Interview with Helmuth Haslacher, QM Coordinator of BBMRI.at

Helmuth Haslacher is resident physician of clinical chemistry and laboratory medicine and Deputy Biobank Coordinator at the Department of Laboratory Medicine of the Medical University of Vienna.

Since 2011, Helmuth has been Internal Auditor and quality representative for ISO 9000, ISO 15189 (Austrian Society for Good Analytic and Laboratory Practice) and since 2013, he is coordinating the QM activities of the Austrian National Node.

interviewed by Andrea Wutte

A: You are the QM Coordinator of BBMRI.at, which comprises a variety of different biobanks. How many biobanks work together in BBMRI.at?

Helmuth: In Austria, professional biobanking has a comparably short tradition. The national biobank landscape evolved during the last decade and is closely connected to the medical universities and their associated university hospitals. Moreover, the degree of organisation is quite variable.

Whereas the Medical Universities of Graz (Biobank Graz) and Vienna (MedUni Wien Biobank) as well as the University of Veterinary Medicine (VMV) run large-scale, centralised biobanking facilities, biobanks are developing through the merger of existing collections at the Medical Universities of Innsbruck and Salzburg.

Besides medical universities, BBMRI.at is complemented by the Life Science Governance Institute as well as the Alpe-Adria University of Klagenfurt, which provide valuable input regarding ELSI and data management issues respectively.

A: Can you please give us some insight on the core competences of these biobanks?

Helmuth: Due to the association of biobanks with university hospitals, most of the collections are disease-oriented. Because of the broad spectrum of diseases that are diagnosed and treated routinely at these large clinics, the biobanks as well manage a plethora of different disease-oriented collections ranging from different types of cancer, autoimmune diseases, internal medical diseases, mental disorders and transplantation studies to orphan diseases and even animal diseases. A high number of the collections have been processed under standardised conditions by facilities running a certified quality management system, which ensures sample integrity. Together, they comprise an indispensable resource for basic and clinical research.

A: You are establishing and coordinating a QM network at BBMRI.at. How do you proceed and why do you think this effort will be beneficial for each individual biobank?

Helmuth: The main goal of BBMRI.at as regards to quality is to establish and maintain quality management systems (QM-systems) at those sites, where it has not already been done and to harmonise the

systems. Since we are talking about international quality management standards, it would be highly preferable to harmonise on a European level from the very beginning. Otherwise, we would reinvent the wheel for each national hub separately.

In Austria, each participant's QM-system is managed by so-called local QM-coordinators. They have been nominated by the respective consortium partners and have received special training as QM-system auditors. This could establish a culture of reciprocal quality audits. Personally, I am very excited that different academic facilities provide mutual transparency and therewith support each other in improving their QM-systems.

Another important issue concerns applicable legal regulations and guidelines for biobanks, which will be addressed in close connection with our partners from the Life-Science-Governance-Institute. In Austria, we have the somehow difficult situation that the term "biobank" is not mentioned in any legal text. Hence, it is crucial to collect and interpret all existing regulations that concern the practice of biobanking and biobanks might be subject to.

A: What is, in your opinion, an "adequate QMS" for biobanks? What are the standards that BBMRI.at adhere to?

Helmuth: In Austria, we decided to establish, maintain, and evolve quality management systems according to the classic QM-standard ISO 9001, for the simple reason that there is no biobank-specific standard yet. In compliance with ISO 9001, a QM-system requires a top management level that is responsible for the system. However, the participating institutions of the National Node themselves bear full responsibility for all processes that take place at their biobanks.

In the long run, it would - of course - help to improve the quality of samples and comparability of results if specific work flows could be accredited. Currently, however, there is no international accreditation standard for specific pre-analytical workflows in biobanks. This could be a visionary project for the future and BBMRI-ERIC could provide valuable input.

A: The "Sample Management from Donor to Storage" is one of the daily businesses for biobankers. CEN on the European level and ISO on the international level are now developing standards for pre-analytical sample processes. How will you incorporate these norms in BBMRI.at?

Helmuth: These ISO and CEN norms are very good initiatives, since we all know that the main part of uncertainty produced within the analytical process is caused by pre-analytical variability. In biobanks, the pre-analytical phase is greatly extended, since most of the samples have been stored for at least several years before they are further analysed. Of course, we will not be able to avoid all pre-analytical errors, but we can minimise them through "standardisation".

Nevertheless, it is extremely important that new recommendations are based on a high level of evidence. Only then it can be ensured that we intervene at the right spots in order to improve the quality of the analytical results gained from our samples.

At present, Austrian biobanks apprehend their status quo regarding different pre-analytical workflows. Once the technical specifications will be published, we will be able to match them with our current procedures. Subsequently, the harmonisation of workflows can be done in a joint effort.

A: Next level - Europe! Please tell us your thoughts about "cross boarder biobanking" in Europe.

Helmuth: I am very confident about the future! A functioning, transnational network of biobanks could be very useful for both basic and translational research. Of course, there is still a long way to go. Especially as central issues such as the compliance with national laws in the framework of cross-border collaborations still have to be addressed in a better way.

Moreover, we should aim to avoid a multiplication of efforts. Especially in connection with quality management and standardisation of pre-analytical workflows, decisions should be made on the European level. Otherwise, we risk getting caught up in something that I would call a "never-ending harmonisation loop". Harmonised procedures on an institutional level have to be dismantled to harmonise procedures on the national level, which in turn have to be adapted for the harmonisation on transnational level and so on… Thus, BBMRI-ERIC has an important role to play in coordinating the activities of the National Nodes that concern cross-border biobanking issues. If we approach those issues wisely, I am confident that we can significantly improve medical research.

Dear Helmuth, thank you for this interview and congratulations to this dedicated joint effort of BBMRI.at of constantly improving quality in your biobanks!

FACTS of BBMRI.at

National Node		**BBMRI.at**
National Node Director		**Univ. Prof. Dr. Kurt Zatloukal**
QM Coordinator, BBMRI.at		**Mag. rer. nat. Dr. med. univ. Helmuth Haslacher, BSc BA**
QM Coordinator, local	**10**	**Legend of group picture**
Number of biobanks	**4**	**Medical University of Graz, Biobank Graz (MUG)** **Medical University of Vienna, Biobank Vienna (MUV)** **University of Veterinary Medicine, Vienna (VMV)** **Medical University of Innsbruck (MUI)**
Partners		**Alpen Adria University Klagenfurt (AAU)** **Life Science Governance Institute, Vienna** **Paracelsus Medical University, Salzburg (PMU)**
Type of biobanks		**disease oriented**
Catalogue	**available**	**http://bbmri.at/catalog**
Number of certifications	**3**	**ISO 9001 (MUG, MUV, MUI)**
Number of certification in progress	**1**	**ISO 9001 (VMV)**
Number of accreditation of associated medical laboratories	**1**	**ISO 15189 (MUV)**

QM Coordinator, local

From upper left to bottom right: Elisabeth Pechriggl (MUI), Christian Freyschlag (MUI), Monika Wieser (VMV), Lyudmyla Kedenko (PMU), Cornelia Stumptner (MUG), Christian Schweiger (Trainer), Skaiste Riegler (MUG), Michael Hubmann (Trainer), Michaela Bayer (MUG), Melanie Korb (VMU), Helmuth Haslacher (MUV), Horst Pichler (AAU)