Pharmaceutical Failure Mode and Effects Analysis
Palonosetron (Aloxi®)

· **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 physicians would prescribe palonosetron for oncology patients

Where will the drug be stored?
Inpatient pharmacy storeroom, pharmacy carousel

Who will prepare and dispense it?
The vial will be dispensed by the Central Pharmacy. Nursing will draw up syringe (straight draw – no dilution)

How will it be administered?
IV push over 30 seconds. Administer 30 minutes prior to chemotherapy.

· **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 packaged as a 5 ml glass vial with a blue flip top.

Does the label clearly express the strength or concentration?
Yes

Does the name sound or look like another drug on the formulary?
Aloxi may be confused with oxaliplatin.

Are dosing parameters complex?
No – 0.25 mg once 30 minutes prior to chemotherapy (day 1 of cycle)

Is the administration process error prone?
Timing is such that administration should be 30 minutes prior to the start of chemotherapy. Palonosetron should not be given more than once weekly.
· 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? Less than adequate protection for prevention of nausea/vomiting if given at the wrong time.

· 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).

Add timing requirement “Administer 30 min prior to chemo” to pharmacy label.