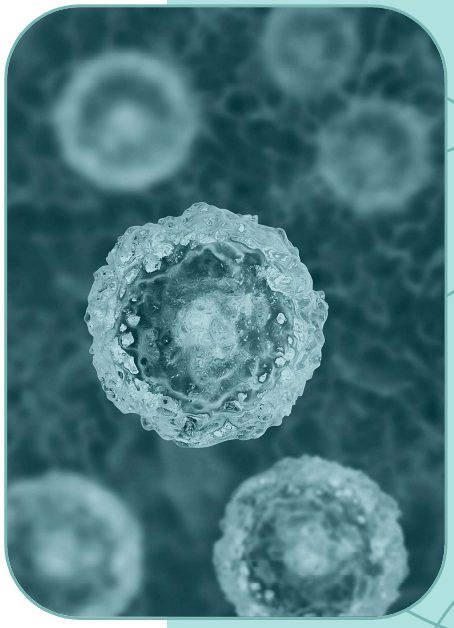
Quality Considerations in Cell Banks

Minda Chiang



Hong Kong Society for Quality

not-for-profit organization, formed in 1986

to be a Hub in Hong Kong and the Region for learning and sharing of knowledge in Quality, Innovation and Best Practices, as well as for facilitating development of a Quality and Innovation Culture

to promote greater awareness of quality evolution in Hong Kong and the Region for ensuring product and service excellence through continuous improvement of quality and customer satisfaction, and to provide continuing education to professionals involved in the quality, reliability and innovation disciplines

Minda CHIANG

a Certified GMP Professional in pharmaceutical manufacturing operations, with specialization in quality assurance of sterile drug manufacturing and cell banking in a GMP environment

significant experience in leading for initial certification for GMP, AABB and FACT standards, and continuous improvement

developed and conducted training and education extensively on quality subjects and GMP requirements

the first woman in Hong Kong elected fellow membership in ASQ & HKSQ

human cells, tissues, and cellular and tissue-based products (HCT/Ps)

- articles containing human cells or tissues that are intended for transplantation, infusion, or transfer into a human recipient, e.g., bone, skin, heart valve, cornea, hematopoietic progenitor cells (HPC) derived from bone marrow, peripheral blood and cord blood

Glossary

manufacture

- means, but is not limited to, any or all steps in
  - recovery,
  - processing,
  - packaging,
  - labeling,
  - storage,
  - distribution of any human cell or tissue,
  - testing of cell or tissue products
- can also include screening/ testing of donor
- not include procurement

