



# QC diagnostic benchmarking

June 2011

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Strategy



Operations Excellence



Project Management



Organizational Development

## ■ Typical requirement

- A diagnostic assessment of QC operations:
  - ◆ Identifying areas of high cost and low performance, and establishing major root causes
  - ◆ Strongly supported by benchmarking with high-performing biotech and pharmaceutical sites and other industries where appropriate
  - ◆ A plan, aligned with existing CI initiatives , to move all sites' QC Operations towards best practices

## ■ Tefen QC Benchmarking Diagnostic

- Tefen's QC benchmark data has >120 QC data points (quantitative & qualitative), gathered from >60 life sciences sites over 10 years
- Combining use of the benchmark data with a diagnostic approach that encompasses performance and practices, in our experience QC test costs can often be reduced by up to 30% and lead time by up to 50%

- 1. Introducing Tefen**
- 2. QC benchmarks**
- 3. Diagnostic approach**

## Delivering Performance Excellence

We are a global consulting firm that helps Senior Executives develop strategy, implement change and generate value.

Our clients include FTSE 100 and Fortune 500 organisations from all sectors.

Over the past 28 years we have built a reputation for effective partnership and tangible results.



## Differentiators / Why Tefen

### Results-oriented (Results-driven)

We are dedicated to the guaranteed delivery of significant and quantifiable performance improvements

### Cooperation

By building trust, our partnership and team work ensure continuous, sustainable improvement

### Organizational culture

Our highly-skilled and professional people are fully committed to equipping you with the knowledge and tools to support you in reaching your goals

- Business Strategy
- Corporate Strategy
- Supply chain Strategy
- Marketing and Sales Strategy
- M&A and Due Diligence
- International Strategy

## Strategy

## Operations Excellence

- R&D and product launch enhancement
- Supply Chain Management
- Production (Lean-Management, Six Sigma, etc.)
- Organisational Quality Excellence
- Sales Maximisation and Service Enhancement

## Project Management

## Organisational Development

- Portfolio management
- PME Process Improvement
- Product launch support
- Training and Coaching
- Process Optimisation
- Value Generation

- Change Management
- Training
- Coaching and Support
- Knowledge Management
- Vision and Core Values Development

**Delivering Performance Excellence**

## All Sectors

Avecia

**Schneider**  
Electric

smith&nephew

WeightWatchers

**ALLINA**  
Hospitals & Clinics

**BAA**

AstraZeneca

**TEXACO**

**IPSEN**  
Innovation for patient care

**DB** SCHENKER

## Recent Life Science Clients

**gsk**  
GlaxoSmithKline

**MSD**

**TEVA**

genzyme

**NYCOMED**

**Pfizer**

**MERCK**  
SERONO

**novo nordisk**

**Baxter**

**JANSSEN**  
PHARMACEUTICA

We have worked with 43 of the top  
50 life sciences businesses

*Tefen worked with a major biopharmaceutical manufacturer to support their global lean manufacturing initiative by redesigning the site level organisation across 13 sites. The aggressive target of reducing operational cost by 30% over three years, and lead-time by 50% was achieved during the programme.*

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**A leading pharmaceutical company was suffering from competition from the East, a weak pipeline, and problems in the market place. The share-price was at its lowest level for many years, and a step change in cost structure was required to bring the company into higher ROI and restore market confidence.**

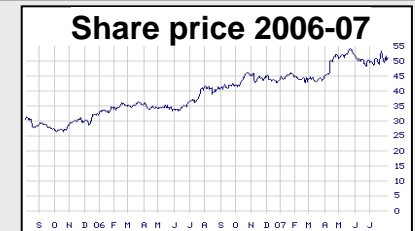
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**A lean manufacturing programme was initiated across all manufacturing sites worldwide. Tefen provided methodology and experience in 4 key areas:**

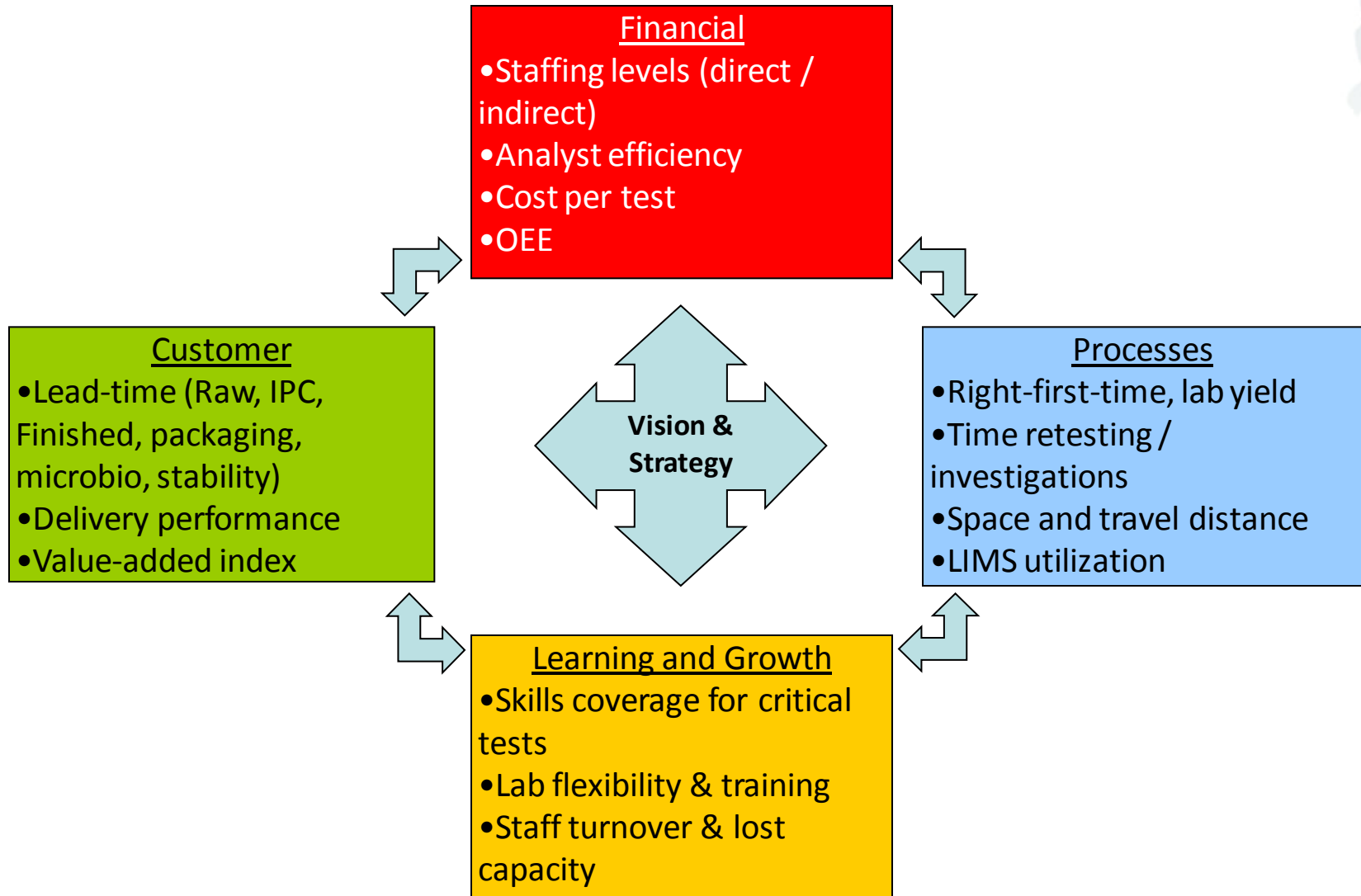
- Ran diagnostic benchmarking to identify organisational waste across 13 sites
- Led the organisational redesign programme within each site
- Supported design and implementation of the management routines and visual systems
- Provided post-go-live support to ensure change was as smooth as possible

