Drug Development Plan

Making it the right way

TeaM Number

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# Executive summary

*Hints – Describe the topic, the objective, the times lines, the challenges, the opportunities of this project. A very short summary of the development plan and how it would benefit the patient and the company.*

# Introduction

*Hints – Identify the strengths and the weaknesses of the product. For example state the following:*

* *Unmet medical need*
* *Life threatening disease and the related lower regulatory expectations and how to negotiate*
* *Ensure GxP compliance for phase 1 (in short)*

# Development Plan:

## Part A. Preclinical Plan

*Hints – expand on the thoughts you have generated in the team.*

## Part B. Clinical Plan

## Part C. Chemistry, Manufacturing and Controls

*Hints – Build on your team work. Describe where you would conduct clinical manufacturing and why. How would you ensure compliance?*

## Part D: Pre-IND Meeting / Scientific Advice

*Hints – Build on your team work. Points you would like to discuss with authorities – for example, does the agency agree that the preclinical package is enough to cover the clinical trial. Comments on the protocol. CMC key question – specification etc*

*Include a summary of the project background, the questions with the opinion opf the company, number of attendees, and the time for the meeting (ideally)*

## Part E: Inspection Readiness

*Hints – What does it take to be ready for a possible inspection. Ensure compliance (GxP) for the entire clinical trial.*

# Overall strategy

*Hints – With the above plans on the domains of preclinical, clinical and CMC, how would you accelerate submission process in Germany, with minimum questions from the health authorities and EC/IRB, and obtain rapid HA and EC/IRB approvals?*

# Advice to Management

*Hints – A short cover letter to the management on the Development Plan!*

# Conclusion

*Hints – A very short (two paragraphs) on why you think the regulatory strategy is well thought through and has the maximum chance of success.*