



Achieving step-change performance improvements through a structured approach

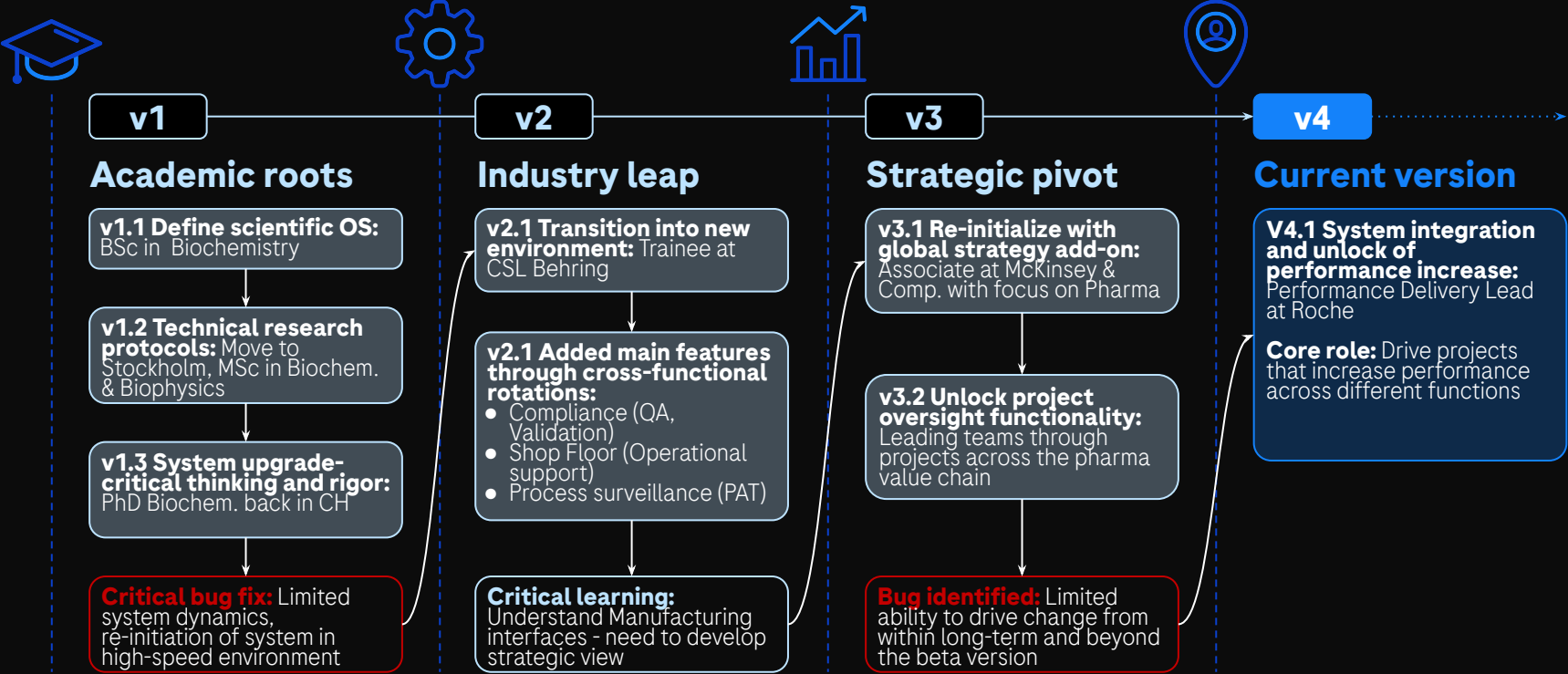
Simone Graf

April 21st 2026 | ETH guest lecture

Agenda

- Who am I and where do I come from
- Roche in a nutshell
- Glossary
- How we want to bring step-change performance improvements to life
- Wrap-up and Q&A

