Loughborough University **The Centre for Biological Engineering**	**Corrective Action & Preventative Action (CAPA) Report**			
Doc Ref: FSOP050.1v5 : HTA-QS-FORM/009	Version N^{o}:	1.0	Issue Date:	

CAPA No: CBE/CAPA/000	**Location of Adverse Event:**
	Adverse Event Report No *(HTA only):*CBE-HTA/AER/000

A. Details of the adverse event/non-conformity (p*roblem definition/description of the event, non-conformity)***:**	
Detected/observed by:	**Date:**

B. Disposition: (*immediate remedial action taken; include an assessment of impact***):**		
Risk to Project - Impact Categorisation: ☐ **Low** ☐ **Medium** ☐ **High**		
Proposed by:	**Date:**	**Implementation date:**

C. Investigation: Details of findings and causes with supporting evidence if applicable: *(There is always a prexisting condition and an action (or catalyst) that when combined result in a problem. Always look for at least 2 causes of any problem).*		
Investigated by:	**Date started:**	**Date finished:**

D. Details of Corrective / Preventative Action(s), including consequences, quality improvement suggestions, SOP changes, verification testing (**indicate as CA or PA e.g. PA/23/001)

**Action Number	Action	Responsible Person	Implementation Date

Submitted to departmental Quality Manager:		**Date:**	

E. Verification of validity of Corrective and/or Preventative Action			
Corrective Action: ☐ Addresses the root cause? ☐ Prevents recurrence? ☐ Valid ☐ Invalid. Issue new CAPA Remarks:		**Preventative Action:** ☐ Addresses the root cause? ☐ Prevents occurrence? ☐ Valid ☐ Invalid. Issue new CAPA Remarks:	
Signature (dQM):	**Date:**	**Signature (dQM):**	**Date:**

F. Follow up of Corrective / Preventative Action taken			
Implementation of corrective action(s) is: ☐ Implemented ☐ Not implemented. Issue new CAPA Remarks:		**Implementation of preventative action(s) is:** ☐ Implemented ☐ Not implemented. Issue new CAPA Remarks:	
Signature (dQM):	**Date**:	**Signature (dQM):**	**Date:**

G. Verification of effectiveness of implemented Corrective / Preventive Action			
Corrective Action is: ☐ Effective ☐ Not effective. Issue new CAPA Remarks:		**Preventative Action is:** ☐ Effective ☐ Not effective. Issue new CAPA Remarks:	
Signature (dQM):	**Date:**	**Signature (dQM):**	**Date:**

Instructions:

1. The person observing or detecting the adverse event or non-conformity shall fill in section A
2. The affected person shall fill in sections B, C, D
3. The departmental Quality Manager (dQM) or Management representative shall fill in sections E, F, G