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## Quality management: a toolbox to reach operational excellence in BRCs



#### ECCO XXXVIII, Turin, 12-14 June 2019)

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#### BCCM · CC **Belgian Coordinated Collections of Micro-organisms** (BCCM) "BCCM, great at small things" **7** biological resource BCCM/LMG BCCM/CC centres Bacteria Coordination Cell **Ghent University** Belgian Science Policy Office **Coordinated by a BCCM/IHEM** BCCM/LMBP central team at **Biomedical Fungi & Yeasts** Plasmids Scientific Institute of Public **Ghent University BELSPO** Health, Brussels **BCCM/ITM** BCCM/DCG **Funded by the Mycobacteria** Diatoms Institute of Tropical Medicine, Ghent University **Belgian Science Policy** Antwerp **Office - BELSPO BCCM/MUCL** BCCM/ULC Environmental and applied Mycology Cyanobacteria Université Catholique de Louvain University of Liège **ISO90**

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#### http://bccm.belspo.be

VINCOTTE

- 1. Standardisation: context
- 2. Quality standards for BRCs
- 3. QM tools for BRCs
- 4. Conclusion

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## 1. Standardisation: context



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## вссм.cc Globalisation & new technologies



#### Common language

Increased need for standardisation



# "Great things happen when the world agrees" (ISO slogan)



# Pro & contra



• Pro:

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- Offers a "Common language"
- High level of consensus
- Improves interoperability
- Facilitate trade and technology transfers
- Source of information
- More efficiency and effectiveness
- Less costs

 $\rightarrow$  Satisfaction of interested parties

 $\rightarrow$  fosters globalization

- Contra:
  - Limit creativity (in the research & innovation process)
  - Costs
- Balance:
  - Drawback of standards are outweighed by the benefits





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**Standards community** 



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# 2. Quality standards for BRCs





# Quality standards

- **ISO 9000 family:** provide guidance and tools for companies and organizations who want to ensure that their products and services consistently **meet customer's requirements**, and that quality is consistently improved
  - ISO 9001: 2015: Quality management systems Requirements
  - ISO 9000: 2015: Quality management systems Fundamentals and vocabulary (definitions)
  - ISO 9004: 2009: Quality management systems Managing for the sustained success of an organization (continuous improvement)
  - ISO 19011: 2011: Guidelines for auditing management systems
- **ISO 14000 family:** provides practical tools for companies and organizations to manage their **environmental** responsibilities
  - ISO 14001: 2015: Environmental management systems -- Requirements with guidance for use
- Other:

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- NFS 96-900: 2011: Qualité des centres biologiques (CRB)-Système de management d'un CRB et qualité des ressources biologiques
- ISO 15189: 2012: Medical laboratories Requirements for quality and competence
- ISO 17025: 2017: General requirements for the competence of testing and calibration laboratories

ISO 17034: 2016: General requirements for the competence of reference material producers

ISO 20387: Biotechnology — Biobanking — General requirements for biobanking

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# Scope and structure ISO 20387

1. Scope

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- 2. Normative references
- 3. Terms and definitions
- 4. General requirements
- 5. Structural requirements
- 6. Resource requirements
- 7. Process requirements

".. all organizations performing biobanking activities, including biobanking of biological material from multicellular organisms (e.g. human, animal, fungus and plant) and microorganisms for research and development."

...but not for BM intended for food/feed production or therapeutic use

8. Management requirements

## **!First standard dedicated to BRCs!**





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# **3. QM tools for BRCs**







# Deming circle



Continuous improvement process, products and services

Plan

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- Establish objectives and processes necessary to deliver results
- Define targets or goals

Do

- Execute the plan
- Implement the processes
- Collect data for analysis

#### Check/Study

- Analyze the actual results
- Compare results with expected results
- Determine differences
- Look for deviations from the plan

#### Act/Adjust

- Identify corrective actions (differences)
- Determine areas which to apply changes and improvements

Standardize → maintain



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# **Deming circle in ISO 9001:2015**

**PLAN** 

DO

ACT

- 1. Scope
- 2. Normative references
- 3. Terms and definitions
- 4. Context of the organization
- 5. Leadership
- 6. Planning
- 7. Support
- 8. Operation
- 9. Performance evaluation **CHECK**
- 10. Improvement

