Pharmaceutical Failure Mode and Effects Analysis
Ranibizumab (Lucentis™)

· **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?
Ophthalmology physicians will prescribe Lucentis for patients with neovascular (wet) age-related macular degeneration.

Where will the drug be stored?
It will be stored in the in the Pharmacy IV room refrigerator protected from light at 2º-8ºC (36º-46ºF).

Who will prepare and dispense it?
It will be prepared by a certified pharmacy technician and be double checked by an IV room pharmacist.

How will it be administered?
It is administered by an intravitreal injection into the effected eye.

· 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 supplied as a 2-mL single-use vial.

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?
No-0.5 mg (0.05mL) injected intravitreally once a month

Is the administration process error prone?
Yes-not administering Lucentis into the correct eye and not administering it intravitreally

· 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? Overdose: excessive pharmacological effects such as intraocular inflammation, increased intraocular pressure, conjuctival or retinal hemorrhage, and an arterial thromboembolic event

· 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 a double check procedure with the IV room between the technician who prepares the medication and the pharmacists who checks the medication. Health care providers follow a two patient identifier policy prior to administration. Duplicate warnings are within Epic, the order entry system.

· 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).

Store Lucentis vials in the refrigerator away from other vials that are prepared for parenteral administration.