Pharmaceutical Failure Mode and Effects Analysis
Fulvestrant (Faslodex®)

· **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?
Oncology physicians will prescribe fulvestrant for postmenopausal women with metastatic breast cancer whose disease progressed on previous first-line hormonal therapy in addition to an aromatase inhibitor.

Where will the drug be stored?
Fulvestrant will be refrigerated at 2°-8° C (36°-46°F) and to protect from light store, in the original carton until time of use.

Who will prepare and dispense it?
Fulvestrant will be prepared by the pharmacy technician and checked by the pharmacist prior to being dispensed.

How will it be administered?
Fulvestrant is administered intramuscularly with a slow injection in the buttock.

· **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?
No

Does the label clearly express the strength or concentration?
Yes

Does the name sound or look like another drug on the formulary?
No

Are dosing parameters complex?
The dose for fulvestrant is 250 mg IM every given once a month.

Is the administration process error prone?
Yes, fulvestrant is available in a one 5 mL pre-filled syringe or two 2.5 mL pre-filled syringes; when using the 2.5 mL syringes both syringes need to be used to deliver the recommended dose of 250 mg.
**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?

Over-dose - there has not been any experience with overdosage of fulvestrant in humans.

Under-dose – Fulvestrant is available in a one 5 mL pre-filled syringe and two 2.5 mL pre-filled syringes. When the two 2.5 mL syringes are used both syringes should be used to deliver the required 250 mg monthly dose. The two 2.5 mL syringes pose the risk of underdosage if both syringes are not used at the time of administration.

**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.

Currently medication pre-filled syringes are kept in the pharmacy store-room. Once the physician places the order for the medication and the pharmacist verifies the order; the medication is pulled by the pharmacy technician and double-checked by the pharmacist.

**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).

To prevent underdosage stock the one 5 mL pre-filled syringe.

**Administration Information:**

What are the most common side effects that Nursing should be aware of to ensure proper monitoring?

Injection site reaction (usually caused by seepage of the medication from the injection site, or by too rapid injection – injection should be done over a minute, deep IM).
Is there any associated laboratory monitoring that Nursing should be aware of to ensure proper patient care?
No routine laboratory monitoring.