DR. REGENOLD GMBH
DEVELOPMENT • REGULATORY • MARKET ACCESS

Starter Package
Regulatory Biopharmaceutical Development

Aims of the Starter Package

I) To negotiate the benefit of strategic and regulatory science consultation at your individual stage of product development

II) To identify suitable tools and measures for stratification of your development roadmap according to scientific, regulatory and financial needs.

III) To identify the top 3 questions concerning regulatory in the context of development milestones.

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Introduction

From a regulatory perspective, the challenge of biopharmaceutical drug development is the need to interpret regulatory guidelines as they apply to the specific molecular structure and mode of action of the molecule of interest, and in line with the latest scientific knowledge and practice. Dr. Regenold GmbH is providing this biopharmaceutical regulatory *development starter package* to support companies aligning biopharmaceutical drug development programs with the most recent regulatory requirements.

Deliverables

At the end of the starter package process Regenold provide a high level development statement. If applicable this statement will be combined with an outlook of a milestone rationale concerning quality, non-clinical development, clinical development and regulatory pathways.

The starter package process

The starter package is divided into five steps. However, the detailed agenda is tailored to the specific needs of the requesting company.

Step 1: Compiling and signing Confidentiality Agreement (CDA)

Dr. Regenold GmbH will provide a CDA template.

Step 2: 30 min teleconference - project/request briefing

Briefing by the sponsor covering the following topics:

- Molecule/program
- Intended usage (indications)
- Business model
- Specific questions to be discussed during the workshop

Step 3: Regenold team definition and preparation of workshop agenda

Based on the briefing, Dr. Regenold GmbH will define a workshop team ensuring ‘best fit’ with the sponsor’s specific situation. On average, the workshop team will include 3-4 senior experts covering non-clinical development, clinical development, analytical development, manufacturing process development and regulatory affairs. The Regenold team will compile an agenda for the workshop; this is to be approved by the sponsor prior the workshop.

Step 4: Workshop (5 hours)

Part A) Identification and description of the 3-5 most relevant topics according to the current project phase and development strategy. Topics will be analysed for their impact on the critical path of development and the individual business model.

Topics to be discussed include, but are not limited to:

- What is the anticipated development/milestone plan estimated to reach the next development stage?
- What are the specific risks with this type of product (Quality, clinical, preclinical, regulatory)?
- Are there any successful examples of others or is the product in a totally new category?
- Which parts of my product product profile need to be adapted, following the characteristics of my lead compound (e.g. indication, molecular target).
- What is the status of regulations for the product in the market the company is entering?
- Are there impending regulations that are as yet undefined?

Part B) Identify and describe a roadmap to answer the questions summarized under A). The topics listed above will be discussed with a view to outlining design inputs for the development plan and the regulatory pathway.

Step 5: Workshop minutes

You will sum up the workshop by a written draft meeting summary. The draft version will be reviewed and finalized by the Regenold workshop team members. This written protocol would further serve as basic briefing document for future projects supported by Dr. Regenold GmbH, if applicable.

Pricing

The overall price of the starter package is **€4,950**.

If you prefer an in-house workshop at your premises, we can provide a quote in accordance with your needs and the travel required.