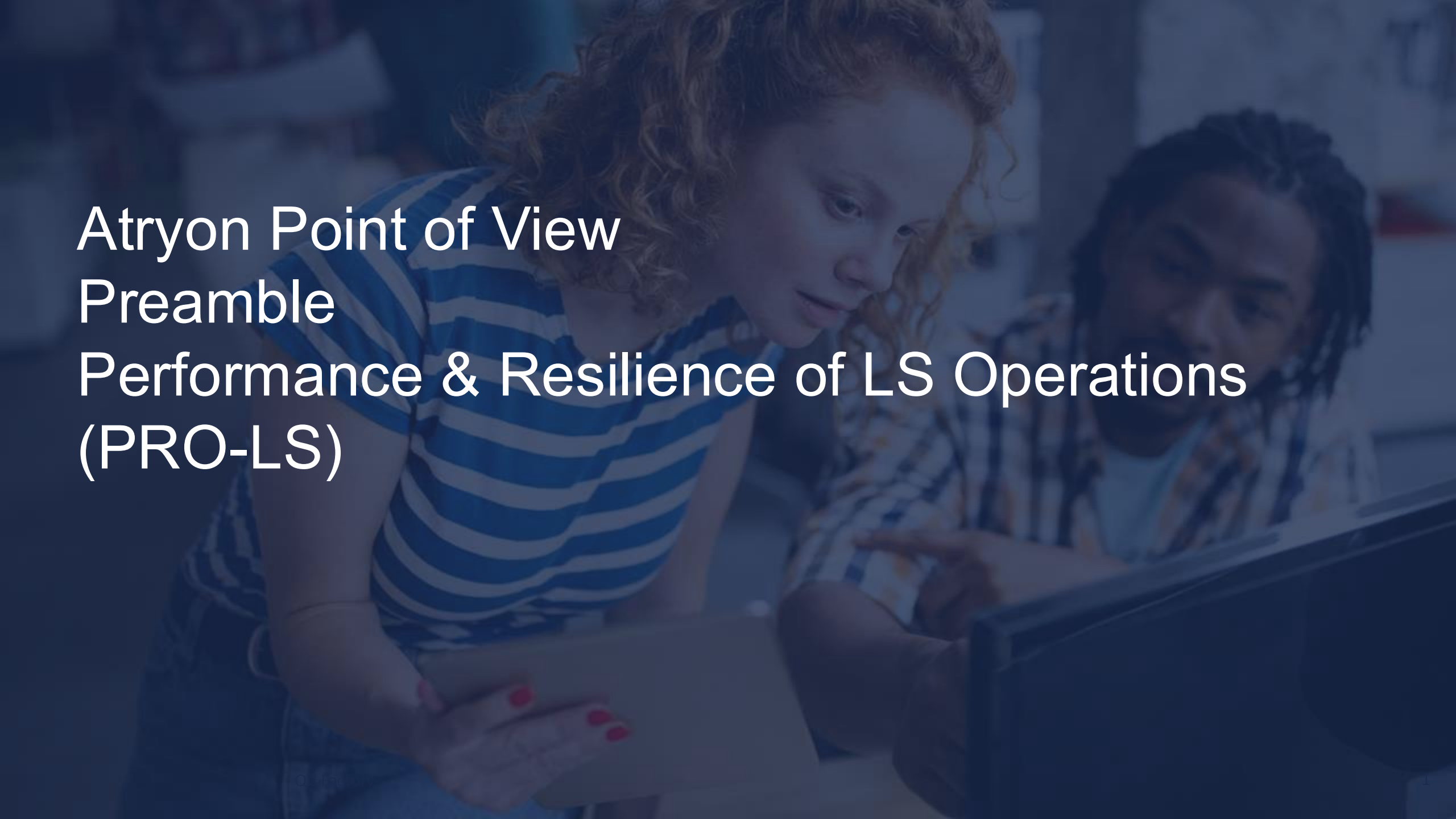
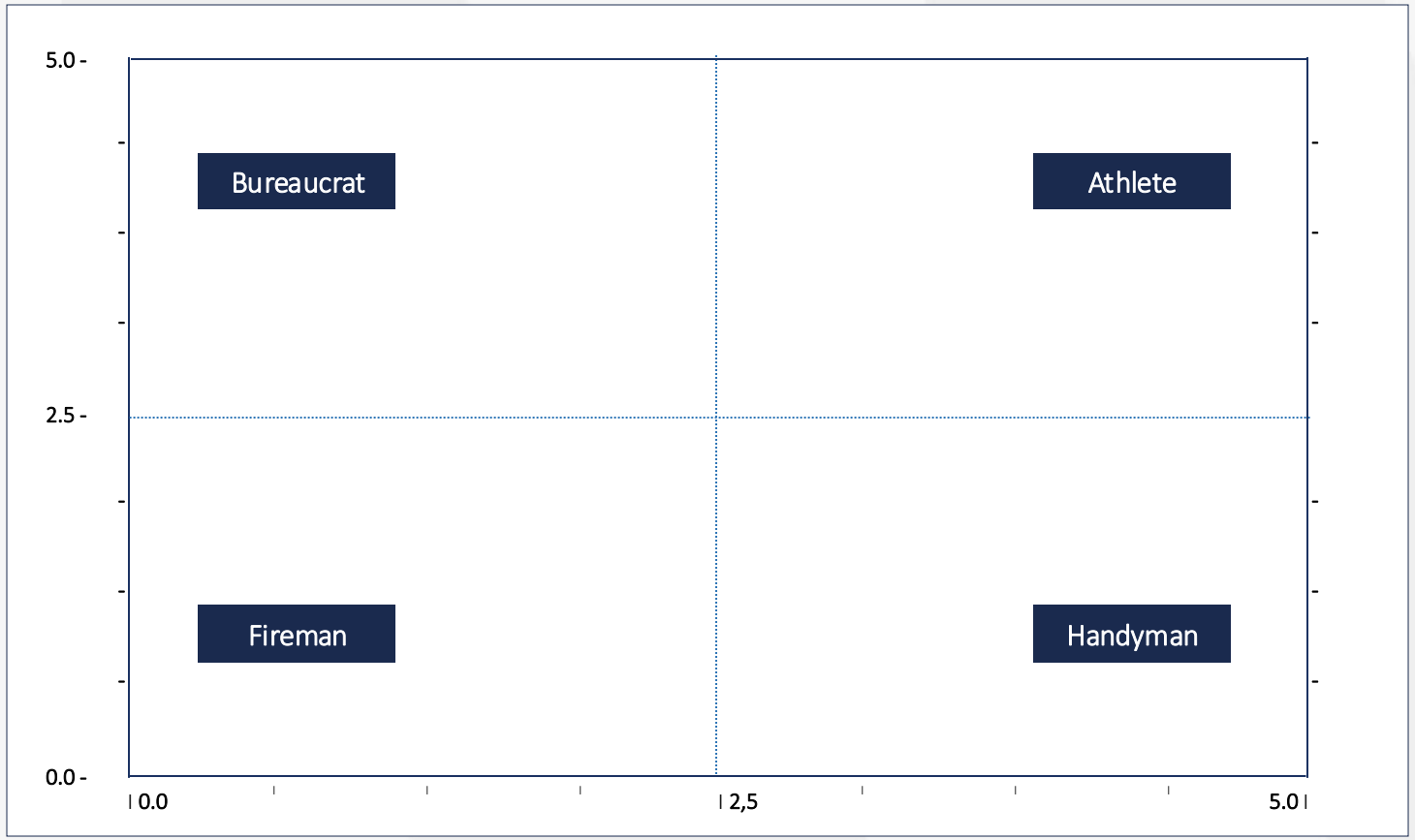


