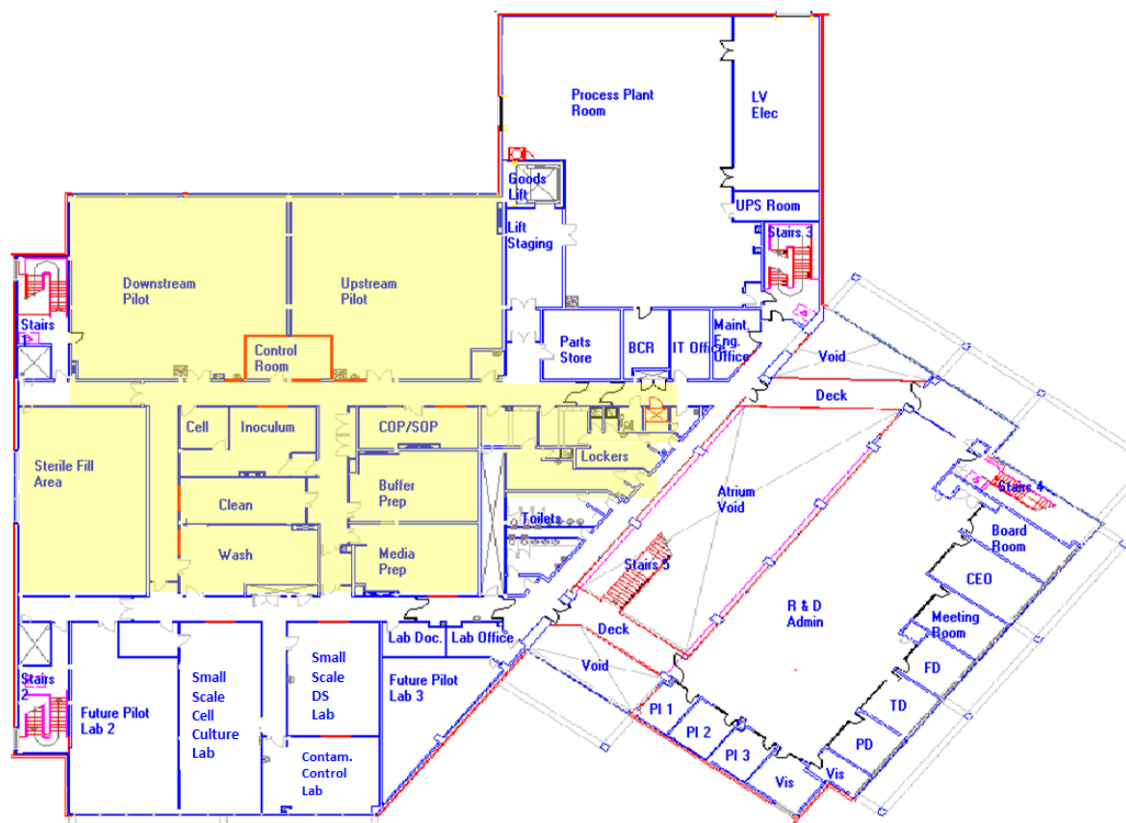


This document outlines the training facilities in NIBRT:

- Pilot Plant (Page 1)
- NIBRT GE SUT Centre of Excellence (Page 5)
- Training Labs (Page 6)
- Clean Utilities (Page 11)

## Pilot Plant:

1. Inoculum and Cell Bank
2. Upstream Processing
3. Downstream Processing
4. Fill Finish
5. Equipment Preparation
6. Media Preparation
7. Buffer Preparation
8. COP/SOP (Clean-out-of place/Steam out-of-place)



**Figure 1:** NIBRT Pilot Plant (highlighted yellow)

## 1. Inoculum and Cell Bank

- 25L Liquid Nitrogen Dewar (Taylor Wharton)
- Bio Safety Cabinet (Bioair Safemate 1.2)
- Biostat Cultibag RM Control Tower (Sartorius Stedim)
- Biostat Cultibag RM Rocker Unit Tower 5-50L (Sartorius Stedim)
- Centrifuge (Hettich Rotina-380)
- Fridge 4°C (Labcold)
- Incubator (Thermo MaxQ6000)
- Lab Freezer -20°C (Labcold)
- Liquid Nitrogen Dewar (Nalgene 4L)
- Liquid Nitrogen Dewar (Statebourne Biorack 750)
- Peristaltic Pump (Cole Palmer Masterflex)
- Peristaltic Pump (Watson Marlow 520S)
- Ultra Low Freezer -80°C (Sanyo)
- Vi-Cell XR (Beckman Coulter)
- Water Bath (GFL)
- Weigh Scales (Fischer Scientific SG402)

