2<sup>nd</sup> Annual Summit on

## STEM CELL RESEARCH, CELL & GENE THERAPY & CELL THERAPY, TISSUE SCIENCE AND REGENERATIVE MEDICINE &

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## TISSUE PRESERVATION, LIFE CARE AND BIOBANKING

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## Quality indicators as a measure of good practice at the National Biobank in South Africa

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The National Health Laboratory Service (NHLS) Biobank is within the National Institute for Occupational Health (NIOH) which has been accredited for ISO: 15189; 17020; 17025 by the South African National Accreditation System (SANAS). Furthermore, there is adherence to ISBER's Best Practices for Biorepositories as well as compliance with the National Health Act 61 of 2003 which provides a framework for a structured uniform health system within the Republic of South Africa. The model of the NHLS Biobank is designed to manage and secure biomaterial collections and storage as well as the associated data for research purposes both in the short-term as well as long-term. The Biobank encompasses multiple components of biospecimen for cancer, cell culture, genetics, molecular biology and for non-communicable diseases. The storage capacity is large scale for internal NHLS and external clients, can store over a million specimens with additional infrastructure recently created with an additional capacity of four million samples. All stages of the quality cycle, as part of the Quality System Essentials (QSEs), are continually being assessed, namely; equipment, facilities, and safety, organization and personnel, purchasing and inventory, documents and records, information management, corrective action, occurrence management. These QSEs grouped into 3 categories; resource management, process management as well as improved management form quality indicators and ensure maintenance of QMS. The biomaterial data tracking system is through specialized software and Biobank Information Management System (BIMS). To date, a substantial amount of resources and time has been invested in continued personal development in ensuring that quality standards are maintained. Future plans of the NHLS Biobank include implementation of the ISO 9001:2015 standard, ISO/TC 276, enhanced networks and stakeholder involvement as well as continued technical improvements on pre-analytical specimen factors which ultimately impact on specimen quality. These future plans tie- in with maintaining quality within the NHLS Biobank.

## **Biography**

Bonginkosi Duma has expertise in Quality and Biobanking and is passionate about innovation and getting solutions to cure diseases. Concerned about health and wishing to improve the health and wellbeing of South Africans and make a lasting impact on people around the world. As a Biobank Manager, he manages one of the largest biobanks in South Africa and is also a Quality Assurance Manager and auditor for South African National Accreditation Systems (SANAS) body for South Africa. He is a member of ISBER and sits on the committee for standards and also the ESBB working group on training. He also serves as a vice chairperson of the WHO BCNET committee based in IARC in France.

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