

Florida Biologix (FB): Fill / Finish Questionnaire

Description

- Briefly describe the bulk substance

Receipt of Bulk and Timeline

- How much bulk will you deliver? (in liters)
- What are the Shipping, Handling and Storage conditions of Bulk substance (storage temp, fill temp)?
- What date will you deliver bulk to Florida Biologix (FB)?
- What is your delivery date for final filled product?

Safety

- Can you provide an MSDS or certificate of analysis/testing for the bulk?
- Is the Bulk Substance hazardous or does it require containment?

Raw Materials

- Besides the bulk, will there be any other raw materials for this fill?
- If there are additional raw materials, do you require any identity testing on these materials upon receipt or is Florida Biologix receipt with review of CoA from the source/vendor sufficient?

General

- Is the final, released product going to be used for research, safety-tox study, clinical trial (what phase) or other use (please specify)?
- Will this project be a one-time single fill? A discount will be considered for signing a multiple fill agreement
- Does bulk require Formulation (Dilution)? If yes, what is the buffer? (THP, WFI, etc). Briefly describe the formulation process.
- Does bulk require stirring or agitation (before or during fill) or is it homogeneous?
- What is the Viscosity of bulk (is it like water, like oil, like pudding)?
- Does bulk require filtration (what type and size of filter e.g. .22 micron)?

Testing Requirements

- Do you require **in-process** testing? If yes, please list tests required.
- Do you require **release** testing? If yes, please list tests required.

Containers

- What type of container would you like to fill (vial, cryovial, bottle, IV bag, syringe)?
- How many filled containers do you need (include # needed for testing, retains, rejects, etc)?
- What is Fill volume (0.5 ml)?
- What is Fill tolerance (\pm 5%)?
- What are the catalog numbers and manufacturer names for your preferred containers, (e.g.vials, bags), stoppers, seals?
- Do you have preferred packaging for final filled product?

Shipping and storage



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- What is the shipping temperature of final product?
- Will we ship final product to multiple clinical sites or to a single destination?
- Will you store the final product at our Facility (storage rates apply upon product release by FB)?