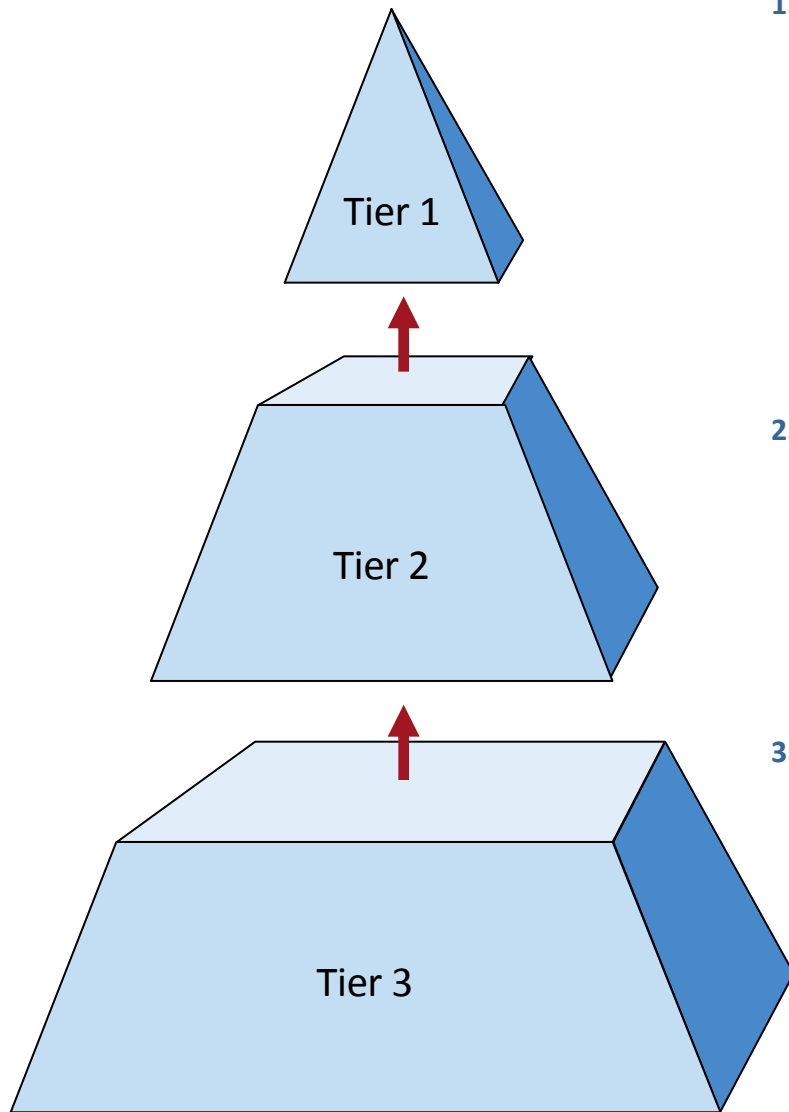
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**Costs and lead-times have been reduced in line with targets. The company's share price has been restored to previous levels, and the programme had a 10:1 ROI**