My iterations from academia to performance delivery at Roche



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Roche at a glance

Who we are and what we do



128 years

founded in Basel in 1896



**A leader in
healthcare R&D**

with CHF 13.2 billion invested
in 2023



3 Nobel prizes and
44 Prix Galien

since 1974



CHF 58.7 billion*

in Roche Group sales in 2023



**45 Roche medicines
& 90 diagnostics****

on the WHO List of
Essential Medicines & Tests



>100,000

dedicated employees
worldwide



>22 million people

treated with our medicines
in 2023



29 billion tests

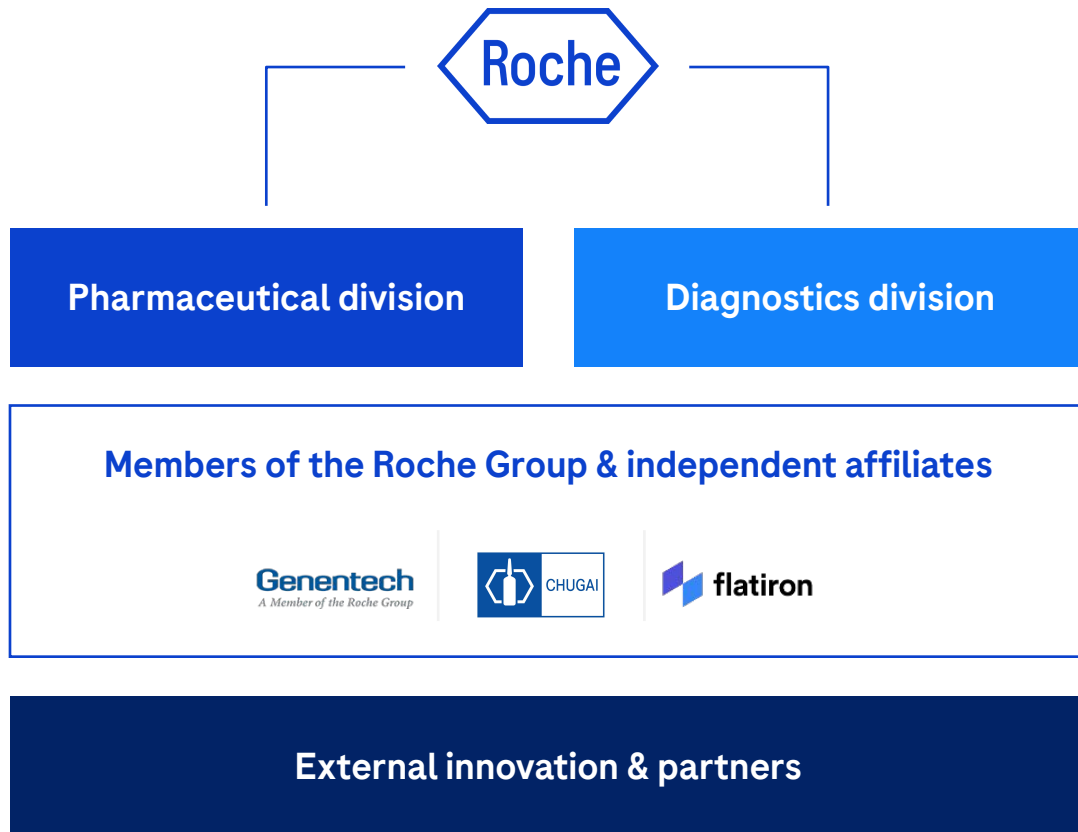
conducted with our
Diagnostics products in 2023

*Unless otherwise stated, all growth rates and comparisons to the previous year are at constant exchange rates (CER; average rates 2023) and all total figures quoted are reported in CHF.

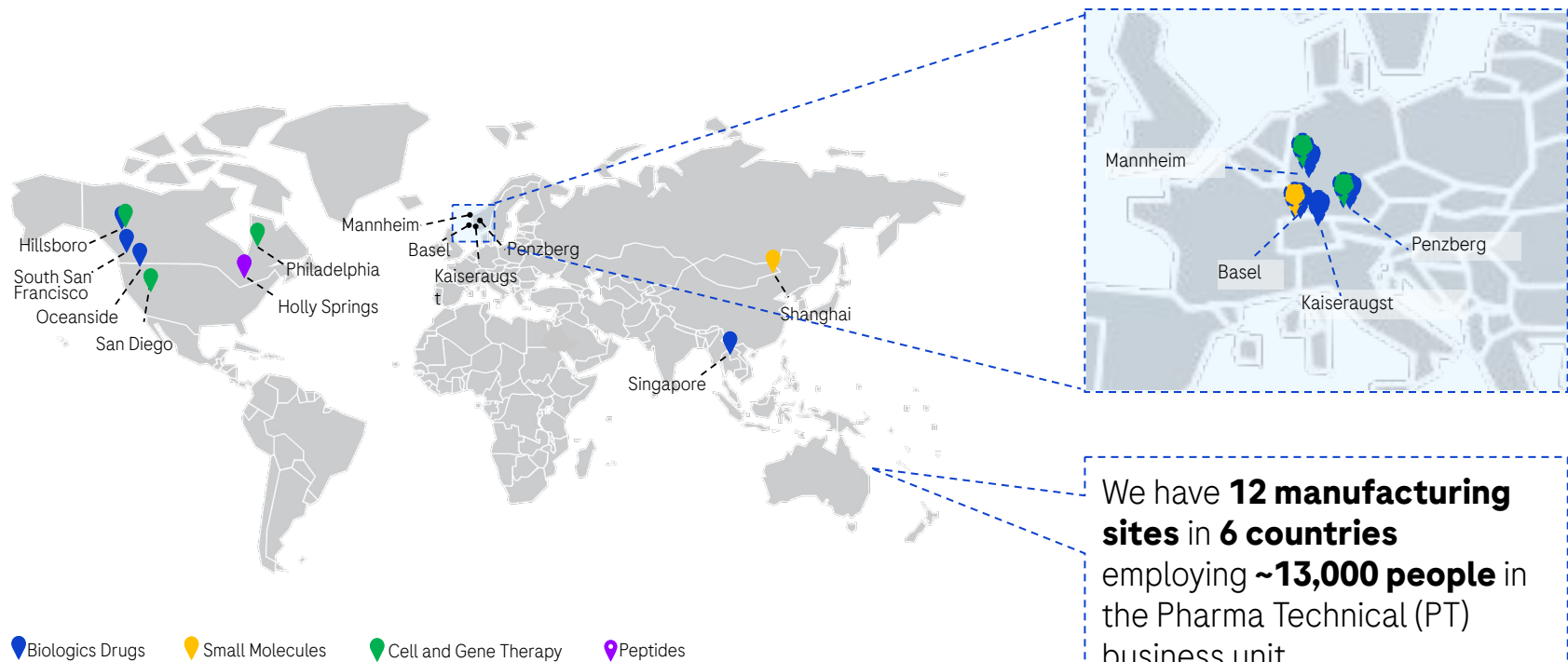
** Medicines and tests that have either been developed or acquired by Roche

Our structure and setup

Providing scientific freedom to work, think and address problems in different ways



