newsletter
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Focus QM

German Biobank Node
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Editorial

Dear Colleagues and Biobankers,

The collection of samples using equivalent quality standards is essential for research projects employing biomaterials from different biobanks. Samples collected in the past were acquired in different infrastructures with diverse processes involved for sample collection, processing and storage. This has led to very heterogeneous levels of quality which makes cross-biobank research with samples from different sources a real challenge. One of the main tasks of the German Biobank Node is therefore to address quality management issues and work towards harmonized protocols, including comprehensive documentation. The substantial interest expressed by the German biobank community has shown that quality management (QM) is a topic that is of increasing importance and topicality - therefore this Newsletter issue is dedicated to QUALITY.

GBN has organized a series of three QM workshops and the results will be compiled as a QM manual with generic templates for all core processes – available in summer 2016. We would like to thank all participating biobanks for their contributions to this very successful process! These activities continue as BBMRI-ERIC cooperates with the international standards organizations (CEN/ISO) and many of our German QM experts have been involved in this endeavor. In this Newsletter, we present three articles to underline the ongoing activities: firstly, the GBN QM work package, secondly the BBMRI QM perspective and thirdly background information on the CEN/ISO standard development. The diary of a virtual quality manager completes the picture of the many facets of QM.

We hope you will find our selection informative and enjoyable and we wish you a prosperous springtime!

Michael Hummel &
Cornelia Rufenach

Quality in Biobanking: "The greatest challenge is the standardization of processes in the pre-analytical phase"

Michael Kiehntopf at the National Biobank Symposium 2015

PD Dr. Dr. Michael Kiehntopf is Head of the Integrated Biobank Jena (IBBJ) and Director of the Institute for Clinical Chemistry and Laboratory Diagnostics of the University Clinic in Jena. Together with Prof. Peter Schirmacher, he coordinates the quality management project in the German Biobank Node (GBN). An interview about the establishment and operation of biobanks, and in particular their quality management.

Dr. Kiehntopf, the quality of samples has a substantial influence on the quality of scientific research results. What contribution can biobanking make to the quality of the material used for research?
The complex conditions that have to be satisfied for research today – in particular requirements relating to ethics, data protection, international standards and quality – represent a considerable challenge, not just for individual researchers but also for larger research collectives. Biobanks can provide the necessary organization and infrastructure and make an important contribution to research. The quality of a sample is subject to a variable number of influences, depending on the complexity of the project. To obtain samples that are of high quality it is necessary to establish procedures that insure quality requirements are met, from the col-

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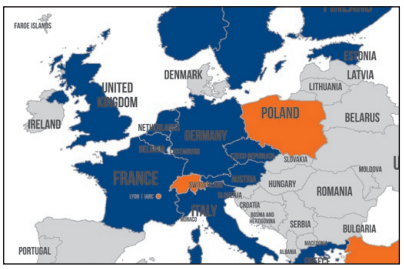

15 European countries join forces to improve the quality output of biobanks

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lection of samples through their processing, storage, release and transport. The pre-analytical phase, from sample collection through to receipt of the sample by the biobank, is of particular relevance to the quality of the sample. This is especially important for multicenter studies in which a large number of different collection centers may be involved and the sample collection phase often has to satisfy specific requirements that are not under the control of the study personnel.

These procedures are already standardized in many biobanks. In some cases the biobanks are certified and subareas like internal quality control processes are also accredited. The quality of the samples stored is documented in such a way that tracking is possible. Biobanks can therefore provide high-quality samples and thus make a valuable contribution to quality assurance for research results. Biobanks do not just actively provide services, they are increasingly taking on research tasks, e.g., in the validation of process steps or in the development of tools for the assessment of sample quality. The results obtained can directly improve the workflow and influence the selection of samples that have to satisfy defined requirements for special analytical methods. Biobanks also support research by driving forward the urgently required national and international harmonization of processes to improve interoperability between individual biobanks and therefore promote the availability of sample collections for research purposes that are larger in scale and of consistent quality.

