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Quality management and accreditation in a mixed research and clinical analytical laboratory setting

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Abstract

Quality management and accreditation in the analytical laboratory setting is developing rapidly and becoming the standard worldwide. Quality management refers to all the activities used by organizations to ensure product or service consistency. Accreditation is a formal recognition by an authoritative regulatory body that a laboratory is competent to perform examinations and report results. The Motherisk Drug Testing Laboratory is licensed to operate at the Hospital for Sick Children in Toronto, Ontario. The laboratory performs toxicology tests of hair and meconium samples for research and clinical purposes. Most of the samples are involved in chain of custody cases. Establishing a quality management system and achieving accreditation became mandatory by legislation for all Ontario clinical laboratories since 2003. The Ontario Laboratory Accreditation program is based on *ISO 15189 - Medical laboratories - Particular requirements for quality and competence*, an international standard that has been adopted as a national standard in Canada. Implementation of a quality management system involves management commitment, planning and staff education, documentation of the system, validation of processes, and assessment against the requirements. Maintenance of a quality management system requires control and monitoring of the laboratory entire path of workflow. The process of transformation of a research/clinical laboratory into an accredited laboratory, as well as the benefits of maintaining an effective quality management system will be presented.

Biography

Netta Fulga has completed her MSc. in biochemistry from the Hebrew University in Jerusalem. She was a team leader at the R&D division of Bio-Technology General (Israel) Ltd. (Ferring group), a biopharmaceutical company with approved products in Israel, USA, and the European Union. Netta has written and designed CMC, SOP and validation protocols for pharmaceutical drugs according to international regulatory guidelines. Currently, Netta is a Quality Manager at the Motherisk Laboratory at the Hospital for Sick Children, Toronto Canada. She has completed the establishment of a Quality Management System in the clinical lab and led to a successful achievement of Ontario Laboratory Accreditation.