

SAMPLE TASK EVALUATION CRITERIA

This section establishes the procedure to be utilized to evaluate the Large Molecule and Small Molecule sample tasks that comprise Technical Factor 2 in the solicitation. The Large Molecule sample task, Subfactor 2.1, is rated as more important than Subfactor 2.2, Small Molecule sample task.

Refer to the Sample Tasks descriptions provided in the solicitation. Twenty-four (24) items to be delivered by the Offerors in response to the Sample Tasks requirements are identified below. The reviewer shall rate each proposal with respect to each of the numbered deliverables in accordance with Table 1. The bulleted items listed below the numbered deliverables are provided for the reviewer to use in determining the rating for the deliverables.

Separate Sample Task Evaluation Sheets for the Large Molecule and Small Molecule are provided at the end of this section. Evaluators shall determine an adjectival rating, as described in Table 1, and record the rating on the appropriate for each sample task deliverable. Evaluators shall use the space provided to enter a narrative concerning their evaluation of the offerors proposal for the sample task evaluated. The completed Sample Task Evaluation Sheets shall be utilized as the bases for completing the Proposal Evaluation sheets for each sample task.

Table 1. Combined Technical/Risk Ratings		
Color	Rating	Description
Blue	Outstanding	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
Purple	Good	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
Green	Acceptable	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
Yellow	Marginal	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
Red	Unacceptable	Proposal does not meet requirements and contains one or more deficiencies. Proposal is unawardable.

A. Integrated Master Plan (IMP):

A.1 Tasks/functions to be performed - Work Breakdown Structure (WBS):

1. WBS and associated text appropriately address means by which transfer of new technologies and methods will be accomplished
2. WBS and associated text appropriately address all aspects of the non-clinical development of the requested product
 - Plan is complete and rational
 - Costs are appropriate given key assumptions as described
 - Expected cycle times and ranges (worst case, best case) are rational
 - Plan reflects appropriate, proactive mitigation of risks
 - Plan accounts for clinical trial material needs
 - Plan demonstrates innovative approach, where appropriate
 - Risks, opportunities and contingency/acceleration measures demonstrate adequate development knowledge
 - Plan accounts for QC/QA activities
3. WBS and associated text appropriately address all aspects of the clinical development of the requested product
 - Plan is complete and rational
 - Costs are appropriate given key assumptions as described
 - Expected cycle times and ranges (worst case, best case) are rational
 - Plan reflects appropriate, proactive mitigation of risks
 - Plan accounts for clinical trial material needs
 - Plan demonstrates innovative approach, where appropriate
 - Risks, opportunities and contingency/acceleration measures demonstrate adequate development knowledge
 - Plan accounts for QC/QA activities
4. WBS and associated text appropriately address program management and regulatory (submission and FDA interaction) requirements
 - Plan is complete and rational
 - Costs are appropriate given key assumptions as described
 - Expected cycle times and ranges (worst case, best case) are rational
5. WBS and associated text appropriately address all aspects of the non-surge post-approval production of the requested product
 - Plan is complete and rational, and meets statement requirements for quantities
 - Costs are appropriate given key assumptions as described

- Expected cycle times and ranges (worst case, best case) are rational
- Plan reflects appropriate, proactive mitigation of risks
- Plan demonstrates innovative thinking/approach, where appropriate
- Risks, opportunities and contingency/acceleration measures demonstrate adequate development knowledge
- Plan accounts for QC/QA activities

6. WBS and associated text appropriately address all aspects of surge production of the requested product

- Plan is complete and rational, and meets statement requirements for quantities and timing
- Costs are appropriate given key assumptions as described
- Expected cycle times and ranges (worst case, best case) are rational
- Plan reflects appropriate, proactive mitigation of risks
- Plan demonstrates innovative thinking/approach, where appropriate
- Risks, opportunities and contingency/acceleration measures demonstrate adequate development knowledge
- Plan accounts for QC/QA activities

A.2. Support and Management:

7. IMP appropriately identifies technical/development staff requirements

- Makeup and quantity
- Cost

8. IMP appropriately identifies QA and regulatory staff requirements

- Makeup and quantity
- Cost

9. IMP appropriately identifies manufacturing staff requirements

- Makeup and quantity
- Cost

10. IMP appropriately identifies management and support staff requirements

- Makeup and quantity
- Cost

11. IMP presents rational plan for use of other entities (e.g. subcontractors)

- Complete description of roles

- Roles are rational/sensible
- Interactions between these entities and ADM are described
- Reasonable assessment of time and costs

12. IMP describes appropriate lines of authority and accountability

A.3 Risk Management Plan:

13. Risk management plan adequately addresses development risks

- Provides appropriate identification of and adequate detail about risks, and reflects an understanding of the impacts of these risks.
- Provides appropriate approaches to mitigating risks, and adequate detail about these approaches.

