



CONCEPT LIFE SCIENCES

a spectris company

STANDARD OPERATING PROCEDURE

SOP_CLS7_QM_0001_02

TITLE: QUALITY POLICY


SOP & Version Number: SOP_CLS7_QM_0001_02

Effective Date: 07 Apr 2020 Review Due Date: 30 Mar 2023

Read groups:	All Personnel
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SOP Author

Your signature verifies that to the best of your knowledge this document is accurate & complies with all company and departmental policies and procedures and any applicable regulatory standards and requirements.

Author:  Date: 25 Mar 2020
 Dorothee Lahaye Quality Officer

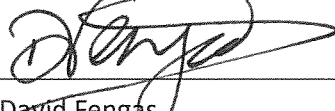
SOP Reviewer

Your signature verifies that you have reviewed this document and to the best of your knowledge it is accurate & complies with all company and departmental policies and procedures and any applicable regulatory standards and requirements.

Reviewer: * Date: _____
 David Leese VP Chemistry & Site Director - Chapel


SOP Approver

Your signature approves this SOP for use; that you consider the activities identified within are accurate and sufficient for successful execution by trained operators and the document complies with all company and departmental policies and procedures and any applicable regulatory standards and requirements.

Approved by:  Date: 30 MARCH 2020
 David Fengas Site Director - Sandwich

Quality Assurance Approval

Your signature verifies that this document complies with company and departmental policies and regulatory requirements, as applicable.

Approved by:  Date: 31 MAR 2020
 Elizabeth Savage Senior Quality Manager

* Refer to attached PDF scan DL 27 Mar 2020



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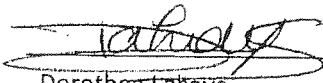
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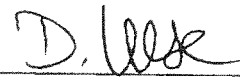
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Author:  **Date:** 25 Mar 2020
Dorothee Lahaye Quality Officer

SOP Reviewer

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Reviewer:  **Date:** 27 March 2020
David Leese VP Chemistry & Site Director - Chapel

SOP Approver

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Approved by: David Fengas **Date:** _____
David Fengas Site Director - Sandwich

Quality Assurance Approval

Your signature verifies that this document complies with company and departmental policies and regulatory requirements, as applicable.

Approved by: Elizabeth Savage **Date:** _____
Elizabeth Savage Senior Quality Manager

1. INTRODUCTION/SCOPE

This policy covers the Quality System at Concept Life Sciences Chapel-en-le-Frith and Sandwich to support the production of Starting Materials (SMs) and Active Pharmaceutical Ingredients (APIs), and the testing of materials to support both GMP and GLP regulatory requirements.

The Quality system will enable Concept Life Sciences Chapel-en-le-Frith and Sandwich to deliver products and services that meet both customers' requirements and regulations, protecting its reputation while reducing costs and driving improvement. This will be achieved by utilising the following activities:

- ▶ Quality planning: ensuring that quality requirements are addressed throughout the product and service lifecycle.
- ▶ Quality control: focus on process outputs to ensure that the agreed and regulated standards are met.
- ▶ Quality assurance: gives confidence that standards and requirements are being met.
- ▶ Quality improvement: a feedback process that is determined by all the points above and the business requirements.

By managing and interlinking cross functional processes as detailed above, Concept Life Sciences Chapel-en-le-Frith and Sandwich will be able to provide consistent high-quality work and satisfaction to both the customer and the business.

2. DEFINITIONS AND ABBREVIATIONS

APIs	Active Pharmaceutical Ingredients
QMS	Quality Management System
Master copy	Original, wet-signed version of a document
SMs	Starting Materials
GxP	Good 'x' Practice, where 'x' is used as a collective term for: <ul style="list-style-type: none"> ▶ GCP – Good Clinical Practice ▶ GDP – Good Distribution Practice ▶ GLP – Good Laboratory Practice ▶ GMP – Good Manufacturing Practice ▶ GPvP – Good Pharmacovigilance Practice

3. RESPONSIBILITIES

All Personnel	It is the responsibility of all Concept Life Sciences Chapel-en-le-Frith and Sandwich personnel to follow the principles of this policy and to abide by the contents of the Quality Manual.
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4. REFERENCES AND ASSOCIATED DOCUMENTS

None

5. PROCEDURE

5.1 Concept Life Sciences Chapel-en-le-Frith and Sandwich personnel will comply with the requirements of:

- ▶ GMP as directed in ICH Q7 and Eudralex Vol 4 part II during the production and testing of RSMs and APIs.
- ▶ GLP as directed by OECD Principles of Good Laboratory Practice (as revised 1997, issued Jan 1998, ENV/MC/CHEM(98)17, including the OECD monographs) during the testing of GLP Study Materials.

In addition to UK and EU commercial legislation and regulations, Concept Life Sciences Chapel-en-le-Frith and Sandwich complies with all legislation and regulations specifically related to its business activities.

5.2 All personnel at Concept Life Sciences Chapel-en-le-Frith and Sandwich will ensure that they understand the requirements of this Quality Policy and commit to following the contents of the Quality Manual.

5.3 All personnel at Concept Life Sciences Chapel-en-le-Frith and Sandwich will maintain and develop the Quality Management System (QMS) through collaboration and engagement by 'owning' the QMS. This is achieved by:

- ▶ Complying with the requirements of the QMS.
- ▶ Continually improving the effectiveness of the QMS.
- ▶ Performing their duties with integrity, diligence and to high professional standards.
- ▶ Empowering all personnel at Concept Life Sciences Chapel-en-le-Frith and Sandwich to own the QMS and endeavour to get it right first time.
- ▶ Working with the other members of the company and quality group to improve systems and processes.
- ▶ Ensuring Customer satisfaction.

5.4 The Quality group will:

- ▶ Continuously engage with all personnel at Concept Life Sciences Chapel-en-le-Frith and Sandwich and ensure transparency.
- ▶ Monitor systems, processes and documents to assure compliance.
- ▶ Hold documentation master copies and control documentation logs.
- ▶ Liaise with management to ensure compliance.

5.5 Management commits to:

- ▶ Ensuring that customer needs and expectations are established and fulfilled, with the aim of achieving customer satisfaction.
- ▶ Communicating the importance of customer needs and legal requirements throughout Concept Life Sciences Chapel-en-le-Frith and Sandwich.

- ▶ Communicating the principles and requirements of the QMS to all employees and ensuring those principles and requirements are understood & adhered to.
- ▶ Developing a culture that drives quality, helps others to succeed and empowering all members to continuously improve the QMS.
- ▶ Guaranteeing the availability of resources.
- ▶ Ensuring personnel are suitably trained for their job role.

6. SUMMARY OF CHANGES

Version	Date	Summary of Change	Author	Training Requirements *1,2,3
02	25 Mar 2020	New Template Introduction/Scope updated GxP added to Section 2 GLP regulations added to Section 5.1	Dorothee Lahaye	1
01	12 Feb 2019	New document	Elizabeth Savage	1

*Training Requirements

1 – new document or revised document that requires full training

2 – revised document that requires limited training

3 – revised document that requires no additional training