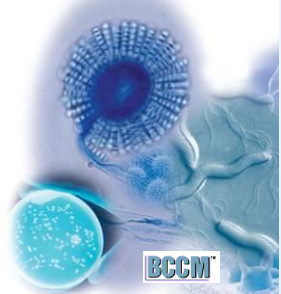


# THE ISO 9001 MULTI-SITE QUALITY MANAGEMENT SYSTEM OF BCCM

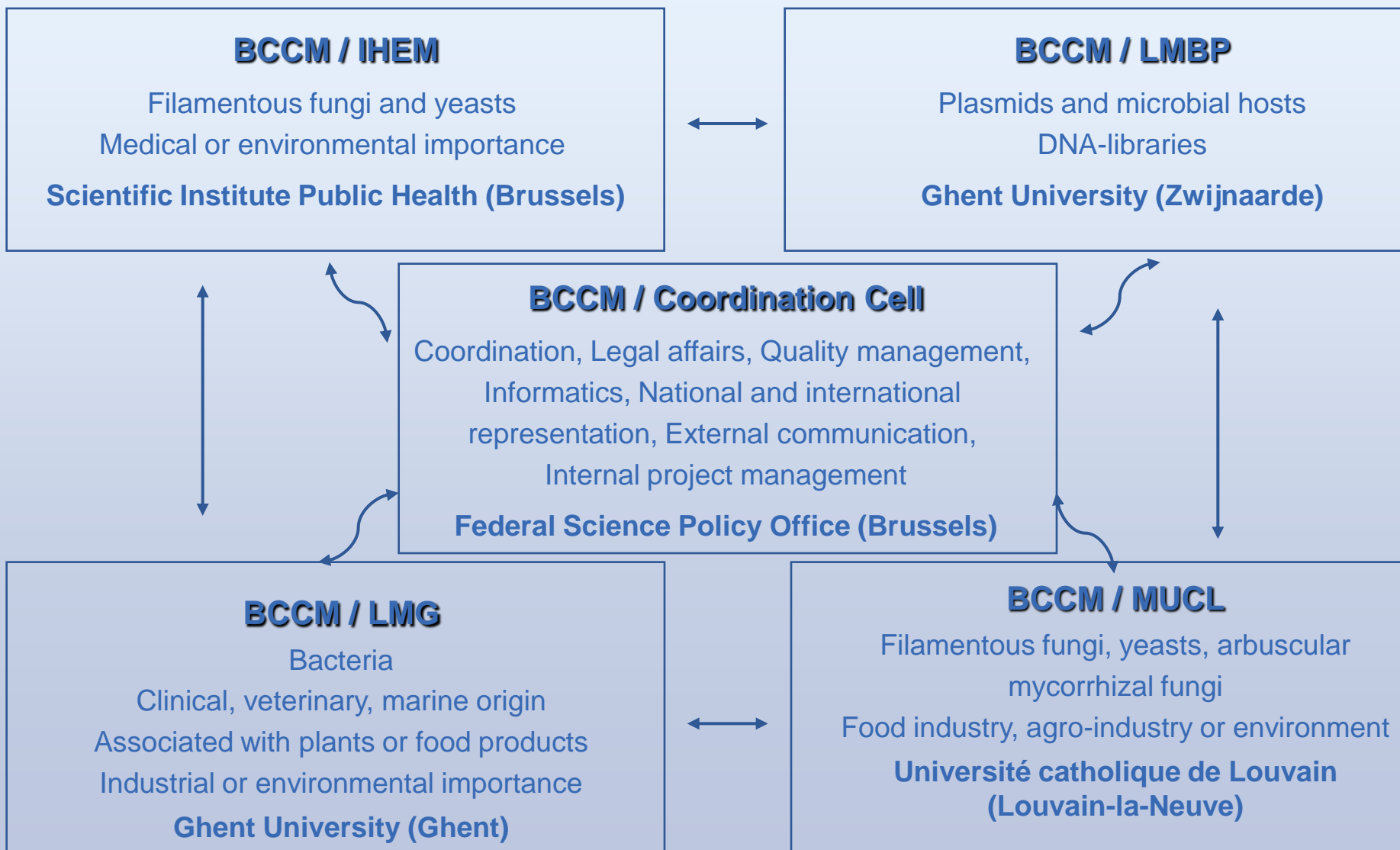
D. Janssens, C. Vereecke, M. Bosschaerts  
Belgian Coordinated Collections of Micro-organisms

