

Implementing BRC best practice and capacity building

GBRCN Workshop Brazil July 2008

Summary



- Quality management/ best practice coverage
- Impact on procedures
- Capacity building

Quality Management coverage

- Accessions to the Collection
- Preservation procedures used
- Stock Control of the Preserved Organisms
- Supply
- Confidentiality
- Staff - Qualifications and Training
- Quality Audit and Quality Review
- Quality Control System

Quality Management coverage

- **Equipment: Calibration, Testing and Maintenance**
- **Measurement Tracibility and Calibration**
- **Methods and Procedures**
- **Laboratory Accommodation and Environment**
- **Receipt and Handling of Organisms**
- **Record system**
- **Handling of Complaints and Anomalies**
- **Outside Support Services and Supplies**
- **Site Security**

Best Practice

Identified, authenticated and characterised strains

Descriptive data, photomicrographs, metabolic profiles, sequencing data

Purity

Strains must be pure (or mixtures defined or noted)

Viability e.g.

Preferred level: >75% of propagules/cells

Acceptable level: 50%.

Any deviation from the standard would need to be explained and recorded.



Best Practice

Stability of strain properties

A programme of tests to ensure stability of strains must be put in place

Methodology

Optimised techniques and standard procedures should be adhered to

A procedures manual is essential to ensure continuity

Accepted level of deviation from measurable parameters must be set

Equipment

Maintained, calibrated and must operate to set limits

Ensure traceability and reproducibility

Best Practice

Long-term security

Long-term preservation

Stored by a minimum of two techniques

Working and security stocks

Stored on another site as a disaster measure

Auditing/ monitoring

It is essential that adherence to set standards is monitored at every level

Best Practice

Compliance with legislation

Packaging, shipping and transport

Quarantine

Health and safety

Patenting

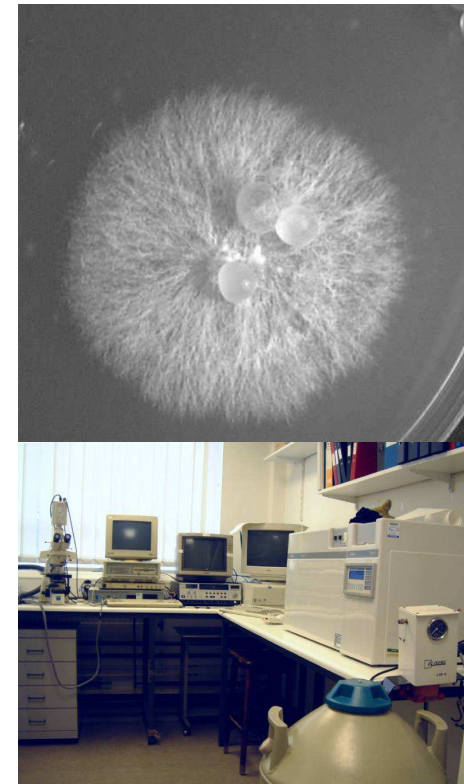
Best Practice Aims

- BRCs must maintain strains without change to ensure their long-term availability for sustainable use
- They must operate to high standards, methods used must be reliable and reproducible
- Common policies and standards must be followed to offer such a service world-wide

High quality reproducible work requires high quality tools – the micro-organisms

BRCs must use optimum preservation technologies

- Continuous growth – cannot simply store strains in the back of the refrigerator
- Adaptation to storage conditions
- Selection of subpopulations – strain drift
- Contamination
- Deterioration or death
- Must adopt long-term methods such as freeze-drying or cryopreservation
- Must also test beyond viability



Impact on procedures e.g. Freeze drying

Need to have records to demonstrate that the correct organism is in the resulting ampoule and it has followed the desired protocol and tested satisfactorily e.g.

- Confirmation of organism identity or traceable to source
- It is pure and viable
- Suspending medium formula and preparation is traceable
- The equipment used recorded
- Key parameters measured and measurements calibrated to an accepted standard – pressure/temperature
- Post preservation tests completed satisfactorily
- Recorded when the work was done and by whom
- The persons involved had the correct training
- Environmental conditions controlled etc.