Our Pharma manufacturing network



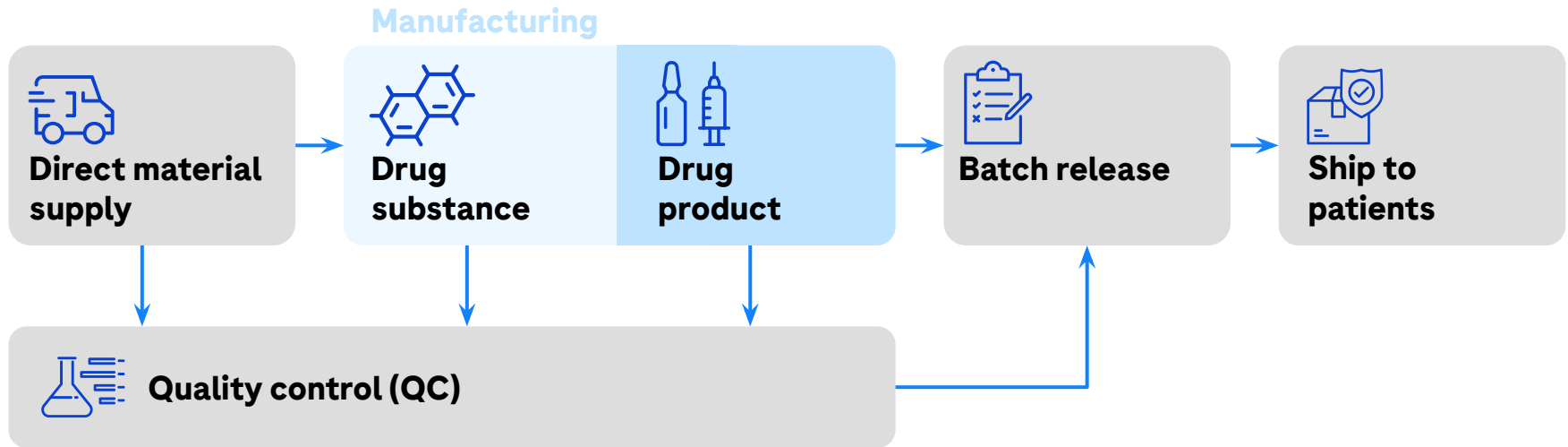
How does pharma manufacturing look like?



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High-level schematic representation of pharma manufacturing value chain



Selected deep dives following

Drug substance is the active ingredient treating the disease

Drug product is how the drug is administered/consumed

Drug substance

- **Drug substance is the active product ingredient (API)** and thus the molecule treating the disease
- **Manufacturing** happens in 2 steps:
 - **Upstream: Production of molecule** via chemical synthesis (small molecules) or cell-based production systems
 - **Downstream: Purification of molecule** via e.g., chromatography, ultra-/diafiltration,,



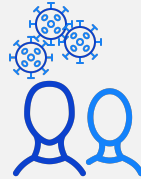
Drug product

- **Drug product is the final product administered to patients** (API plus excipients, potentially plus device)
- **Formulation** is the step where the API is mixed with excipients (inactive ingredients such as fillers, stabilizers etc)
- **Fill & Finish** is the part of the process where the drug is put into its specific form and primary container (e.g., tablet, injectable vial, prefilled syringe)
- **Packaging** is the part where the primary container is labelled and packaged

Monoclonal Antibodies are targeting molecules involved in disease in a highly specific manner, blocking their action

Antibodies from an immune reaction in our bodies

As **pathogens enter our body** our **immune system creates antibodies** to recognize and fight them



These natural antibodies are a **mix of antibodies recognizing different aspects** of the original pathogen

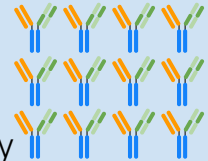


Monoclonal Antibodies are custom built biological keys

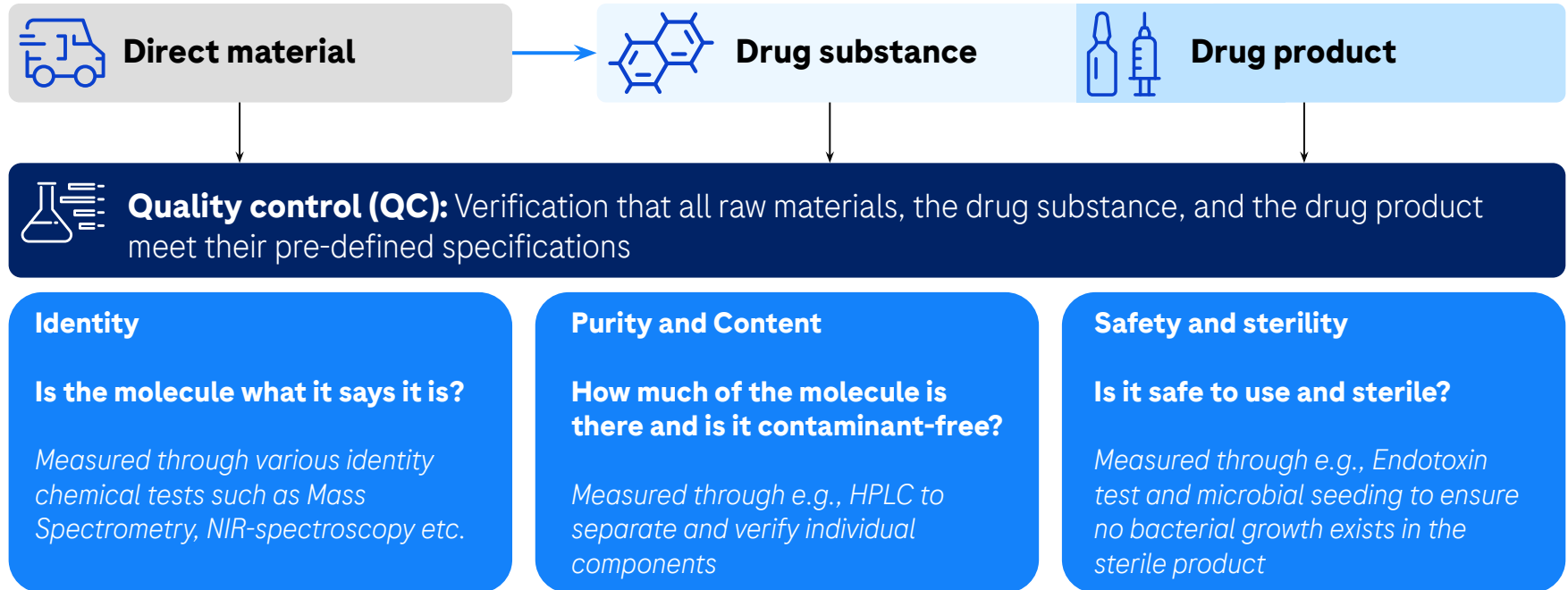
Monoclonal Antibodies are **designed in the lab** to **recognize one specific aspect** on a disease causing molecule