1. Introducing Tefen
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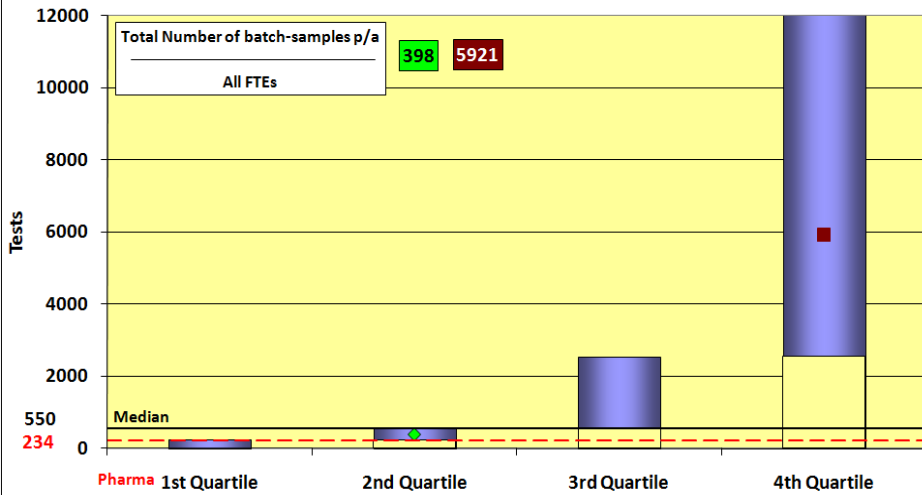




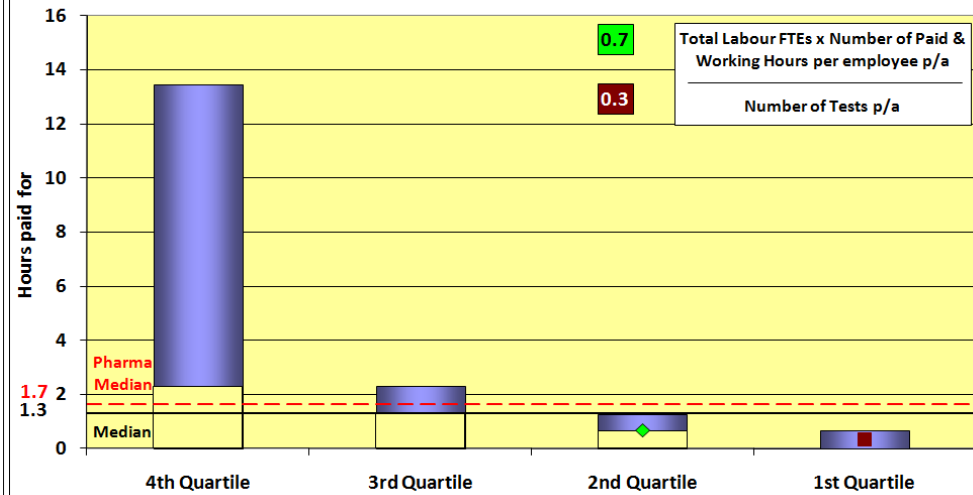
- 1. Financial, Customer, Quality performance outputs**
  - including QC cost & FTEs per site; cost per batch & test; batch & test per FTE / direct FTE; QC & QA lead-time for test and release; delivery performance / schedule adherence; OOS, OOT ...
  - Data split by raw material, IPC, bulk, finished, packaging, microbiology, stability
- 2. Quantified metrics enabling Tier 1 performance**
  - including direct to indirect ratios, value-added content, equipment OEE, RFT, lab errors, investigations, time spent on investigations and retests, analyst flexibility / skills cover...
- 3. Detailed operational practices**
  - including org structure, roles, span, analyst & support staff activities, availability, absenteeism, space per analyst and test, workplace organisation, travel time, LIMS utilization, planning and scheduling tools, use of technology, maintenance practices, outsourcing, reduced testing, CofAs, training practices, CI processes and culture, use of KPIs, management routines...

# Tier 1 – Performance outputs (selected graphs)

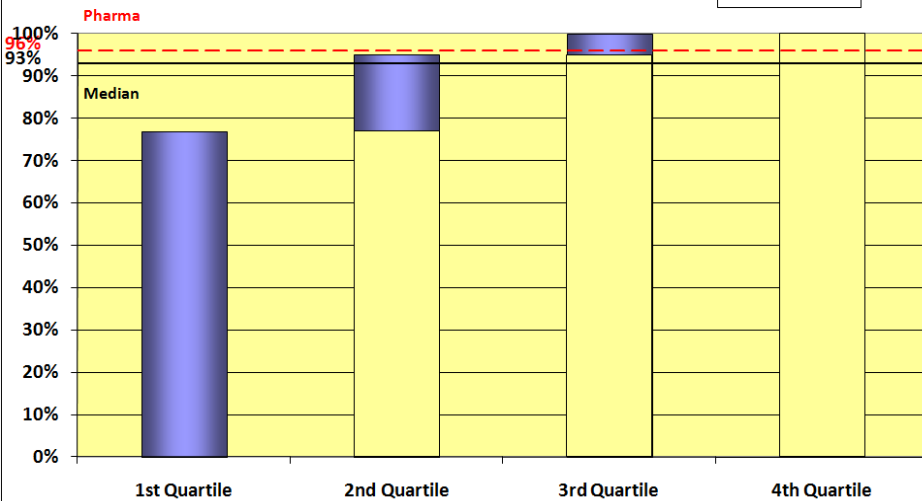
### Batches per FTE (all FTEs) annually



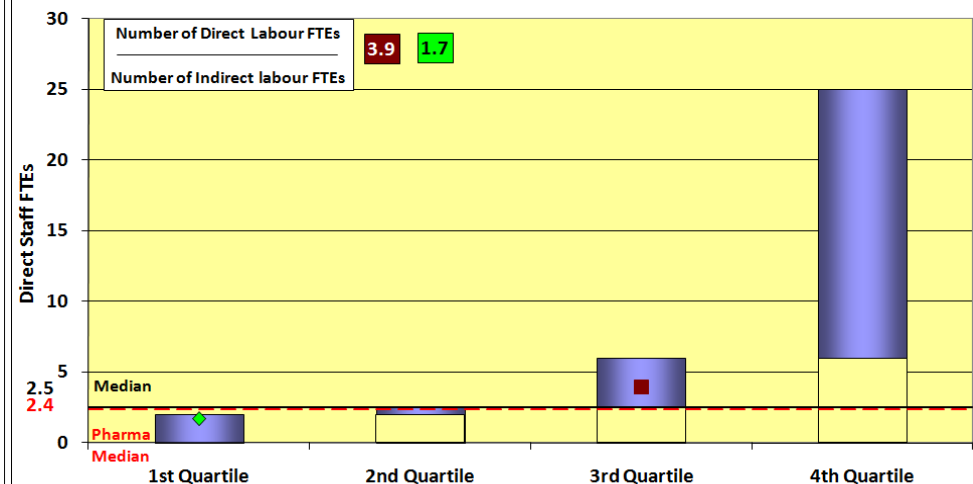
### Hours per test ("paid for" hours)