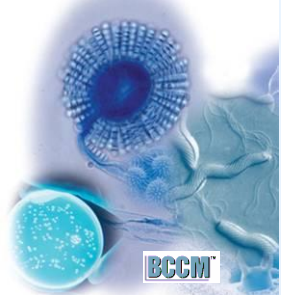
ICCC-12

Florianópolis, Santa Catarina, Brazil, 26 September – 1 October 2010

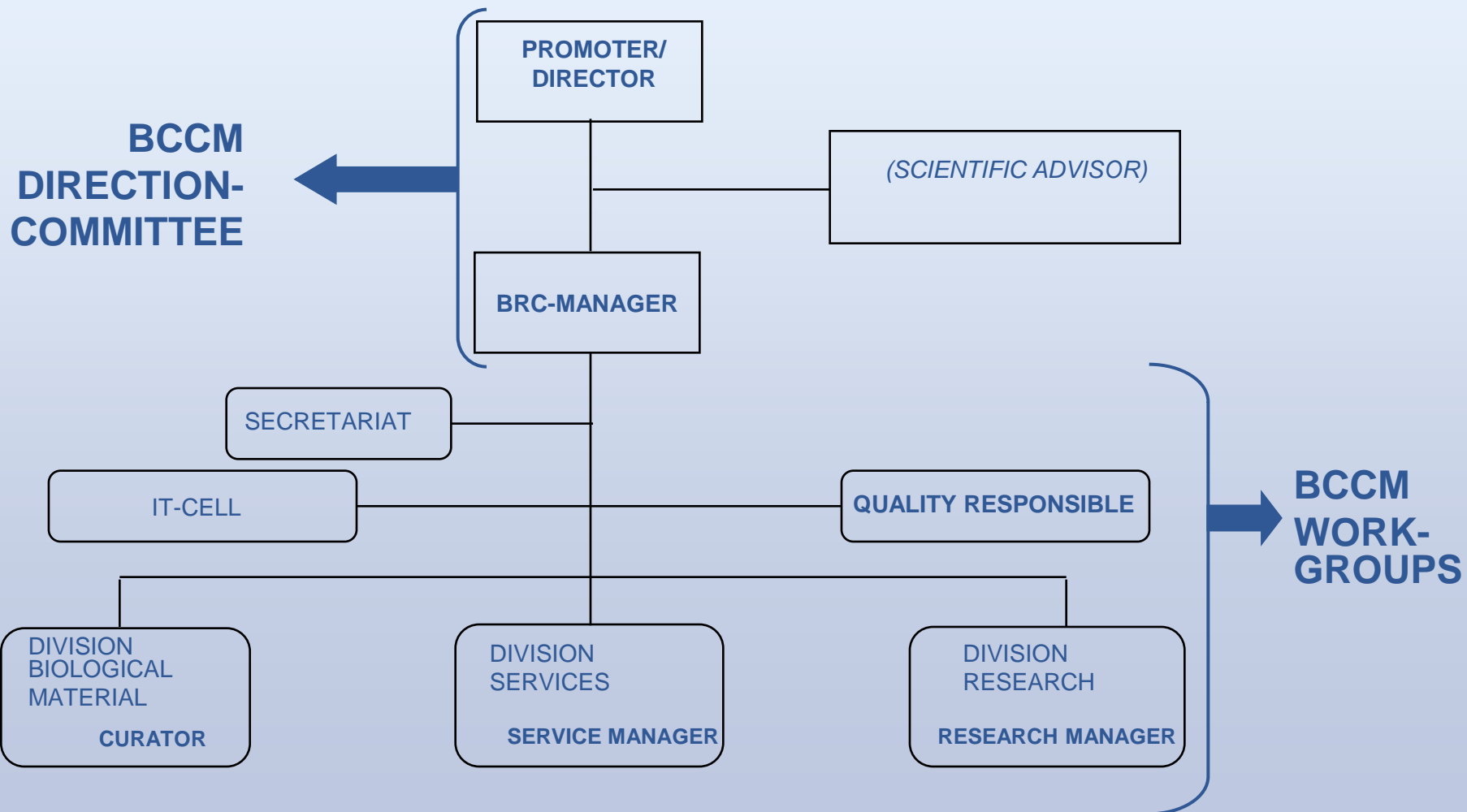


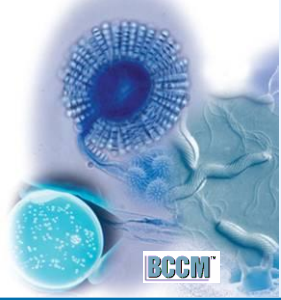
# Structure of the BCCM consortium





# Functional organization chart of each entity





# BCCM is a Multi-site organization

“An organization having an identified  
**central function**

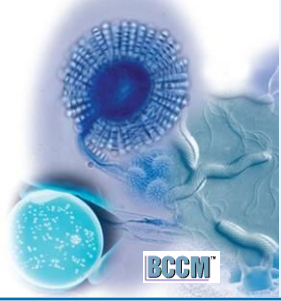
at which certain activities are planned, controlled or  
managed and a

**network of local offices or branches (sites)**

at which such activities are fully or partially carried out”

- Quality Management System must be centrally organized and managed

*(IAF GD 2: 2003 Guide 62 Issue 3 annex 3).*



# **BCCM**

## **Quality Management System**

### **Rationale:**

- **Meeting customers' expectations / needs**
- **Deliver authentic material and quality services**
- **Formalize internal operations and know how**
- **Ensure traceability of activities**
- **Empower employees**
- **Become a BRC (*sensu* OECD)**



The management system of

# Belgian Coordinated Collections of Micro-organisms (BCCM™)

Rue de la Science 8 Wetenschapstraat  
B - 1000 Brussels, Belgium



has been assessed and certified as meeting the requirements of

## ISO 9001:2008

for the following activities:

**Accession, control, preservation, storage and supply of biological  
material and related information in the frame of public deposits,  
safe deposits and patent deposits.**

This certificate is valid from 27/07/2009 until 18/07/2011.  
Issue 4. Certified with SGS since 19/07/2005.  
