1. Installation qualification objective

The purpose of this Installation Qualification (IQ) protocol is to provide documented evidence that the Cell Isolator of the Biocell Center of Busto Arsizio has been installed in accordance with the manufacturer's design criteria and drawings and customer specifications. This document also defines the qualification requirements and the acceptance criteria required to ensure that the Cell Isolator is installed properly. This work will be accomplished by verifying the proper installation of the machine and appropriately documenting the results.

2. Scope

The scope of this IQ is limited to the isolator mod. Cell Isolator, ser. n° 08001, installed in Biocell Center of Busto Arsizio.
The Cell Isolator is an isolator developed by Sintetica S.A. conceived for manipulation of staminal cells according to the customer procedure described in the following chapter, in aseptic conditions and in compliance with the current GMP.

It is designed to provide EU Class A in conditions of temperature and overpressure controlled. Sterility of the isolator is achieved with vaporized hydrogen peroxide supplied by an external VHP generator.

Operations inside the working cabinet are possible without compromising the sterility and integrity of the Class A environment through a pair of gloves held on the doors.
The Cell Isolator is composed of the following parts:

1. HEPA filtration units and fan;
2. Air cooling system;
3. Working cabinet with 2 gloves;
4. Decontamination pass box;
5. Egress pass-box (IDC transfer port);
6. Criovials and Falcon tubes cooling system.

Air inside the working cabinet is recirculated by a fan through a HEPA filter located on the top of the cabinet.
Overpressure is automatically controlled by entering dry compressed air or by discharging air through a HEPA filter. Temperature is automatically kept within the established range thanks to a cooling system. External cold lights provide the illumination of the working cabinet.

Alarms, interlocks and sensors controllers are installed to control the main process parameters and ensure the safety and the reliability of the process.

VHP generator and isolator are connected with a Tri-clamp port and a pneumatic butterfly valve.

3. Work procedure

1. A solution containing staminal cells is contained in a 15 ml vial (Falcon type).
2. The vial is centrifuged to have the separation of the staminal cells from the mother liquor.
3. A small stainless steel rack containing the Falcon vial, an empty Falcon vial and an empty criovial is put inside the Pass box.
4. The external surface of the above mentioned materials is biodecontaminated via Vaporized Hydrogen Peroxide.
5. The rack is entered inside the sterile working cabinet (previously sterilized).
6. The mother liquor is transferred in the empty Falcon vial, by using a disposable sucking device.
7. A freezing solution is obtained by adding a 10 % of DMSO (available sterile in a sealed bottle) to the mother liquor.
8. The freezing solution is cooled at 2-3 °C thanks to the internal cooling system of the working cabinet.
9. 1 ml of cooled freezing solution is added to the staminal cells then the solution is transferred in the criovial.
10. The criovial is transferred outside of the isolator passing through a Biosafe port and frozen in liquid nitrogen.

Operations 1, 2 and 10 occur outside of the isolator. During a work shift the above mentioned operations can be repeated up to 4 times.