What are national and international efforts to harmonize biobank procedures that are relevant to quality?
Efforts are being made to develop and establish internationally standardized and quality-assured procedures for biobanking on a global basis. For this it is first necessary to define generic standards and quality criteria for the implementation and evaluation of biobank procedures. National activities must be matched to international ones for this. This is carried out under the leadership of the German Institute for Standardization (DIN) with the aim of developing an ISO standard specifically for biobanks. The aspects discussed at a national level in the national standards committee (NA 057-06-02AA, working group 2 biobanks/bioresources) flow at an international level into the technical committee ISO/TC 276 Biotechnology, WG/2 Biobanks/Bioresources.


Photo: Thomas M. Pieruschek

How do German biobanks and the GBN compare to international efforts to harmonize quality management procedures?
Germany is at an excellent stage since GBN bundles German expertise and actively brings it to the European level. GBN/WP3 is a project that has the aim of developing a comprehensive quality management (QM) approach to biobanking for both liquids and tissue samples, coordinated by Prof. Schirmacher in Heidelberg and myself. A large number of biobank experts are working at a national level to develop a practice-oriented QM manual with generic SOPs. To this end we have analyzed those standards that are relevant to biobanks – such as EN ISO 17020, 17025, 15189 and 9001 – and have attempted to summarize them. All applicable legal and regulatory requirements were also integrated. The manual has been made available to the German biobanks who actively participated in the project. We will make the results of this process available to BBMRI via GBN. In parallel, BBMRI-ERIC, with the assistance of experts from European and various German biobanks, is evaluating the implementation of CEN standards for targeted sample handling. These have just been published as a standardized method and are on the brink of becoming an ISO standard. Hopefully, we will have a biobank standard of international validity in the near future.

What are the greatest challenges for liquid and tissue biobanking? How will they be tackled?
In my opinion the greatest challenge is the further standardization of processes in the pre-analytical phase in particular, which lie outside of the direct control of biobanks, such as sample collection. These processes can only be standardized, for example, by the issue of SOPs by the biobank. The necessity of developing standardized tools and criteria for the direct determination and evaluation of sample quality is thus a further challenge for biobanks. The identification and establishment of quality control markers (QCMs) can be helpful here. These markers are analytical variables that have a concentration that varies according to one or more biobank process stages. It is important that these quality control markers have a high specificity with regard to pre-analytical influencing factors and are independent of the clinical phenotypes of interest in the study in question. QCMs that are promising have already been identified in a range of studies, but they must still be validated in larger-scale collectives of diseases under real study conditions. A further challenge is for the drafted standards to be used in the biobanks in a harmonized manner since local conditions are frequently very different.

What QM measures would be required by anyone wishing to set up a liquid/tissue biobank today?
The biobank must be set up to meet the demands of the users and offer a long-term service. Samples that are

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collected today may be used only several years from now within the framework of a cooperation that has defined quality requirements. The biobank therefore has to meet the quality requirements of a potential user at a later date before the samples are stored.

What arguments can biobank operators use to persuade those persons collecting samples that they maintain high standards throughout the collection process, and how can they support them?
I do not think that they require very much persuasion. There is clear agreement that high-quality samples are required for the use of highly advanced analytical methods and that the pre-analytical stage is the greatest influencing factor. The problem is that the assessment of resources necessary for an optimal and standardized collection of samples differs tremendously. However, the award of research funding depends increasingly on the length of time for which the samples can be used, as well as the existence of a quality-assured infrastructure. Biobanking has to be viewed in this context as an activity that spans different fields and requires close co-operation and agreement between researchers and the biobank. The overall quality is always the sum of the quality of the sub-processes and the motivation to act is derived from the information on the possible benefits.

Interview: Wiebke Lesch

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GBN Inside

GBN Work Package 3: Quality management in German biobanks and requirements for a QM manual

The authors: Dr. Sabrina Schmitt/Biomaterialbank Heidelberg and Bettina Meinung/IBBJ at the 3rd GBN QM Workshop in February 2016

