Volunteer Roles and Needs for Pharmaceutical Day

Overview of Day

FDA has reason to suspect that Norvin Pharma, Inc. has manufacturing issues with their cholesterol-lowering drug, Duracor Tablets. FDA has approached S2S as an independent laboratory to analyze samples from 3 different production plant locations. The products the students will test are these 3 production batches and the Analytical Research and Development (AR&D) research batch.

When the students arrive they will be divided into 4 teams with each team responsible for one of the 4 production samples (AR&D and 3 plants). Members from each of those teams will go to each of the 4 major analytical technologies (HPLC, gas chromatography, dissolution, and identity testing using melting point, UV and IR spectroscopy) to work together on all the samples.

At then end of the day, the team members will reassemble and compile the data for their particular sample from the technique they used. They will then make a presentation to the FDA representative on whether or not there are any issues with any of the Duracor manufacturing batches and to confirm that the AR&D batch meets Norvin's specs.

FDA Representative

The FDA representative will explain why the students are here and what they will be doing for the day. The FDA rep will also explain their purpose at S2S, what information they hope to get by the end of the day, and a brief overview of the drug approval process. This should take approximately 30 min.

At the end of the day, each team will make a formal presentation to the FDA representative, making recommendations regarding manufacturing issues for their batch or problems with the AR&D batch meeting specifications.

Team Leader

Each team will have a mentor that acts as a Team Leader. Each team will spend ~30 min with their mentor/Team Leader to discuss important drug product parameters (drug potency, drug degradation products, other impurities, rate of drug release from the tablet, API identification, tablet-to-tablet uniformity, tablet aesthetics) and analytical chemistry technologies that could provide information about these various parameters. Together with the Team Leader, the students will choose the four major analytical technologies and techniques they'll be using, and what information these technologies will provide about the product. This is important since each team member will only do experiments in one technology. The Team Leader will also explain how the data from all technologies and tests will be compiled at the end of the day, and how the information will be presented to the FDA.

Team members will then go into the lab and work for ~2 hours. The Team Leaders will roam the lab and see how their team members are doing, and start to compile any available

data. They will also help compare and explain data (e.g. the tablets with high tablet breaking force provide a reason for the corresponding low dissolution results).

After a 20 min lunch, team members will have ~30 min to wrap up their experiments and compile data. The teams then reassemble with their Team Leader for ~30 min and put together a presentation of the results of the analyses to present to the FDA representative. All teams assemble in the meeting room and each team presents their data (with a student who did GC presenting GC data, disso student presenting disso data, etc.). The team will then make recommendations regarding manufacturing issues for their batch or problems with the AR&D batch meeting specifications. All four presentations should take ~45 min.

Laboratory Roles

HPLC
Instructor, 2 assistants

GC
Instructor, 2 assistants

ID
Instructor, 2-3 assistants

Disso
Instructor, 1-3 assistants

Minor Tests – Tablet Breaking Force, Appearance, Friability, Average Tablet Weight
Instructor, 1 assistant