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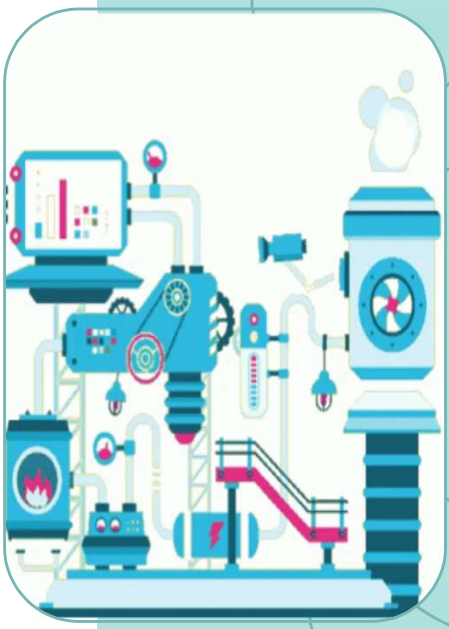
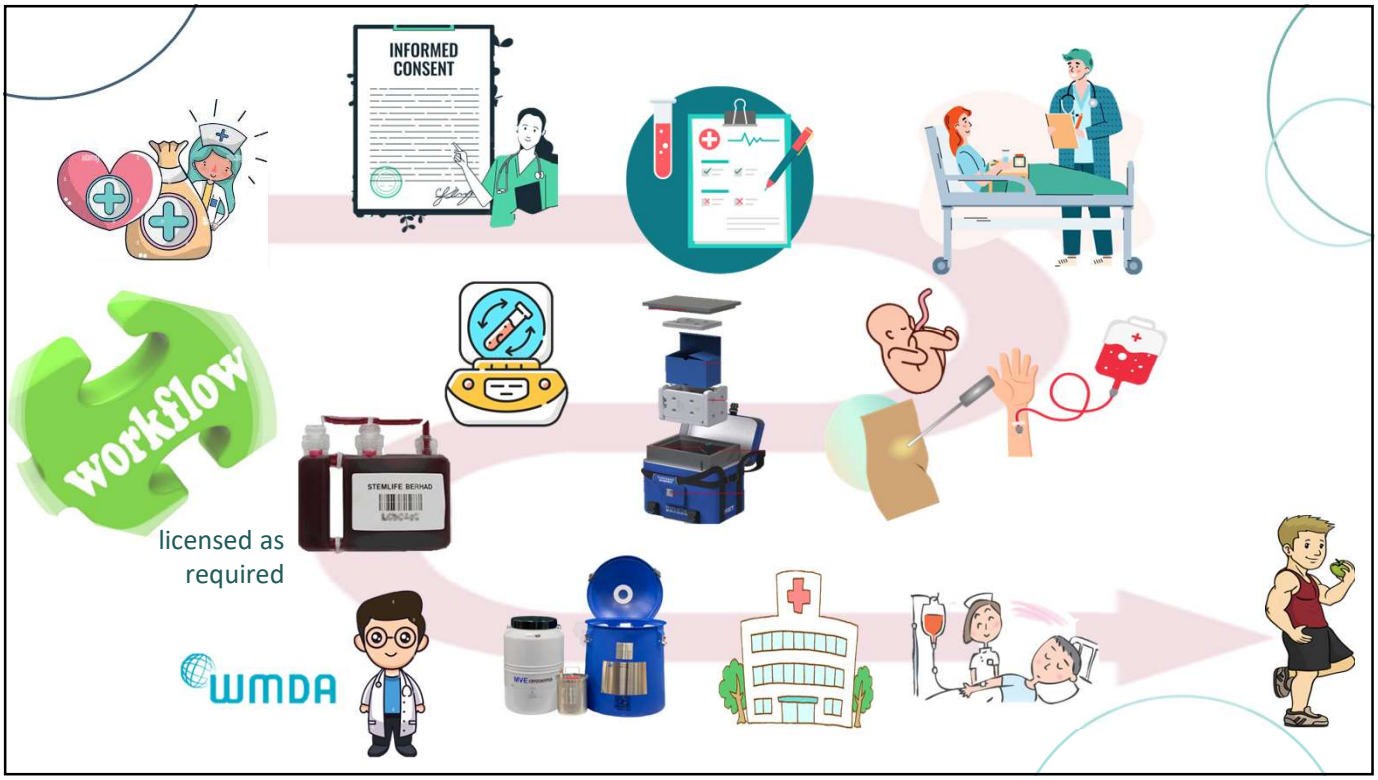
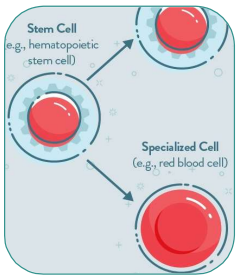
Operational Flow & Critical Controls

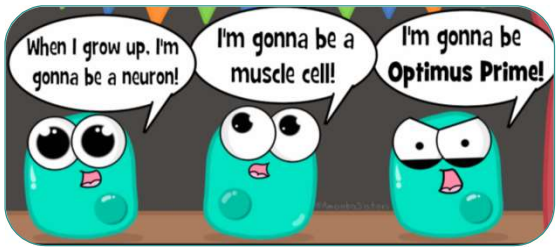


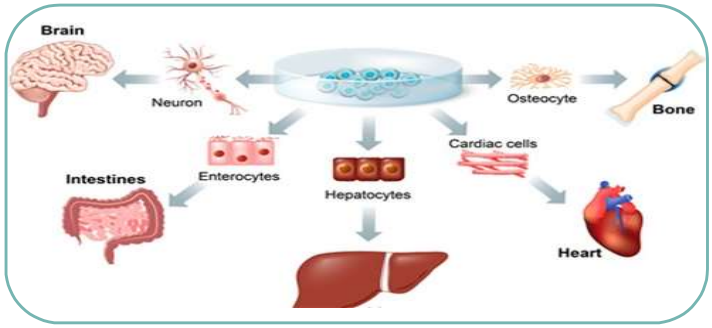


Cellular Therapy Products

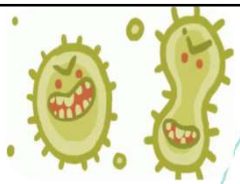


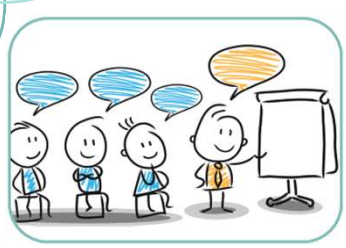
- derived from human cells or tissues
- contain living human cells and intended for use in patient treatment