Recertification audit due May 2011.

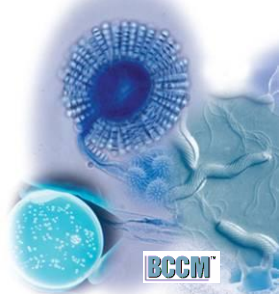
This is a multi-site certification. Additional site details are listed on the  
subsequent page. This certificate consists of 2 pages.

Authorised by

Maria Schittecatte  
Certification Manager



Authorized Person  
117-0208



# BCCM: ISO 9001 Multi-site certification

Certificate BE05/01135.04

The management system of

**BCCM™/IHEM**

Juliette Wytsmanstraat 14  
B – 1050 Brussels, Belgium

1 of

3

Certificate BE05/01135.02

The management system of

**BCCM™ / LMG**

K.L. Ledeganckstraat 35  
B – 9000 Gent, Belgium

has been assessed and certified as meeting the requirements of

**ISO 9001:2008**

for the following activities

**Accession, control, preservation, storage and supply of bacteria  
and related information in the frame of public deposits, safe  
deposits and patent deposits.**

This certificate is valid from 27/07/2009 until 18/07/2011.  
Issue 4. Certified with SGS since 19/07/2005.  
Recertification audit due May 2011.

Multiple certificates have been issued for this scope.  
The main certificate is numbered BE05/01135.00.



**BCCM™ / LMBP**

Technologiepark 927  
B – 9052 Zwijnaarde, Belgium

has been assessed and certified as meeting the requirements of

**ISO 9001:2008**

for the following activities

**preservation, storage and supply of plasmids  
and related information in the frame of public  
h deposits, safe deposits and patent deposits.**

is certificate is valid from 27/07/2009 until 18/07/2011.  
Issue 4. Certified with SGS since 19/07/2005.  
Recertification audit due May 2011.

