Pharmaceutical Failure Mode and Effects Analysis
Supprelin LA®

· 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?
Pediatric Endocrinologists will prescribe Supprelin LA® for pediatric patients with Central Precocious Puberty.

Where will the drug be stored?
The insert will be stored in the pharmacy storeroom.

Who will prepare and dispense it?
Pharmacy technicians will prepare the dose and pharmacists will dispense the dose.

How will it be administered?
Insertion of the implant requires a surgical procedure to be done by the Department of Surgery.

· 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?
Supplied in a shipping container with two inner cartons: one carton containing the Supprelin LA® that is shipped with a cold pack inside a polystyrene cooler that must be refrigerated upon arrival to the facility and a second, larger container with the Implantation Kit, which is not to be refrigerated. This specific container should not be mistaken for other containers.

Does the label clearly express the strength or concentration?
Unknown.

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

Are dosing parameters complex?
No – implant every 12 months.

Is the administration process error prone?
Insertion of the implant requires a qualified healthcare provider. The process is an outpatient procedure.

· **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?

Implanting Supprelin LA® in a pregnant patient could cause fetal harm.

· **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 are several double check opportunities. The patient will be seen by two different doctors – a pediatric endocrinologist and a surgeon. A nurse should be present during the procedure. A pharmacy technician will pull the medication which will be double checked by a 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).

A practice guideline for the use of GnRH analogs for the treatment of precocious puberty was submitted with the formulary request. Treatment processes for both leuprolide depot and histrelin implant were summarized. The processes will standardize treatment procedures.

**Administration Information:**

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

Pain, redness or swelling at the implant site (usually upper arm)
Is there any associated laboratory monitoring that Nursing should be aware of to ensure proper patient care? If yes, please list.

No laboratory monitoring necessary during implant procedure. Therapeutic monitoring will be conducted during follow-up visits in the UTMB Pediatric Endocrinology outpatient clinic.