PERFORMANCE MANAGEMENT AND MATURITY IN QC

WHAT ARE THE LEVERS TO ACHIEVE EXCELLENCE?

PREPARED BY F. HENRY, L. TERZI, P. PATENERE, D. FABRIS.
SUPPORTED BY S. VAN CAUWENBERGHE, P. WATTIEZ
## Agenda

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# Participants

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<thead>
<tr>
<th>First Name</th>
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<th>Company</th>
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<tbody>
<tr>
<td>Frédérique</td>
<td>Backaert</td>
<td>PI Life Sciences consultancy</td>
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<td>Coline</td>
<td>Borel</td>
<td>PI Life Sciences consultancy</td>
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<tr>
<td>Sarah</td>
<td>Bourg</td>
<td>GSK Vaccines</td>
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<tr>
<td>Andrea</td>
<td>Cuozzo</td>
<td>Catalent</td>
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<tr>
<td>Niels</td>
<td>De Blende</td>
<td>PI Life Sciences consultancy</td>
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<tr>
<td>Eric</td>
<td>Kooremans</td>
<td>Johnson &amp; Johnson</td>
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<td>Stefan</td>
<td>Langers</td>
<td>Kela</td>
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<td>Gino</td>
<td>Lefevere</td>
<td>Stexcon</td>
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<td>Angela</td>
<td>Llorente Pardo</td>
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<td>Daniel</td>
<td>Marroyen</td>
<td>Emerson</td>
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<td>Sébastien</td>
<td>Mayeur</td>
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<td>Xavier</td>
<td>Mol</td>
<td>Technord Automation</td>
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<td>Dirk</td>
<td>Van Gorp</td>
<td>Alten</td>
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<td>Cresens</td>
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<td>Patrick</td>
<td>Van Steirteghem</td>
<td>Omnichelem</td>
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<td>Antony</td>
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<td>Trevalco</td>
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<td>Nicolas</td>
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<td>Pierre</td>
<td>Patenere</td>
<td>BQG</td>
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<td>Frederic</td>
<td>Henry</td>
<td>UCB</td>
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<td>Sylvia</td>
<td>Van Cauwenbergh</td>
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<td>Philippe</td>
<td>Wattiez</td>
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<td>Redwane</td>
<td>Zouggari</td>
<td>UCB</td>
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<td>Magali</td>
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UCB: reinventing itself, leveraging a solid heritage

1928: Emmanuel Janssen establishes UCB in Brussels
1936: UCB enters the United States
1952: UCB discovers Atarax®, U.S. license awarded to Pfizer
1972: A new state-of-the-art R&D center in Brainse-l'Alleud, Belgium
1980s: UCB registers its novel antihistamine Zyrtec®
1990s: approval of Keppra®, a novel anti-epileptic
2004: UCB acquires British biotech company Celltech
2006: UCB acquires German pharma company Schwarz Pharma
2008-2010: Launch of Cimzia®, Vimpat® & Neupro®

Combine leadership in antibody research & chemistry expertise to better treat severe diseases

Launch of a new anti-epileptic

Chemical Group  Primary Care Pharma  Specialty Bio-pharma
What UCB stands for

Everything we do starts with a simple question:

“How will this make a difference to the lives of people living with severe diseases?”

Creating value for patients
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 billion
- Operations in ~40 countries
- R&D Spend: 23% of revenue
4 core medicines for patients with severe diseases

- Rheumatoid arthritis
- Psoriatic arthritis (PSA)
- Ankylosing spondylitis (AS)
- Axial spondyloarthritis (AxSpA)
- Crohn’s disease

- Epilepsy
- Parkinson’s disease
- Restless legs syndrome
A unique syringe designed with users for users

Oversized plunger rod
provides stability

Oval syringe barrel
helps prevent spinning between fingers and magnifies graduation, allowing patients to see medication

Large thumb pad
makes it easy for patients to push the plunger

Nonslip finger grip
allows patients to hold the syringe steady using various grip positions

Rounded finger loop
for easy removal of pull cap

Syringe designed in partnership with OXO GOOD GRIPS®
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 HCl*)
- Seasonal allergic rhinitis

Xyzal® (*levocetirizine dihydrochloride*)
- Allergies and chronic idiopathic 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

BQG Inputs of the Maturity Model Performance & Compliance at QC Lab
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
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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UCB Lab Visit
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Breakout Sessions

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

**Business Process**
- Input gathering:
  - Product
  - Supply / Demand
  - Uptime Use Equipment
  - Resources
- Governance on QC
- Segmentation of activities

**Mindset & Behaviour**
- QC is a manufacturing entity
- Customers awareness
- Stakeholders active management
- HR to recruit flexible profile

**KPI**
- Agile approach on planning weekly
- Standard lead time adherence

**System & Technology**
- Electronic batch record
- QC on line for Quality attributes
- QC test reduction
### How to address QC priorities?

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<tr>
<th>From…</th>
<th>System &amp; Technic</th>
<th>To…</th>
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<tbody>
<tr>
<td>50% Priority coming from Supply Chain</td>
<td>Communication&lt;br&gt;Competences increase / multiskilled team&lt;br&gt;Respect of the FIFO groups/series testing</td>
<td>20% Priority coming from Supply Chain</td>
</tr>
<tr>
<td>Variability of the product tests and Customer demands</td>
<td>Experienced Product Manager&lt;br&gt;Decision making skills&lt;br&gt;QC &amp; Procurement commitment to improve batch size and order frequency</td>
<td>Planning</td>
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<tr>
<td>Define THE priority</td>
<td>Prioritization matrix, agreed with all department &amp; with governance meeting&lt;br&gt;New product vision at QC&lt;br&gt;Supply chain vision at QC</td>
<td>Clear Vision</td>
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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

**Process**

- Coaching + Onboarding

- 1 expert (senior / intermediate) is identified
  - Lab management, organisation
  - Technic, Analysis
  - SOP / protocol
  - 3 Steps approach
  - Virtual reality

- Training effectiveness
  - KPIs (Right First time, Lead time…)
  - Training Material review
Next meeting:

Operational Excellence in Supply Chain

Event host at:
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