Atryon Point of View
Preamble
Performance & Resilience of LS Operations (PRO-LS)

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



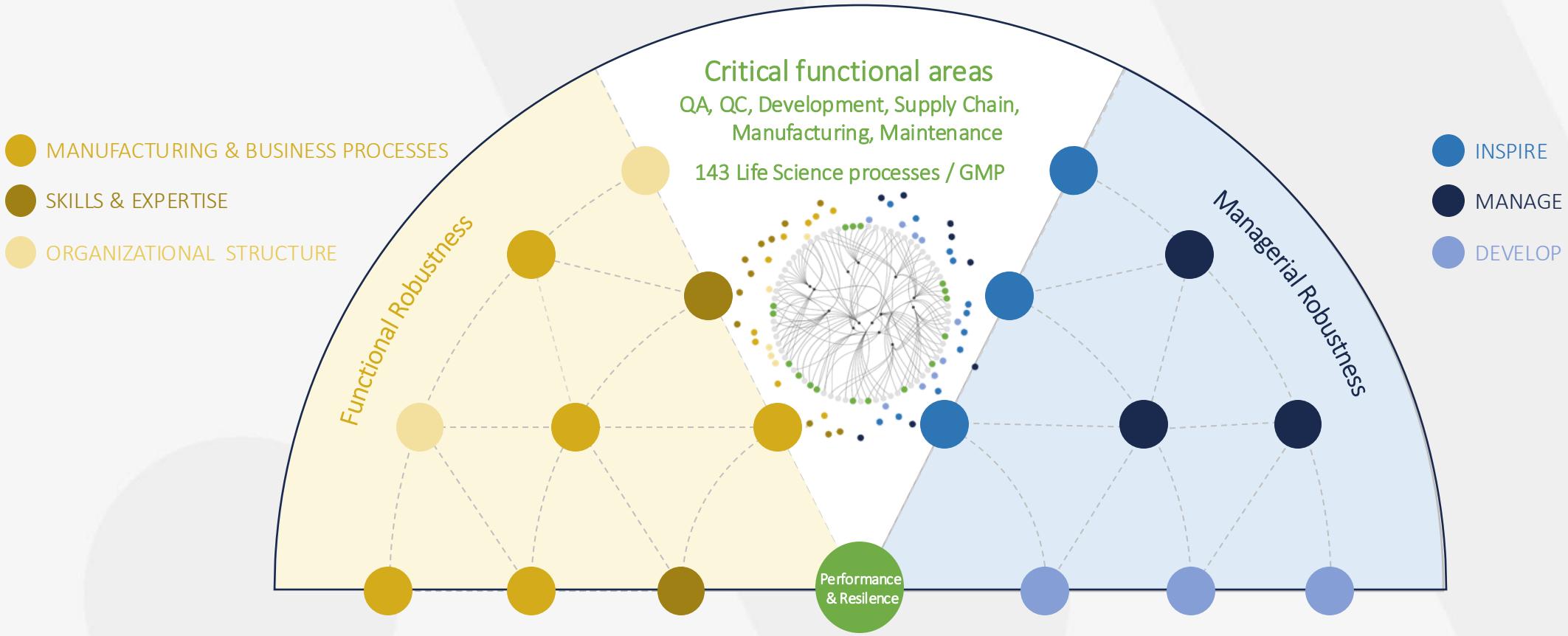
MANAGERIAL ROBUSTNESS

- 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

Sources : atryon Competency Development Center