They are **produced as identical, purified clones** that target this exact aspect on this molecule, blocking its disease causing activity



Quality control is the lab-based physical testing of samples against an extensive set of strict specifications



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We are a global OE team supporting sites & functions to unlock stepchange improvements in a data driven approach

Context



Increasing operational complexity leads to performance and quality challenges



Competing priorities impact focus and discipline to implement improvements



Variable OE maturity across sites and functions necessitates a tailored deployment strategy



Our mission



We are working side by side with local teams in a clear framework to deliver performance improvements



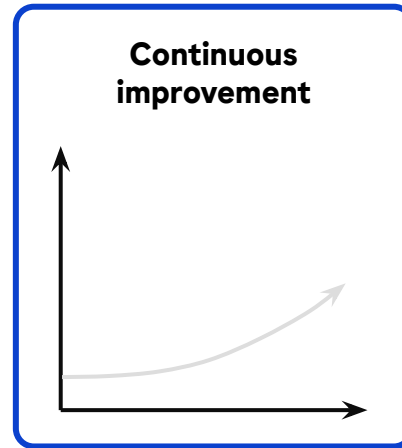
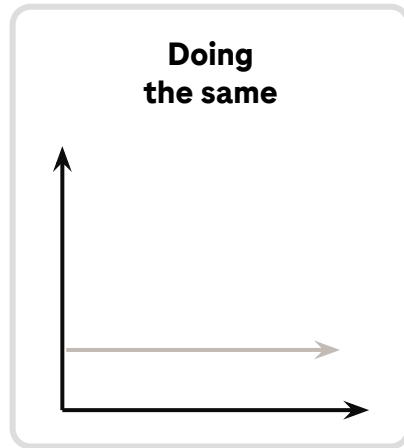
Key targets:

- **Define aspiration** based on data and facts
- **Deliver performance improvement** and support implementation
- **Sustain improvement** through capability building

Through concerted and targeted actions we want to achieve step change improvements

Maintain status quo

Improve performance



By identifying high impact areas, and prioritizing levers targeting those areas, we want to create step-change improvements

We follow a holistic methodology with strict timelines and focus on capability building



Holistic and proven methodology

- **Based on Roche Lean Production System** looking at Business, Technology, People
- **Designed for sustainability** of implemented improvements



Rigorous timeline

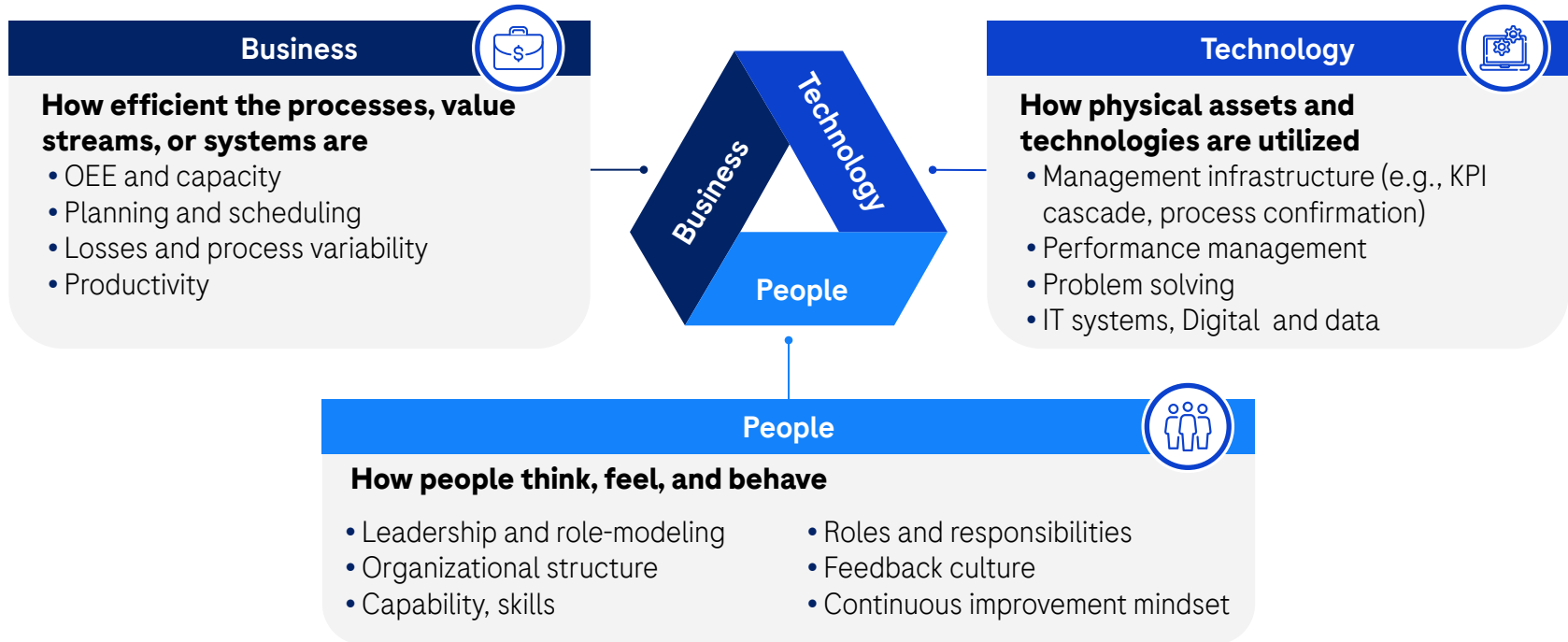
- **Clearly defined process** (incl.milestones, meeting cadence, LS involvement)
- **Clear deadlines and standardized phases** to ensure efficient progression



Integrated global support and capability building

- **Team of global and site** resources driving the program
- **Dedicated training & coaching** to enforce OE capabilities and Lean leadership

The performance excellence delivery (PED) approach bases on the Roche Lean Production System



We deployed this approach in several lines and sites...



