The SOPs provided in the NanoCare and NanoNature projects have to be relevant and specific for nanomaterials and also have to work beyond single projects.

Every step must be reproducible for everyone!

This document provides instructions on how to fill the text fields

Mandatory fields are:

* Responsible partner for this SOP
* Title
* Authored by and date
* Reviewed by and date
* Purpose
* Procedure a)-g)

Please delete the blue instructions and save as a pdf.

| AUTHORED BY: | DATE: |
| --- | --- |
| XXX | DD/MM/YYYY |

| REVIEWED BY: | DATE: |
| --- | --- |
| XXX | DD/MM/YYYY |
|  |  |

| APPROVED BY: | DATE: |
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|  |  |

DOCUMENT HISTORY

| Effective Date | Date Revision Required | Supersedes |
| --- | --- | --- |
| DD/MM/YYYY | DD/MM/YYYY | DD/MM/YYYY |

| Version | Approval Date | Description of the Change | | Author / Changed by |
| --- | --- | --- | --- | --- |
| 1.0 | DD/MM/YYYY | All | Initial Document | Name |

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1. **PURPOSE**

This section describes the purpose of the Standard Operating Procedure.

1. **OBJECTIVE**

This paragraph should contain a description about the objective of this Standard Operating Procedure.

1. **REGULATORY BASIS, REFERENCE DOCUMENTS**

This section should include the regulatory references that were used to produce this SOP.

E.g.:

21 CFR 211.xx

21 CFR 211.113: Control of Microbiological Contamination

21 CFR 820.70 (c): Production and Process Controls, Environmental Control

EU GMP Guide § xyz

International Standard, ISO 14644-1, First edition, 1999-05-01  
Clean room and Associated Controlled Environments, Part 1: Classification of Air Cleanliness,

2005 USP 28, U.S. Pharmacopoeia, <1116> Microbiological Evaluation of Clean Rooms and Other Controlled Environments

1. **RELATED DOCUMENTS**

Table 1 : References to documents needed to proceed according to this procedure

| Document ID | Document Title |
| --- | --- |
|  |  |
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1. **DEFINITIONS**

Table 2: Glossary of Terminology used in the SOP

| Term | Description |
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1. **PROCEDURE**

This Paragraph should give a detailed description of the individual steps of the related process and the instructions on how to execute the process.

1. Short description
2. Materials and devices
3. Sample preparation
4. Detailed description of the procedure
5. Controls
6. Data analysis
7. Testing errors

1. **SCOPE/AREA OF APPLICATION**

This section should focus on delimitations, e.g. ..."only valid for..."

1. **ATTACHMENTS**

# 1 Title of attachment 1

# 2 Title of attachment 2

1. **HEALTH, SAFETY AND ENVIRONMENTAL CONSIDERATIONS**

This Paragraph should give relevant instructions in regard to related health, safety and environmental conditions.