…and are based on 18 functional and managerial components

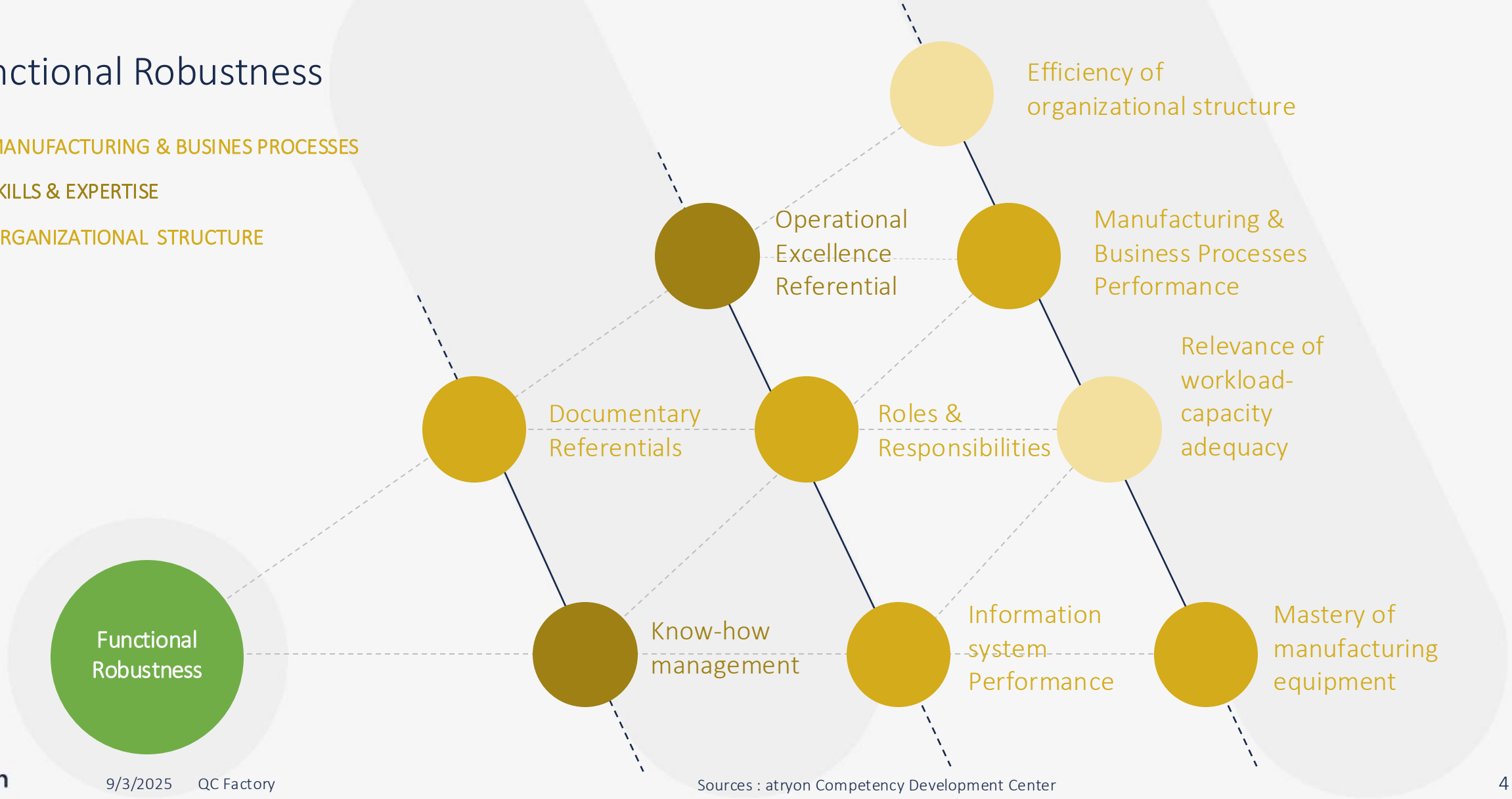
18 inter-related components



9 Functional components

Functional Robustness

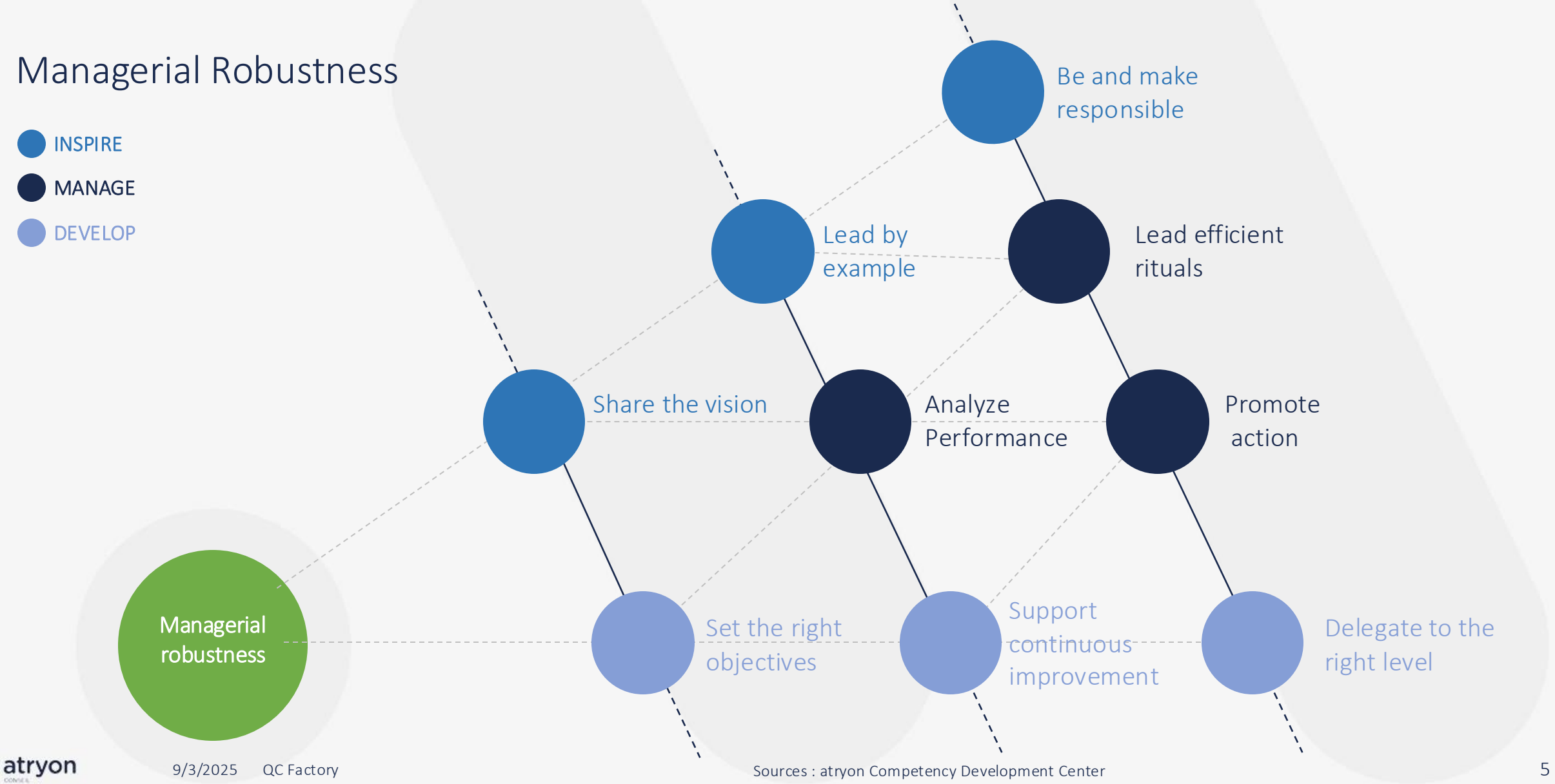
- MANUFACTURING & BUSINES PROCESSES
- SKILLS & EXPERTISE
- ORGANIZATIONAL STRUCTURE