## 2. Upstream Suite

- 150L SS Bioreactor x2 (Pierre Guerin)
- 30L SS Bioreactor (Pierre Guerin)
- Bench-top disk-stack centrifuge (Westfalia)
- BioSealer Tube Sealer (Sartorius Stedim)
- Centramate bench-top TFF (Pall)
- Depth/Sterile filtration skid (Pall)
- Disk-stack centrifuge (Westfalia)
- Disposable depth filter (3M)
- Hollow fibre Perfusion Skid (Pall)
- Microfiltration skid (Pall)
- STR 200L Disposable Bioreactor (Sartorius Stedim)
- Tubing Welders (Sartorius and Terumo SCD IIB)
- Turbidity Meter (Merck)

### 3. Downstream Suite

- AxiChrom Master (GE)
- Bag Trolley x 8 (Pall)
- BioWelder Tube Sealer (Sartorius Stedim)
- Capture Pooling Vessel (Kells)
- Chromatography Column (10cm) x 4 (Kronlab)
- Chromatography Skid x2 (Pall)
- Instrumentation Skid (Endress & Hauser)
- Integritest 4 x2 (Millipore)
- IsoPak Column 440mm (Millipore)
- IsoPak Column Packing System (Millipore)
- KrosFlo TFF system (Spectrum)
- Palltronic Flowstar IV Filter Integrity Tester (Pall)
- Palltronic Flowstar LGR (Pall)
- pH Viral Inactivation Vessel (Kells)
- Post-Viral Ultrafiltration Skid 15L (Pall)
- Pre-Viral Ultrafiltration Skid 50L (Pall)
- Sartochek 4 (Sartorius Stedim)
- Sartochek 4+ (Sartorius Stedim)
- Viral Inactivation Vessels (15L) x 2 (Kells)

### 4. Fill Finish Suite

- Glove Integrity Testers x2
- Inspection Light Box (Bosch)
- Lux Meter
- Non-Viable Particle Counter (Climet CL153 1 CFM )
- Non-Viable Particle Counter (Lighthouse Solair 3100+)
- Qube (M19 isolator) (Bioquell)
- RABS (Extract Technology)
- Viable Air Sampler (Millipore)
- Viable Air Sampler (SAS)
- Vial Filling Line (Watson Marlow Flexicon FPC50)

### 5. Equipment Preparation

- Portable TOC Analyser with Autosampler (Sievers 5310C)
- Autoclave (Getinge)
- Autoclave Trollies (x2)
- Water Sampler (Aztec)

- Kaye Validator LTR- 40/140 (GE)
- Partswasher (Suncombe)
- Sterile Tube Sealer (Wave Biotech IRC)
- Heat Sealer (Hacona C4200)
- Triple bucket systems (x6)

## 6. Media Preparation

- 200L Mobile Media Prep Vessel (Kells)
- Allegro mixer biocontainer (PALL; 50L)
- Bench Top Scales (Acculab and ScoutPro)
- Biosafety Cabinet (Safemate 1.2 )
- Conductivity meter (OSMOMAT 030)
- Disposable Bag Holder Trolleys (Pall)
- Fridge (Labcold)
- Hot Plate Stirrer (Stuart)
- Lev mixer (Sartorius Stedim)
- Mobile BR (Sartorius Stedim)
- Mobile Dust Collector (Delphin)
- Osmometer (Five Easy FE-30)
- Peristaltic Transfer Pumps (Watson and Marlow)
- pH Meter (Thermo Scientific)
- Scale Printer (Sartorius)
- Tube Sealers (Sartorius Biosealer P3 2.4mm and P8 3.2mm)
- Tubing Welders (Sartorius and Terumo SCD IIB)
- Weigh Scale Platform (Sartorius Combics 3)

