
Preparing Quality System Documentation

1. PURPOSE

This document describes the procedure to ensure that all controlled documentation is drafted, reviewed, authorised and revised in a standardised manner within the Haemopoietic Stem Cell Transplant (HSCT) Programme of the Children's Cancer Centre (CCC) at The Royal Children's Hospital (RCH).

2. SCOPE

This procedure applies to all controlled documentation within the HSCT Programme Quality System and all associated trained staff. The Cell Therapy and Flow Cytometry Laboratory prepares quality system documentation according to the Royal Children's Hospital Laboratory Services Quality System requirements.

3. RESPONSIBILITIES

All staff are responsible when reading documentation to make suggestions to the relevant authorising officer concerning document amendments etc.

It is the responsibility of the Document Author to;

- Ensure that the document complies with the requirements of this procedure for formatting, review and authorisation.
- Initiate an accompanying Document Flyer, QS-F-002.
- Ensure that Document Control Procedure, QS-P-002 is followed in conjunction with this procedure.

It is the responsibility of the Document Reviewer (or reviewing committee(s)) to;

- Review the draft document for accuracy, clarity and compliance with the respective standard / guideline the document is addressing.
- Co ordinate with the author and undertake responsibility for the document.
- Complete the accompanying Document Flyer as appropriate.

It is the responsibility of the Document Authoriser to;

- Take overall management of the document including final approval for submission of the document (electronic, preferred) and accompanying Document Flyer (QS-F-002) for final Document Control and distribution (to the Quality Manager or equivalent).

Individuals responsible for approving documentation are managers, senior or experienced staff of the respective section according to their level of qualification, training and authority.

It is the responsibility of the Quality Manager (QM) or equivalent to ensure Document Control, (utilising the Qpulse Quality Management System Software), implementation, maintenance and compliance to this procedure and in conjunction with Document Control procedure (QS-P-002).

4. DEFINITIONS

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Controlled Documentation – Documents which describe how to perform or record organisational and technical processes. This includes Policies, Procedures, Work Instructions and Forms generated by the HSCT Programme or may refer to;

- documents from other Departments within the RCH organisation and
- external documents such as company procedures and equipment manuals.

Controlled documents are identified by a unique document control and version number and follow an approved template.

Policies – A guiding principle designed to influence decisions / actions adopted. A policy designates a required process or procedure within an organization.

Procedures – An established or correct method or process of performing a task.

Forms – A document used to record information. A form is associated and referenced within a procedure.

Work Instructions – Concise step by step instruction of how to perform a procedure, used as a reference when performing the task.

Document Flyer – QS-F-002, form used as a record defining details, request and distribution information required to control the document.

Author – The individual or team who documents the process.

Reviewer – The individual or team who reviews the document for accuracy, clarity and compliance.

Authoriser – The individual who authorises the document for final document control, issue and implementation.

5. EQUIPMENT AND SUPPLIES

Not applicable.

6. PROCEDURE

6.1 Developing Quality System Controlled Documentation

6.1.1 Procedures may be documented using text, flowcharts, illustrations, graphs, tables or any combinations of these. Select the format that makes the steps of the procedure easiest to understand and communicate. Attachments may be included in a procedure, but must be referenced appropriately within the body of the document.

6.1.2 It is recommended that a minimum of two individuals perform the functions of preparing, reviewing or authorising documentation.

NOTE: Individuals responsible for final authorisation of documentation are managers, senior or experienced staff of the respective section according to their level of qualification, training and authority.

6.2 Document Formatting

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6.2.1 Templates with the correct formatting and headings are available in the HSCT Templates Folder located at \\rchfs\ccc\bmt_fact and should be used when writing controlled documentation.

6.2.2 The author must ensure that the document is clearly identified as a draft until authorisation. In the case of subsequent document review, unique document and version numbers should be used when documents are being circulated.

6.2.3 The recommended font is "Arial" with sizes:

- 14 for titles (in Header);
- 12 for sub-headings;
- 10 for body text of document
- and 8 for headers and footers.

The margins for documents have been set in the templates.

6.3 Layout for Policies

6.3.1 There are no prescribed headings for Policies. These are at the discretion of the author and authoriser. However, the standard HSCT template for controlled documentation must be used.

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6.4 Layout for Procedures

6.4.1 The title of the Procedure is completed in the Header and appears in all subsequent pages of the document.

6.4.2 Procedures include the following:

| HEADING | INFORMATION |
|------------------------|---|
| Purpose | Brief statement of the objectives and processes of the Procedure. |
| Scope | Defines the function, department or processes to which the Procedure applies. |
| Responsibility | Identifies key personnel responsible for ensuring that all aspects of the procedure are followed. |
| Definitions | Provides clarification of words, abbreviations or acronyms used in the procedure which may be ambiguous or not readily understood. |
| Equipment and Supplies | List of the equipment and supplies (inclusive of all relevant details, eg brand etc) required to perform the procedure. |
| Procedure | Description of how to perform the process. Utilising text, illustrations, graphs, tables or any combinations of these. |
| Endpoint | Acceptable endpoint and the range of expected results, where applicable. |
| Attachments | Any associated documentation which is used during the procedure inclusive of forms and examples. |
| References | List all references that are applicable to the Procedure, this is inclusive of any primary, organisational or other Quality System documentation. |

6.5 Layout for Forms

6.5.1 These are uniquely identified and are formatted as required by the author. Examples include work sheets, training records, monitoring charts etc.

6.6 Layout for Work Instructions

6.6.1 These are uniquely identified simple concise step by step instructions of how to perform a procedure, they are used as a "quick reference" when performing the task. Work Instructions refer to the main "parent" Procedure. The document comprises of a **Purpose** statement and a list of **Actions**.

6.7 Document Review and Approval

6.7.1 Quality system documents are reviewed and authorised prior to issue for controlling, issue and implementation.

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6.7.2 The **Author** must:

- Nominate the document reviewer(s) ensuring that adequate stakeholder review is conducted.
- Consult and incorporate reviewer comments as appropriate.
- Ensure circulation of the draft document for final authorisation.
- Initiate an accompanying Document Flyer, QS-F-002.

6.7.3 The **Reviewer** must:

- Review the draft document for compliance, accuracy and clarity.
- Consult and forward comments to the author and other reviewers as required.
- Complete accompanying Document Flyer as appropriate.

6.7.4 The **Authoriser** must:

- Review the draft document. Documents requiring correction are returned to the author.
- Submit the document and flyer for final Document Control and distribution to the Quality Manager or designee.

6.7.5 The **Quality Manager or designee** must:

- Ensure the document is controlled utilising a paper based system and the Qpulse Quality Management System Software.
- Circulate and file the controlled document to the respective applicable section and designated contact for subsequent implementation.
- Ensure that all copies of superseded (prior versions) or withdrawn documents are removed from circulation.
- Provide a summary of released controlled documentation at the HSCT Multidisciplinary Meeting.

6.8 Review of Existing Documents

All controlled existing documents are reviewed annually for currency. The review and approval procedures (section 6.7) described in this Procedure also apply to document revision.

7. ENDPOINT

Not applicable.

8. ATTACHMENTS

Document Flyer, QS-F-002.

9. REFERENCES

9.1 Document Control Procedure. Haemopoietic Stem Cell Transplant Programme Quality Systems Manual. Doc. No. QS-P-002. Version: 001. 2008.

9.2 ISO9001:2000 Quality Management Systems – Requirements. 2000.

9.3 International Standards for Cellular Therapy Product Collection, Processing and Administration. FACT-JACIE. Fourth Edition. October 2008.