Pharmaceutical Failure Mode and Effects Analysis
Erlotinib (Tarceva®)

· **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 erlotinib for oncology patients.

Where will the drug be stored?
Inpatient pharmacy storeroom, outpatient pharmacy.

Who will prepare and dispense it?
Pharmacy technician will pull the medication from storage area and a pharmacist will perform the final check prior to dispensing.

How will it be administered?
Oral administration.

· **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?
Packaged in a white bottle with maroon lettering. “Tarceva (erlotinib)” is clearly expressed.

Does the label clearly express the strength or concentration?
Yes – 25 mg, 100 mg, and 150 mg

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

Are dosing parameters complex?
No – typically 150 mg/day.

Is the administration process error prone?
No – give on an empty stomach.
· **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? Possible side effects include rash, fatigue, itching, diarrhea, anorexia, and nausea.

· **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).

All doses are dispensed from the pharmacy. Erlotinib should be administered only under the supervision of a physician who is experienced in the use of cancer chemotherapy agents.