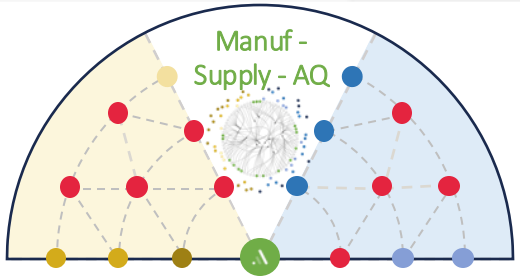
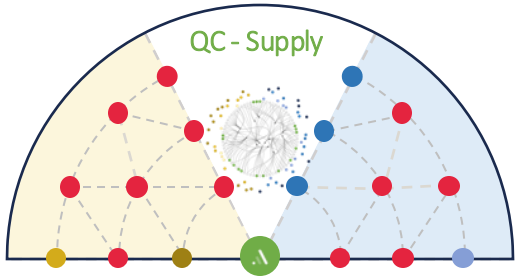
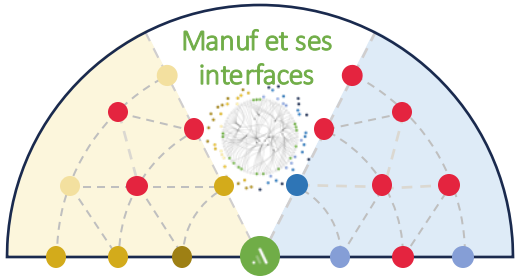
Sources : atryon Competency Development Center

9 Managerial components

Managerial Robustness



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

Context	Approach	Components	Results
• **Middle Pharma / Injectable :** 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	• Jointly develop Manufacturing / Maintenance managerial skills, focusing on Tier meetings management • Set up a Supply / QA task force to accelerate return to planning adherence		**+28%** of planning adherence in 6 months, generating a drastic reduction in penalties linked to the risk of market failure
• **Middle Pharma / Dermatology :** 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	• Analysis planning and scheduling processes redesigned • Implementation of an "Analytical Excellence" dynamic (robustness of methods, efficiency of organization, rationalization of documentation (digital) and of the QC Management Operating System)		**+20%** productivity in 3 months, including re-synchronization of Supply - QC flows and implementation of a Supply - QC SLA
• **Big Pharma / Pharma Solid Forms:** 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	• Complete transformation of the Management Operating System • 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..		**+26%** productivity in 5 months and **+17%** of OEE on targeted lines (3 sites)

● *Targeted components*

Sources : atryon Competency Development Center

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

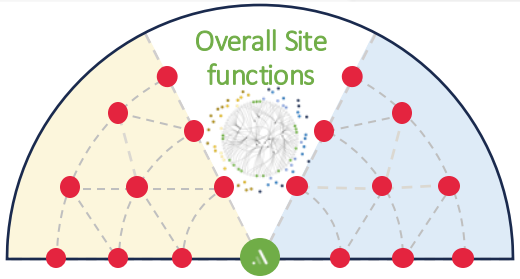
Context

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

Approach

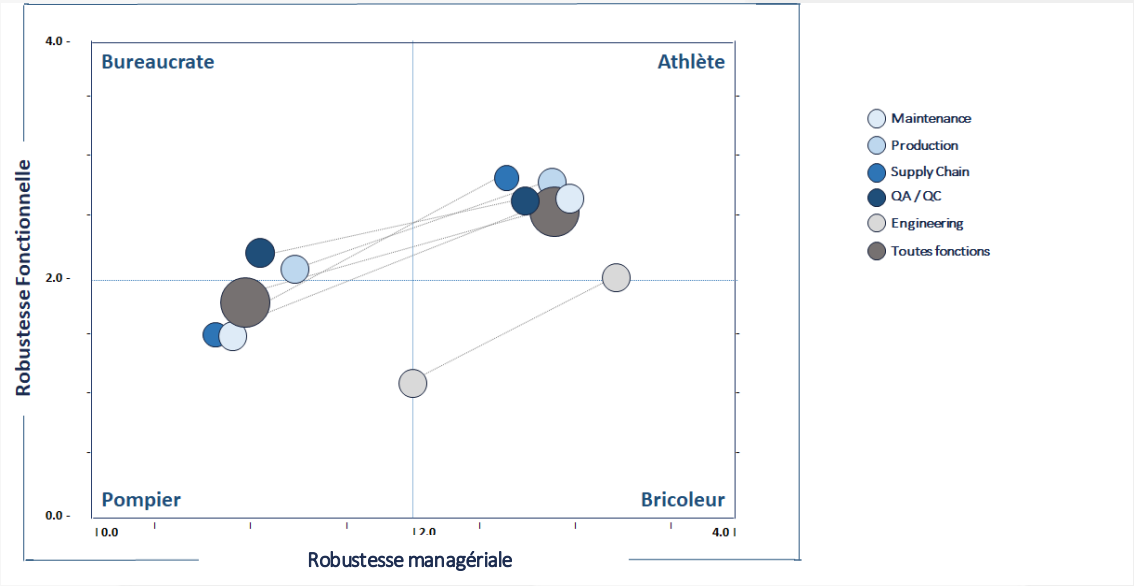
- Diagnosis and design of a Site roadmap
- Implementation of a site vision and operational objectives
- Complete overhaul of the Management Operating System and major changes to Site processes and organization (across all functional areas).

