Case Study

CMO's Cannot Produce SP2/0 Working Cell Bank: Cytovance® Identifies Problem and Successfully Produces Working Cell Bank

Benefits of the Case:

- A viable Working Cell Bank (WCB) that thaws with good viability and demonstrated logarithmic growth necessary for expansion
- Further Characterization of Cell Line

Background and Challenge:

- The client had purchased a Master Cell Bank that had been manufactured in 1999.
- The client is able to grow cells successfully in the R&D laboratory.
- The client transferred vials of MCB to a well-known CMO to manufacture a WCB
- The CMO failed several times to successfully manufacture a WCB
- Poor viability and no growth

Strategy:

- Cytovance® to perform tech transfer utilizing data from Client R&D and CMO
- Cytovance® to manufacture Engineering lot using tech transfer parameters from R&D to demonstrate transfer

Engineering Run data:

- The MCB thawed with a good viability and had adequate growth to scale-up to achieve cell numbers to lay down 350 vial WCB

- Post Freeze Testing of the engineering run showed good viability at thaw, but viability declined and growth was not achieved.
- The beginning, middle, and end of bank was tested with the same results
- Filling process run at room temperature and cells were exposed to DMSO for 60 minutes
- Cryogenic freeze profile utilized forced nucleation

Development Strategy:

- Using MCB utilize Manufacturing and Process Development technicians to study DMSO hold times
- Using MCB utilize Manufacturing and Process Development technicians to study room temperature versus cold process temperatures
- Using MCB utilize Manufacturing and Process Development technicians to study Cryogenic freeze profile (1°per minute, < 1° per minute)

Value for Client:

- A GMP run was commenced with the new freeze profile and after Post Freeze Testing of the newly manufactured WBC the bank thawed with good viability and achieved the required growth rate
- The clients may now continue production and get their product into clinical trials
- Client ecstatic!