

# *Quality – It's In Our Blood!*



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# *Program*



- **Mission**
- **Introduction to the Quality Program at United Blood Services**
- **Video**
- **Questions**

## *Mission*



**United Blood Services exists to make  
a difference in people's lives by  
bringing together the best people,  
inspiring individuals to donate blood,  
producing a safe and ample blood  
supply, advancing cutting-edge  
research and embracing  
*continuous quality improvement***

# *Quality Program*



- **Management commitment to quality**
- **Quality Staff**
- **Control**
- **Personnel & Training**
- **Quality Processes**

# ***It Starts at the Top!***



## **Management is Committed to Quality**

- **All management staff members are role models for quality!**
- **Compliance is a priority!**
- **Supports quality initiatives**
- **Provides opportunities for staff professional growth**

# *Quality Staff*



- **UBS Centers and Corporate Office**
- **Internal consultants**
- **Audits**
- **External Inspections**
- **Licensure – Regulatory**
- **Deviation Management**

# *Control*



- **Processes and Production**
  - **Standard Operating Procedures**
- **Equipment and Materials**
  - **Storage and tracking of critical materials**
  - **Equipment maintenance and QC**
  - **Supplier Qualification**

# **Control** *(Cont'd)*



- **Non Conforming Product Control**
  - Identification
  - Quarantine
  - Retrieval & Notification
- **Deviation Management**
  - Identification
  - Reporting
  - Root Cause

# *Personnel & Training*



- **Educational Background**
- **Training**
  - **Initial training**
  - **Continuing Education**
  - **Other training opportunities**
  - **Management development**
- **Competency**

# *Quality Processes = Quality Products*



- **Donor Screening/Phlebotomy**
  - Comprehensive medical screening
  - Personal health history
  - Sterile techniques
  - Assignment of unique tracking number
- **Processing**
  - Manufactured according to cGMP
  - Traceability and Trackability!
  - Quality Control

# *Processes*



- **Testing**
  - **FDA required testing**
    - **Viral markers – HIV, Hepatitis B & C**
    - **ABO and RH**
    - **Quality control testing**
- **Labeling**
  - **Automated labeling system**
  - **Controlled, quiet area**

# *Processes*



- **Storage**
  - Storage areas carefully monitored
  - Back up storage facilities
  - Automated and computerized monitoring
- **Distribution**
  - Careful inspection
  - Validated shipping containers
  - Traceability and trackability!

*Questions?*