BRC Information requirements

- **Use a standard terminology and format for data exchange and a standard protocol for data transmission**
- **Each record should contain a minimum data set laid down in domain specific criteria**
- **Spell checking for every field is a basic requirement**
- **Vocabulary should be checked against standard reference list**
- **Language of data provided to the GBRCN: International English**

Enhancement at the BRC and Network Levels



BRC developmental needs

- Taxonomists
- Information storage, analysis and distribution
- Co-ordinated acquisition programmes
- Improved technologies and facilities
- Characterisation and screening
- Compliance with international agreements and conventions

Initiatives in place

Training programmes:

WFCC; MIRCENs; CABI; National networks e.g. UKFCC; USFCC; Brazil; Thailand; Philippines; Cuba etc.; Individual collections: 489 on WDCM – 199 offer training

Government investment e.g.

Japan; Thailand; Vietnam; Taiwan; China

Data access and distribution

Global Biodiversity Information Facility

BioCASE; WDCM; BioCASE

Initiatives in place

Taxonomy training

CBD - Global Taxonomic Initiative

BioNET International

EU project SYNTHESYS NA-B;

CC management

ECCO; WFCC; ISBER; National Organisations

EU projects: CABRI; EBRCN; COBRA;

CABI Member Country BRC Initiative

OECD GBRCN

Culture Collections to BRCs

Drive

Enhance quality management

Biodiversity conservation

Biosecurity

Bioeconomy

Programmes to support **Development**

DIFD; UNIDO; UNESCO; UNEP; World Bank; GEF; Asian Development Bank etc.

Recommendations

Co-ordination to maximise output from effort and reduce duplication

Organisations carrying out this important work should collaborate with Governments and focus efforts on the OECD initiative to get value for money and realise long-term goals

Topics identified in OECD survey



- Lack of digital documentation
- Lack of sustainability of financial support
- Equipment needs (analytical, sterile flow cabinets)
- Collections very often depend on individual specialists or limited governmental support
- Inability to Implement new technologies for material conservation and quality control
- Training needs
- Access to informatics tools, on-line access to the scientific data
- Lack of coordination at international level
- Lack of long-term preservation technology

Topics identified in OECD survey

- Need for quality management and control
- Need for technology transfer, use of biological resources
- Inadequate institutional capacity to manage Animal Genetic Resources *in situ* and *ex situ*
- Lack of the linkage between conservation and use
- Legislation and policies are developed piecemeal with little regard to practitioners
- Absence of public awareness on biodiversity and biological resources preservation issues
- Lack of policies to protect genetic resources from privatisation or to insure equitable exchange

Possible model for collections to become BRCs

- National governments identify candidate BRCs
- Meeting threshold requirements e.g. authentication of materials their long-term preservation and validated associated information
- Join the global network after preparation of development plan
- Third party assessment: Accreditation/certification procedure
- Capacity development process ensured via the collaboration with donor, implementation and development agencies (e.g. GE; World Bank, JSPS) and with national programs
- Accreditation/certification processes can be ensured by national accreditation/certification bodies
- Candidates can network or twin with BRCs

Candidate BRCs

Three levels culture collection

Basic – pre BRC and GBRCN

Intermediate – threshold level register in GBRCN

High

→ BRC

Basic

Biological material is preserved by using just the basic technologies;
no developed infrastructure and quality management

Assessment of needs

National/Regional/International programmes to support development

Project support

Governmental level: Implementation of national policies aiding the
fundraising and staff hiring and training

Intermediate

Technically improved collections which are participants of national/regional networks with established material exchange procedures within the networks

Institutional level: ● Quality management development with national or institutional help

Governmental level: ● Implementation of policies to ensure the preservation and sustainable use of biological material ● development and implementation of fundraising policies ● Development and implementation of the programs for national and regional training activities ● raising of public awareness on the collections' activities

High

Technically improved collections with:

- well established quality management
- MTAs
- biosafety and biosecurity standards
- IP regulations; accredited or certified to the ISO standards
- highly trained staff
- clear management program and collection strategy in place
- sustainable fundraising mechanisms with governmental support

High

Institutional level: • Introduction of OECD operational and domain specific standards • harmonization of information exchange and biosecurity standards using the OECD recommendations • complying with relevant national, regional or international policies • internal and external audits implementation • management of traceability through information system • collaboration with high quality collections worldwide • broader involvement of stakeholders

Governmental level: • Implementation of policies facilitating the BRC establishment and its sustainable functioning through fundraising • human resources development and sustainable use of biological material • put in place the accreditation/certification systems for candidates BRCs

BRC

- High quality collections accredited and certified to the OECD standards; functioning through the use of the OECD instruments complying with national laws, regulations and policies
- Registration of the collection as a BRC; resulting in third party audits
- Partner in the GBRCN

Summary



Current initiatives need supporting with common tools

Gaps need identifying and filling

Funding needs to be sort

Tools need to be developed and harnessed