**Drug Substance
Manufacturing**

**Cell & Gene
SUT line**

MAb line

**Drug Product
Manufacturing**

**Ocular devices
Lyophilization line**

Different filling lines

QC

Direct material testing

**Process analytical
technology**

Some selected deep dives following

...to address and improve performance



Exemplary

XX OEE change in %

Site 1



+47%

“Together, we reached the 6.3Mu target on the Ocular Device line—a strong example of teamwork in action.”

Site 2




+37%

“Our collaboration on Line 2 and QC was a real eye-opener that continues to shape our performance roadmap.”

Use Case 1: Increasing throughput at a Monoclonal Antibody (MAb) Drug Substance line

How to increase the output generated by our MAb manufacturing line...



 ...with the same resources

 ...by increasing efficiencies

 ...by reducing waste

Increasing complexity and demand are what causes the need to raise our throughput



Increasing operational complexity

We face an expanding product portfolio = more different products are manufactured in the same line

This increases operational complexity and also inefficiencies such as adjusting the line between different products



Increasing output needed

Increasing demand and also more products means we need to manufacture more

We are already at the limit of our current capacity so our manufacturing operations need to become more efficient

To increase Monoclonal Antibody manufacturing productivity we looked at 3 main areas



How can we produce more by increasing the speed of our line through optimization of processes



How can we minimize the time lost between batches and products by improving the changeover process



How can we minimize the time lost due to maintenance by optimizing maintenance activities and planning

We conducted various workshops, Gemba walks, interviews, and data analyses to identify improvement opportunities

Time block categories: ■ Product 1 ■ Product 2 ■ B2B changeover ■ P2P changeover ■ Planned downtime

Production plan = How many batches can we produce now and how can we increase throughput?



Batch-to-batch changeover

- Can we clean and refit the line for a new batch of the same product faster?
- Where do we lose most time in B2B changeover?

Product-to-product changeover

- Can we clean and refit the line for a new product faster?
- Where do we lose most time in P2P changeover?

Batch cycle time

- Can we decrease cycle time i.e, produce 1 batch faster?
- Can we parallelize more?
- Where do we lose time during manufacturing process?
- Where do we have waiting time?

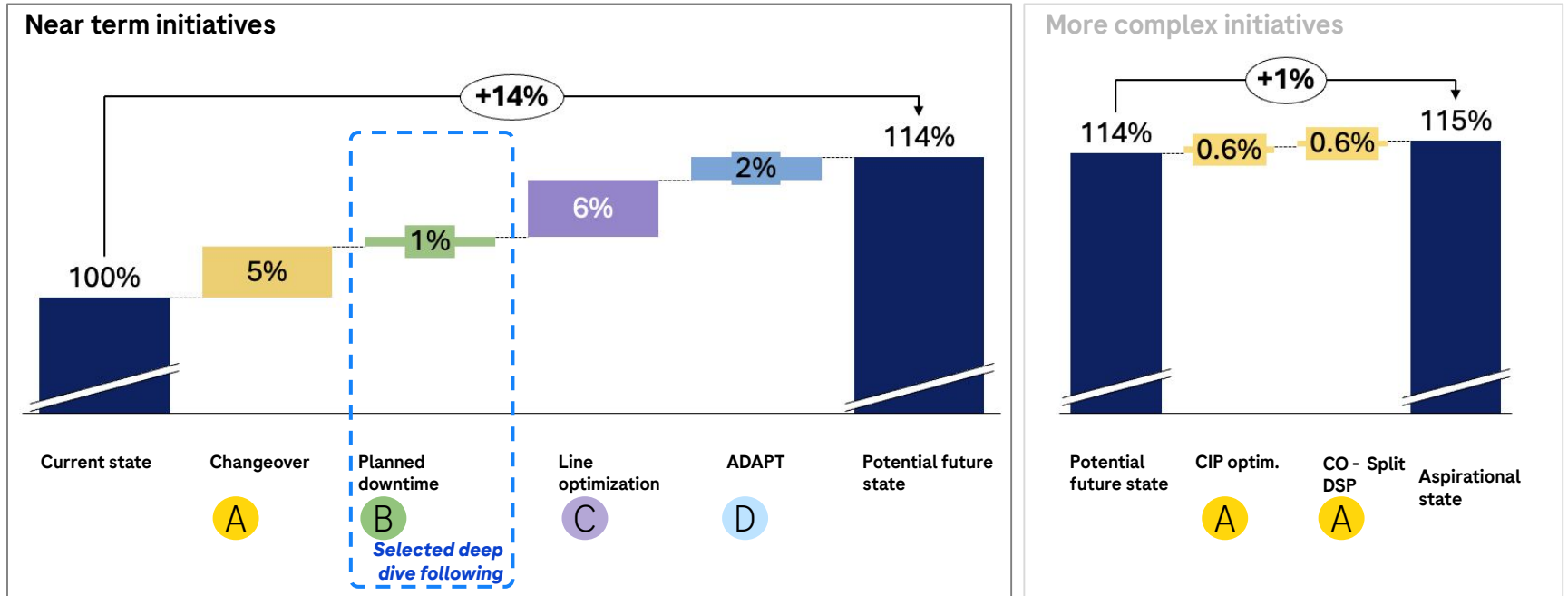
Planned maintenance

- Can we decrease the duration of the planned downtime?
- Can we parallelize activities during maintenance?
- Can we reduce the frequency of complete shutdowns?



