

Loughborough University	Document, Record & Data Management			
The Centre for Biological Engineering				
Document Ref: QS-POL-002	Version N°:	1.0	Issue Date:	January 2016

## Documentation requirements

The Centre for Biological Engineering (CBE) Quality Management System (QMS) documentation shall include:

- Documented statements of a quality policy and quality objectives,
- A quality manual,
- Documented procedures and Codes of Practice required to meet applicable quality and safety compliance requirements,
- Documents needed by the CBE to ensure the effective planning, operation and control of its processes,
- Documented records required to provide evidence of conformity to specified quality and safety requirements and of the effective operation of the QMS.

## Quality manual

The CBE shall establish and maintain a quality manual that includes:

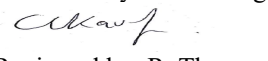
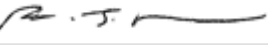
- The purpose and scope of the QMS, including details of and justification for any exclusions,
- Reference to the documented policies, practices and procedures established for the QMS,
- A description of the interaction between the processes of the QMS.

## Control of Documents


All documents required for the QMS shall be controlled and maintained according to a Document Control procedure. This procedure will define the process to ensure that:

- Controlled documents relating to the QMS are prepared and reviewed by appropriately qualified personnel,
- Controlled documents relating to the QMS are approved by the appropriate approving authority prior to issue,
- The current revision status of controlled documents is identified,
- Relevant versions of applicable controlled documents are available at points of use,
- Controlled documents remain legible, accurate and readily identifiable,
- Obsolete controlled documents are withdrawn from points of use, and/or are clearly identified to prevent their unintended use.

Written by: Paul Hourd Date: 25/01/2016  
Reviewed by: C.Kavanagh Date: 08/12/2025

  
Reviewed by: R. Thomas  
  
Date: 09/12/2025

Approved by N.Medcalf Date: 25/01/2016  
Review Approved by: K Coopman

  
Date: 09/12/2025

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### Control of Quality and Process Records

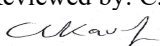
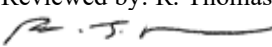
Quality and process records shall be established to provide evidence of conformity to specified requirements and of the effective operation of the QMS. Records shall be controlled and maintained according to a Document Control Procedure, which defines the process for:

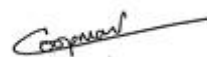
- The identification and indexing of the pertinent quality and process records required,
- The designation of storage locations to ensure secure access and retrieval,
- Preventing loss, deterioration or damage to records, including measures to back-up or recover records/documents in the event of system breakdowns or failures that could result in a permanent loss of computerised records,
- The retention and disposition of quality records, as specified by current legislation, regulations and guidelines.

### Information System Management

The CBE shall establish and maintain a system for recording, storage and retrieval of data related to the operation and control of its QMS. The CBE shall establish and maintain procedures to ensure that the information management system is:

- Readily available to authorised users,
- Protected from unauthorised access and safeguarded against tampering and loss,
- Recoverable in the event of systems failure or malfunction,
- In the case of computerised systems, is operated in an environment that complies with applicable supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription,
- Maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions,
- Compliant with national or international requirements regarding data protection,

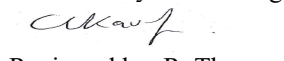
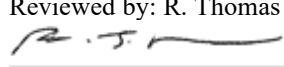
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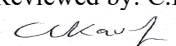
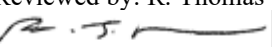
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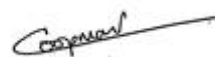
### Version History

Version Reviewed	Date Revised/ Reviewed	DCN No	Revision Summary	New Version Number
1.0	4 <sup>th</sup> December 2017 By C.Kavanagh	N/A No changes	No changes. Minor editorial only to include review details.	1.0 No new version required
1.0	2 <sup>nd</sup> December 2019 by C.Kavanagh	N/A No changes	No changes. Minor editorial only to include review details.	1.0 No new version required
1.0	6 <sup>th</sup> December 2021 by C.Kavanagh	N/A no Changes	No changes. Minor editorial only to include review details.	1.0 No new version required
1.0	4 <sup>th</sup> December 2023 by C.Kavanagh	N/A no changes	No changes. New review date only	1.0 No new version required
1.0	8 <sup>th</sup> December 2025 by C.Kavanagh	N/A no changes	No Changes . New review date only	1.0 No new version required

### Document Control

The Master Copy of all Controlled Documents is filed by the Departmental Quality Manager. The latest version is maintained on the CBE network. This document is not a controlled copy once printed from the network.

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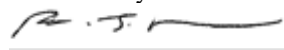
### **Security Statement**

This document is the intellectual property of the CBE within the University of Loughborough and as such, must not be circulated outside of the University without the written approval from the Departmental Quality Manager and the author.

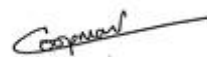
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