



PERFORMANCE MANAGEMENT AND MATURITY IN QC

WHAT ARE THE LEVERS TO ACHIEVE EXCELLENCE?

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Agenda

13h00 - 13h10 Welcome

- 13h10 13h15 ISPE SIG, Introduction
- 13h15 13h30 UCB presentation
- 13h30 14h00 Performance management and Maturity in QC
- 14h00 15h00 UCB QC labs tour : NCE and NBE labs
- 15h15 16h45 Workshop What are the levers to achieve Excellence ?
- 16h45 17h00 Next topics, way forward and feedback
- 17h00 18h00 Networking drink









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Participants

First Name	Name	Company	First Name	
Frédérique	Backaert	PI Life Sciences consultancy	Jenny	
Coline	Borel	PI Life Sciences consultancy	Patrick	
Sarah	Bourg	GSK Vaccines	Antony	
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Stefan	Langers	Kela	Ludovic	
Gino	Lefevere	Stexcon	Pierre	
Angela	Llorente Pardo	Catalent	Frederic	
Daniel	Marroyen	Emerson	Sylvia	
Sébastien	Mayeur	GSK	Philippe	
Xavier	Mol	Technord Automation	Redwane	
Dirk	Van Gorp	Alten	Magali	



Company

Pfizer
Omnichem
Trevalco
Catalent
Catalent
GSK
Catalent
BQG
UCB

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UCB: reinventing itself, leveraging a solid heritage









What UCB stands for



Creating value for patients

diseases?"



"How will this make a difference to the lives of people living with severe

UCB: creating value for patients Bringing solutions to people living with neurological or immunological diseases

Key facts and figures 2017:

- About 7500 employees globally
- Revenue: € 4.5 billion
- rEBITDA: € 1 375 million
- Operations in ~40 countries
- R&D Spend: 23% of revenue









4 core medicines for patients with severe diseases



BRIVIACT.







A unique syringe designed with users for users



Syringe designed in partnership with









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Other key products

Keppra® (levetiracetam)

- Epilepsy adjunctive therapy (also in monotherapy in Europe)
- Sold as E Keppra[®] in Japan

Keppra XR® (levetiracetam – Extended-release tablets)

Epilepsy adjunctive therapy – U.S. only

Zyrtec® (cetirizine HCI)

Seasonal allergic rhinitis

Xyzal® (levocetirizine dihydrochloride)

Allergies and chronic idiopatic urticaria















UCB Braine: 51 hectares & 20 buildings R&D, Production, Warehouses, Laboratories, Offices





