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PROOF THAT CAN TRAVEL – DOCUMENTED CLONALITY REPORT FOR REGULATORY SUBMISSION

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Clonality is a key element of cell line development and is an important component of a regulatory submission. Indeed for BLA, the clonality of MCB is mandatory. Historically, the regulator has insisted upon 2 rounds of cloning for developing a cell line and assurance of monoclonality based on statistical outgrowth measurements. Recent improvements in high resolution whole well imaging of cells in microplates, enables the creation of indisputable image-based evidence for the growth of a colony from a single cell. This evidence eliminates a round of sub-cloning and results in several months of cell line development time being saved. However, current compilation of images using 'cut and paste' into a report is laborious, error-prone and difficult to audit.

A new standardized report for evidence of clonality images is described here. The user selects wells based upon growth characteristics and dynamically interacts on-screen with the original time course images to determine which wells were originally seeded with a single cell. Single cell features are annotated along with any other features in the well. Once analysis is complete, the user automatically generates the contemporaneous report in paper or electronic form with the click of a button. The content of the report is designed to meet the recommended guidelines from the regulator (1).

We will show an illustrative Clonality Report generated from raw data with a commercial CHO cell line.

Benefits of this report are:

1. Simple and fast to generate from within the instrument software
2. Report uses contemporaneous images
3. Raw images are available for review and audit for the lifetime of the record
4. Images used in the report are traceable back to the image raw data
5. Standard format for print or emailing which can be directly inserted as part of the IND

References

1. Kennett S. "Establishing Clonal Cell Lines – a Regulatory Perspective" - FDA presentation at WCBP, Jan 30, 2014