In a series of three QM workshops organized by German Biobank Node (GBN) the participating biobanks reached a common understanding of the needs and parameters to be defined, which lay the grounds for a QM manual with generic templates. After the first workshop last summer in Heidelberg the participating biobanks had given their feedback to different questionnaires concerning the core processes and related SOPs. A detailed analysis of the questionnaire results was discussed during the second workshop in December 2015 in Berlin. After intense and fruitful discussions the group of quality managers successfully reached agreement: The goal of this GBN work package should be to concentrate on the creation of a process-oriented quality manual - including harmonized SOPs that predominantly describe general requirements for efficient quality control and assurance - rather than specifying pre-analytical parameters in detail.
Nevertheless, a set of minimum standards needs to be established and the respective parameters have to be documented– at least for the core processes in the context of sample acquisition, transport, entry, processing and storage. These harmonized SOPs can then be used as a blueprint with local adaptations in all German biobanks. The responsible persons of the QM work package from Heidelberg, Jena and Munich will now meet every month to finalize these documents for the preparation of generic SOPs. A draft version of a GBN QM manual will be available to the community in summer 2016.
Close ties have been established with the personnel responsible for the BBMRI-ERIC quality work plan to link these national activities with ongoing international efforts. European technical specifications for pre-analytical workflows influencing sample quality have been recently published (DIN CEN/TS). Comparative analysis and implementation of these specifications and other existing standards (DIN EN ISO 17025, DIN EN ISO 15189) will be the next step in the GBN work package in close cooperation with BBMRI.

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Feature

A day in the life of a Quality Manager

Jane Doe (25) works as a quality manager in the Biobank of Sample City, a large scale centralized biobank at a university hospital. Her duties include the definition of quality assurance procedures for the collection, processing and storage of biomaterials and insuring that personnel adhere to those procedures. Her day is taken up to a large degree by appointments and meetings as she is in continuous dialog with all of the biobank personnel and the clinics that supply samples. The quality management activities are in full swing at the moment as the successful certification of the biobank in summer 2016 is a considerable milestone for Ms. Doe.

08:00 Ms. Doe starts her day by preparing for her meetings.

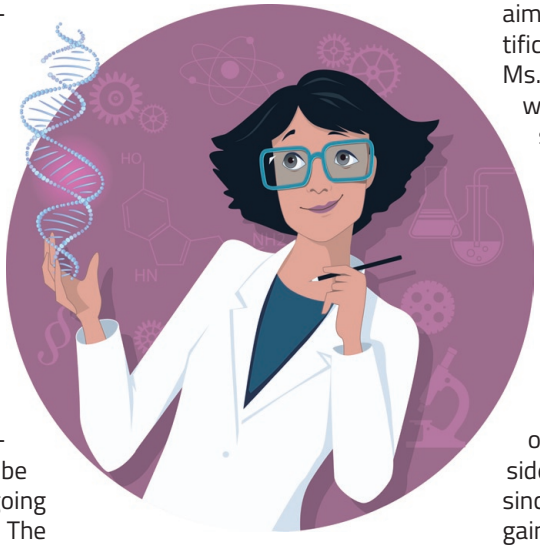
08:30 The first meeting is with the tissue laboratory personnel. Ms. Doe discusses how the samples are to be processed and stored in the central tissue bank. She reassures herself that the optimal solution is found for the processing and storage of the samples. Sub-processes are defined for study-specific tissue samples and for those that have been derived under the "broad consent" of the biobank. Each individual action of the process is recorded and documented. The discussions of procedures and recording of data are a major aspect of her work.

10:00 The next meeting is in the clinic, involving a discussion with the study team of a major research center. The topic of discussion is the documentation of the daily workflow and the smooth integration of the collection of liquid samples for the biobank into the routine procedures of the outpatient clinic. Liquid biosamples are also to be stored by the biobank for the ongoing studies of this research center. The baseline situation and aims of the procedures involved are defined and the procedures described. The documentation of the entire procedure is then stored in the biobank in a standardized format. The document must satisfy the requirements of DIN EN ISO 9001:2015, i.e., the document in the system must always be the latest version and must be accessible to all of the biobank personnel.

11:00 Ms. Doe discusses the preparation of a QM presentation for the steering committee with her boss, as well as the meeting of an external advisory board in which she will present the current status of the quality management system and how the future looks.

12:00 Lunchtime. The biobank team lunch together.

12:30 The next meeting starts. The members of the biobank management board meet personnel from the neuropathology department to discuss links to the biobank.



They discuss the current situation, the nature of the biological material to be collected (study specific versus broad consent) and the expectations of the clinic with regard to the biobank and the associated costs. The most effective way for the materials to reach the biobank is to be determined. Is it necessary for them to be stored in the clinic on a temporary basis? What are the costs of long-term storage? The processes are later discussed with personnel in the clinic in more detail so that the workflow does not impact the daily routines in the clinic to an unacceptable degree. A large number of factors have to be taken into account before a decision can be made on how to proceed. Ms. Doe will then inform all of the neuropathology department personnel on the agreed workflow and organize a training.