Critical Control





Personnel

- donor
- collector
- cell bank staff
- treatment physician

Process Control

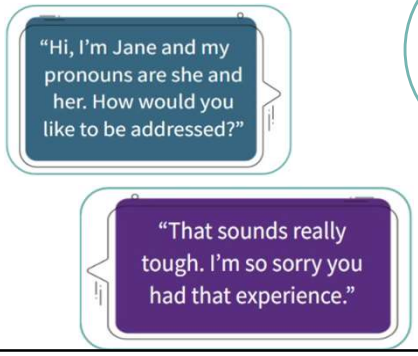
- labeling system
- process validation
- environmental monitoring
- cryopreservation
- cryo-storage

Quality Control

- donor test
- incoming material review
- in process test
- product test after production & before release

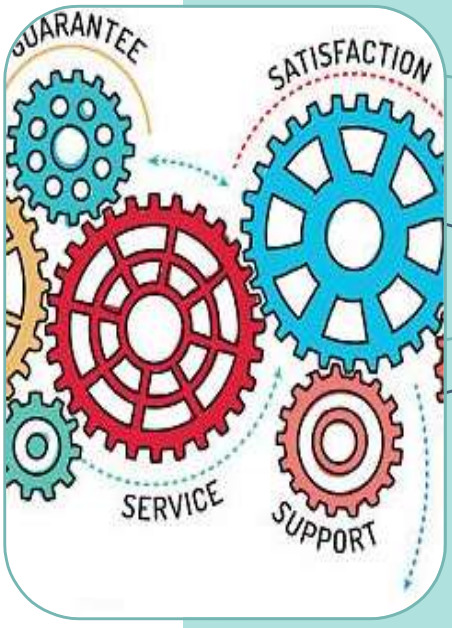
Critical Control

- training for collecting health questionnaire accurately
  - to maintain goodwill and trust & to ensure **blood/ tissue safety**
    - ➢ demonstrate welcome, appreciate, respect and sex-positivity



02

Quality Assurance



Accreditation Programs
GMP, AABB, AATB, FACT, ISO 15189, ISO 20387, CAP

PIC/S

Association for the Advancement of Blood & Biotherapies

FACT FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY

AATB American Association of Tissue Banks

ISO 15189

COLLEGE of AMERICAN PATHOLOGISTS

- purification
- fermentation
- culture
- formulation
- aseptic operations
- filling
- storage
- distribution

PIC/S

ISO 15189

COLLEGE of AMERICAN PATHOLOGISTS

Association for the Advancement of Blood & Biotherapies

FACT
FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY

AATB

- traceability
- confidentiality

Release of Protected Information

- reason of the request
- whom (name, address and contact) the information be released to
- type of information to be released
- identity of information (name & identity of donor/ patient)
- approval of Medical Director for release of protected information
- when and what information released; who released
- when and who received the information

- traceability
- confidentiality
- risk assessment
- donor eligibility
  - autologous use
  - related allogeneic use
  - unrelated allogeneic use

Glossary

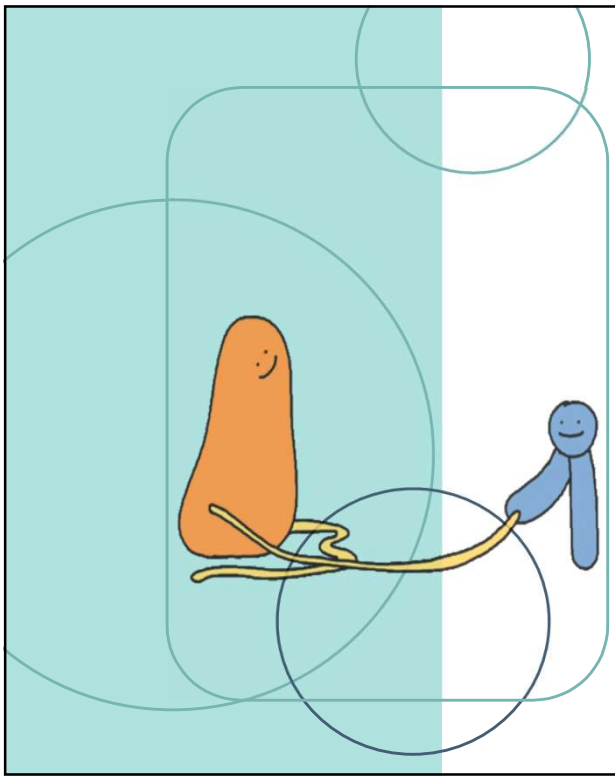
autologous use (related use)

