Pharmaceutical Failure Mode and Effects Analysis
Pegfilgrastim (Neulasta®)

· Step 1:

Describe how the intended product will be procured and used, from acquisition through administration.

Who will prescribe the drug and for what type of patient?
Hematology/Oncology and Gyn/Oncology physicians for patients with non-myeloid oncologic diagnosis receiving myelosuppressive chemotherapy with expected incidence of febrile neutropenia greater than 20%.

Where will the drug be stored?
The drug will be stored in the pharmacy storeroom.

Who will prepare and dispense it?
It will be prepared by pharmacy technicians and dispensed by a pharmacist.

How will it be administered?
Pegfilgrastim is administered subcutaneously.

· Step 2:

Identify potential failure modes (how and where systems and processes may fail) while considering how the product will be used.

Could the drug be mistaken for another similarly packaged product?
It is available as a prefilled syringe (0.6 mL).

Does the label clearly express the strength or concentration?
Yes.

Does the name sound or look like another drug on the formulary?
May sound like filgrastim.

Are dosing parameters complex?
No. The dosing regimen is 6 mg subcutaneous injection once.

Is the administration process error prone?
Pegfilgrastim should not be administered in the period between 14 days prior to and 24 hours after chemotherapy.
· Step 3:

Once failure modes have been identified, determine the likelihood of making a mistake and the potential consequences of an error.

What would happen to the patient if the drug were given in the wrong dose, at the wrong time, to the wrong patient, by the wrong route, at the wrong rate? Pegfilgrastim should not be administered in the period between 14 days prior to and 24 hours after administration of cytotoxic chemotherapy because of the potential for an increase in sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy.

· Step 4:

Identify any preexisting processes in place that could help detect the error before it reaches the patient, and evaluate their effectiveness based upon knowledge of human factors.

There is a double check between the physician and the pharmacy and again between the pharmacy and nursing. There is also a double check procedure within the pharmacy between the technician who pulls the medication and the pharmacist who dispenses the medication.

· Step 5:

If failure modes could cause errors with significant consequences, what actions could be taken to prevent the error, detect it before it reaches the patient, or minimize its consequences? (A few examples include: using an alternative product; preparing the drug in the pharmacy; standardizing drug concentrations, order communication and dosing methods; using auxiliary warning labels or computer alerts; and requiring entry of specific data into computer systems before processing orders).

Administration Information:

What are the most common side effects that Nursing should be aware of to ensure proper monitoring?
Bone pain, injection site reactions.

Is there any associated laboratory monitoring that Nursing should be aware of to ensure proper patient care?
No routine laboratory monitoring on date of injection. CBC would have been done prior to chemotherapy administration.