14:30 Ms. Doe drafts the minutes of the meeting. She prepares documents for the next day and sends out the agenda for the planned meeting.

15:15 The Biobank of Sample City is aiming for DIN EN ISO 9001:2015 certification by summer 2016. For this, Ms. Doe must briefly present the work of the biobank and then describe the scope of its activities and the expectations and evaluation criteria to the certifying company.
The successful certification of the biobank requires the presentation of a large number of different documents and discussion of management topics. An exchange of experience with other quality managers is of considerable assistance for this work since hardly any experience has been gained to date in the certification of centralized biobanks that span various faculties.

16:30 Ms. Doe discusses various matters with a colleague in another centralized biobank, who provides advice on the certification. Ms. Doe has some questions on the checklists. It is then time to go home, although her working day is not quite over yet.

22:30 Ms. Doe checks that her cell phone is sufficiently charged as she is on call this week in case there is some emergency in the biobank....

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International Standardization

Increased reliability of laboratory tests through pre-analytical standards

Inadequate attention has been paid to date to the quality of biospecimens for molecular tests in diagnostics and research. New European Standards have now been drafted with the assistance of Prof. Karl-Friedrich Becker of the Institute of Pathology of the Technical University of Munich and were published by the European Standards Body CEN last October (http://standards.cen.eu). These will contribute to more reliable results in laboratories in the future.

Millions of biological samples are investigated in laboratories around the world every day. The results of such analyses of just a few milliliters of blood or very small tissue samples will often have a substantial bearing on the further treatment of a patient. For example, tumor cells of certain types of cancer have increased quantities of protein molecules – so-called receptors – on their surface. These receptors modulate growth signals that enable the cancer cells to divide more rapidly. Some modern anti-cancer drugs inhibit those proteins and therefore slow down the spread of the disease. Such drugs may only be prescribed, however, if the receptors are shown to be present on the surface of the tumor cells of the tissue sample in very high quantities. Otherwise the drugs will not be effective. Some blood and/or tissue samples are stored in biobanks for analysis at a later date. Specimens stored in biobanks and the corresponding clinical data are used by researchers in academic and industrial labs to develop new medicines or improve diagnostic methods. There have been very considerable advances in analytical methods for molecular studies in recent years, bringing benefits for patients. The tests are now much more precise and less susceptible to external influences, with very few deviations. However, there is still room for improvement. As Prof. Karl-Friedrich Becker, Head of the Laboratory for Experimental Pathology, explains: "Although the advances in the molecular tests have been enormous in terms of their sensitivity, throughput, accuracy and reliability, the quality of the biological samples derived for testing, for example blood or tissue samples, has been neglected." There were no international standards covering the steps before the test itself – the pre-analytical phase. It is estimated that approximately 68% of the problems encountered in lab tests in hospitals are due to a failure to follow the correct pre-analytical procedures. In addition, many pre-clinical research results are not reproducible, leading to financial losses of billions of dollars. Experts are agreed that the quality of blood, tissue and other specimens for clinics and research laboratories can only be improved through the use of international standards. The researchers working in association with Prof. Becker have successfully integrated the results of their research into the standards.

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How are national and international standards developed?

Standards are drafted by subject experts on behalf of national standards bodies such as the German Institute for Standardization (DIN), the European CEN and CENELEC, and the International Organization for Standardization (ISO). The subject experts reach agreement on the wording of each standard, taking into account the latest technology and procedures. Prof. Becker is a member of the Medicine Working Committee NA 063-03-03 AA "Quality management in medical laboratories" of DIN. He is furthermore a member and project leader of the European Committee for Standardization (CEN) TC140 "In vitro diagnostic medical devices" and the Technical Committee TC212 "Clinical laboratory testing and in vitro diagnostic test systems" of ISO. The derivation of biospecimens for in vitro diagnostics and their storage in biobanks for use in academic and industrial labs is a complex process, requiring coordination of input from various sources, such as physicians, surgical staff, pathologists, lab personnel, biologists and IT specialists. The influence of the procedures to which the tissue is subject, such as its removal from the patient, transport, fixing and storage, on the integrity, stability and expression of biomarkers has been inadequately researched. Once the impact of sample derivation and preparation parameters on the outcome of biomarker determination are known, then such impact can be minimized, so that better biomarkers can be developed in future and more

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reliable results derived for the patients.

