The new electronic forms are user friendly and are quicker to complete than previously released versions. Drop down menus are built in to ease the data entry process electronically. Just click and select the option within the form that applies. Use the tab key to navigate through the form. After completing the form, print, sign/date, and include it with your shipment.

Please send the samples to the following address:
NAMSA
Sample reception - Porte B
115 rue Pasteur
ZI de l'Islon
38670 Chasse-sur-Rhône - FRANCE

Please send a Sample Submission Form per test article. If for the same study, you have to send two different batches, please fill in two separate forms. If one product is sent several times, please attach a copy of the form to each shipment or complete several forms if there are different batches.

The Sample Submission Form can be sent by e-mail or fax before the arrival of samples, so preliminaries can begin like the drafting of a protocol. In this case, please still attach a copy of the form with the shipment in order to facilitate its identification and treatment.

1 - How to select the right Sample Submission Form

GLP Sample Submission Form - Select this form when submitting a test article for studies that require compliance to Good Laboratory Practice regulations (tests that are being submitted to FDA or other regulatory agencies).

GLP Sample Submission Form with Control article - Select this form when submitting test and control articles for studies that require compliance to Good Laboratory Practice regulations (tests that are being submitted to FDA or other regulatory agencies).
NAMSA will specify in the Cost Estimate and Proposal when a sponsor-submitted control article is necessary.

Sample Submission Form - Select this form for non-GLP biocompatibility or chemistry projects (projects that are not being submitted to a regulatory agency).

Sample Submission Form: Microbiology studies - Select this form for microbiology studies whether it is GLP or not.

Animal Explant Submission Form - Select this form when submitting an animal specimen for histological study.

Human Explant Submission Form - Select this form when submitting a human specimen for histological study.

2 - How to complete the Sample submission form

The information requested in the Sample Submission Form is necessary for the proper conduct of the studies, therefore complete the entire document. You will find below definitions/explanations about the requested information.

If you have any questions or need help with the new Sample Submission Forms, please feel free to contact our Customer service at 33 (0)4 78 07 92 34. We will be happy to assist you.

First, clarify the information on the Sponsor in the left frame (Ship To Information). The final report will be sent to the address indicated. You can also provide a different billing address in the right frame (Bill To Information). **Include the purchase order reference (which will then appear on the invoice) and the corresponding Cost Estimate and Proposal number.**

- **Article description**

- **Type**

Start by indicating the category of the submitted sample (medical device, pharmaceutical...) using the drop down menu. If the sample is to be classified in several categories, you can use the field “Other" to complete the information provided.
When the sample is a biological product, please tick the appropriate box after completing the applicable category ("biological product" is not regarded as a category).
As part of a GLP study, the category "Other" is not acceptable. Information must be accurate in order to apply the appropriate GLP regulation.

- **Name**

Please indicate the product name as it appears on the packaging (consider the special characters).
To ensure the accuracy of the information indicated in the report, no translation will be performed by NAMSA.

- **Reference**

The reference is the commercial reference of the product, which is indicated on the packaging. This is the code that identifies the product (registration number, benchmark).

- **Batch/Lot number**

The batch/lot number corresponds to a specific quantity of product manufactured in one process or one series of processes as it may be considered homogeneous.

- **Physical description**

Please indicate the materials, the colour…

- **Intended clinical use [for GLP studies only]**

Please specify the intended clinical use of the submitted sample.
e.g. orthopaedic implant, bone substitute…

- **Surface area, thickness**

As per ISO 10993 standard part 12, the sponsor has to provide the exact surface area and thickness of the test article, as this information is needed for determination and application of the extraction ratio. **This information is under the Sponsor’s responsibility, it can not be forwarded onto study direction by NAMSA**. However, when necessary for the proper conduct of the trial, the Study Director might have to adapt the required conditions, while remaining in accordance to ISO 10993 standard part 12.
How to calculate the surface area of the submitted element? The entire surface area that will be in contact with the extraction vehicle has to be considered. So include the external surface but also possibly the inner surface. If only a portion of the submitted article has to be tested, specify the surface area of this part only.
Regarding the thickness of the test article, please indicate if it is less than 0.5 mm or higher than or equal to 0.5 mm.

- **Dimensions, weight**

Please indicate the dimensions of the submitted element.
For tests that require extraction and when the surface area can not be provided, please specify the weight of a piece. If only a portion of the submitted article has to be tested, specify the weight of this part.

- **Quantity submitted**

Please specify the number of parts delivered.
In the case of a GLP study on pharmaceutical or cosmetic, **a sample of each batch of tested article should be retained as sampling product for analysis**, therefore anticipate this and send an extra part for each batch tested.