### On-time delivery (finished products)

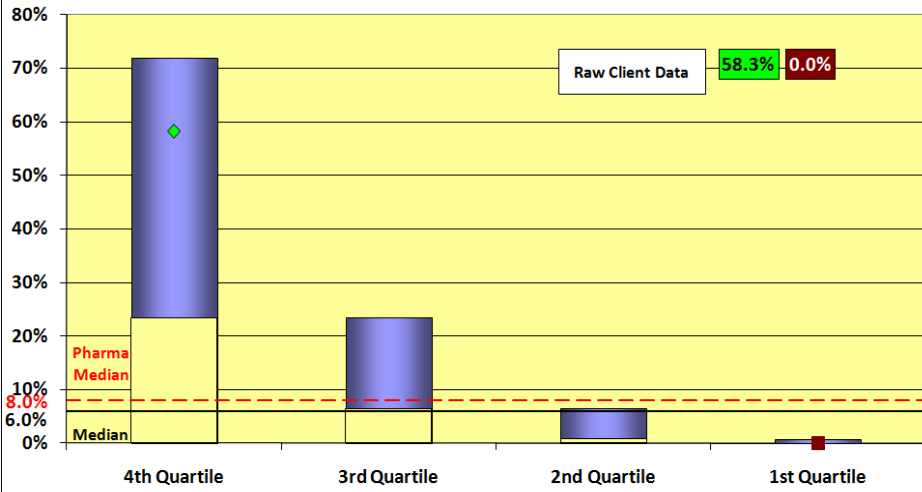


### Direct to Indirect labour ratio

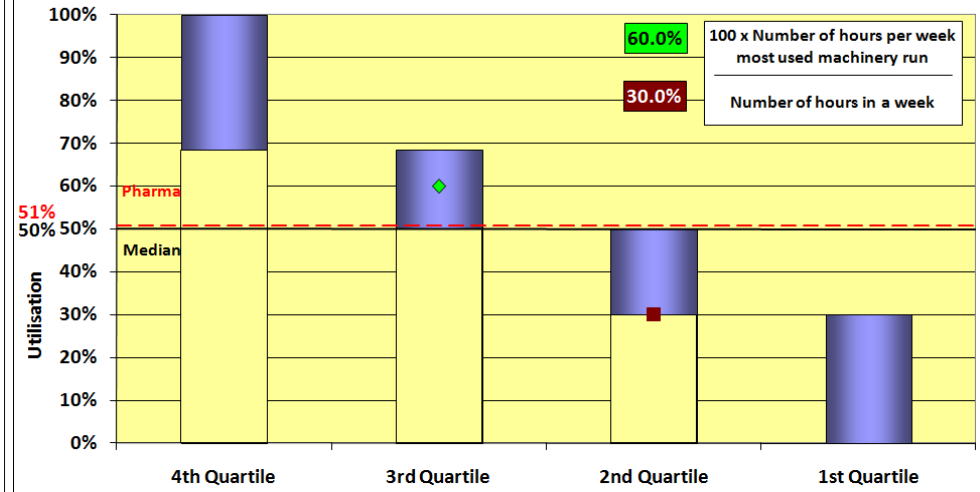


# Tier 2 – Enablers (examples)

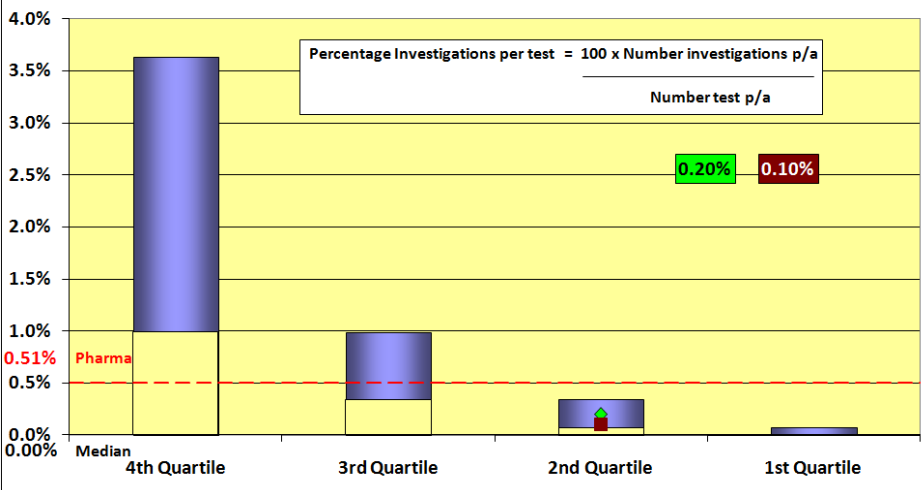
### Lab errors as proportion of all Investigations



