5 Miki is informing a new trainee about what she has learned regarding a certain investigational drug at Vine Pharmaceuticals. Complete the excerpt using the correct form of the words in exercise 4.

First of all, it is the _____[1] of the company to complete the preclinical trials by the end of the year. After that, regulatory agencies have to give _____[2] to commence with the clinical testing in humans, which is also done at our company. But before that can happen, our scientists determine how to _____[3] the active pharmaceutical ingredient into a suitable administration form. We have to _____[4] each step of every test very thoroughly before the regulatory agencies give their approval to proceed to the next stage. The _____[5] must show that the _____[6] of the investigational drug is safe for our subjects.

AUDIO 10

Now listen and check your answers.

DESCRIBING A PROCESS (PART 1)

The passive is often used to describe a process. We use it because it focuses on the action, rather than on the person or thing (agent) doing the action. Often the agent is unclear, unknown, or irrelevant.

An experiment A trial/study	is/was	carried out/conducted/done/performed.
A drug		absorbed/administered/formulated/manufactured/prescribed/taken.
The data	are/were	provided/transmitted.
A number of experiments Several tests		conducted/done/performed.
The criteria	can must be will	met.
A study		carried out/ conducted/done/performed.

6 Complete the sentences about preclinical development using the correct form of the verbs in the box.

be administered • be conducted • be determined • be formulated • be provided • be used

1 We started the trial after tests on investigational drugs _____ in vivo and in vitro over a period of up to five years.

2 Last year, results of preclinical testing _____ to come up with the best formulation of the intended drug.

3 Extensive documentation must _____ to the appropriate regulatory authorities.

4 A drug intended to act on the skin can _____ as a cream.

5 Potential risks to humans _____ in toxicity studies.

6 The requirements of drug bioavailability determine how it will _____ to humans.

Now describe an SOP or process in your company using the phrases above.

AUDIO 11

7 Miki has been invited to join an impromptu lab meeting about drug substance MPP 010098, which is being tested in dogs. Miki, Linda, an animal caretaker, Jake, a biological lab technician, and their supervisor, Roger, are talking about a problem. Listen to the conversation and decide if the statements below are true (✓), false (✗), or not mentioned (–).

1 Someone told Linda that the dogs were vomiting. ☐

2 Some dogs were not affected negatively by the drug substance. ☐

3 Linda doesn't know if the animals in the control group are affected. ☐

4 Dogs are more sensitive than mini-pigs. ☐

5 The study protocol will have to be changed. ☐

6 Roger will contact the study director by the end of the day. ☐

7 Miki is going to write the report on what happened. ☐

THE INS AND OUTS OF CLINICAL TRIALS

A **chemistry lab technician** assists chemists and chemical engineers using chemicals and related products, whereas a **biology lab technician** works with living organisms.

A **control group** in preclinical studies is a group of test animals that is not exposed to the medication under study. In an experiment, this group is treated just like the other animals, but does not receive the active ingredient. This group is then compared with the treated animals in order to validate the results of the test.

Low-dose/mid-dose/high-dose groups are three groups of animals which receive different concentrations of the medication under study.

In preclinical trials, at least **two different animal models** are necessary:
1 Testing is done in rodents (e.g. mice, rats, but also rabbits, and/or guinea pigs).
2 Testing is then carried out in animals which have systems more similar to humans, e.g. dogs, mini-pigs, and/or monkeys.

The active ingredient can be tested in humans only after these tests have been successfully completed and authorization has been given.