Multiple certificates have been issued for this scope.  
The main certificate is numbered BE05/01135.00.

Authorized by



Marnix Schittecatte  
Certification Manager

SGS Belgium NV, Systems and Services Certification

Certificate BE05/01135.03

The management system of

**BCCM™ / MUCL**

Croix du Sud 3 bte 6  
B – 1348 Louvain-la-Neuve, Belgium

has been assessed and certified as meeting the requirements of

**ISO 9001:2008**



activities



Certificate BE05/01135.05

The management system of

**BCCM™ / Coordination Cell**

Rue de la Science 8 Wetenschapsstraat  
B – 1000 Brussels, Belgium

has been assessed and certified as meeting the requirements of

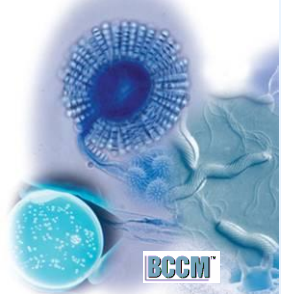
**ISO 9001:2008**

for the following activities

- Coordination, optimisation and valorisation of the  
BCCM™ consortium
- Project management
- National and international representation

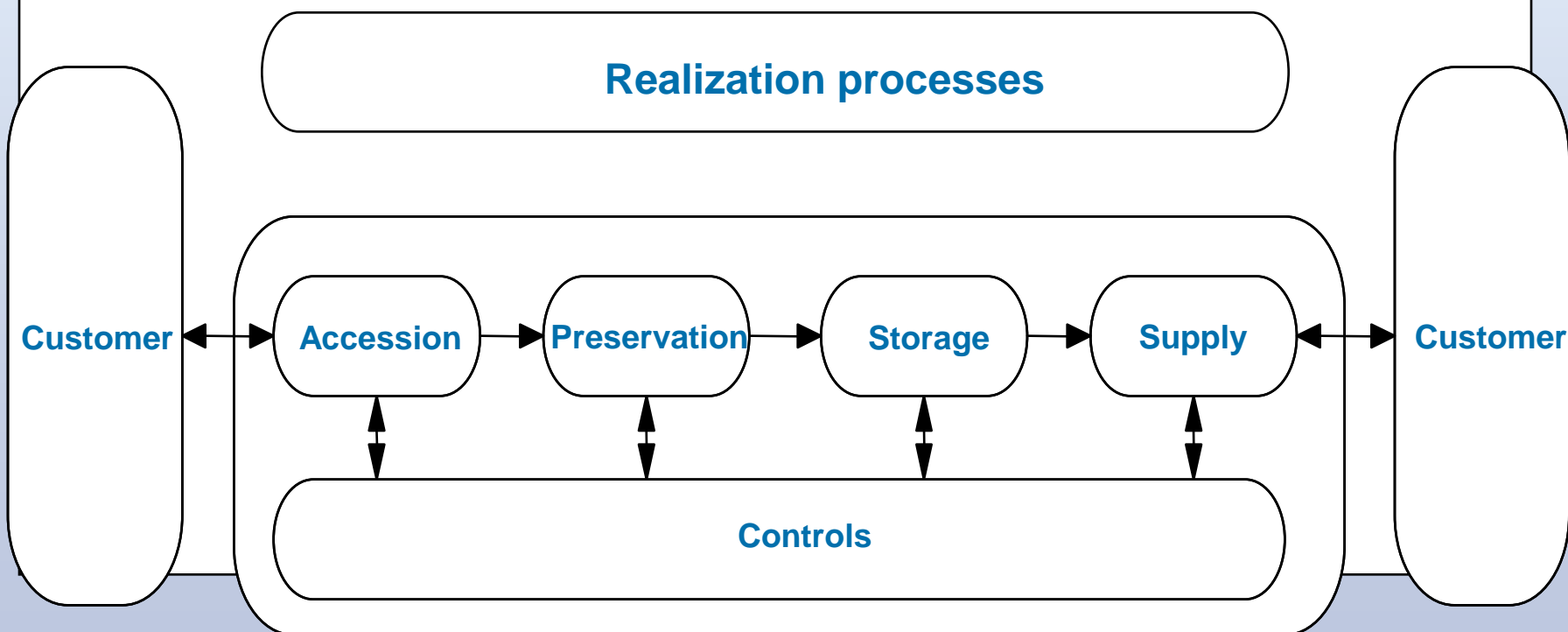
This certificate is valid from 27/07/2009 until 18/07/2011.  
Issue 4. Certified with SGS since 19/07/2005.



