GxP at the Zurich location - spotlight

On November 14th, 2019, part of the 10th annual CABMM Symposium held at the animal hospital of the University of Zurich was dedicated to presenting the GxP competence at the Zurich location followed by a panel discussion about translational medicine grouping experts in GLP, GMP, GCP, academia and industry.

Prof. Simon Hoerstrup, chairman of the CABMM Steering Committee and co-founder of the CABMM, opened the session, highlighting that translation was built into the DNA of the CABMM, which was originally designed to bring people together from different disciplines and skills for translating a science idea into a therapy, treatment or product. He then presented the Wyss Zurich model: translating science into life, which focuses on regenerative medicine and robotic technologies to bridge the 'valley of death'. He highlighted the successful collaboration with the Vetsuisse Faculty Zurich, bringing a promising invention or idea from the bench in a proof of concept in living animals. He stressed the importance of securing intellectual property rights, despite skepticism among researchers. Prof. Hoerstrup then described how Wyss Zurich was designed to fund the delicate phase in bringing a successful pre-clinical proof of concept to first in man clinical trials, thereby having a positive impact on technologies and on the whole ecosystem.

The following talk was given by Dr. Martin Kayser from Wyss Zurich. He presented Good Manufacturing Practice (GMP) and the challenges it poses for academic institutions, particularly with the missing regulatory knowledge, lack of funding, no access to GMP infrastructure, high risk of failure and the different mindset required. He highlighted that GMP ensures safe and efficacious products and is essential to bring treatments to the clinic. Dr. Kayser presented the Wyss Zurich regenerative medicine technology platform, its infrastructure, knowledge, qualified equipment, biobank infrastructure and quality management system as well as what was required to run and maintain a facility licensed to produce investigational drugs, biologics and cellular products.

Dr. Regina Grossmann from the Clinical Trials Center of the University Hospital Zurich presented Good Clinical Practice (GCP) and the highly regulated clinical research field. She summarized the purpose of GCP in safeguarding rights, security and well-being of study participants as well as ensuring the validity and quality of data in compliance with the Helsinki Declaration. She also presented the Clinical Trials Center (CTC) and its role in supporting the planning and conducting of clinical research projects, highlighting its ISO9001.2015 certification, its regulatory affairs unit, monitoring team, data management team, clinical research ward, quality management team, as well as training and education team.

Prof. Dr. Brigitte von Rechenberg from the Musculoskeletal Research Unit (MSRU) of the Vetsuisse Faculty Zurich then presented the importance of Good Laboratory Practice (GLP) and its link with animal welfare and ethics. She highlighted the importance of considering regulatory requirements early on in the development of a technology and the importance of planning research and building evidence accordingly. She then emphasized the connection between the Reduce, Replace, Refine (3R) guidelines and GLP, a connection that has been a guiding principle at the GLP accredited Musculoskeletal Research Unit. Indeed, performing pre-clinical *in vivo* studies in compliance with GLP is in alignment with reducing animal numbers, and refining study designs by performing preliminary tests, while ensuring thorough documentation and data collection, thereby maximizing the value of in vivo pre-clinical data.

Finally, Mr. Beat Lechmann from DePuy Synthes (Johnson and Johnson Family of Companies) gave a presentation about the translation from proof of concept to market access in the medical device sector. He presented innovation as a closed loop, starting from an invention, then a proof of concept, design, review, feasibility, implementation, clinical outcome, clinical evaluation pre- or post-market and the feedback loop which allows to refine the process. He also emphasized the importance of building an evidence plan in accordance with the medical device regulation (MDR), highlighting the MDR's tight regulation and requirement of conformity assessments, discussion with notified bodies, registration and CE marking as well as the necessity for vigilance and post-market follow up. Mr. Lechmann underscored the importance of systematic and reproducible evidence collection as well as the importance of GLP, GMP and GCP in producing systematically elaborated data as opposed to anecdotal evidence.

The GxP session was followed by a panel discussion of all speakers. Prof. Hoerstrup highlighted the unique situation in Zurich with the presence of GLP, GMP and GCP. Prof. von Rechenberg spoke of the challenges in building the required facilities and ensuring compliance, particularly with limited funding. She highlighted how, now that these accredited facilities are up and running, they provide a great asset for translation and praised the unique situation in Switzerland, where collaborations between industry and academia are fostered through funding instruments such as Innosuisse. Dr. Grossmann emphasized the difficult challenge to raise awareness, particularly in streamlining evidence collection. She further highlighted that the mission of the Clinical Trials Center should go beyond ensuring GCP by activating collaborations and communicating that standards of data collection must be set and met when research projects are designed. Dr. Kayser emphasized the importance of communication between the GLP, GMP and GCP facilities in Zurich to provide researchers with necessary resources and raise awareness. Mr. Lechmann highlighted the challenge when confronted by the academic setup. With external innovation, he underscored that Zurich has an excellent situation. He highlighted the importance of building and fostering partnerships as well as the importance of systematic and structured data collection. The panel highlighted the importance of education into the requirements of clinical translation, including entrepreneurial skills and how to build a spin off. Prof. Hoerstrup emphasized the increased value of innovations at the University of Zurich because of the existing GxP chain. Underscoring the importance of transparency to avoid conflicts of interest, he then closed the panel discussion.