

Quality management and biological resource centres

The 2001 OECD report *Biological resource centres: underpinning the future of life sciences and biotechnology*¹ resulted in the establishment of the *Guidance for the operation of BRCs*. This document still is in its final stage of discussions and has not yet been passed. Nevertheless, many traditional service culture collections already comply (or try to) with these guidelines in their daily work.

One criterion for acceptance as a BRC is the demand of a quality management system which should be accepted across international borders. The DSMZ (German collection of microorganisms and cell cultures)² is introduced in the OECD report as a model of a future BRC with the following tasks: preserve and provide biological resources for scientific, industrial, agricultural, environmental and medical R&D and applications; perform R&D on these resources; conserve biodiversity; and serve as depository of biological material for protection of intellectual property.

What was still missing in 2001 at the DSMZ? The internationally accepted quality management system! Accordingly, the DSMZ decided for the process-oriented standard ISO 9001:2000³ which in the meantime was implemented into its daily work. The ISO 9001 standard was chosen because it specifies requirements for a quality management system where an organisation first needs to demonstrate its ability to consistently provide products that meet customer and applicable regulatory requirements, and secondly aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of this system (Figure 1).

Because of the wide scale of different biological materials and offered services,



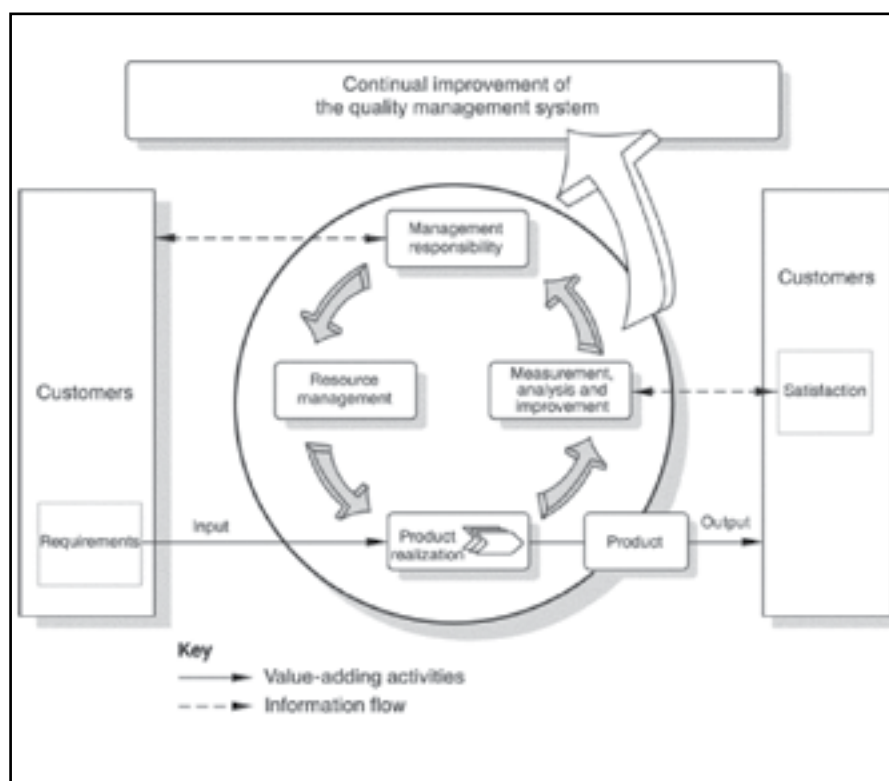
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DSMZ has opted against an alternative quality management system, the ISO 17025 accreditation. This standard addresses the proficiency of the organisation to perform testing and calibration activities. This is layered on top of an ISO 9001 certification and is not meant for a company as an entity, but for single laboratories and respectively single laboratory processes dealing with testing, calibration or sampling.

