Quality control and standardization in flow cytometry – requirements of GLP, GMP, ISO, and clinical studies

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Flow cytometric methods are well established in patients' diagnostics, process control, and even preparation of cellular therapeutics. Every of these topics are subject to regulatory systems that are as far as possible harmonized in the European community. By growing implementation of ISO 15189 based standardization in European laboratory diagnostics, flow cytometric labs are more and more challenged to introduce compliant quality management systems. Although in most countries accreditation of such laboratories is not yet compulsory, proof of following these rules is widely requested. In contrast, implementation of such systems in preclinical and clinical studies is well established; quality control in transfusion medicine and ATMP manufacturing is daily practice. In general, adherence to quality management systems is considered to be very hard for cytometry. Therefore, we analyzed consequences of accreditation process for cytometric labs and investigated flow cytometrists' attitudes and misgivings according these requirements. As major challenges, staff qualification, adaptation of multicolor antibody panels, and quality assessment has been identified.