Request for Proposal Checklist

INTRODUCTION & SUMMARY

- ☐ Company overview (description, founding, high level clinical development)
- ☐ Contact information
- ☐ Clinical needs including regulatory status and submission strategy
    - Will you need CMC writing support for a regulatory submission?
        - IND through NDA/ANDA/BLA/505(b)(2)
- ☐ Indication and clinical trial regions/locations
    - Explain any other clinical developments (additional indications, trials, etc.)

SCHEDULE

- ☐ Basis for award contract including but not limited to the following:
    - ☐ Proposed proposal due date
    - ☐ Target timeline for site visit
    - ☐ Target timeline for Quality Audit
- ☐ Manufacturing timelines
    - ☐ Availability of API or BDS
    - ☐ Deadline for released GMP material

PROJECT DESCRIPTION

- ☐ Technical requirements
    - ☐ Target batch size (liters and vials/syringes/bottles)
    - ☐ Container closure size, fill volume per vial and final product concentration
    - ☐ Lyophilization cycle length and parameters (if applicable)
    - ☐ Number of batches required (ER/GMP)/quantity needed to meet clinical trial needs
        - Is placebo required?
        - Do you need diluent to reconstitute the finished product?
    - ☐ Forecast and long-term strategy for commercialization (if applicable)
- ☐ Process flow diagram and/or step-by-step detailed instructions of current manufacturing process
    - ☐ Equipment train and utility requirements (if applicable)
        - Is the process fully developed or will the process development/optimization be required to support a transfer to a new CMO?
- ☐ Container closure information including vendor and vendor part number
- ☐ If clinical, are LSNE common use vials, stoppers, and overseals acceptable?
- ☐ Excipients and grade requirements, include vendor and vendor part number, if available
- ☐ API (ID), in-process, release, and stability testing requirements
    - ☐ Who will be responsible for testing? CMO/BSD vendor/external lab
    - ☐ What analytical methods will be required to transfer to the CMO?
- ☐ Labeling and packaging requirements (if applicable)