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Troubleshooting the recover of mater cell bank for a commerical product

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TROUBLESHOOTING THE RECOVER OF MASTER CELL BANK FOR A COMMERICAL PRODUCT

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Key Words: Recoverability, Master Cell Bank, Commercial Manufacturing

Poor recoverability was observed for the Master Cell Bank (MCB) during the preparation of Working Cell Bank for a commercial product. The presentation will describe the investigation process, root causes identified and corrective actions implemented. A new Working Cell Bank was successfully manufactured after implementing the corrective actions. Our strategy to test the WCB prior to commercial manufacturing will also be discussed. In addition, preventative actions were also implemented as a result of the event.