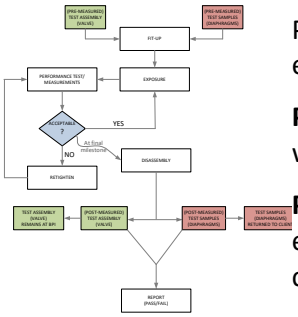
Downstream Process Improvement Project

THE CHALLENGE:

BPI performed a Risk Assessment for a client, where some steps in their downstream process were open to the environment in Biological Safety Hoods and ISO7 rooms. BPI recommended the closing of the process with Single Use Technology. The client did not want to radically change their process materials of construction and requested a solution utilizing the existing materials of construction.

OUR SOLUTION:



BPI reviewed the process in depth, and provided documentation to characterize the process and evaluate the impact of proposed changes. Prototype assemblies were generated and tested in a simulated process, to provide assurance that the process will function for the client. .

Process Description--The process was defined and Process Flow Diagrams were generated of the existing process. Areas of concern were noted and were reviewed with the client.

Procedures--Detailed accurate procedures were generated, which captured may steps which were not specifically listed in the Batch Records and Standard Operating Procedures.

Prototypes--prototypes were generated quickly at The BioProcess Institute. BPI's extensive experience and valuable contacts allowed for new technologies to be introduced quickly to the client to provide them better control of their process at a lower cost.

Process Demonstration--The process was simulated utilizing the prototypes with client manufacturing personnel. Adjustments were made and final configurations were agreed to in a few days.

Vendor Packages--Vendor bid packages were generated listing materials of construction and configuration details.

THE RESULTS:

The downstream process was able to be closed and significantly reduce its risk of contamination from the environment. Prototypes and process demonstration was delivered very fast and in a cost effective way. The BPI-generated vendor packages allowed multiple vendors to bid on the assemblies without generating their own prototypes which can take weeks to make and usually has some cost.

For more information on testing and analysis or marketing claim support, please contact:

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