

CENTER OF EXCELLENCE FOR REGENERATIVE HEALTH BIOTECHNOLOGY EDUCATION CENTER		
SOP No. BEC-FA-001		Revision No. 00
Approval – Operating Unit	Date	Supercedes 01
Approval – Quality Assurance	Date	Issue Date

TITLE:

GOWNING FOR THE MANUFACTURING FACILITY

CHANGE HISTORY:

REV. NO. 00 NEW

CENTER OF EXCELLENCE FOR REGENERATIVE HEALTH BIOTECHNOLOGY EDUCATION CENTER	
SOP No. BEC-FA-001	Revision No. 00
Title: GOWNING FOR THE MANUFACTURING FACILITY	Page 2 of 4

1 PURPOSE

To describe the garment requirements and procedures for gowning to enter the Class 10,000 and Class 100,000 cleanrooms.

2 SCOPE

This procedure applies to all personnel, vendors, contractors, repairmen, and visitors entering the Class 10,000 and Class 100,000 cleanrooms. The requirements of this procedure may be suspended when the cleanrooms are in official shutdown.

3 REFERENCES

- 3.1 SOP #QC-042 – Environmental Monitoring Program
- 3.2 SOP # FA-016 – Cleaning and Sanitizing the Manufacturing Facility
- 3.3 All other Manufacturing SOPs and BRs.

4 RESPONSIBILITIES

It is the responsibility of Manufacturing and QC personnel to follow this procedure and to ensure that all vendors, contractors, repairmen and visitors follow this procedure. It is the responsibility of supervisory personnel to ensure compliance with this procedure and to train employees responsible for performing this procedure.

5 GOWNING SUPPLIES

- 5.1 Gloves, powder-free, bulk packaged, disposable
- 5.2 Gloves, Safe Skin, sterile, wrapped in pairs, disposable
- 5.2 Bouffant caps, disposable
- 5.3 Coveralls, disposable
- 5.4 Masks, disposable
- 5.5 Shoe covers, disposable
- 5.6 Hoods, disposable

CENTER OF EXCELLENCE FOR REGENERATIVE HEALTH BIOTECHNOLOGY EDUCATION CENTER	
SOP No. BEC-FA-001	Revision No. 00
Title: GOWNING FOR THE MANUFACTURING FACILITY	Page 3 of 4

- 5.7 Boots, disposable
- 5.8 Arm sleeves, disposable
- 5.9 Eye Protection, re-usable

6 GOWNING PROCEDURE

- 6.1 Be sure to remove all jewelry and make-up before entering facility to gown. Wash hands with disinfectant soap and warm water, then dry with low lint wipes.
- 6.2 Step on the tacky mat, lifting feet up and down, several times, when entering the Facility.
- 6.3 Put on shoe covers.
- 6.4 Treat hands with hand sanitizer.
- 6.5 Put on disposable face mask, re-usable eye protection (cleaned with 70% IPA), and bouffant cap or hood. Make sure bouffant cap or hood covers hair and ears completely. Be sure the face mask is worn so there are no gaps around nose or mouth.
- 6.6 Put on powder-free bulk packaged gloves. Clean glove liners may be worn beneath gloves, if desired.
- 6.7 Enter the gowning room.
- 6.8 Obtain coveralls, boots, a second pair of gloves and armsleeves (if necessary) from supply rack.
- 6.9 While on the dirty side of the dirty/clean line, step into coverall, one foot at a time, being careful not to let the gown touch the floor.

NOTE: Take care not to tear garment. If any tear occurs, remove garment and replace immediately with a new one.

- 6.10 Sit on the steel bench with both feet on the floor of the dirty side of the room. Carefully lift one foot off the dirty floor, swing that leg over the dirty/clean

CENTER OF EXCELLENCE FOR REGENERATIVE HEALTH BIOTECHNOLOGY EDUCATION CENTER	
SOP No. BEC-FA-001	Revision No. 00
Title: GOWNING FOR THE MANUFACTURING FACILITY	Page 4 of 4

line and place boot over shoe cover. Touch the outside of the boot as little as possible. When the boot is on, place that foot on the floor on the “clean” side of the line. Repeat with the other foot.

- 6.11 Put on second pair of gloves, and armsleeves (if necessary). **MAKE SURE GLOVES ARE OUTSIDE AND OVER COVERALL AND ARMSLEEVE CUFFS.** Bare hands or wrists should **NEVER** be exposed inside the cleanroom.
- 6.12 Enter the class 10,000 room(s).
- 6.13 Prior to working in a BSC, remove outer gloves and put on arm sleeves from bin in production rooms. Put on a new pair of **STERILE** gloves found in bins in production rooms.
- 6.14 The outer gloves and arm covers may be changed as necessary while working in the Class 10,000 cleanroom. Bare hands or wrists should **NOT** be exposed inside the cleanroom. After working in the BSC, place outer gloves and armsleeves in Biohazard Waste Bag.

7 DEGOWNING PROCEDURE

- 7.1 Enter the de-gowning room.
- 7.2 Cross over the clean/dirty line to the dirty side. While **STANDING** on the dirty side, remove gowning.
 - 7.2.1 **DO NOT SIT ON THE BENCH.** Remove outer gloves, boots, armsleeves, and coveralls.
 - 7.2.2 Place garments in waste bag.
 - 7.2.3 Place outer gloves and arm covers in Biohazard Waste Bag.
- 7.3 Exit the cleanroom facility.
- 7.4 Remove hood, facemask, bouffant cap, shoe covers and gloves.