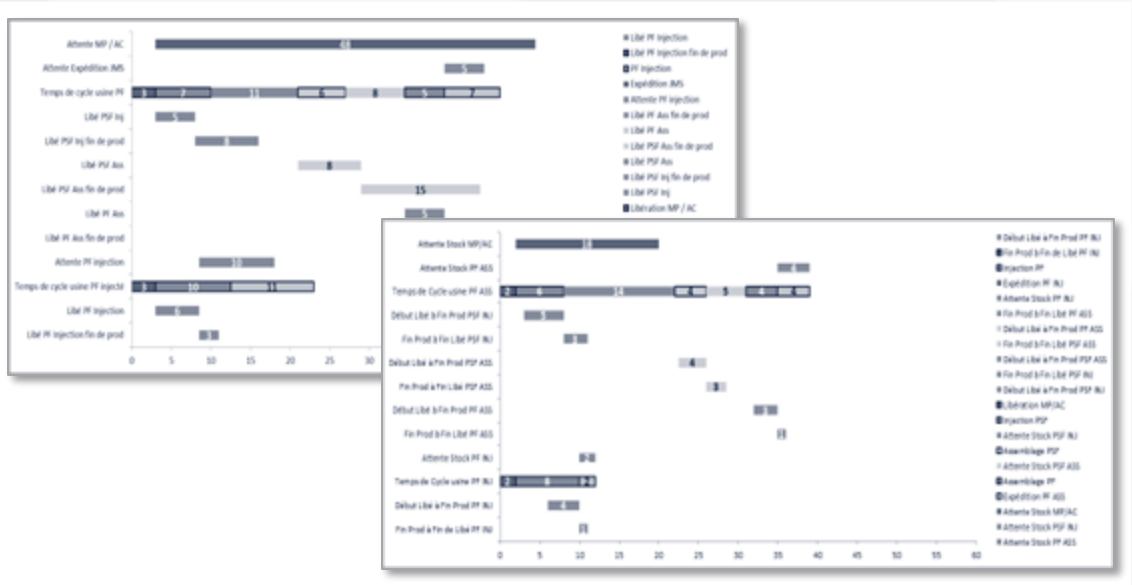
Components



Results

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

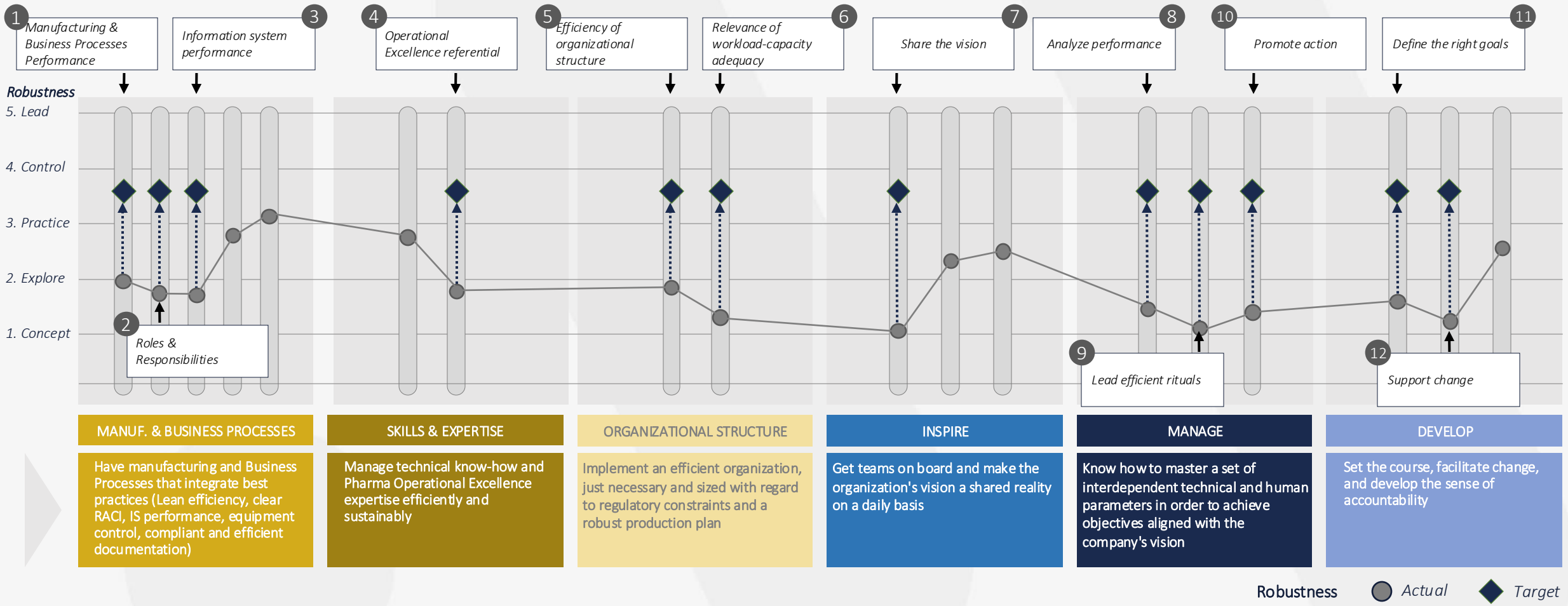




● *Targeted Components*

Sources : atryon Competency Development Center

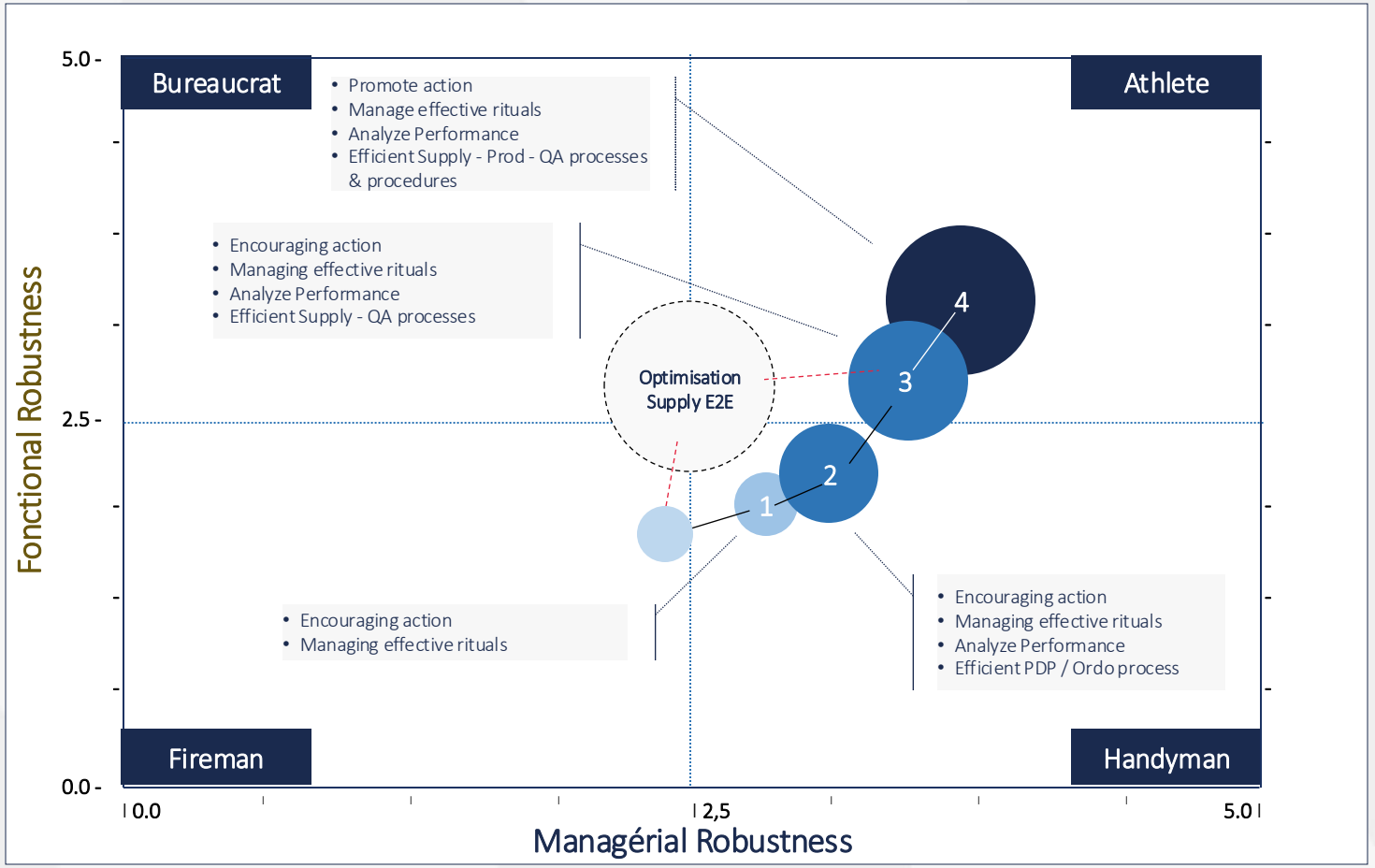
For the jointly agreed scope, we target the functional and managerial components to be developed



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

