ACCEGEN
BIOTECHNOLOGY

# Quality Control SOP

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Though a great deal of attention is typically paid to optimizing the conditions and reagents used in cell-based assays, quality control of the cells themselves is frequently overlooked. Human errors such as mislabeling, or cross contaminating cell lines can lead to researchers working with cells of unintended identity.

Moreover, even in the absence of errors/contamination, the inherent genetic instability of many cell lines and the epigenetic modifications resulting from culture conditions/passage number can have an effect on cellular phenotype – confounding fundamental research or drug screening efforts. Genotyping methods such as short tandem repeat profiling can verify cellular identity but do not exhaustively prove the absence of genetic modification and cannot elucidate changes in cell behavior resulting from epigenetic modification.

While obtaining cells for an investigational project may seem straightforward, it is actually one of the most important decisions a researcher can make. Collection protocols, cell isolation, and handling methods all affect overall quality of the cellular material that supports biomedical research.

**AcceGen QC testing is used for:**

Evaluating large lots of material to assure performance prior to purchase
Testing new lots of product to ensure batch-to-batch consistency in manufacturer
Beta testing new cell culture products to receive feedback from trusted experts
Assessing materials for use in the stem cell field when culture expertise isn't available internally

**Types of products tested include:**

Basal medium
Supplemental medium
Culture additives
Substrates
Culture vessels
Filter units
Storage containers

**QC Procedures Flowchart**

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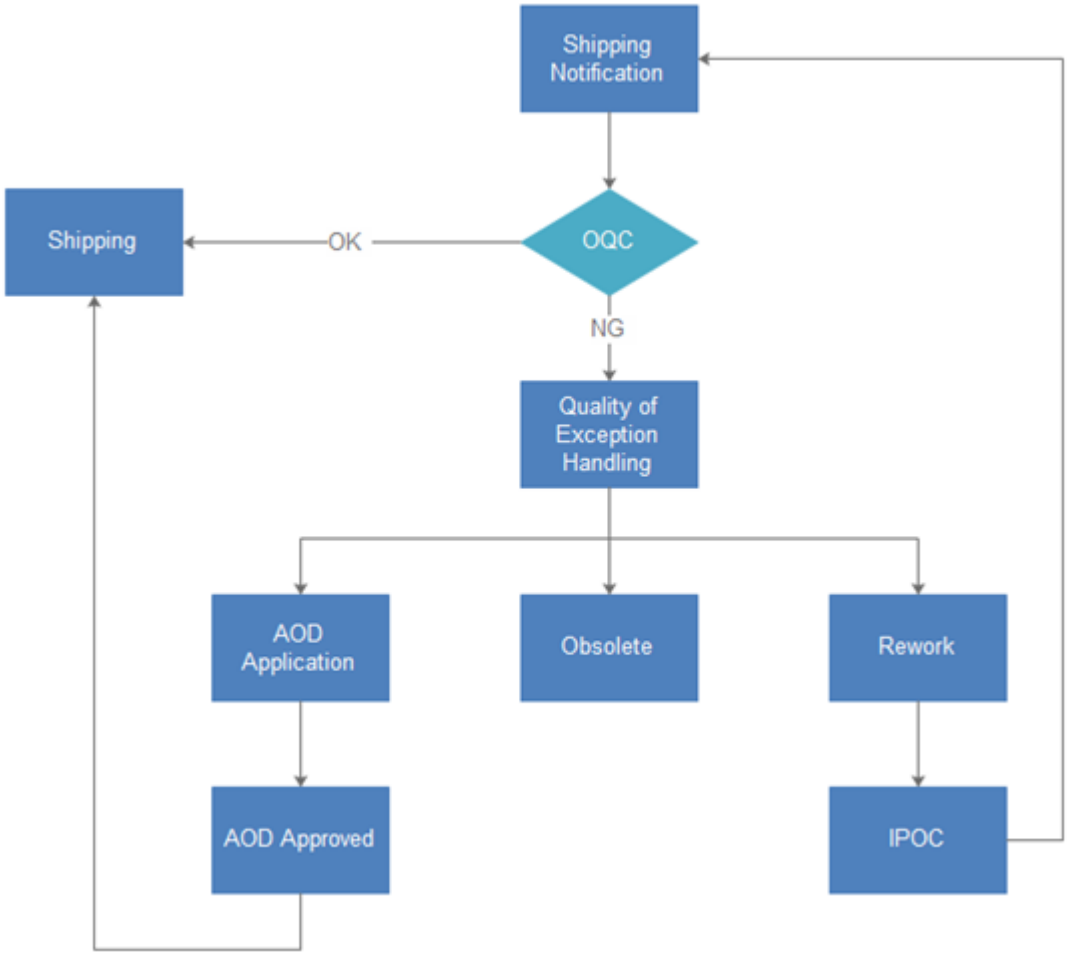


**QC Training Procedures**

Qualified individual, knowledgeable in the subject/topic who is able to effectively communicate the information should conduct training. A person of supervisory or managerial cadre is most often required to give training.

Permanent and temporary employees must also be trained for new or changed procedure in addition to the regular job.

The program should include the following kinds of training:

- orientation/general information for new and temporary employees
- GMP and GLP concepts and procedures
- theoretical knowledge for job-related training
- on the job training
- safety
- general operations/procedures
- outside seminars, conference, etc.

Training require to be imparted to the personnel should be decided in the month of July every year. A program is to be established for the entire subsequent year by the HOD and record as per format for

training schedule. Depending upon the individual job requirement the areas of training to be imparted and goals of the training are to be decided by the HOD and QA/QC Manager.

Training should be on continuing basis and with sufficient frequency. It should include the topics to be covered, the people to attend and the approximate timing for each session. In some instances, it may be necessary to schedule the same topic more than once to ensure that all relevant employees attend.

True to our mission, AcceGen provides our products to serve the needs of the life science research community around the world in their pursuit of curing disease and improving life.

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