Northeastern University
College *of* Professional Studies

RGA6463 Regulatory Strategy for Product Development and Life-Cycle Management

Final Paper

Description

The Final Paper for the course involves assembling a regulatory compliant commercialization plan to support pursuit of a biopharmaceutical product from concept through launch, through to obsolescence. As discussed throughout the course, commercialization of a biomedical product involves consideration of many variables unique to the healthcare sector including financial, technical, legal, regulatory, manufacturing, and marketing concerns. A major objective for the course is to give students an opportunity to translate regulatory requirements for medicinal products into broadly applicable regulatory strategies and submissions. This necessarily involves practicing analytical thinking, and effective communication of scientific and technical information. In completing this Assignment students will have the opportunity to use these skills to demonstrate their understanding of the concepts involved in constructing a lifecycle management strategy for a new class of biopharmaceutical products.

Instructions

1) Utilize the following case study to evaluate and communicate your thinking on developing a compliant life-cycle management strategy:

> *Imagine that you, as a regulatory science expert, go camping in a remote area of the world, and find an isolated tribe of people that has not yet communicated with the rest of the world. You discover that this tribe uses several types of "magic dust" to treat a wide variety of human ailments, each with varying safety profiles and degrees of efficacy. For example, the tribe uses "magic dust #1" to treat headaches, nausea, fever and mild systemic pain, "magic dust #2" to treat cuts and bruises, and "magic dust #3" to treat insect bites. In fact, you observe that the tribe has isolated or developed at least 12 different kinds of "magic dust" and your observations suggest that the "magic dust" category as a whole seems to have a novel mechanism of action. You ask the tribe if you can have samples of each magic dust type to bring back home with you for analysis and they agree. When you get home, you give these samples to the medical research community, which discovers that indeed, these "magic dusts" might possibly be used effectively in the US to treat the conditions for which they are utilized by the tribe, and that their pharmacodynamic mechanism of action is, indeed, unique*.

2) As a regulatory expert, you are charged with developing a product development plan to support an NDA submission to the US Food and Drug Administration (FDA) for each magic dust type. You are also responsible for developing a post-market approval plan to ensure ongoing maintenance of regulatory compliance after receipt of an NDA approval. Your plan should address the following "magic dust" associated questions and/or issues:

    - *What pre-clinical requirements should be summarized in the clinical development plan?*
    - *How can the indications for use for each "magic dust" be isolated and refined? Why is it important to do this?*
    - *How can the risk vs. benefit profile associated with utilization of the "magic dust" for clinical purposes be established?*
    - *Should a randomized controlled trial design be utilized to conduct clinical research to support an NDA submission for the "magic dusts" or should an adaptive platform design be utilized instead?*
    - *Are there intellectual property issues that should be addressed?*
    - *How would you go about addressing pricing and reimbursement considerations?*

3) You may collaborate with and submit your work with **at most 1 colleague** from the course in completing your work – *collaboration with a course colleague is an option rather than a requirement of the Assignment*
4) The commercialization plan should take the form of a 10-12 page written document supported by a 10-12 slide MS Power Point presentation
5) When submitting your work please ensure that your name(s) are on the file(s) that you submit. Two separate submission links will be provided in the Week 12 Course Materials section of the Blackboard course shell: **a**. A Turnitin link which should be used to submit your written document, and **b.** A Blackboard Assignment link which should be used to submit your Power Point presentation

Due Date

The submission for this in class exercise is due by 5:00 PM Eastern Time on Friday June 26, 2020 – no late submissions will be accepted for this Assignment

Weight

The written portion of this Assignment is worth 15% of your Final Grade for the course, while the Power Point portion of the Assignment is worth 10% of your Final grade for the course.