Pharmaceutical Failure Mode and Effects Analysis
Paclitaxel Protein Bound (Abraxane™)

· 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 Abraxane™ for breast cancer patients.

Where will the drug be stored?
It will be stored in the pharmacy storeroom at room temperature in its original packaging.

Who will prepare and dispense it?
Abraxane™ 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 IV infusion by a chemotherapy certified nurse.

· 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 100 mg 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?
Paclitaxel (Taxol®)

Are dosing parameters complex?
260 mg/m² every 3 weeks. Adjustments based on neutrophil count and side effects.

Is the administration process error prone?
No – administer over 30 minutes.
· 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, wrong rate: higher incidence and severity of side effects

· 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 prepares the medication and the pharmacist who dispenses the medication. Nurses follow a two patient identifier policy prior to administration. All chemotherapy is delivered in a distinct chemotherapy bag. The chemotherapy order entry process includes a second pharmacist check and verification of a nursing checklist.

· 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 “Administer over 30 minutes” to the final product label.
Do not store regular paclitaxel and Abraxane™ side by side in the pharmacy storeroom.