# PLAN? (a) Context

- External context: legal, technological, competitive, market, cultural, social and economic environments
- Internal context: vision, mission, values, culture, knowledge and performance of the organization
- →Quality policy
  →Strategic plan
  Quality objectives

Quality requires commitment of the leadership



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Cfr Chapter 4.1. in ISO 9001:2015



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Cfr Chapter 4.2. in ISO 9001:2015

# BCCM·CC PLAN? (c) Needs and expectations

Key player	Needs and expectations	Risks?
Critical supplier	<ul><li>Contract</li><li>Purchase order</li></ul>	- Only supplier
Other BRCs	- Exchange of BM	- Overlap in holdings

Cfr Chapter 4.2. in ISO 9001:2015



Cfr Chapter 6.1. in ISO 9001:2015



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 $\rightarrow$  Input for Risk analysis

Cfr Chapter 4.4. in ISO 9001:2015, chapter 7 in ISO 20387:2018

# вссм · CC PLAN / DO (b) map interaction between processes



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 $\rightarrow$  Input for Risk analysis

Cfr Chapter 4.4. in ISO 9001:2015, chapter 7 in ISO 20387:2018

BCCM · CC DO (c) Focus on processes with added value Value stream mapping **GREAT AT SMALL THINGS**  $\succ$ Tasks/activities that Tasks/activities that give added value to don't give extra value the product/service directly, but is needed  $\succ$  This is what the **Activities** (company, client pays Secondary government,...) of added activities value Wastes Tasks/activities or use of resources that **Belgian** Science don't give extra Policy value to the Office product/service

## DO (d) Avoid waste

The 7 Wastes

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Unneccessary movement things (parts or machines) between processes Defects Transportation Not right first time, Inventory repetition or correction of Raw material, a process work in progress or finished goods which is not having Overprocessing value added to it Processing beyond the standard Π Movement required by М Unnecessary movement the customer of people within a process Overproduction 0 ш Waiting To produce sooner, faster or in greater People or parts that quantities than the wait for a work customer demands cycle to be complete

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### DO

## (e) Organise work environment

- 5S: Create/maintain a clean and efficient work environment
  - 1. Sort: -Discard everything unnecessary

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-Replace/discard broken or out-of-spec equipment 2. Straighten/ Structure: give the remaining objects a fixed place in a fixed recipient

- 3. Shine: clean the laboratory on a routine basis
- 4. Standardize: steps 1-3 become a habit
- 5. **S**ustain: 5S responsible checks the lab every day (and correct if necessary)



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part of the closet



#### Standardization:

- Divide inner closet in zones and mark with tape
- Label each zone with a description

If I had an hour to solve a problem and my life depended on it, I would use the

I would use the first 55 minutes determining the proper questions to ask.

Albert Einstein

• 5 Whys technique

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#### Problem: Strain XXX does not grow

- 1. Why did the strain XXX not grow? Growth conditions were not right
- 2. Why were the conditions not right? The temperature of the incubator was out of spec
- 3. Why was the T out of spec? The yearly maintenance was not done
- 4. Why was the maintenance not done? No follow up of the maintenance planning
- 5. Why was the planning not followed? Person in charge on sick leave, no back-up

## CHECK Root cause analysis

#### • Fishbone Diagram (Ishikawa-diagram)

→use 5 whys technique to drill down root causes when the inputs are established



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• SMART goals:

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– Specific (what?, where?, how?, with whom?,...)

ACT

- Measurable (concrete evidence)
- (Assignable)/Attainable/Acceptable (time, costsbenefits)
- Realistic/Relevant
- Time-related
- Weigh the cost and risks of every option (Budget? Time?...)

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# 4. Conclusion

- Standardization is important to build trust and to facilitate cooperation
- ISO 9001 and ISO20387 contain inspiring ideas for quality management in BRCs
- Lean management principles reduce the risks of "heavy" quality management systems

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# Acknowledgments

• BCCM coordination cell

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- Vincent Van de Perre (BCCM quality manager)
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- Philippe Desmeth (BCCM international cooperation manager)

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**Questions?** 



John Ruskin