

BBMRI.QM Academy – Live Educational Webinar

Validation and verification of processing methods and biobanking

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Programme	Thursday, June 1, 2023
	Host: Prof. Jens K. Habermann, M.D., Ph.D., Moderator: Andrea Wutte, MSc
13:00-14:15 CEST	Validation and verification of processing methods and biobanking,
	Discussion, Q&A
	Speaker: Dr. Fay Betsou
General description, scope and objectives:	

Key expert Dr. Fay Betsou will present processing methods in biology laboratories. Processing methods are being applied in research laboratories, biobank laboratories or technological platform laboratories. Validation of such methods is an important undertaking to ensure the fitness for purpose of the biological specimens that are the output of these methods. This course will explain the concept of a processing method, and of its validation or verification. It will go through different approaches that can be followed, the steps that can be taken, the statistical tools and the acceptance criteria to perform method validation, as well as the required documentation. The concept of exploratory methods will also be approached and the risks that are concomitant to a non-validated processing method will be illustrated with different examples. The course will largely follow the recommendations of the international Standard ISO21899:2020 but will present application of the concepts to concrete laboratory situations.

This webinar is designed for managers and associates of biobanks, laboratories and quality departments, as well as medical doctors and researchers, pathologists, but also for anyone wishing to update their scientific knowledge on the topic.

After watching the webinar, participants will be able to:

- o To define a processing method
- o To design a validation or verification plan
- o To explain the need for method validation to partners and colleagues
- o To apply statistical tools for method validation
- o To define the fitness for purpose
- o To decide when revalidation is needed
- o To recognize critical preanalytical variables
- o To design internal and external quality control for method validation
- o To find relevant international standards

During the webinar, participants will be encouraged to send questions via chat and to interact with the key speaker who will provide live feedback.

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