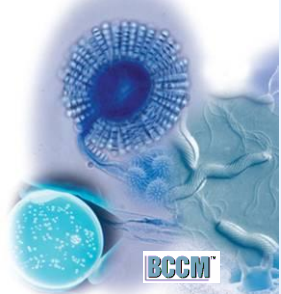


# Scope of BCCM certification

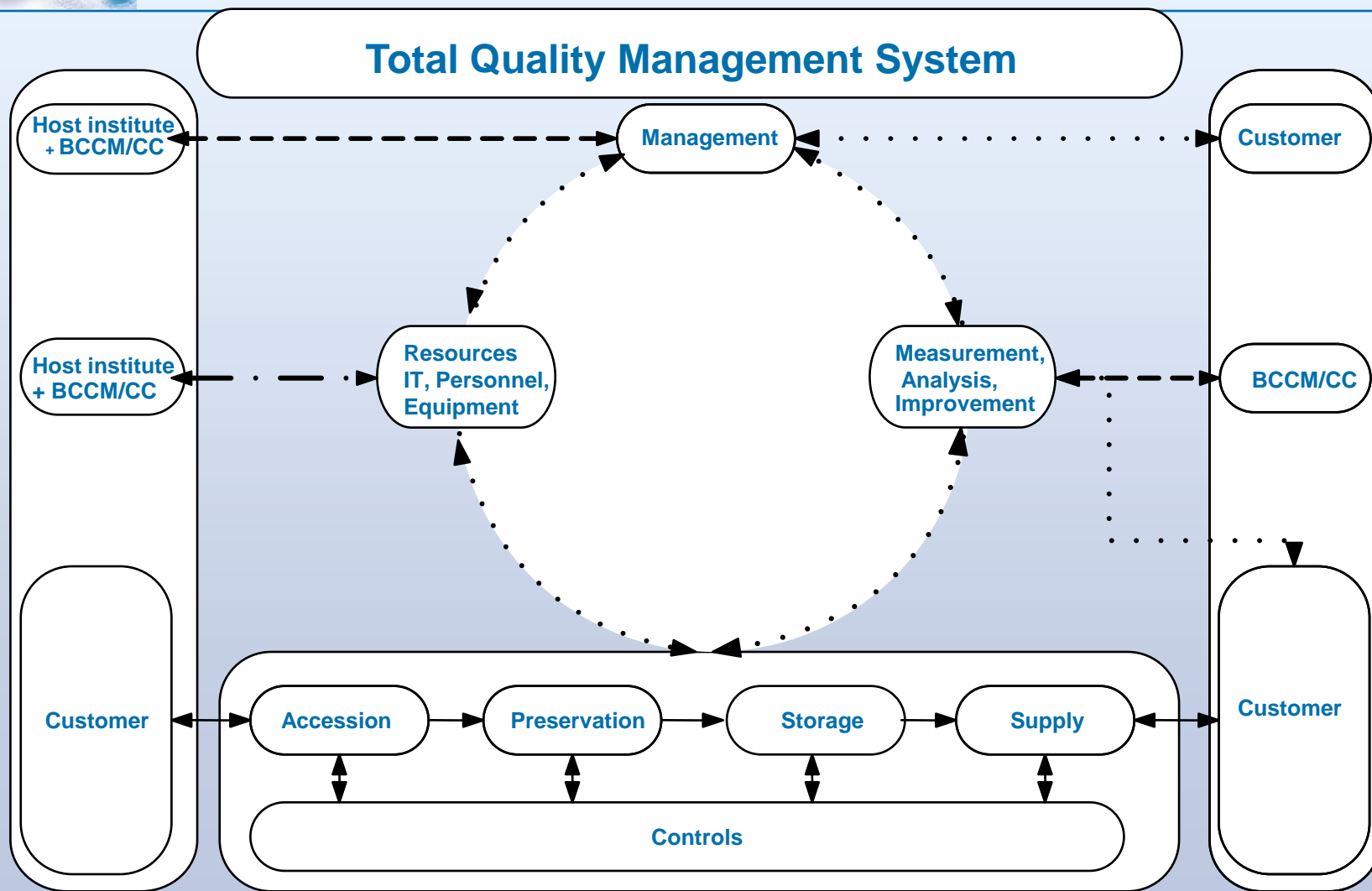
**Accession, control, preservation, storage and supply of biological material and related information in the frame of public deposits, safe deposits and patent deposits**

