RISK ASSESSMENT REVIEW/REVISION RECORD

Risk Assessment Ref No:	**CBE BRA 158** **CBE GMO 158**	Version Number 5

This risk assessment should be reviewed **annually** or more frequently if there is any change in the work, or if new information becomes available that indicates the assessment may no longer be valid. **This form should be attached to the front of the current version of the risk assessment or to the new version of the risk assessment if one is issued**

The following review has been carried out on the dates indicated and either the assessment remains valid or it has been amended as indicated.	
Name(s) of reviewer: Angharad Elizabeth Evans	Date: 20/01/2020
Signature: AEE	

Reason for Review:

There are no changes to the risk assessment, the only change will be the use of a suspension variant of the HEK293 cell line (CRL-1573.3) and an adapted cell culture process.

Revision Required (Y/N)	**Y**

If Yes, give details of the revision:

The HEK293 suspension cells will be purchased from the same supplier as the previous cell lines (ATCC) and have undergone the same rigorous safety testing prior to purchase.

They are classified as biosafety level 2, the same as the cells covered in the original risk assessment, and therefore require no additional safety measures to what was previously stated.

The HEK293 suspension cells will be cultured slightly differently to what was stated in the original risk assessment as they no longer require a disassociation reagent, for instance trypsin or TrypLe, to detach the cells from the surface of the flask.

Approval:

Instructions for Reviewer:

1. *The completed form should be forwarded to the CBE Quality Manager. NOTE: Significant revision (See Guidelines GN006 & GN007) will require approval by the person supervising the work and subsequent review and approval by the original approving authority. This may require a revised version of the risk assessment to be issued for re-approval.*
2. *Where an annual review concludes that the risk assessment is still valid ie no revision is required, this should be recorded and the completed form forwarded to the CBE Quality Manager.*

Name of Approver: C. Kavanagh. Position: EXPERIMENTAL OFFICER. Signature: CKav.	Date: 21/1/2020.
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