- cells or tissues removed from and applied to the same person

allogeneic use (related/ unrelated use)

- cells/ tissues removed from one person and applied to another who may/ may not be genetically related to the donor

- traceability
- confidentiality
- risk assessment
- donor eligibility
  - autologous use
  - related allogeneic use
  - unrelated allogeneic use
- outcomes data
- validation – target results achieved

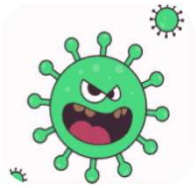


03

Challenges in Cell Banks

Challenges

- regulations
- infectious disease panels
- experienced people
- novel technologies
- complex training and assessment
- variance in living materials
- medical history of donor
- reagents and standards
- contamination



Challenge

- processing facility
- outsourced activities
- validation
- release time for cell products
- expiration date
- outcome data
- outcome data analysis, especially for dual unit administration

04

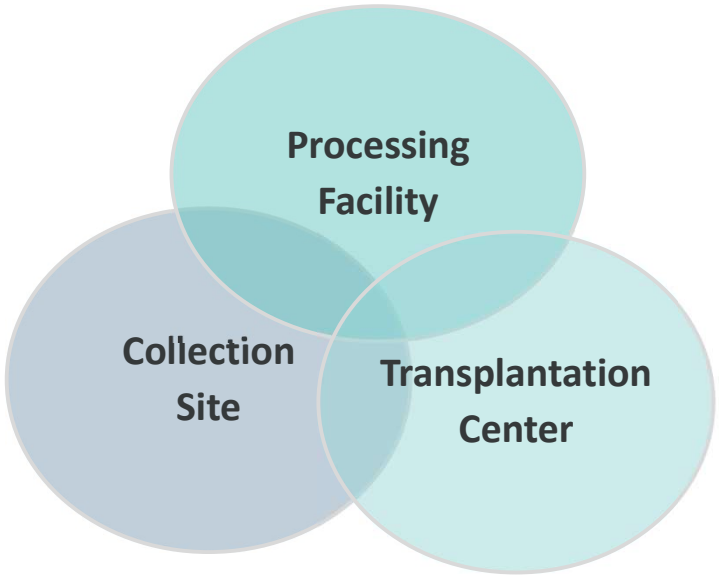
Enablers

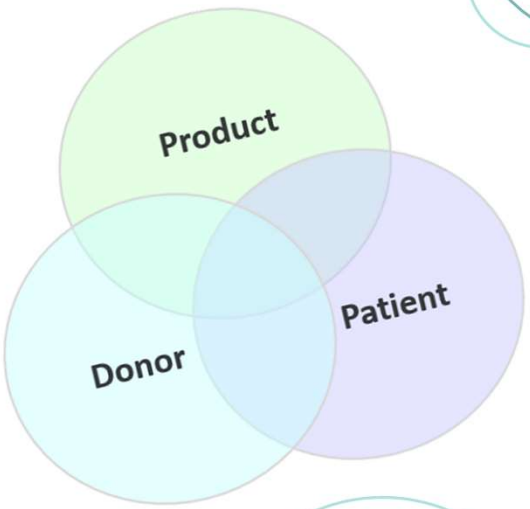
香 港 品 質 學 會
Hong Kong Society for Quality