The Munich Leading-Edge Cluster m4

The Munich Leading-Edge Cluster m4 "Personalized Medicine" (www.m4.de) and the European SPIDIA project (www.spidia.eu) have collated experimental data to identify the critical steps of specimen derivation. Personnel carrying out tests in in vitro diagnostic labs or in clinical research labs at present do not generally know how a sample has been treated before it reaches them. The researchers working with Prof. Becker have demonstrated that analytes such as proteins and phosphoproteins can undergo changes before stabilization of the tissue samples. Not all proteins and phosphoproteins in every patient and in each organ studied react in the same way. These and other findings formed the basis for the drafting of the European Standards that have been published by CEN. These are of relevance to a number of parties, including in vitro labs, the customers of such labs, the developers and manufacturers of in vitro diagnostics, molecular pathology labs, organizations active in biomedical research, biobanks and the regulatory authorities. ISO has since declared the improvement of specimen quality to be a global aim. Prof. Becker is now the Project Leader for two out of eight ISO standards on pre-analysis that are scheduled for publication in 2017. Prof. Becker bears responsibility, together with others, in work package 3 for the drafting of the QM Manual that will be published in summer 2016 for the German Biobank Node.

With the kind permission of the university hospital Klinikum Rechts der Isar of Technische Universität München (TUM). This article first appeared in German in its December 2015 Newsletter.

BBMRI-ERIC

15 European countries join forces to improve the quality output of biobanks

BBMRI is focusing in 2016 on the improvement of the biobank Quality Management System (QMS) and especially on the quality of samples: To date, 69 technical experts and researchers from universities, biobanks and laboratory infrastructures of 15 Member States and the WHO International Agency for Cancer Research (WHO/IARC) are contributing to an unprecedented pan-European harmonization effort for biobanks. The aim is to achieve a higher quality output of the biobanks by improving the main procedures used for samples – their acquisition, receipt, labeling, tracking, access, processing, replication, storage, packaging, distribution and transport. All work is carried out in compliance with ethical, legal and societal requirements and in particular data protection requirements, taking measurement, analysis, quality control and risk management considerations into account.

Member states and observers of BBMRI-ERIC

Biological samples and associated data are of fundamental importance to the development of new approaches to therapy, new drugs or diagnostic assays and therefore decisive advances in health research, ultimately leading to personalized medicine and a better understanding of diseases in humans. Biobanks aim to provide samples of defined quality and associated data, as well as information for basic and applied research. The environment and lifestyle both impact on health and biobanks play an important role in the development of disease prevention programs and ultimately the improvement of public health.

The recently published CEN[2] Techni-

About BBMRI-ERIC

Seventeen Member States and one International Organization have joined forces in establishing BBMRI-ERIC, which, to date, is the largest research infrastructure for health in Europe[1]. BBMRI-ERIC serves as a platform for efficient communication between experts of the Member States and aims to support close collaboration and knowledge exchange to improve the quality output of biobanks and promote excellence in research based on high-quality specimens from humans. Germany - represented by the German Biobank Node (GBN) - is contributing to the European vision as a major partner within the European Research Infrastructure BBMRI-ERIC.

Further information:
European infrastructure BBMRI:
www.bbmri-eric.eu
German biobank network GBN:
www.bbmri.de

cal Specifications (CEN/TS), developed for 'Molecular in vitro diagnostic examinations - Specifications for pre-examination processes', as well as an appropriate QMS for biobanks, will be evaluated by 5 Expert Groups. In a joint intra-biobank and inter-biobank benchmark process, the primary focus is to encourage biobanks to (1) compare this CEN/TS to the biobank "in house" sample processing procedures (intra-biobank benchmark to CEN/TS) and to (2) motivate biobanks to adapt "in house" processes to the CEN/TS and additionally implement and/or improve general QMS to safeguard biobank processes.
In the course of working group meetings at monthly intervals, experts discuss the optimization and standardization of sample processing procedures as well as any deviation from the appropriate standards that might impact specimen integrity.

