## As is

- The cycle time reduction target is challenging - around 28% / 2 weeks
- Supply process robustness questionable (ad minima Manufacturing Planning -> Scheduling)
- Complexity of the batch tracker system, requiring batches to be tracked through each manufacturing steps
- Visual management of batch tracking focused on its function, a lack of improvement actions and questionable robustness of flow control
- Ad hoc updates of manufacturing standards and performance is questionable
- Several deviations (only 5% of full batches without deviation) sometimes discovered at the end of the process or concerning manufacturing steps prior to the current step



## To Be

- **Scenario 1**  
Evolution of Visual Management, possibly including a consolidated view in Excel and the reintroduction of deadline targets  
Modification of the first line manager rituals and of the scheduling process to promote action
- **Scenario 2 (additional)**  
Design and implementation of a digital solution integrated to SAP / Trackwise / Rombio (AI), to switch from “lagging” to “leading” mindset and additional supply improvements.
- **Scenario 3 (additional)**  
improved deviation management process and rationalization of paper flows
- **Scenario 4 (additional)**  
Redesign of manufacturing standards and Supply / Manufacturing / QA performance management, in order to “pull” other improvement opportunities to feed Operational Excellence action plan

Scale of implementation effort

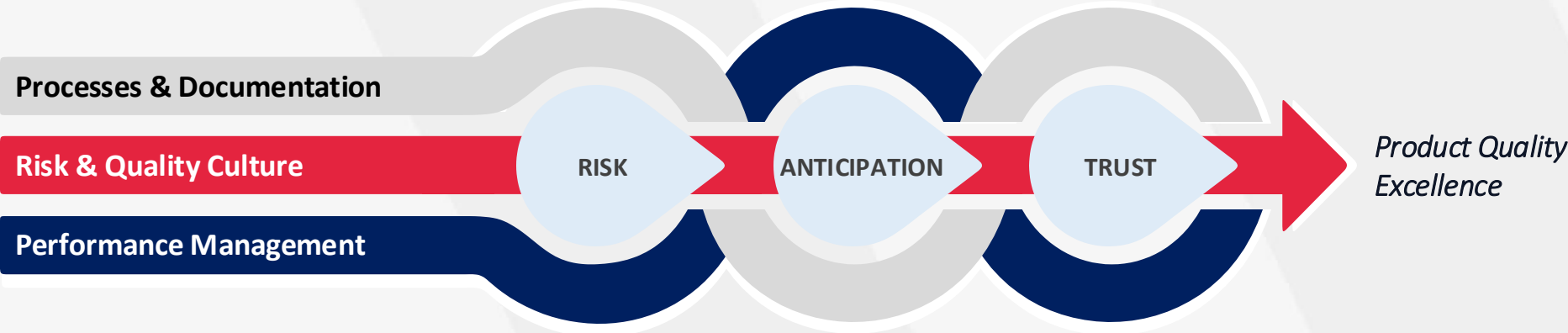


A woman with curly hair wearing a blue and white striped shirt is leaning over a desk, looking at a laptop. A man with dreadlocks is sitting behind her, pointing at the screen. The background is a blurred office environment. The entire image has a blue tint.

# Point of View Atryon Product Quality Excellence

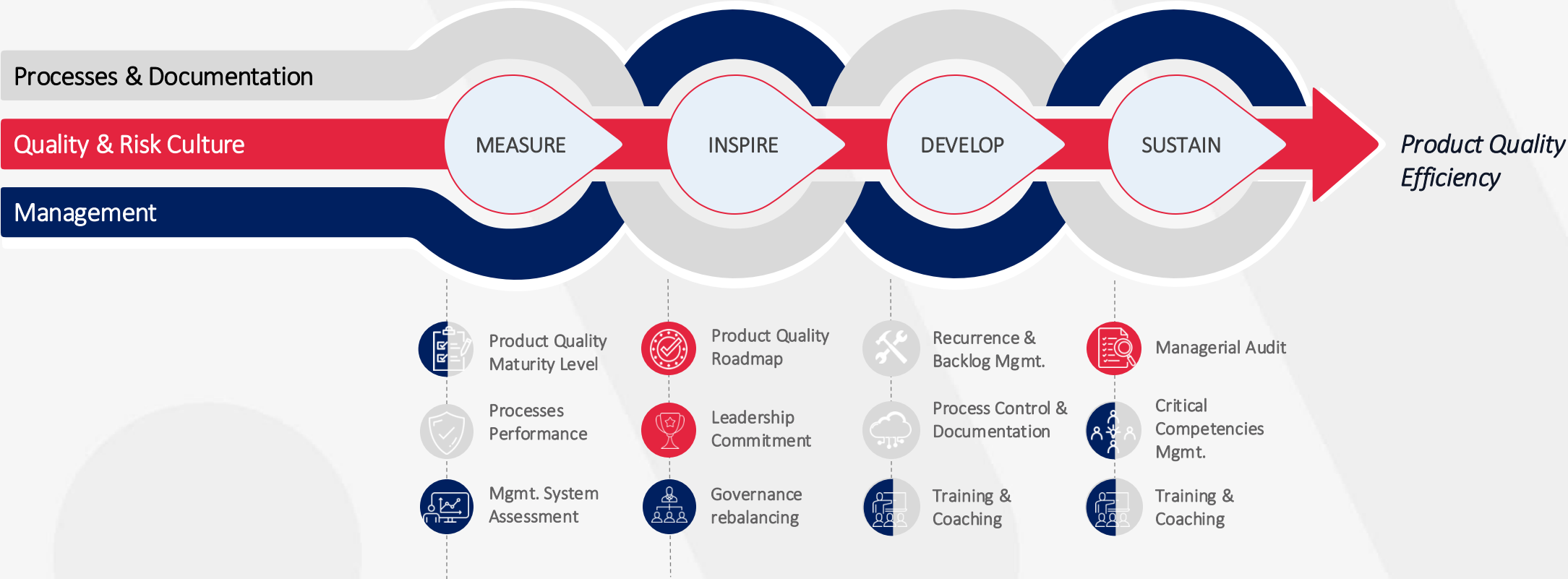
# Product Quality Excellence : How to take another step ?

From Process Control to Robustness Anticipation...



# Our turnkey solution for Product Quality Efficiency focuses on “fresh air”, process robustness anticipation & sustainability

## Product Quality Excellence – Building blocks



A woman with curly hair wearing a blue and white striped shirt is leaning over a laptop. A man with dreadlocks is pointing at the screen. The background is a blurred office setting. The entire image has a blue tint.

What's next for success ?