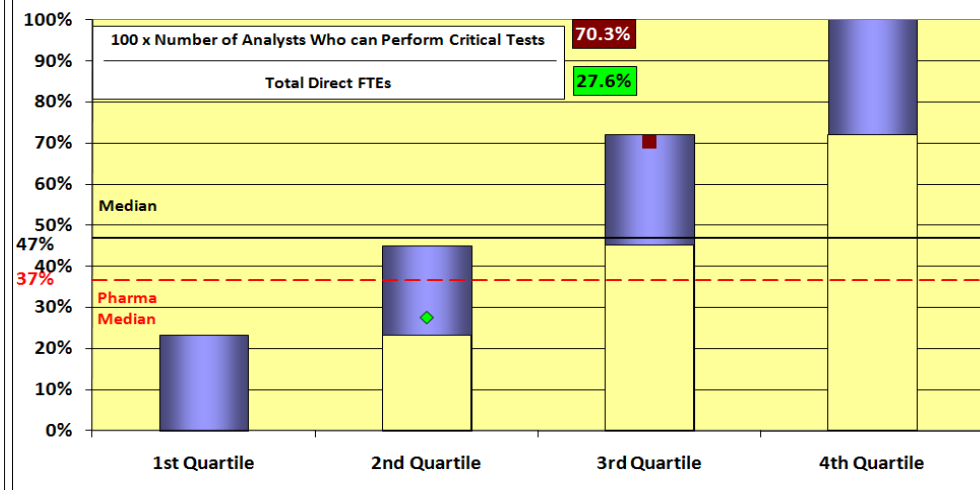
### Utilisation of equipment bottleneck



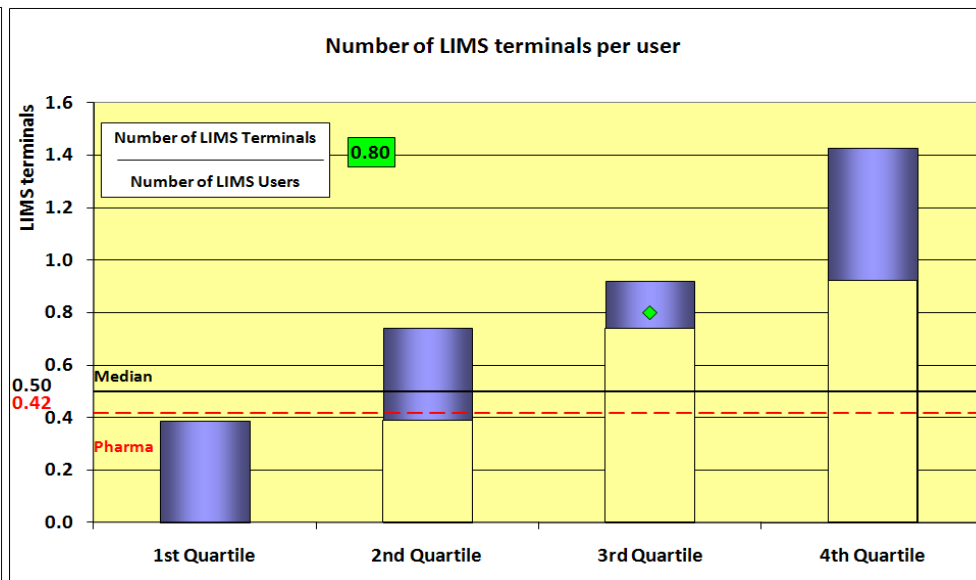
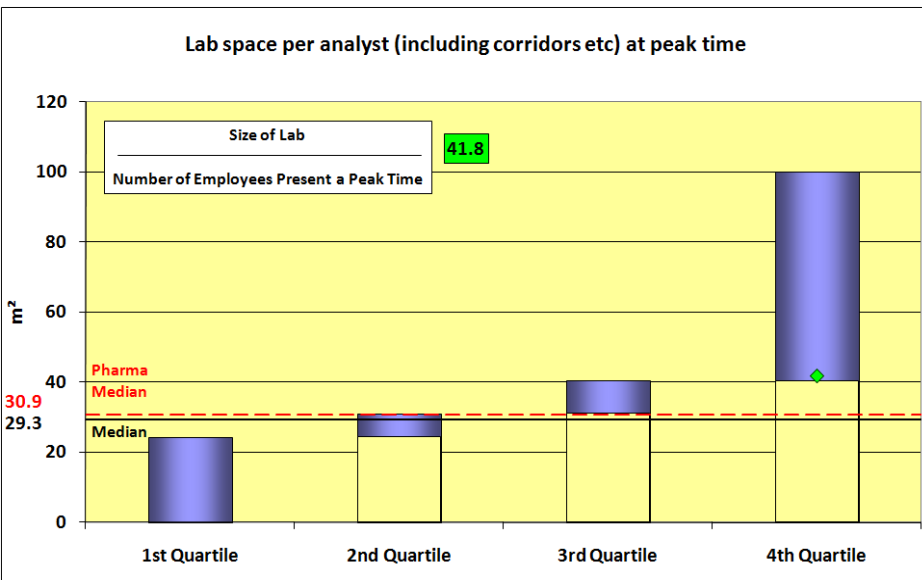
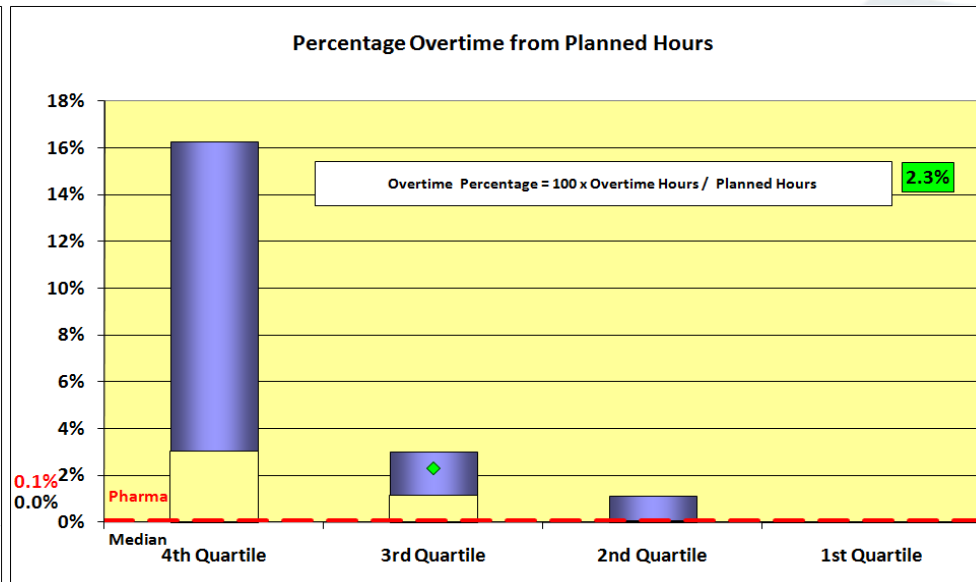
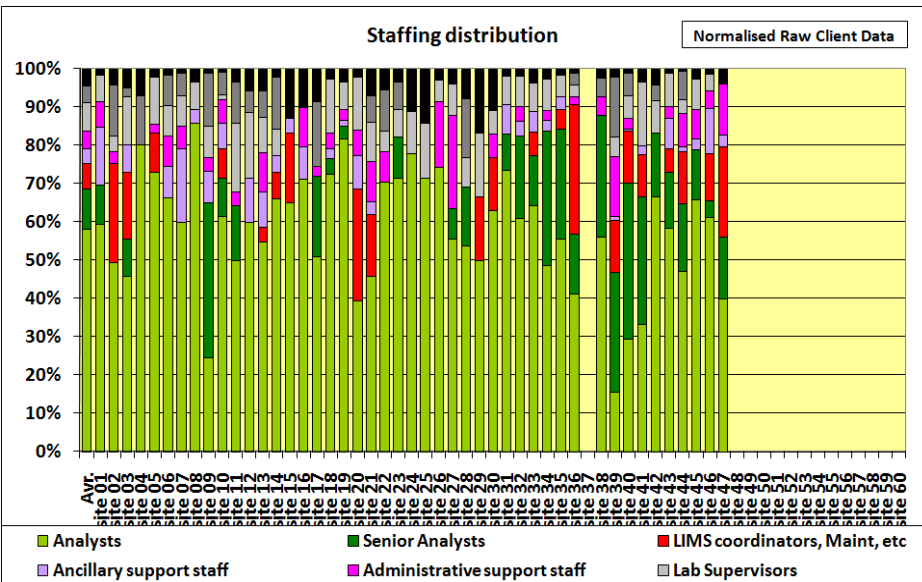
### Investigations per Test



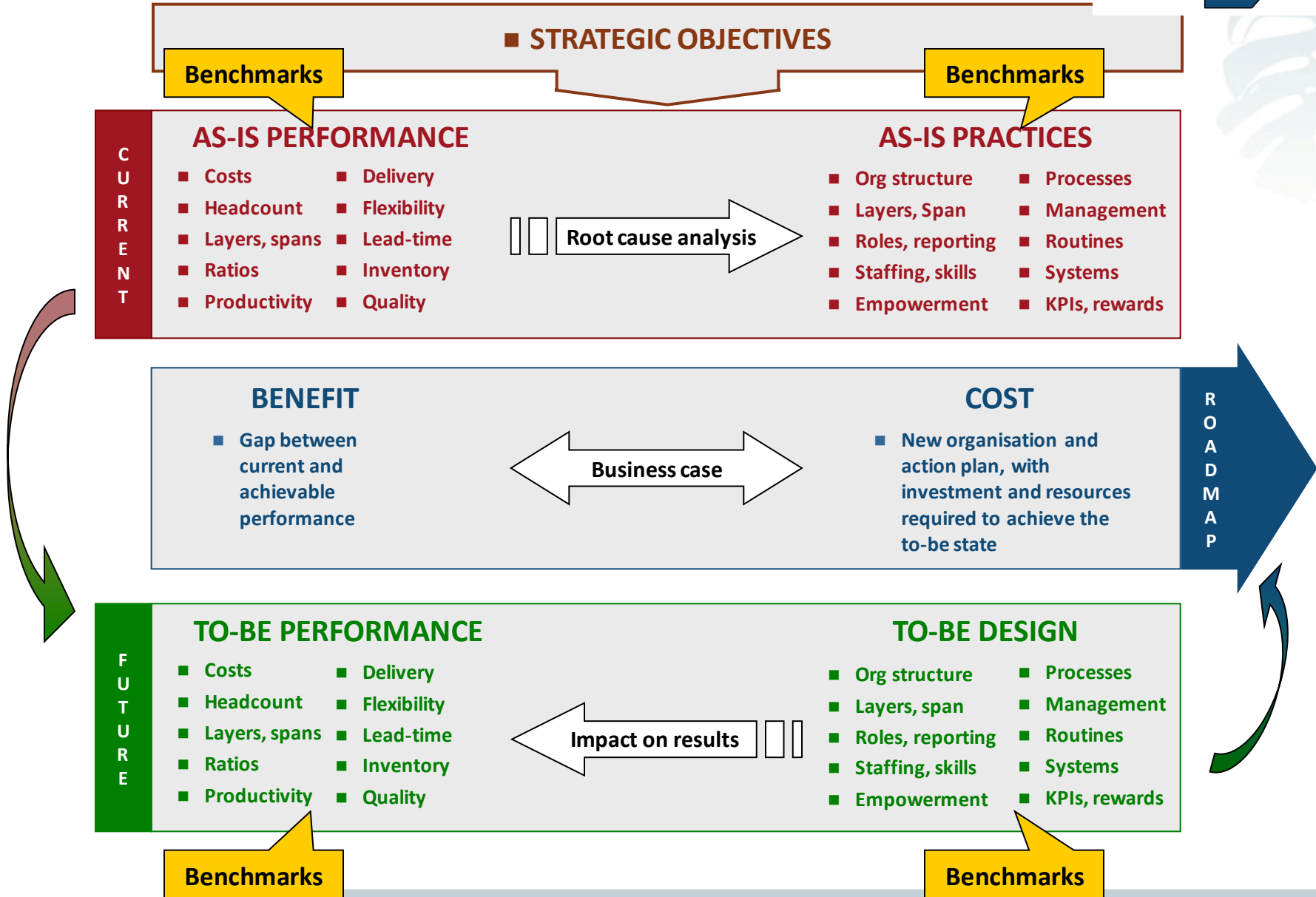
### Proportion of staff that can perform 'critical' tests