UCB Braine a key strategic site in the UCB Manufacturing and R&D network





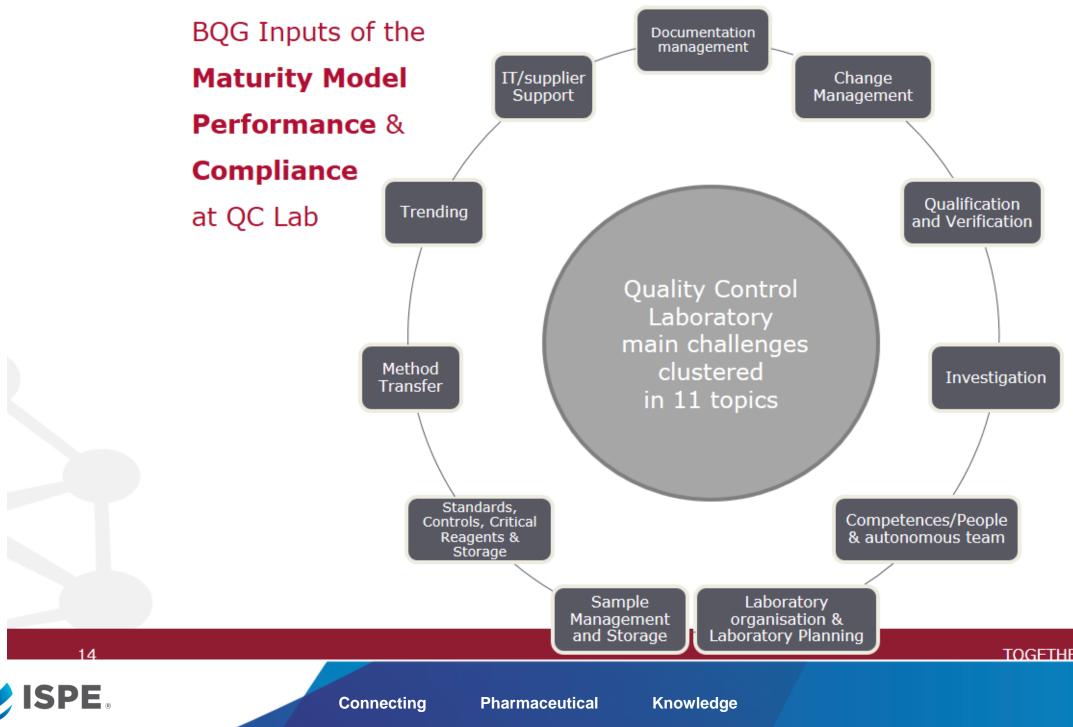




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Performance management and Maturity in QC





TOGETHER WE dARE

Performance management and Maturity in QC

BQG Maturity Model

Performance &

Compliance

at QC Lab

Technology **Robustness:**

- Sample Management and Storage
- Standards, Controls, Critical Reagents & Storage
- Method Transfer
- Trending

Organisation & Interface Mgmt:

- Competences/People & autonomous team
- Laboratory organisation
- Laboratory Planning

System & **Technologies:**

- Digital Platform
- Equipment & software
- IT/supplier Support

QA systems:

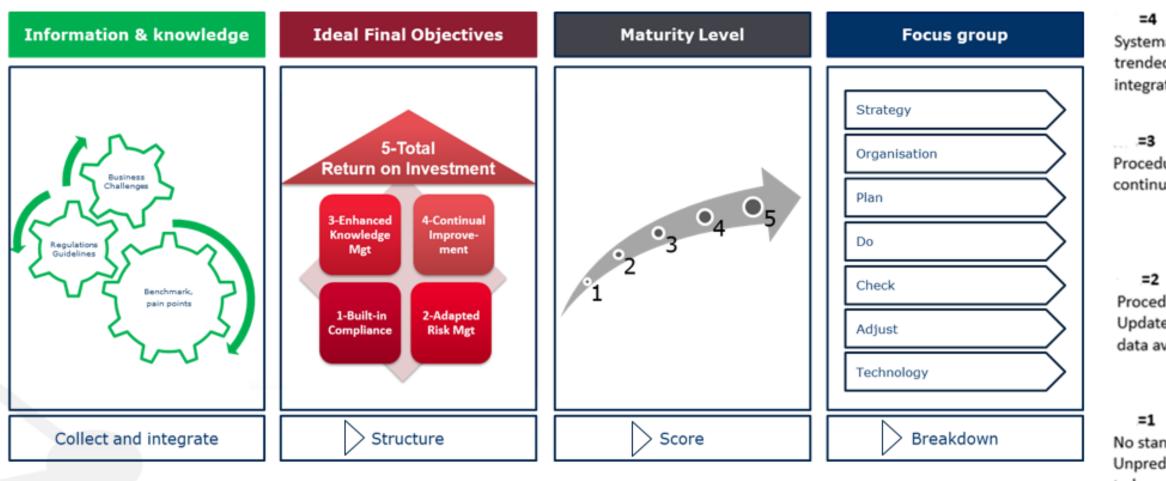
- -Documentation management
- Change Management
- Qualification and Verification
- Investigation





Maturity Model – Performance at QC Lab

=5 Product & process life cycle optimized. External benchmarks in place. Involvement with external parties (reg. bodies, association...). People, Process & Systems systematically improving



BQG benchmarked the maturity improvement model from other industries to design an approach dedicated to the Life science industry: the Apollo Maturity ™



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Systematic improvement process in place. trended data showing improvements. Clear integration between departments.

Procedures in place. Some data created from continual improvement initiatives.

Procedures in place - with potential gaps. Updates mostly driven by deviations; limited data available on improvements.