In the MAb project we found that we can increase throughput by about 15% through a mix of Lean and digital initiatives

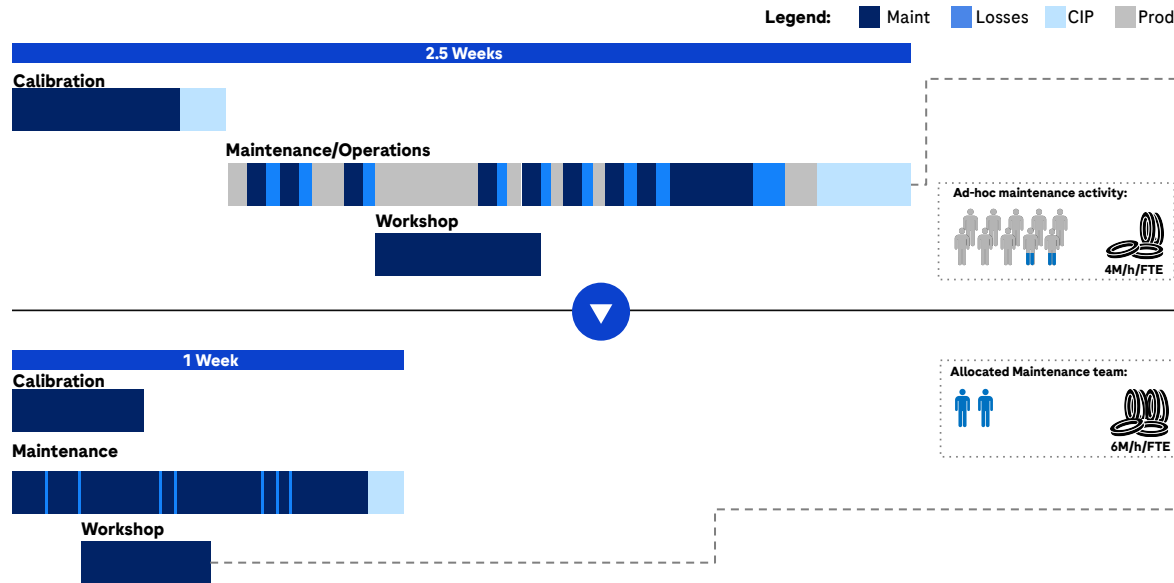
Projection of potential throughput increase impact through 4 main levers, in runs/year indexed to 100



B Coordination of calibration and maintenance activities and refined operating model allow 60% compression of time

Activity coordination and adjusted operating model compress downtime

Levers


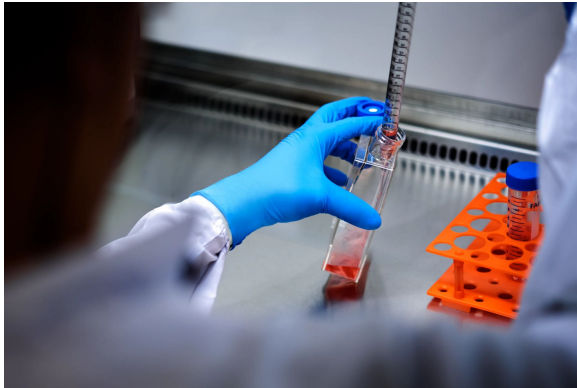


Operating model adjustment:
Fully allocate FTEs for maintenance to remove gaps between activities as involved people have full focus

Coordination of activities:
Improve planning between maintenance and calibration to allow parallelization

Use Case 2: Raising productivity in one of our QC labs

How to become more productive in our QC lab to do more tests faster...



...with the same resources



...by increasing efficiencies



...by reducing waste

Increasing demand and limited capacity causes the need for us to be able to do more QC tests in a shorter period of time



Increasing workload

We face an increasing number of material shipments

This increases the number of materials we need to test and thus also an increase in the number of tests we need to conduct



Capacity overloading

In the past years, we did not have enough capacity to fulfill the demand

The higher demand vs the capacity we had resulted in a backlog of workload that needs to be completed on top of an increasing demand

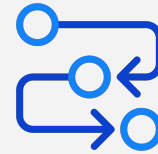
To address the gap between QC demand and capacity and to raise productivity we followed a 4-pronged strategy