As is

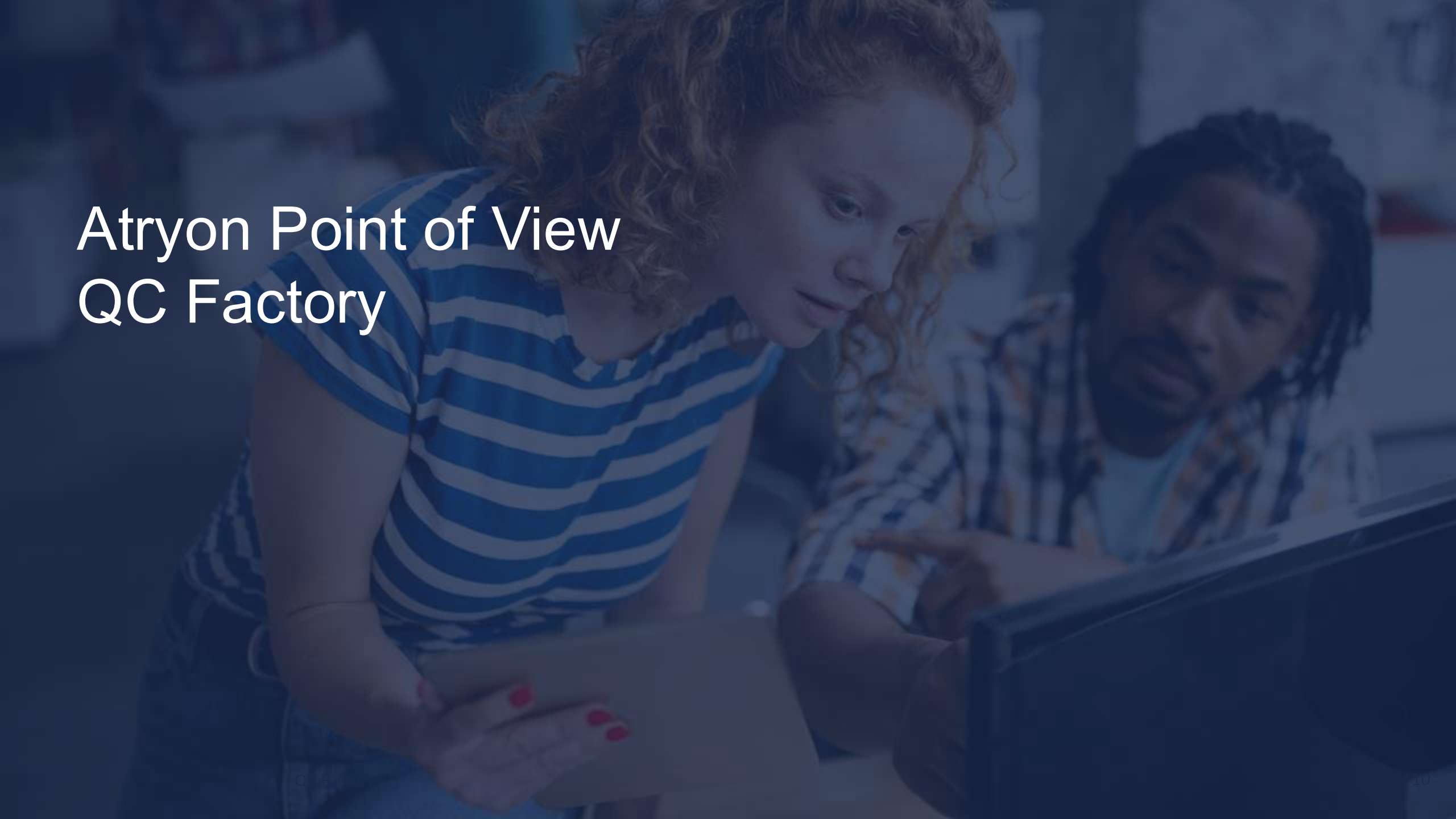
- The cycle time reduction target is challenging - around 28% / 2 weeks
- Supply process robustness questionable (ad minima Manufacturing Planning -> Scheduling)
- Complexity of the batch tracker system, requiring batches to be tracked through each manufacturing steps
- Visual management of batch tracking 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