# Tier 3 – Detailed operational practices (examples)



1. Introducing Tefen
2. QC benchmarks
3. Diagnostic approach



# 1) Establish and prioritise strategic objectives



- Structured interviews with Site and Quality Leaders
- Prioritise objectives, critical success factors, constraints and conflicts
- Set high-level targets for cost, quality, delivery metrics

## Establish strategic drivers

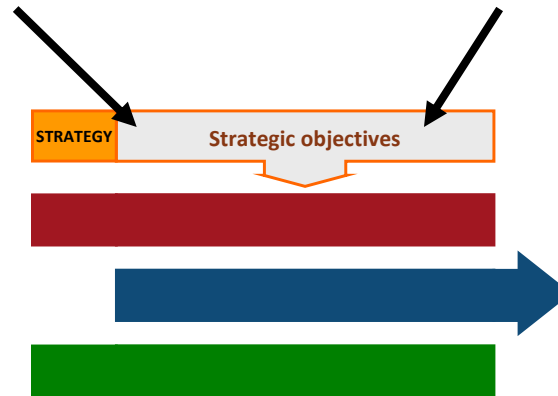
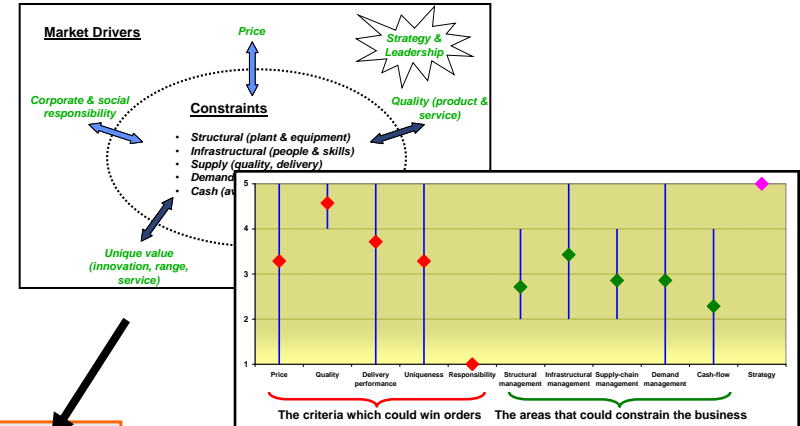
### Competitive drivers

- Cost targets
- Foreseen changes (new products, volumes)
- Delivery, flexibility, lead-time targets
- Quality, scrap, environmental targets
- Other performance drivers analysis

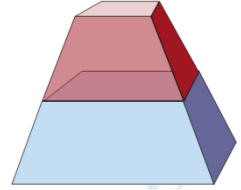
### Constraints

- Infrastructural (historical org, culture)
- Structural (test equipment, calib, maint)
- Supply (quality, delivery)
- Demand (volume, variability)
- Cash (inventory targets)

