

TPP.

*The student should have considered inputs, largely from the TPP, and have given a narrative explaining the product design. Then the student should have outlined outputs that are recommended action items for development.*

## **Section 2. Project Management**

Identify the project and its purpose and provide an overview of the project from the standpoint of the project manager. Include a purpose, scope and technical and management objectives.

*The student should clearly state a purpose for the project and a narrative overview perhaps with a very general outline of the Work Breakdown Structure to reflect major objective and milestones. There should also be indication of project scope.*

Provide the composition of the project team enlisted for this project. Identify team members, their affiliations and locations and authorities and responsibilities and the rationale for these choices. Identify stakeholders to the project and define their roles apart from the team.

*Students should have indicated the job titles or positions assigned to the team along with some idea of whether or not they are in-house, collaborator or contractor affiliations. Those residing at a distance from the Sponsor's primary location should be identified. Apart from team members, a very few Stakeholders should be identified along with an explanation of their roles.*

Describe the team communications plan to include types of communication and frequency of meetings.

*A relevant and workable communication plan should reflect both the project objectives and the composition of the team and locations of team members. The student should have identified methods and frequency of communication.*

Describe metrics that would be used to measure progress of the project.

*The student should describe how the project manager will measure progress of the project against stated objectives and milestones and how this will be reviewed or considered periodically by the team and by upper management.*

Describe the methods the project manager will apply for allocating, tracking and managing resources allocated to the project.

*The student should consider in a narrative how the project manager will budget and manage financial and human resources. Interactions with contractors, partners and collaborators should be discussed as they apply to project objectives.*

Identify the ten major risks this project is likely to encounter. Outline the risk assessment and risk management plans for the project, focusing upon risk mitigation early in the project. Describe the roles for the project manager in risk management. *Students should at some point in the planning process consider risks to the project team and how these will be identified and addressed by the team. A risk assessment and mitigation plan might be outlined.*

Describe your plan for identifying actual problems or issues and resolving them as a team.

*Students should consider the team leadership and dynamics in the problem solving method, describing how resolution of most issues will be addressed by the team.*

Establish a Work Breakdown Structure both as a narrative explanation and as an illustration (e.g., Gantt or PERT chart).

*Students should at the end have a clearly stated, in narrative and illustrative format, a Work Breakdown Structure for their development project.*

### ***Section 3 and Section 4. Regulatory Affairs and Regulatory Compliance***

*The student should demonstrate in all questions under Regulatory Affairs an understanding of how the product and similar products and indications have been and likely will in the future be handled by FDA.*

Is there regulatory precedent for treatment of this indication and population and if so, are the predicate products approved by FDA or any other regulatory agency for marketing? How might this history of predicate products impact the regulatory development of your product? Is there precedent for this type of product (e.g., molecular or cellular nature) having received market approval or having been tested as an investigational drug? If so, what were the outcomes and how might this precedent impact the development and regulatory activities for your product? What do you think is the status of your product in