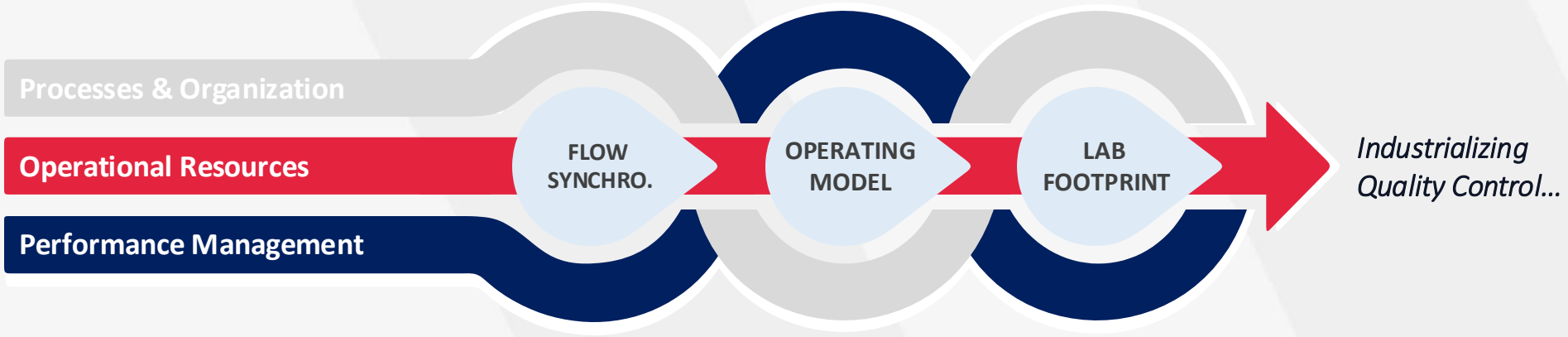
- **Scenario 1**
  Evolution of Visual Management, possibly including a consolidated view in Excel and the reintroduction of deadline targets
  Modification of the first line manager rituals and of the scheduling process to promote action
- **Scenario 2 (additional)**
  Design and implementation of a 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

Sources : Client Pharma Bio / Fonctions Supply – AQ - Production



Atryon Point of View
QC Factory

QC Factory : How to take another step?