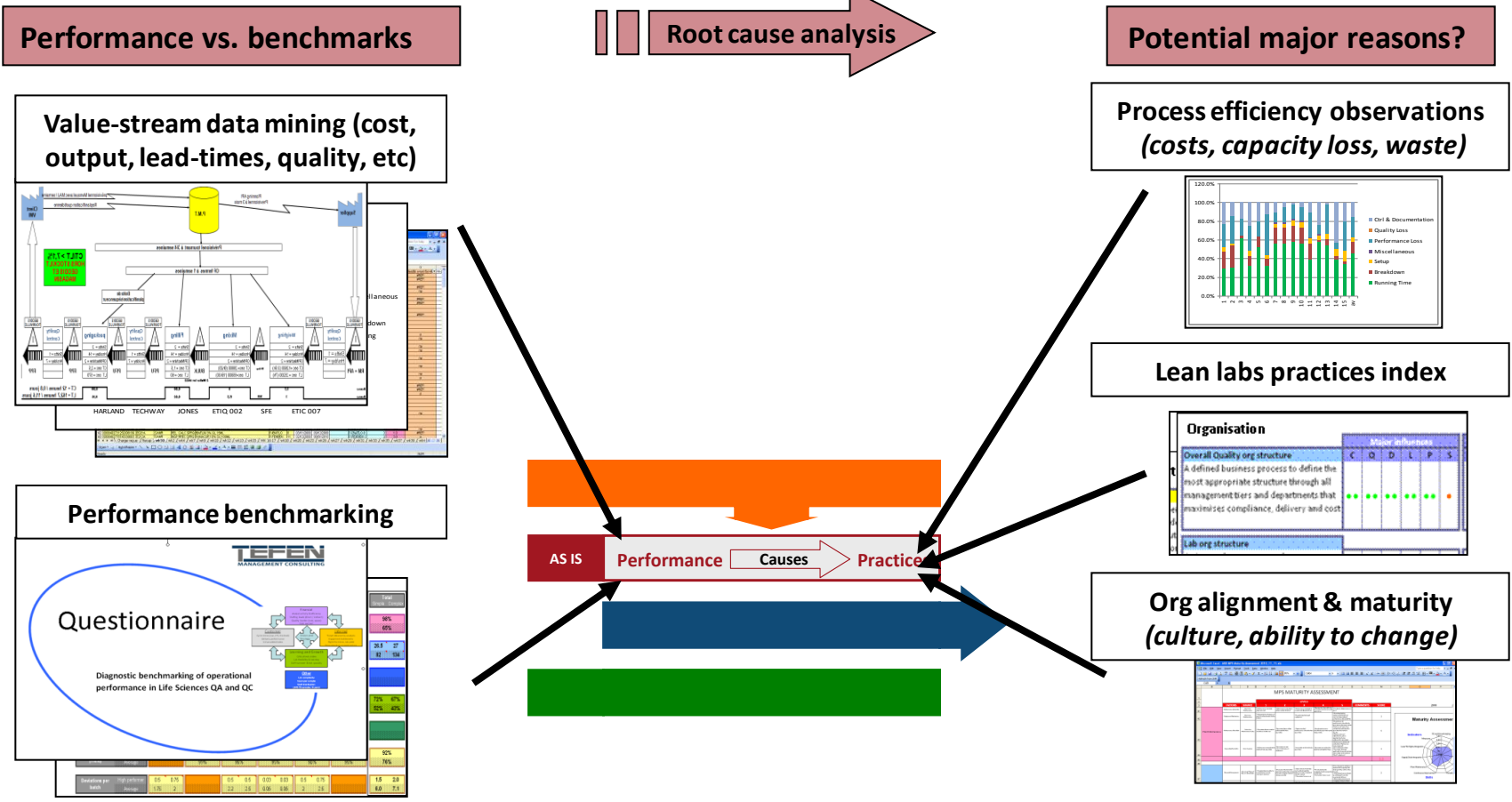
## Prioritise critical success factors



## 2) Conduct as-is benchmarking and identify root causes



- Performance assessed against Tefen's lean lab benchmarks (>60 LS labs)
- Practices assessed by observations against Tefen's QC best practice index
- Capability maturity model used to assess organisational effectiveness

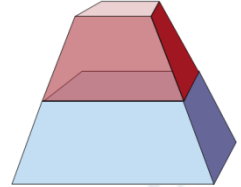


Overall Quality org structure		Major Influences					
		C	Q	D	L	P	S
A defined business process to define the most appropriate structure through all management tiers and departments that maximises compliance, delivery and cost		●	●	●	●	●	●
Lab org structure		●	●	●	●	●	●

MPS MATURITY ASSESSMENT		Maturity Assessment				
		1	2	3	4	5
Strategic Alignment		●	●	●	●	●
Operational Alignment		●	●	●	●	●
Financial Alignment		●	●	●	●	●
Customer Alignment		●	●	●	●	●
Supplier Alignment		●	●	●	●	●
Internal Alignment		●	●	●	●	●
Overall Maturity		●	●	●	●	●



## 2) Measuring *practices* against Tefen's best-practice index



Impact of each practice on target performance levels; used to prioritise actions

Best practices supported by models, pictures, process maps, systems, tools

The 9 elements of Lean Labs investigated – structural, infrastructural, process and cultural

KPIs	Practices	Capability maturity					
		1	2	3	4	5	
Planning Capacity KPIs Add items Add items Add items Add items Add items Add items Add items Add items	<b>Performance</b> Performance and compliance, delivery rates to customers and out production stream	Low score definition: Traditional site organization, established practices and objectives, staff working on routine, no reference to customer needs or end-user and supply chain performance					High score definition: Has been demonstrated throughout all processes
	<b>Job org structure</b> An internal organizational structure in the lab that supports value stream needs without compromising compliance or economies of scale	Traditional functional structure without internal assignment to products or material type (e.g. IPC, finished), difficult to coordinate and synchronize between different labs					Strong production line, single-stage production, Production line single control for each batch/sample
	<b>Value stream involvement</b> For a customer-focused lab to deliver, regardless of the formal structural arrangement above, staff need to recognize their customer and have roles that include service and problem-solving	All world's operations require results of quality, regardless of whether there is a risk to compliance or benefit to their customer (i.e. Production)					Operations, which are frequent enough or simple enough report to the value stream, including QC scheduling, testing, release coordination and simple deviation problem solving. Only strategic
	<b>Span of control</b> The right span of control ensures that there is enough management capacity for staff development and coordination, but not too much to stifle growth or be too costly	Traditional hierarchical structure, with more than 5 layers including Site Head of Quality. Employees have a structured career progression, but Management costs high					Span of 5-7 for the GC Head, and 0-12 people per Manager, 3 levels between Head of Quality and Analyst, efficient use of resources to ensure good management of people and process
	<b>Empowerment</b> Empowerment, particularly so that structure can improve decision-making and problem solving speed, whilst reducing escalation, this particularly relevant in a flat organization structure	Low empowerment, people do what they are told. Planning and KPIs are measured by a central function, lab staff do not get involved in local scheduling or customer problem solving					High empowerment, and good finding of root-cause, the tasks of planning and releasing performance are integrated into the process, decisions are pushed to the lowest level
	<b>Skills flexibility</b> The right amount of skills flexibility ensures great customer satisfaction and the ability to respond to mix or volume fluctuations, without creating too much in increasing of unwanted skills	No formal process to measure and drive flexibility, resulting in unnecessary high multi-skilling (so anyone can do everything) or mismatch between actual and needed skills					Highly flexible on-site gives the customer choice on duration, skills, flexibility to do a
	<b>Support</b> Activities are expensive, and should not waste their time on simple support activities; check time should be spent on multi-skilling, running shorter campaigns, etc	Analysis spending up to 2 hours per day, walking to sites, driving equipment, ordering reagents, calibrating equipment, collecting samples from production, etc					Support or controls are not too high

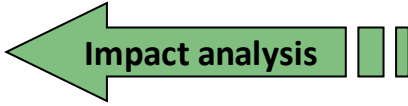
Each site measured against good practice, through observations, interviews, measurements

*Our lean labs experts will observe lab practices, interrogate IT systems, monitor management routines, etc; and compare against Tefen's Lean Labs best practices*