Reduce the number of tests that need to be performed



Accelerate lab throughput through Lean and digital



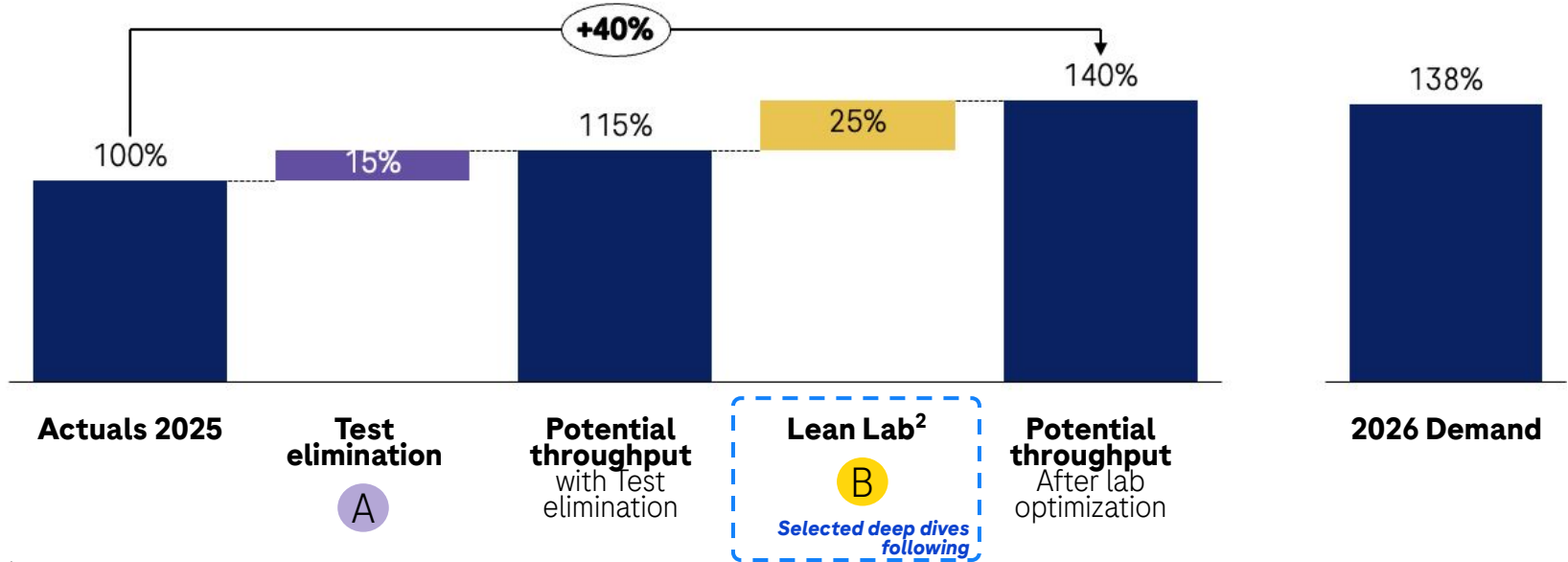
Streamline End-to-End process by improving interfaces and trackability



Introduce visual performance dialogue to clear roadblocks

We believe QC DMT laboratory throughput can be increased by ~40% by activating two main levers

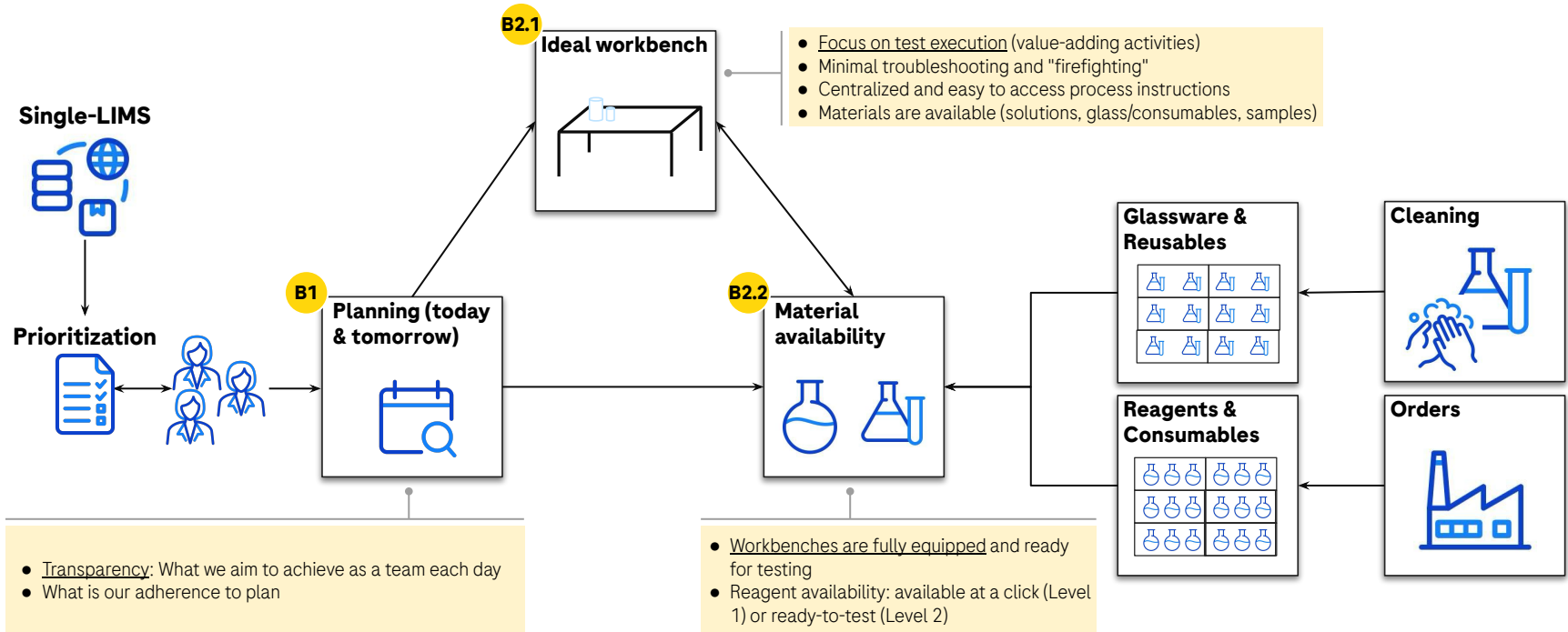
Potential throughput increase through 2 main levers,
 as throughput in batches¹ per year indexed to 100, done with the same number of lab technicians



1) Based on average number of tests per batch

2) The potential in Lean Lab depends on foundational prerequisites including for example: ability to shift focus of laboratory employees towards core activity of testing, coverage of material management by a person, buffer preparation (material mgmt or robotics)

