The Team Case Study Project is designed to teach you how to:

* Work across line functions and disciplines.
* Be objective as opposed to subjective.
* Prioritize.
* Sift through the myriad of guidance to find the right answer.
* Write a review-friendly document (ensuring compliance and consistency of information).
* Be conscience of the cultural sensitivities -- “Culture eats strategy at breakfast” -- Language, hierarchy/power-distance, low/high context, individualism, risk-tolerance.

The instructor has provided two case studies for this project – one for a drug and the other for a device. However, we also encourage students to bring their own case studies if they fall in line, even in principle, with the requirements below; this may also include a corresponding team formation. Such case studies need to be approved by the instructor no later than Sunday of Week 1.

In Week 1 of the course, students will sign up for a team on either a drug or medical device track. Each team will consist of 3-5 team members. (Note that choosing a track does not guarantee a place in that track, as we may have to place you on another track for reasons of space. You will be notified in Week 1 of the course if you've been moved.) **Teams A, B, C, D, E... will be on the track for drugs, teams P, Q, R, S, T... will be on the track for devices. Students who wish to participate on the Student-Provided Case Study should sign up for that team.**

When selecting your track, keep in mind your interest, your domain, and your job chances, i.e., where the current needs are in industry. This is easy to find through a Google search. Most important is your interest! The rest should fall in place.

Students will decide amongst themselves who will act as the team leader. **If a team leader is not chosen by Sunday of Week 1, your instructor will appoint one.** Each team member will be developing an Individual Case Study Report. Team members will work with the team leader to develop a single presentation to be recorded by the team leader based on the work contained in the individual reports. This team presentation must be submitted by Wednesday of Week 4.

Each team will have a team discussion board for interacting with other team members. This will be an essential tool for communicating and coordinating your work. Your instructor will consider your discussion board interactions in the grading of your final presentation. The Team leader will organize team meetings to prepare for the required presentation.

**Individual Case Study Report**

**The Individual Case Study Report (ICSR) should be based on the case study description linked above and written using the provided template.**

The requirements for this report are as follows:

* 4 pages in length
* double-spaced (not including references)

For the track on Drugs: Each team member will write a case study report including a minimum of two obligatory EU Health Authority requirements (following, among other references, the EU and ICH guidelines, as referenced in the required readings) for the each of the following five sections and write a short executive summary and a conclusion by himself or herself.  This report (maximum 4 pages) should be submitted by Wednesday of Week 3 to the instructor and to their team members.

Required sections for ICSR-Track on Drugs:

1. Preclinical Plan
2. Clinical Plan
3. Chemistry, Manufacturing and Controls (CMC)
4. Pre-IND Meeting / Scientific Advice
5. Inspection Readiness

For the track on Devices: The ICSR should contain the general requirements of identifying EU and US regulatory requirements for your Insulin Infusion Pump.

Each team member will include a minimum of two obligatory Health Authority requirements (EU and US) and two points of comparison (EU versus US), as mentioned in the template provided. Each should write the executive summary and conclusion by himself or herself and submit their report (maximum 4 pages) by Wednesday of Week 3.

**Team Case Study Presentations**

The team members and team leader should participate in intensive discussions to develop a PowerPoint presentation covering the key points in the Individual Case Study Reports.  The team leader will record a 15-20 minute presentation in Other teams members may also participate in the presentation if that is the team's decision.

**Schematic Representation of Team Case Study Project**