Key deliverables will be process descriptions (PD), standard operating procedures (SOPs) and appropriate auxiliaries for common use. The requirements of an appropriate QMS for biobanks will be drafted with the aim of developing and implementing an 'IT-based functional sample-characterization tool' (working title) for biobankers and associated partners. This tool will provide comprehensive details on sample processing. It will support the biobanks with descriptive and recording pre-examination processes from the donor stage through to storage, making data available for further use. This tool will help bring about the standardization of samples across all biobanks in the BBMRI-ERIC Member States.

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[1] BBMRI-ERIC: the novel gateway to biobanks, Michaela Th. Mayrhofer et. al Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz, 59(3), 379-384; DOI 10.1007/s00103-015-2301-8

[2] CEN European Committee for Standardization, cen.eu

BBMRI-ERIC

Common Service IT: Collaboration is a priority

The Biobanking and Biomolecular resources Research Infrastructure (BBMRI-ERIC) Common Service (CS) IT which officially started end of 2015 is already very active in the first quarter of 2016. All local development teams adopted Scrum as an interactive and incremental agile software development process. A process to scale Scrum up to large projects – Scrum of Scrums – has also been implemented. There is a weekly meeting, involving all work packages, in which the activities are summarized, previous activities are described, tasks set for the following week and any impediments described. Scrum has helped to improve teamwork and communications and has already enabled a swift start of the project.

Online platforms and tools speed up cooperation

Collaboration is a priority for BBMRI-ERIC CS-IT due to its large scale and the heterogeneity of the teams involved. Different processes have therefore been established to ease communication and speed up cooperation processes. Redmine – a project management web application – was installed, with a Scrum plugin. All partners are actively using it to manage tasks and track the project's development. Google Docs has been used intensively for easy and simultaneous editing of documents, discussion, reviews, commenting and tracking

of changes that involve partners in different locations. Stable document versions are then cataloged in the BBMRI intranet, where there are also wikis. Most meetings and webinars are held through Adobe Connect dedicated to BBMRI-ERIC CS-IT and partners have also individually arranged frequent meetings through other online platforms.

Good progress in all work packages

Directory (WP1, Directory) services are already under development. WP2 - Sample Locator is documenting the state of the art of sample finder information systems in collaboration with other work packages and refining the architecture of the Sample Locator, Connector, Negotiator and the integration with WP1 and WP8 (Tools for Collaboration). In the scope of WP3, the colon cancer metadata items collection is being defined and the final list of mandatory, recommended and optional items will be issued soon. BiBBix was installed in the CS.BBMRI.it infrastructure and a first development version is online, with demo data (WP4, Service for National Nodes). WP5 (Tools for Biobanks) is in the process of cataloging biobank tools and evaluating it. The use cases, requirements and overall user interaction are being developed in WP6, in collaboration with mainly WP1, 2 and 8. The main tasks of WP6 (User Requirements) are to update and support the CS-IT portal, optimize Redmine and install virtual machines. WP8 intervenients have been reviewing ontologies to develop the best approach for BBMRI.

Diogo Alexandre

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Publications

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Overview ISO and CEN standards
http://bbmri-eric.eu/standards
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* *Bundesgesundheitsblatt 2016 59(3) - Special issue on biobanks edited by Michael Hummel and Iris Pigeot. For more information see www.bbmri.de/bundesgesundheitsblatt*

For more information about the results and output of the GBN QM workshops please contact the GBN office: germanbiobanknode@charite.de

Forthcoming Events

ISBER 2016 Annual Meeting & Exhibits
Breaking down walls: Unifying Biobanking Communities to Secure our Sustainability
5 - 8 April 2016
Berlin/Germany
http://www.isber.org

BBMRI National Nodes Meeting
Quality matters: Improving the quality of biological resources
17 - 19 May 2016
Nice/France
http://www.biobanques.eu/fr/meeting-2016

100th Annual Meeting of the German Society of Pathology (DGP)
19 - 21 May 2016
Berlin/Germany
http://www.pathologie-kongress.com/

Europe Biobank Week 2016 (BBMRI / ESBB)
Biobanking for Health Innovation
13-16 September 2016
Vienna/Austria
http://europebiobankweek.eu/

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