- **Sterility**

Please indicate if the submitted element is sterile, not sterile or has to be sterilized at NAMSA.
Be aware that it is not whether the product has been sterilized, but if it is being sent in sterile conditions. Some tests, in particular in vivo trials, are required to be performed on sterile samples. NAMSA offers steam sterilization only, with a choice of which cycle to apply: 121°C for 20 min or 134°C for 18 min. Please refer to the Cost Estimate and Proposal for payment conditions.

- **Sterilization process**

In the case the element is sterile, please specify the sterilization process (gamma irradiation, ethylene oxide…). If the element has to be sterilized at NAMSA, the process will be steam sterilization.

- **Expiration date**

Please indicate the expiration date if it has been determined for the submitted article. Be aware that we expect a specific date and not a duration.
If the stability study is still in progress, please specify that the product is considered as stable for the duration of the study.

- **Storage conditions**

Please indicate the storage conditions when receiving the submitted article.
In case some special conditions are required, please contact us before sending the sample to verify if NAMSA can guarantee these conditions.

- **Article disposition**

Please specify what has to be done with the submitted article once the study is over.

- Discard unused article, 1 month after the end of the study (the used samples are systematically discarded after use).
- Return unused article (the used samples are systematically discarded after use).
- Return used and unused article.

Please refer to the Cost Estimate and Proposal for payment conditions.

- **Comments or Special Instructions**

Please indicate the precautions for use. Join the instructions for use if necessary.
Describe the part that has to be tested in case the whole article should not be used (e.g. remove plastic protection, cut the printed area…).
Be aware that without special instructions, the whole article will be tested. This means that everything that is in the blister after opening packaging will be tested. Therefore, we suggest that you send a sketch with the precise description of the part that has to be tested.

- **Article characterization [for GLP studies only]**

The Sponsor should assure the article has been characterized for identity, stability, strength, purity, homogeneity and composition as required by Good Laboratory Practice regulations. Characterization is the responsibility of the Sponsor and is subject to GLP authorities' audit.
The information you provide to NAMSA should be detailed enough to meet the requirements of GLP regulations. This information is necessary in order to allow test(s) to be performed according to the GLP. The information given by the Sponsor needs to provide the NAMSA Study Director details regarding the characterization of the article which will ensure that testing is conducted properly. If full characterization is not available before the beginning of the study, testing could begin in agreement with the Study Director, but missing information should be provided during the course of the study. A

thorough description of the article is required in the GLP final report. **If characterization information is not provided by the Sponsor, the GLP certificate will not be provided with the final report.**

- **Stability** is the property of an article to remain in the same state without degrading or loosing its effectiveness. Shelf life is a common stability before opening packaging test.

- **Mixture analysis** is required for the articles that are dissolved, suspended or diluted with solvents or vehicles. Analysis is required by the GLP to demonstrate proper concentration, homogeneity and stability of the mixture tested.
  If the article is not dissolved, suspended or diluted before testing in a solvent or vehicle, analysis is not necessary. Articles extracted according to the ISO 10993 standard part 12 are not submitted to mixture analysis (check the first box in the Sample Submission Form).

- **Strength** is the concentration or amount of active ingredients in the tested article. If there is no active ingredient, this will not apply (check the second box in the Sample Submission Form).

- **Purity** is typically described as the percentage of a specific material, chemical component or active pharmaceutical ingredient with respect to impurities. Impurities can arise during the manufacture, storage and handling of the specified material. When the article is a solid consisting of more than one material or component (multi-component device), purity may not be applicable (check the second box in the Sample Submission Form).

- **Homogeneity** is only applicable to liquids, gels and powders which require sampling before testing (e.g. sampling of a defined quantity in the submitted vial). Homogeneity is not applicable when no sampling is needed (testing of the totality of the vial), or when the article is a solid (check the third box in the Sample Submission Form).

- **Composition** is the list of ingredients or materials used to make up the article.

3 - Documentation

- **Security**

A detailed composition list and current MSDS must accompany any chemical, pharmaceutical, cosmetic, biologic or medical device presented as a liquid, powder, paste, gel… A certificate of testing or reprocessing must be submitted for any human-tissue-derived sample or clinically used medical device.

- **Characterization**

For GLP studies, please join a certificate of analysis for each batch tested. The document must indicate the identification of the tested element and be approved.

- **Picture, scheme**

Please attach a picture or a scheme of the article to the Sample Submission Form, especially when the packaging does not allow the visualization of this element before opening.