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## QUALITY MANAGEMENT & TRACEABILITY IN TISSUE BANKING

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### SUMMARY

A tissue bank must implement a Quality Management System (QMS). A systematic approach to quality management should be implemented and maintained throughout the entire process, from the identification of a potential donor through processing and storage of the tissues to the final preparation for clinical application. There are various standards and guidelines to be considered as a tool to assist tissue banks to implement and operate QMS. The general aspects of Quality Management include personnel and organization, premises, equipment and materials, documentation and record keeping, quality control, traceability, quality risk management etc. Traceability process from donor to recipient and the materials, reagents and equipment that come into contact with tissues is fundamental to recipient safety. Traceability is essential to ensure successful tracking and rapid action to prevent harm, when links in the safety and quality chain are found to have been compromised. Quality and traceability is the responsibility of all personnel involved in the process of providing tissues for transplantation. Universiti Sains Malaysia (USM) Tissue Bank engages in services involving tissue from living and deceased individuals for transplantation purposes. These services include assessing donor suitability, tissue recovery, tissue processing, storage, labelling and distribution. It is also responsible for sterilization and testing of tissues. USM Tissue Bank is currently certified compliance to ISO 13485:2016, MS 1900:2014 and ISO 9001:2015. The presentation will highlight the challenges of implementing QMS and traceability in USM Tissue Bank.