14. Risk management plan adequately addresses non-surge post-approval production risks

- Provides appropriate identification of and adequate detail about risks, and reflects an understanding of the impacts of these risks.
- Provides appropriate approaches to mitigating risks, and adequate detail about these approaches.

15. Risk management plan adequately addresses surge production risks

- Provides appropriate identification of and adequate detail about risks, and reflects an understanding of the impacts of these risks.
- Provides appropriate approaches to mitigating risks, and adequate detail about these approaches.

A.4 Surge Production Plan:

16. Overall adequacy of surge production plan

- Practicality/soundness
- Match to stated needs, including timing
- Efficiency
- Risk containment
- Quality management
- Cost

A.5 Facilities and Equipment:

17. Overall description of facility and equipment requirements for task

- Complete
- Appropriate
- Efficient
- Knowledge of new/innovative technologies that can be used to most efficiently meet needs
- Facility control

A.6 Critical Milestones:

18. Description of critical manufacturing milestones

- Complete
- Correct
- Includes go/no go decision points

19. Description of critical milestones for non-clinical studies

- Complete
- Correct
- Includes go/no go decision points

20. Description of critical milestones for clinical studies

- Complete
- Correct
- Includes go/no go decision points

21. Description of critical milestones for regulatory submissions

- Complete
- Correct
- Includes go/no go decision points

B. Integrated Master schedule (IMS):

22. IMS effectively illustrates the integration of steps towards product licensure, including all appropriate dependencies

- Complete
- Correct
- Includes adequate government review times

23. Correct key milestones and critical path are highlighted on the IMS

24. IMS represents a schedule that has 50% probability of success

SAMPLE TASK EVALUATION WORKSHEET

FACTOR II - TECHNICAL – SAMPLE TASKS
SUBFACTOR 2.1: LARGE MOLECULE SAMPLE TASK INCLUDING SURGE PRODUCTION

OFFEROR:

REFERENCES:

RATING	DELIVERABLE
BEST VALUE: (Refer to adjectival rating definitions) check one.	
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	1. WBS and associated text appropriately address means by which transfer of new technologies and methods will be accomplished
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	2. WBS and associated text appropriately address all aspects of the <u>non-clinical</u> development of the requested product
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	3. WBS and associated text appropriately address all aspects of the <u>clinical</u> development of the requested product
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	4. WBS and associated text appropriately address program management and regulatory (submission and FDA interaction) requirements
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	5. WBS and associated text appropriately address all aspects of the <u>non-surge post-approval production</u> of the requested product
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	6. WBS and associated text appropriately address all aspects of <u>surge production</u> of the requested product
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	7. IMP appropriately identifies technical/development staff requirements
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	8. IMP appropriately identifies QA and regulatory staff requirements

OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	9. IMP appropriately identifies manufacturing staff requirements)
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	10. IMP appropriately identifies management and support staff requirements
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	11. IMP presents rational plan for use of other entities (e.g. subcontractors)
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	12. IMP describes appropriate lines of authority and accountability
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OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	15. Risk management plan adequately addresses surge production risks
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	16. Overall adequacy of surge production plan
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	17. Overall description of facility and equipment requirements for task
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	18. Description of critical manufacturing milestones
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	19. Description of critical milestones for non-clinical studies
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	20. Description of critical milestones for clinical studies
OUTSTANDING [] GOOD [] ACCEPTABLE [] MARGINAL [] UNACCEPTABLE []	21. Description of critical milestones for regulatory submissions

SAMPLE TASK EVALUATION WORKSHEET

FACTOR II - TECHNICAL – SAMPLE TASKS
SUBFACTOR 2.2: SMALL MOLECULE SAMPLE TASK INCLUDING SURGE PRODUCTION

OFFEROR:

REFERENCES:

RATING	DELIVERABLE
BEST VALUE: (Refer to adjectival rating definitions) check one.	
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