Our approach enables us to assess the maturity of your QC Factory

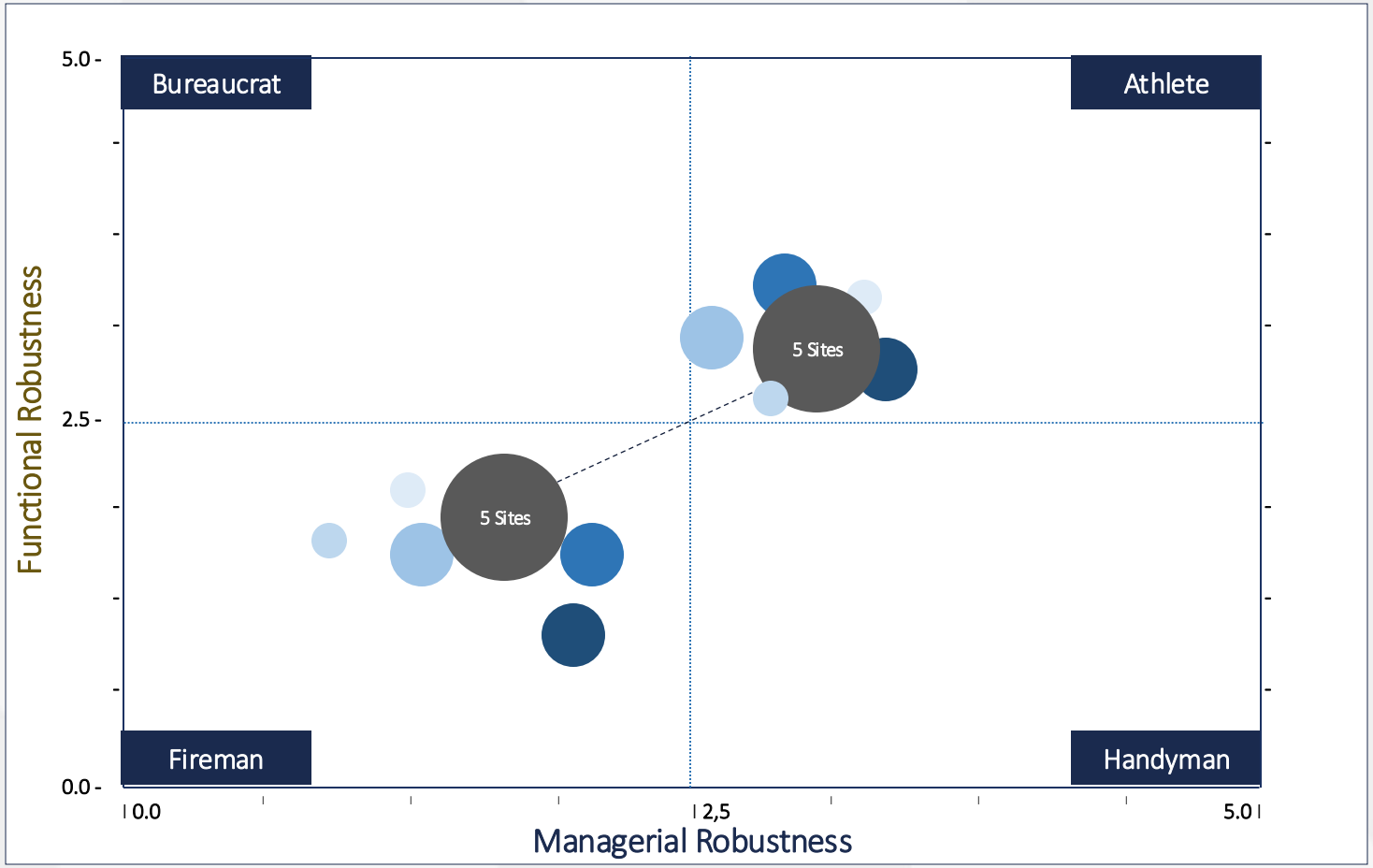
Entirely based on our PRO-LS Model

QC Factory Maturity Level			1 CONCEPT	2 Explore / 3 Practice / 4 Control	5 LEAD
Processes & Organization	QC Lab & Business Processes Performance		• QC Lab processes performance are questionable • Some Business Processes don't exist or request excessive effort		• QC Processes are optimized, including lab pulled-flow & test methods harmonization. Business processes are well-developed, especially those linked to scheduling and workload/capacity
	Efficient Organization	Efficiency of organizational structure	• The IL/DL ratio is far away from the bench, the span of control is not adapted, and the distribution of roles doesn't serve efficiency		• The organizational structure is appropriate, reflects good "Span of Control" practices, respects IL/DL ratios, enables processes to operate efficiently and optimizes the DL's day-to-day work
		Roles & Responsibilities	• R&R are not fully formalized, working on silos with often complex relationship linked to unclear R&R		• The R&R of QC and its interfaces are clearly defined (RACI) and applied. Meetings and associated actions are properly allocated, reinforcing responsibilities
Operational Resources	Know-how Management		• There is not or partial skills matrix, the level of poly-competencies is not or too much developed, tech daily role is not described, Long and short-term workload / capacity is not monitored		• There is an individual/collective training plan, aimed in particular at managing the critical mass of targeted skills and incorporating a tutoring plan. Technicians' daily activities are modeled on standard activity sequences, formalized and regularly adjusted to optimize laboratory productivity
	Mastery of QC Lab Equipment		• Failure rate are questionable, without systematic understanding. Equipment are not fully available, with qualification delayed / not anticipated. Practices are heterogeneous		• All equipments are reliable, practices are standardized for all technicians, and benchmark intelligence on new analytical technologies exists and new technos are implemented when relevant
	Information System Performance		• Many data are not operable and dashboard/KPIs require an important re-work. Few managers are invested in monitoring and analysis of KPIs. IS functional coverage is incomplete, heterogeneous or questionable		• KPI from the IS meet needs, Process & R&R regarding master data management are documented (QC & Interfaces) • Testing Mgmt. is digitized, and most of lab activities are paperless / automated
Performance Management	Efficient Management	Analyze Performance	• Main indicators are lagging, without priority in terms of performance, and no defined standard. Mgmt. is not involved in daily Perf monitoring. Continuous Improvement actions is very low, the "fireman" mode is regularly observed		• Practices are homogeneous, with trends analysis and regularly revised Mgmt. System. KPI's are linked to the strategy with a multilevel KPI Tree. Standard time are defined and regularly optimized for QC. Performance Mgmt. is cross-functional, root causes are analyzed to support efficient action plan
		Lead efficient rituals	• Most of the meetings are on a weekly or monthly basis, mainly focused on communication, without KPIs and action plan		• Practices are homogeneous at all level with a Mgmt. System defined, well-balanced and applied, constantly looking for efficiency
	Support Continuous Improvement		• Operational Excellence is the main function to be involved in CI. Some managers are coached, but most of initiatives are led by CI, Quality either SHE		• Practices are homogeneous inside the organization, with coaching plan on managerial and functional components. Teams escalate deviations to standard practices, shopfloor rituals support the CI mindset

… and to improve your QC functional and managerial robustness

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



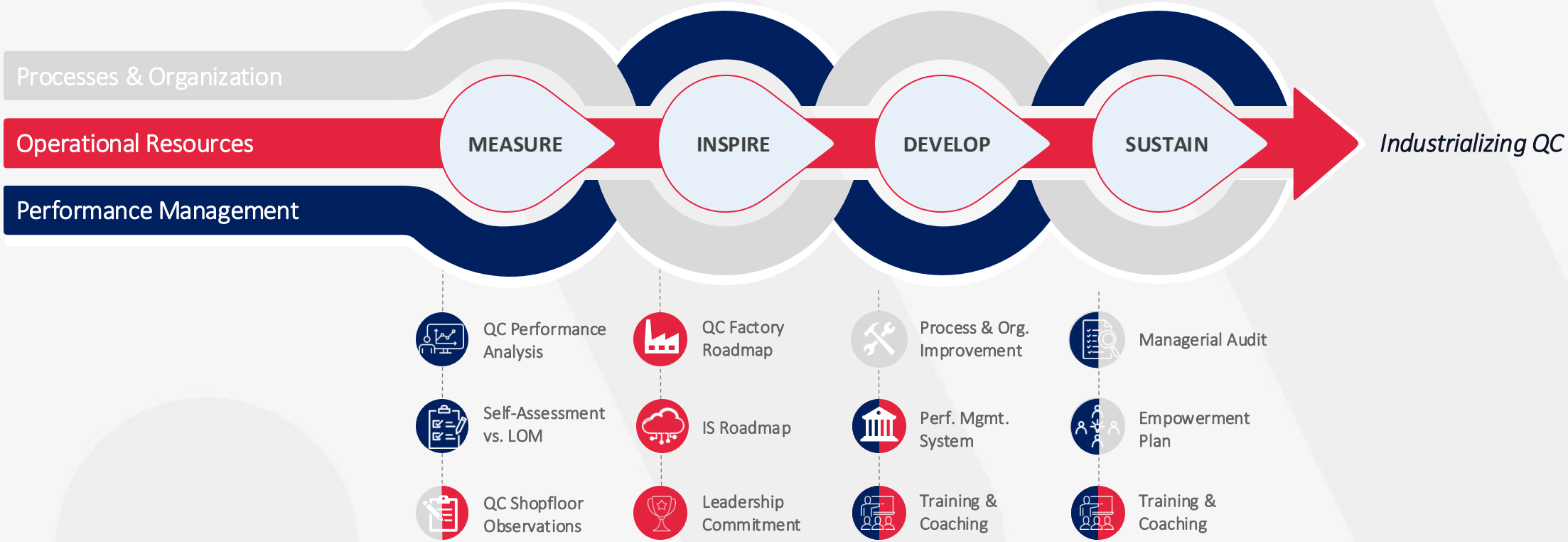
To Be

- 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)

Sources : CDMO customers – 5 Sites / Dept Supply - QC

Our turnkey QC Factory Solution focuses on the implementation of your Laboratory Operating Model, based on 117 atryon standards

QC Factory – Building blocs



What’s next for success ?