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EATB-Q-M-001

Organigram that clarifies what the structure of the bank is and the relationship of

Change Control

Deviation etc. DISC

Document control

Validation and Verification

Risk assessment

Product recall

Quality Review

Where do you have:

Product Review –dealt with Quality Review

Validation Plan – VMP

RECALL

There was one product recall

“Ocular Tissue”

Initial notification

Pathology- testing lab notified of a cornea positive

DISC-17/6-48

Notification by from the pathology lab that there was microbial contamination in the OCT media 27/04/2017

“ OCT” showed contamination for Candida

Two corneas pre-cut affected

Notified the surgeons of the recipients 24/5/17

Grafts were removed- TGA notified an

urgent recall was sent

26 April evidence of

-sighted- both

Investigation

Incident report –same number DISC

Review of the Donor History

1) Contamination by operator What do you do to sample during processing media + where are the cabinet locations!
2) Contamination when sampling – no recall
3) Contamination of the transport media antimycotics were *below* the standard therapeutic level
   There is no validated assay
4) Contamination by mechanical action

---------->Two more patients meet the correct negative culture

3 other donors

DNA sequencing----------> E

3 more recipients

On same day of the original MC

contamination

Only one related

3 Cornea all pre-cut - and no al cornea ocular T

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4th infection was before the presentation

Last infection presented 11 days' after

After their prepared *unreadable*

Same day of the original contamination

Same as the other

PCR performed

2nd *unreadable* Sept 2017

Review the next report

One recommendation is to spell out that the assessment of causality has to be done by the Medical Director

Not clear in the corrective actions that this is the case

Will look at this

1 hour break for lunch