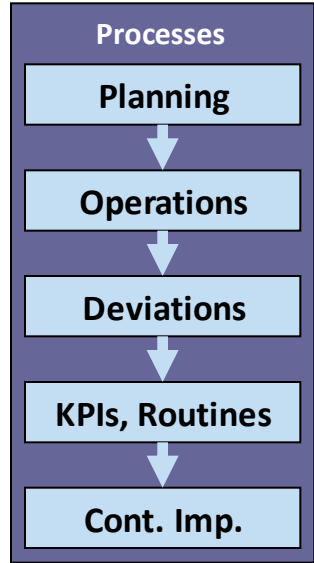
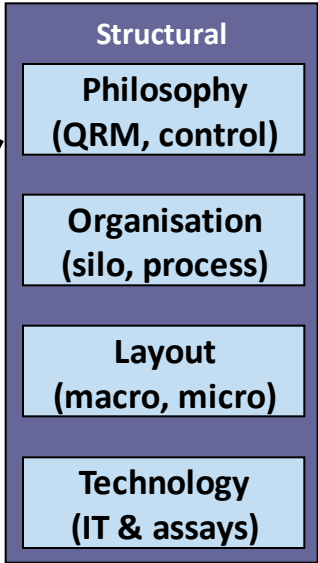
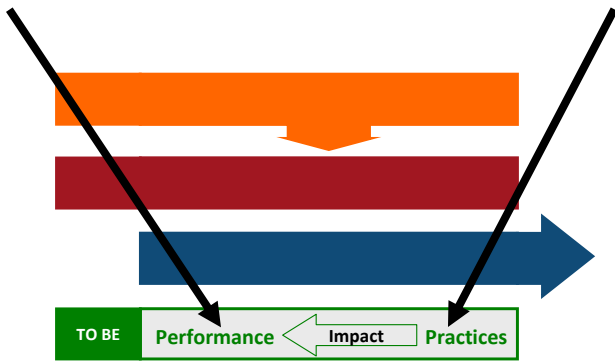
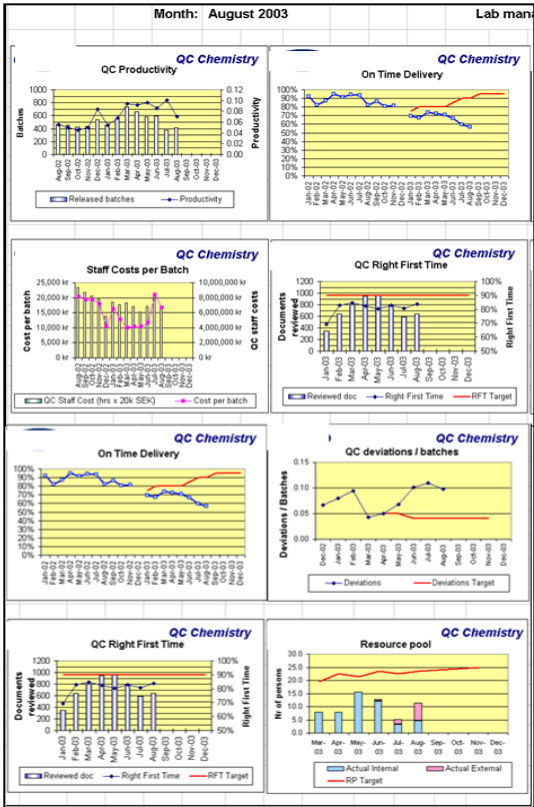
# 3) Create a vision & quantify impact on results

## ■ Reengineering design workshops & impact analysis

Target performance levels



Vision to-be concept design



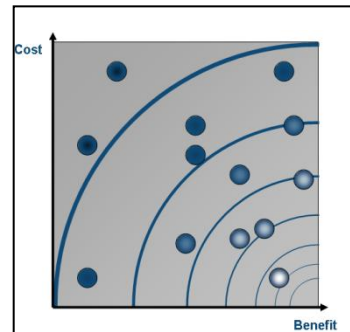
# 4) Roadmapping and action plan

- Action-planning workshops to agree the future state and how to reach it
- Gaining consensus amongst the Quality Leadership and Management teams

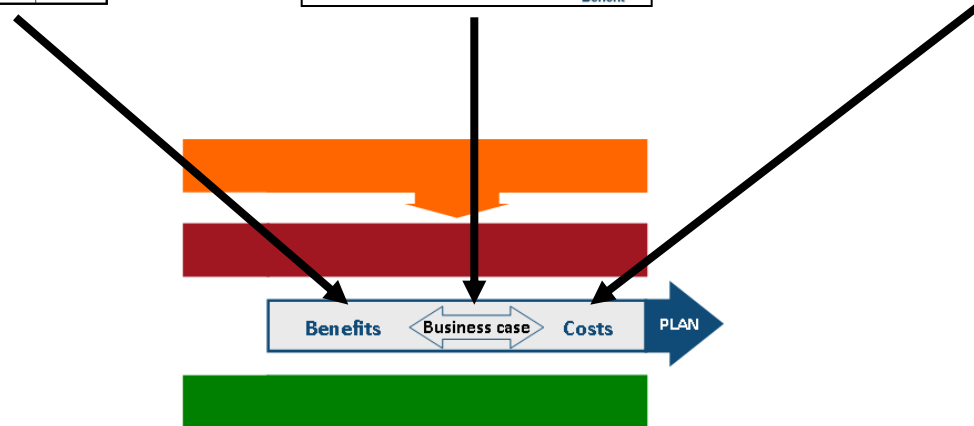
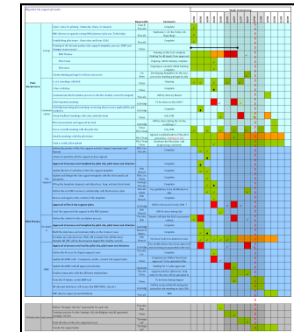
## Gap analysis (benefits)

	Objective	Low cost operation	Reliable delivery	Right first time	More focus, less stress
<b>MPS factors</b>	Success metric	CoGS down €1M	Delivery to 100%	Deviations down 50%	Even workload
<b>Line Design</b>	Low process reliability, changes to plan	☹	☹	☺	☹
	Unsyncronised planning and uneven workload	☹	☹	☺	☹
	Very stringent processes and documentation	☹	☺	☺	☺
<b>Organisation design</b>	Functional organisational structure, some conflicting objectives	☹	☹	☺	☹
	Operational teams not multi-skilled	☹	☹	☺	☹
	Lack of resource, or empowered staff to take decisions and make change	☺	☹	☹	☹
<b>Visual management</b>	Not enough simple, value-stream-wide, operational KPIs or ownership	☹	☹	☹	☹

## Business case



## Action-planning & costing



## Deliverables

- **A report and feedback presentation, delivered within the context of each sites local strategy**
- **Data collected and analysed against benchmarks (cost, quality, delivery, inventory, flexibility ...)**
- **A high level assessment of potential improvement benefits**
- **A balanced set of Lab targets based on the model being implemented**
- **Major reasons for performance gaps, across the entire lab's operations**
- **A proposed engagement approach to support the site to reach the defined targets, if appropriate or necessary**

## Benefits

- **Secures a clear, common, objective and data-driven understanding of true lab performance**
- **Proven to support**
  - reduction in cost per test
  - reduction in lead time
  - elimination of backlogs
  - increase in OTD
  - reduced investment needs (space, equipment)
- **Supportive of CI culture**



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