The initial certification procedure for ISO 9001 took 10 months, in which DSMZ in its whole entity has been certified, including all departments (departments of microorganisms, plant, animal and human cell cultures, plant viruses, identification service, patent depository, administration).

Figure 1. Model of a process-based quality management system





For most scientists who have not yet been confronted with quality management systems, it might evoke fears and denials. Indeed, it means to be frank, ready and open-minded to enter into a new world of hitherto unusual definitions. The curator of a specific group of microorganisms is confronted with the fact to be addressed as 'production manager'; yes, the curator is the responsible person for the preparation of the freeze-dried ampoules used for sale. The ampoules containing a bacterial or fungal strain change to 'products'. But don't be afraid, the curator still will have the opportunity to do research which, for sure, has not to be performed following ISO guidelines.

As before, an institute working under ISO guidelines will comply with laws and regulations applicable to the handling of living biological material – laboratory safety guidelines, genetic engineering legislation, dispatch restrictions, transport regulations. The biosafety and biosecurity issues, however, perhaps will be followed and documented in a more standardised manner. The staff has always been qualified and trained for the job. This will continue to be like this, perhaps happening more regularly and intensively.

The aim of ISO 9001:2000 is to serve the whole institution. It is postulated that the main aim of the institution DSMZ, to be a modern biological resource centre offering science and service within one entity for the benefit of scientific and industrial customers as well as scientific staff, curators and guests, will be reached more easily when everybody – from cleaning personal, secretary, technician, scientist to director – is highly motivated, knowing to be integrated in the house. Everybody's contribution is necessary, highly appreciated and recognised as one important brick in the wall. Also the customer is involved in the process; a customer has to be content with the biological material delivered and the services offered by the collection.

Satisfaction is checked by means of opinion polls.

A quality manager has to be appointed. Often it is a person not belonging to the staff. The advantage is that this person is independent and has a more global view of the whole institution. The quality management representative will reveal similarities/differences in working techniques between the various working groups and thus can try to help to improve processes. Problems will become evident and responsibilities will be delegated and given. Communication between the diverse groups within an institution is supposed to be fostered.

In parallel to all this, standard operation procedures (SOPs) are developed to facilitate and standardise the reworkability of processes. The certification process is a continuous one because all necessary SOPs cannot be in place from the very beginning. They will be written one after another as a result of continuously improving and data analysis. Documentation thus is a key word.

Recording has always been an extremely important issue at culture collections in order to assure location of stored biological material. Databases for the documentation of cultivation methods, preservation protocols, traceability records in-house and outside, databases for the strains have been or have to be created. The final aim is a global network of databases of culture collections/BRCs worldwide, listing their holdings of biological material. This issue is already followed by using regional approaches as EBRCN in Europe (European Biological Resource Centres Network) or proposed to be followed at AMRRN in Australia (Australian Microbial Resources Research Network).

Outlook

Certification to ISO 9001:2000 enables DSMZ to ensure for internal and external interest that activities and outputs are 'fit for purpose' by following the Plan–Do–Check–Act principle, which means that every activity will be planned, carried out, then monitored and be continuously improved. On this basis, DSMZ will be adequately prepared to respond to new standards for customers or public interests.

In the meantime, at least a few collections worldwide have been certified or accredited. Their number will certainly increase after ratification of the OECD BRC guidelines. These collections will be recognised by an international body (independent of the OECD) as BRCs playing an important role in future advancement and support of biotechnology and preserving the world's biodiversity and genetic resources.

The global network of BRCs will be of highest importance for the development in the biological sciences and their capacity to contribute to sustainable growth. Controlled access to biological resources will be enhanced and international collaboration fostered. The final aim is the establishment of a Global BRC Network (GBRCN) which will be an international body independent of the OECD.

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References

1. OECD. *Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology*. OECD Publishing, Geneva. 2001. ISBN 92-64-18690-5 <http://www.oecd.org/dataoecd/55/48/2487422.pdf>
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