No standardization; Procedures missing. Unpredicatable outputs. Very high likelihood not to be compliant



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UCB Lab Visit















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Breakout Sessions

- How to address QC capacity management ? **A)**
- How to address QC priorities (supply, manufacturing, others)? B)
- How to address skills and expertise to get the appropriate level of performance ? **C**)



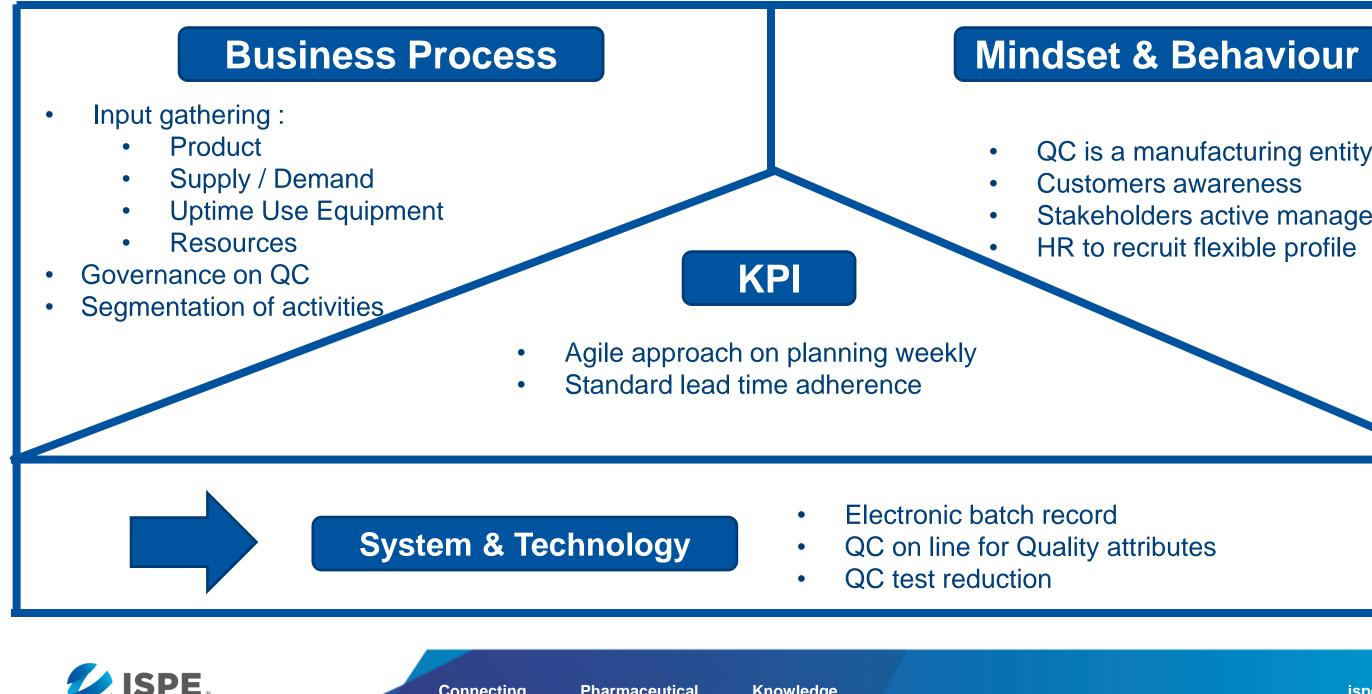




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How to address QC Capacity Management



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QC is a manufacturing entity Stakeholders active management HR to recruit flexible profile

How to address QC priorities ?

From	System & Technic	
 50% Priority coming from Supply Chain 	 Communication Competences increase / multiskilled team Respect of the FIFO groups/series testing 	•
 Variability of the product tests and Customer demands 	 Experienced Product Manager Decision making skills QC & Procurement commitment to improve batch size and order frequency 	
 Define THE priority 	 Prioritization matrix, agreed with all department & with governance meeting New product vision at QC Supply chain vision at QC 	·
ISPE.	Connecting Pharmaceutical Knowledge	

То...

20% Priority coming from Supply Chain

Planning

Clear Vision

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How to address skills and expertise to get the appropriate level of performance ?

Strategy

- Identification of competences & knowledge needed → Depends on the complexity of the method
- Specialisation or not → Depends on lab activity and product
- Increase boundaries between QC Lab (business) & Human Resources (Recruiters) to have the right people for the identified needs
- Increase boundaries with the transfer organisation in order to identify the competences needed to perform the transferred analysis



- - → Lab management, organisation
 - → Technic, Analysis
 - → SOP / protocol
 - → 3 Steps approach
 - → Virtual reality
- Training effectiveness → KPIs (Right First time, Lead time...) →Training Material review





Process

1 expert (senior / intermediate) is identified

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Operational Excellence in Supply Chain

Event host at :





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