Request for Regulatory Advice by the RegulatoryExperts@*ETH*zürich

Please send the completed form to info@dtip.ethz.ch

PROJECT TITLE:		
Applicant		
***Company/Institution*:**		
***Address*:**		
Contact person		
Name:		
Department:		
Phone No.:		***Email:***
Project team		
No. of team members:		
Professional background of the team members:		
Details of the Product		

What is the Product?

□ *Medicinal Product*

□ *Medical Device*

□ *Combination Product*

□ *In vitro Diagnostic Device*

□ *Unclear*

IDEA READINESS LEVEL - SELF ASSESSMENT

*Please choose in each category **the** statement that best describes your level of knowledge.*

1) Regulation & legal basis

□ We do not know any special legal basis that has to be applied to our project.

□ We have already heard about the legal regulations and its scope (Medical Device Regulation, In-Vitro-Diagnostic Regulation, Human Research Act, Therapeutic Products Act etc.).

□ We are familiar with the relevant legal regulation (e.g. Medical Device Regulation, In-Vitro-Diagnostic Regulation, Human Research Act, Therapeutic Products Act etc.).

□ We are familiar with "harmonized norms", common specifications and their use.

□ We are already working according to the legal regulation and international standards.

2) Design & Development

□ We are aware of the importance of documenting the development of a product.

□ We have started to document our development.

□ We are familiar with important development stages/phases/milestones (e.g. Chapter 7 of ISO 13485, Investigator's Brochure)

□ We already have a plan how to establish a development fulfilling regulatory requirements (e.g. Chapter 7 of ISO 13485, Investigator's Brochure).

□ We have started to document our development corresponding to regulatory requirements (e.g. Chapter 7 of ISO 13485, Investigator's Brochure IB, Common Technical Document CTD).

3) Clinical evaluation/development

□ We do not know the requirements for a clinical evaluation/development.

□ We know the importance of clinical evaluation/development and what the legal regulation requires.

□ We are familiar with the elements of clinical evaluation/development.

□ We already have a clinical evaluation/development plan.

□ We have started to document our clinical evaluation/development.

4) Design a clinical study

□ We are aware of the need of clinical studies in order to access the market.

□ We know the requirements for a clinical study design.

□ We are familiar with the different types/different phases of clinical studies.

□ We are familiar with the process to conduct a clinical study.

□ We already know what we need to prove with clinical studies, and we have defined relevant endpoints.

5) Intellectual Property
□ We know the basics of intellectual property rights and copyright law.
□ We know the distinction between different concepts of intellectual properties.
□ We have analysed which intellectual property rights apply to our project.
□ We have conducted a freedom to operate analysis.
□ We have already applied for a patent.
6) Data Protection
□ We are aware that we have to comply with data privacy laws and want to learn more.
□ We are familiar with the distinction between pseudonymous and anonymous data.
□ We already have drafted and concluded data privacy addenda (Auftragsverarbeitungsvereinbarungen / Datenverarbeitungsvereinbarungen).
□ We have observed the principles of data privacy by default and data privacy by design in our product.
□ We are familiar with the challenges of international data transfers.
7) Health care system in the country where you want to enter the market
□ We have not yet dealt with the health care system.
□ We have basic knowledge of the stakeholders in the health care system.
□ We have a good understanding of the health care system.
□ We already have first practical experience with several stakeholders (health insurance companies, authorities, notified bodies, reimbursement organizations/authorities etc.)
□ We have already launched at least one product and have some market experience.
8) Reimbursement
□ We do not have a payer strategy and we do not know who will end up paying for our product.
□ We have initial ideas and basic regulatory knowledge in the area of reimbursement.
□ We have created a reimbursement concept.
□ We have started to implement our reimbursement concept and have contacted the stakeholders.
□ We operate with at least one product in the market and our product(s) is/are reimbursed.