

	Office of Sponsor and Regulatory Oversight	Document #: 104
	Corrective and Preventive Action Policy	Revision #: 1
		Effective Date: 12AUG2019

1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Corrective and Preventive Action (CAPA) policy.

2. Scope

2.1. OSRO in the Center for Cancer Research (CCR), National Cancer Institute (NCI) shall establish and control the policy.

3. Responsibilities

- 3.1. CCR Management is committed to providing resources to meet the requirements for implementing a CAPA program within OSRO's Quality Management System (QMS) to achieve quality objectives and supporting its continual improvement.
- 3.2. OSRO personnel are responsible for understanding and using the QMS and its ancillary systems.
- 3.3. The OSRO Director is responsible for establishing and maintaining OSRO's QMS.

4. References

- 4.1. U.S. Department of Health and Human Services' Guidance for Industry: E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1), dated March 2018
- 4.2. International Conference on Harmonisation (ICH) Harmonised Tripartite Guideline: Q10: Pharmaceutical Quality System, dated June 2008
- 4.3. International Standard ISO 9001:2008(E): Quality Management Systems – Requirements, dated 2008

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

- 6.1. OSRO shall establish and maintain procedures for implementing corrective and preventive action.
- 6.2. The procedures shall include requirements for:
 - 6.2.1. Analyzing processes, work operations, audit reports, and other sources of quality data to identify existing and potential causes of nonconformance.
 - 6.2.2. Investigating the root cause of a nonconformance.
 - 6.2.3. Identifying the action(s) needed to correct and prevent recurrence of nonconformities and other quality issues.

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6.2.4. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the investigational product, clinical trial, patient or quality system.

6.2.5. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality issues.

6.2.6. Ensuring that information related to quality issues or nonconforming products/systems are disseminated to those directly responsible for assuring the quality of such product or the prevention of such issues.

6.2.7. Submitting relevant information on identified quality issues, as well as corrective and preventive actions, for management review.

6.2.8. Documenting all activities and their results.

6.3. This Policy shall be reviewed periodically and updated as necessary.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	12AUG2019	New Document