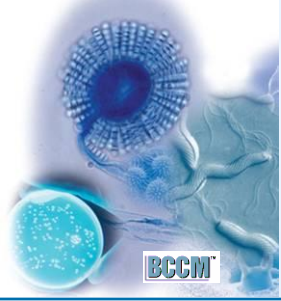




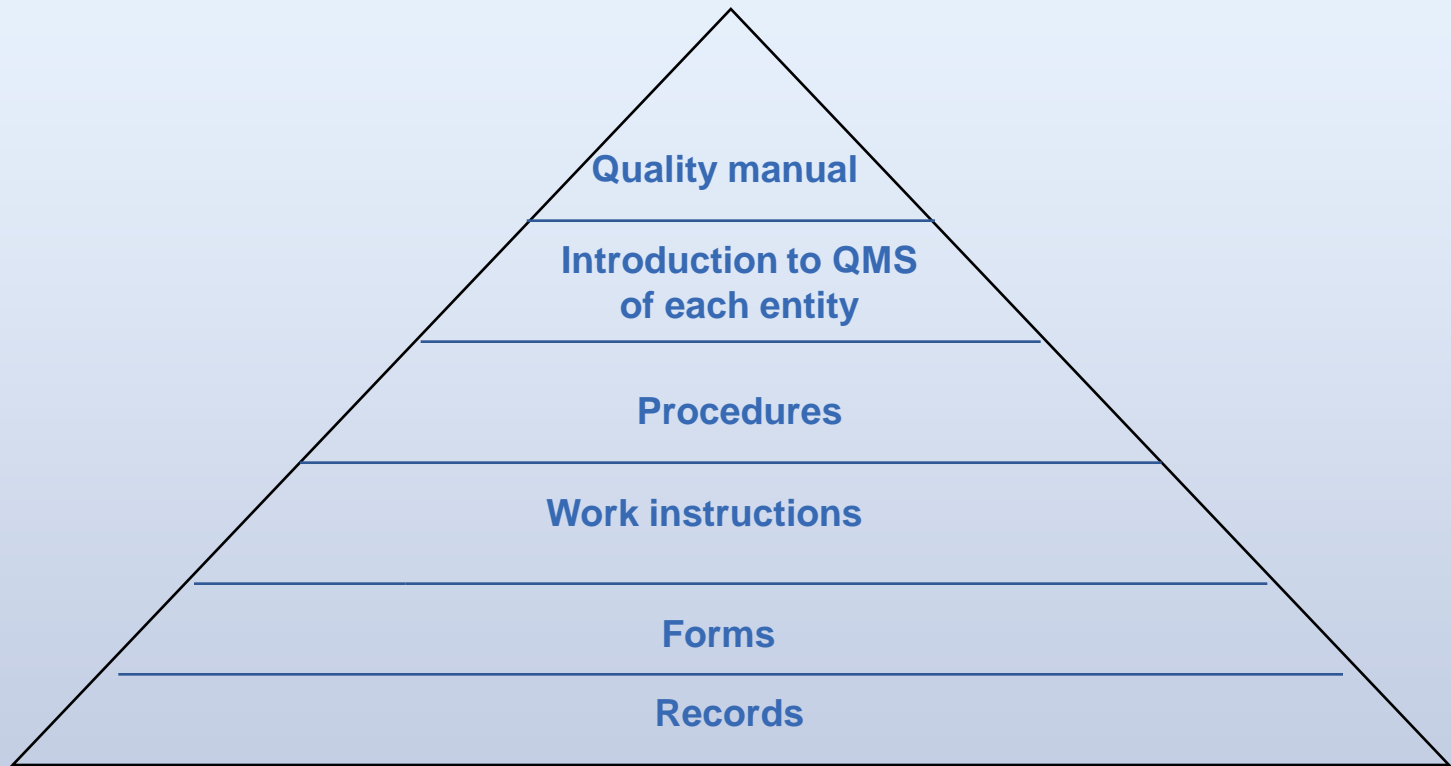


# BCCM process map

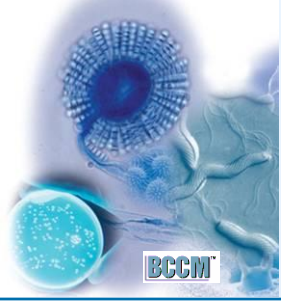




# Quality Management System: documentary structure



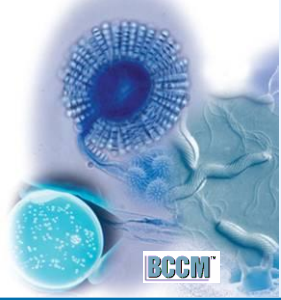
**Multi-site: three types of documents**



# Documentation:

## Three types of documents

- 1 - **Consortium** documents
- 2 - **Common** documents
- 3 - **Specific** documents



## Documentation

# 1 - consortium documents

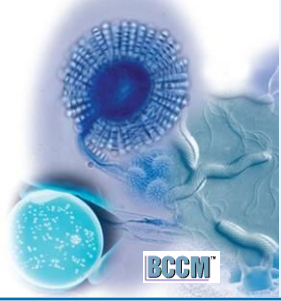
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Content: one document for whole consortium

Managed by: BCCM Coordination Cell

Applied by: all entities

Examples: quality manual, quality policy, strategic plan, direction responsibility, internal audits, document management, non-conformities, indicators



# Documentation

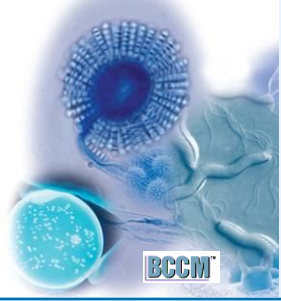
## 2 - common documents

Content: identical code & title for all entities  
content specific for each entity

Managed by: each entity