Workshop on QMS in Cell Banks

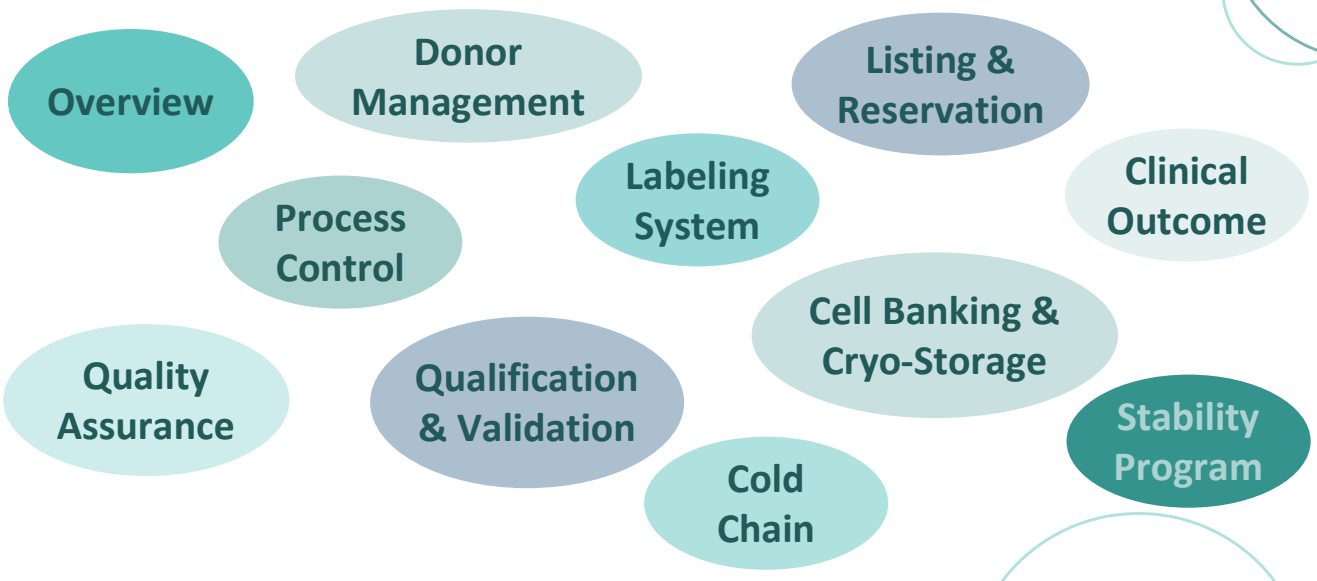
- ensure all operations are performed in a consistent manner in order to ensure
  - the quality, safety, and potency of units collected, and products banked, stored, and released for clinical use

Workshop on QMS in Cell Banks

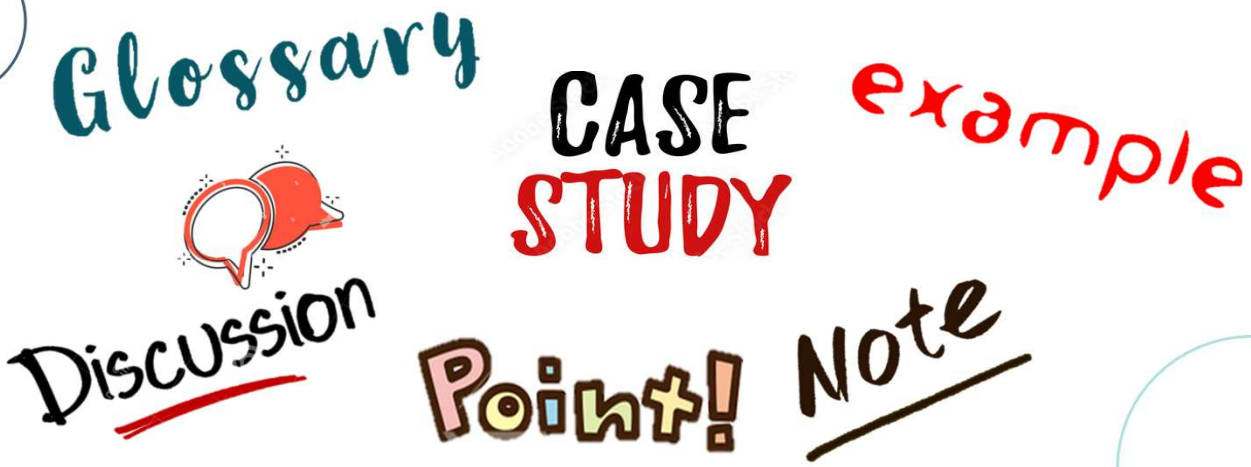




Workshop on QMS in Cell Banks



Workshop on QMS in Cell Banks



Workshop on QMS in Cell Banks

- to introduce quality system of cell bank for collecting, manufacturing, storing and releasing human cells, tissues, and cellular and tissue-based products (HCT/P's)
- to understand the evaluation of donor-eligibility
- to explore the measures taken to produce safe and high quality of HCT/P's

january 2024

Attention

a drug shall be deemed **adulterated** if

the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do **not conform** to or are **not operated** or **administered** in conformity with **current good manufacturing practice** to assure the **safety**, **identity**, **quality**, **purity** and **strength**

Thank You