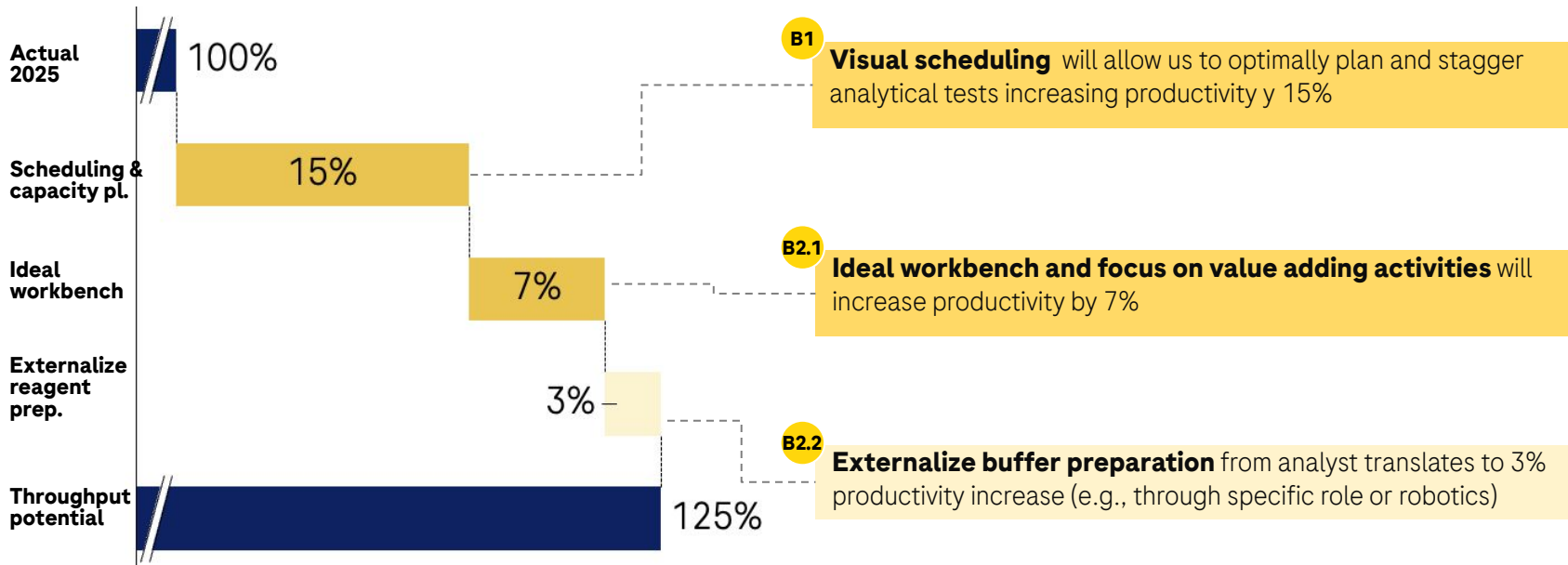
B Tomorrow's QC lab focuses on value-adding test activities and builds the required processes around them



B Scheduling/capacity planning and workbench optimization are linked to a productivity increase by 25%

Throughput potential, in # of batches/year indexed to 100, done with same capacity

Improvement levers

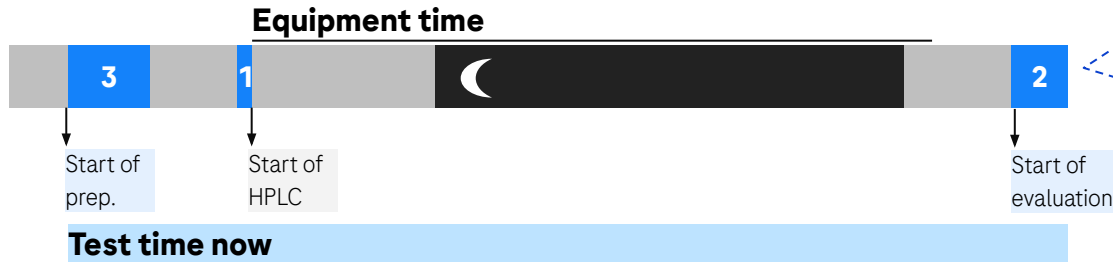


1) Impact is coupled to availability of enabling factors (e.g., maintenance of ideal workbench, material management, see prerequisites page, point 58)

B1 Example of how scheduling helps us unlock potential throughput

Legend: ■ Hands-on ■ Time between hands on ■ Night

From



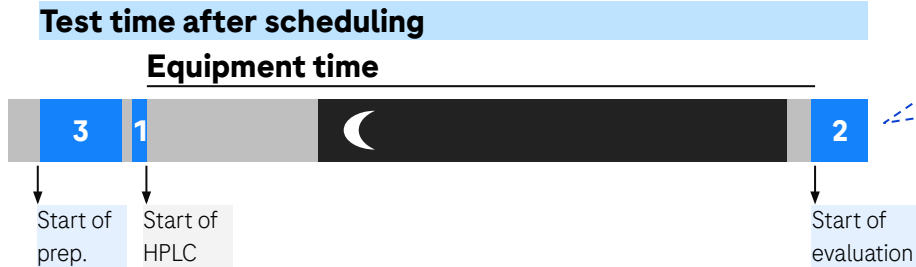
Currently, non value adding activities (e.g., fire fighting) happen between hands on time

The total test time is driven by 3 key factors:

- Equipment time: ~12h (cannot be lowered)
- Time between: can be streamlined
- Hands-on time: ~6h (streamlined in B2)

-33%

To



Scheduling moves non-value adding times out of the test workflow freeing up white space which we can re-employ to unlock potential throughput

- Equipment time: ~12h (remains)
- Hands-on: ~6h (remains)
- Time between: Following an optimal plan, we can focus on value adding activities and driving throughput increase

Thank you for
your attention!



Questions
and thoughts?

Doing now what patients need next