Applied by: each entity

Examples: personnel, infrastructure



## Documentation

# 3 - specific documents

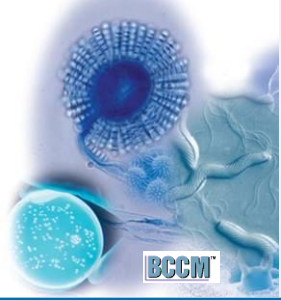
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Content: specific code & title for the entity  
content specific for the entity

Managed by: specific entity

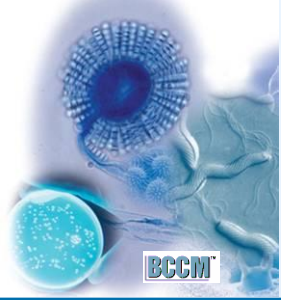
Applied by: specific entity

Examples: preservation, storage, supply of samples,  
performing 16S sequences, ...  
(mainly technical procedures and work instructions)



# Functioning of Multi-site QMS

- 1 - **Working group** on quality management
- 2 - **Management reviews**
- 3 - **Internal audits**
- 4 - **External audits** by certification body

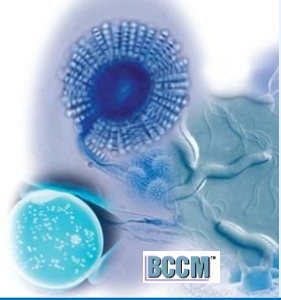


## Functioning of Multi-site QMS

# 1 - Working group on quality management

- Who: Quality responsible of each entity  
& BCCM quality manager
- Goal: To develop, implement and maintain  
the BCCM QMS  
Exchange and harmonize practices
- When: Meetings on monthly basis





# Functioning of Multi-site QMS

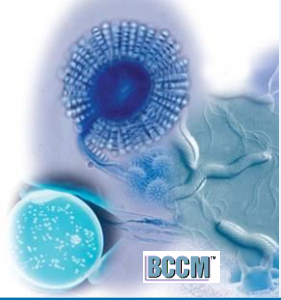
## 2 - Management reviews

### Local Management reviews

- Organized by each entity
- Based on harmonized agenda & format
- BCCM quality manager participates

### BCCM consortium Management review

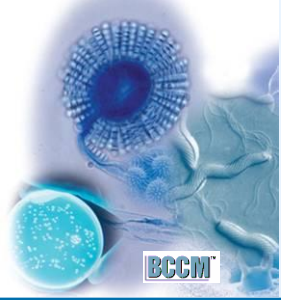
- Consolidated data for whole consortium
- Common decisions and actions



# Functioning of Multi-site QMS

## 3 - Internal audits

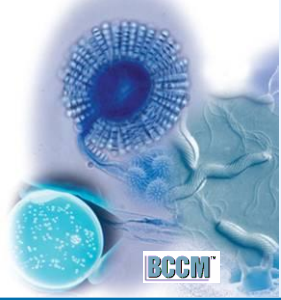
- One procedure for all entities
- Harmonized audit planning and audit reporting
- Exchange of internal auditors between entities
- Follow up of realization of the planning by BCCM quality manager



# Functioning of Multi-site QMS

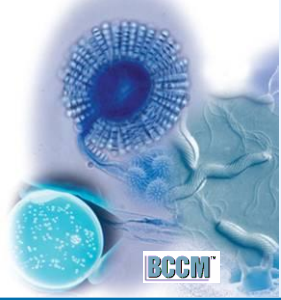
## 4 - External audit

- One combined external audit
  - by visiting and (partial) auditing each entity
  - with one common closing meeting
- Non-conformities and Opportunities for Improvement observed at one entity are also dealt with by all other entities



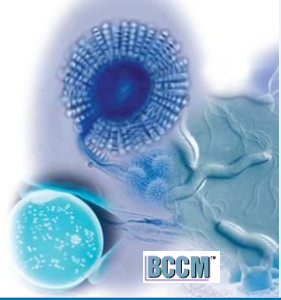
# Advantages of Multi-site QMS

- ✓ Continuous exchange of expertise/experiences between the entities, and selection of best practices
- ✓ Synergetic effect
- ✓ Less external audit time and less costs per entity

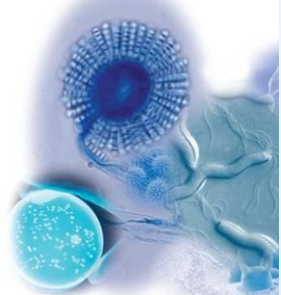


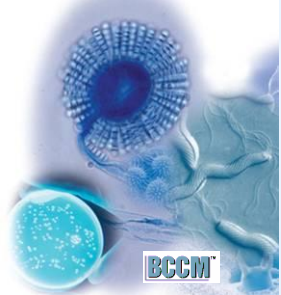
# Disadvantages of Multi-site QMS

- o Many common rules limit freedom of entities
- o Slower progress since consultation and agreement on BCCM level is often needed
- o All entities share responsibility for Multi-site certificate, if one entity does not comply, the certificate is lost



**Thank you for your attention**





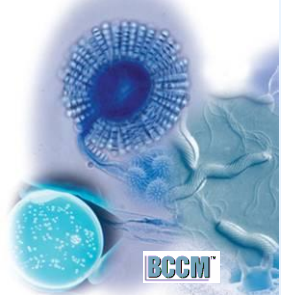
# Results of self-assessment OECD best practice guidelines

**For most aspects, BCCM complies with  
OECD best practices**

**Opportunities for improvement:**

- Validation of methods
- User validation
- Biosecurity guidelines





## Perspectives

When BCCM wants to obtain independent recognition of compliance with OECD best practice guidelines, all entities have to comply with these guidelines

→ a common effort is needed