## 7. Buffer Preparation

- Bench Top Scale (Acculab)
- BioSealer Tube Sealer x 2 (Sartorius Stedim)
- Biowelder Tube Welder (Sartorius Stedim)
- Fume hood (Waldner MC6)
- Hot Plate (Fisher)
- LevMixer and LevTech unit (Sartorius Stedim)
- Mobile Buffer Prep Vessel ( Kells Stainless Steel 60L)
- Mobile Buffer Prep Vessel (Kells Stainless Steel 60L)
- Mobile Dust Collector (Fumex Type MB1500-50ESD)
- Peristaltic Transfer Pump (Watson Marlow 520S)
- Peristaltic Transfer Pump (Watson Marlow 520S)

- pH Meter (Thermo Orion 3 star)
- Sonicator (Fisher)
- SU Mixer System (Millipore Mobius Mix 200)
- Weigh Scale (ADAM)
- Weigh Scale Platform (Sartorius Stedim)
- Weigh Scale Printer x 2 (Sartorius Stedim)

## **8. COP/SOP**

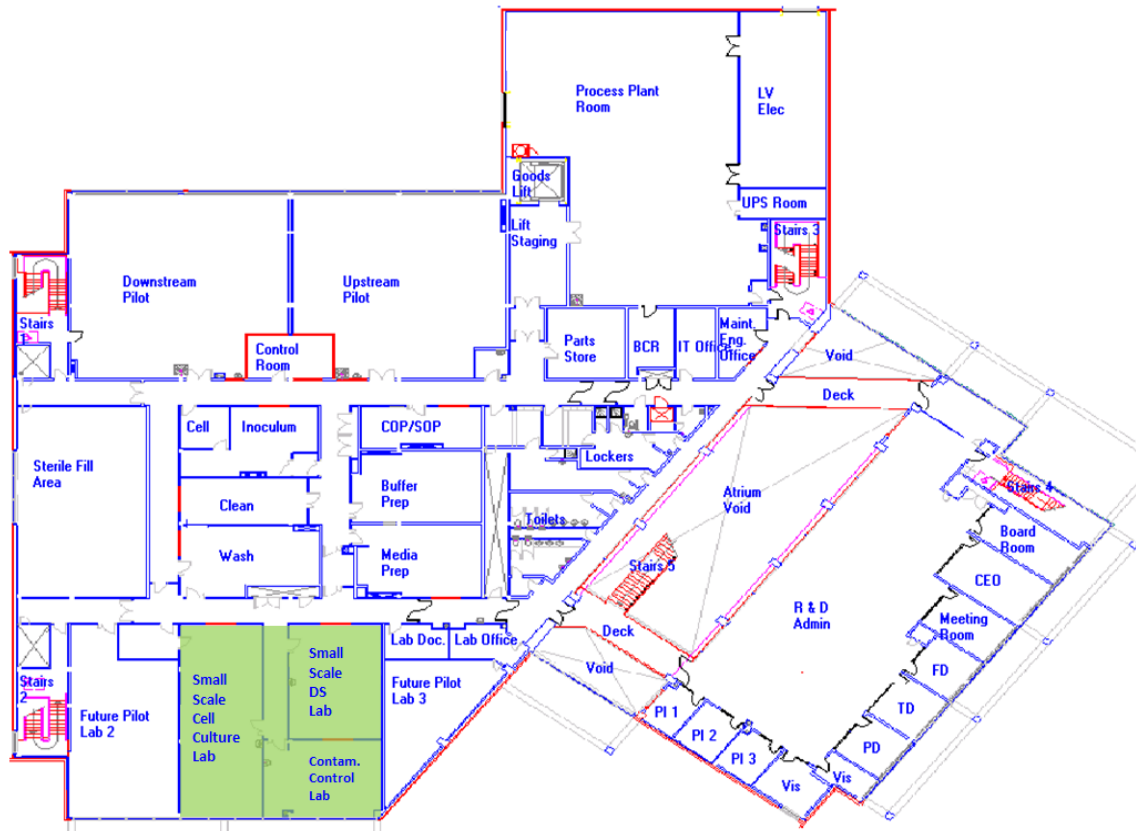
- Coupon swab kit (Globepharma)
- Telescopic swab sampling assembly (Globepharma remote swabbing and microbiological sampling tool)
- TOC swab sampling kit
- UV torch (Magnaflux model ZB100F)

## **NIBRT GE SUT Centre of Excellence**

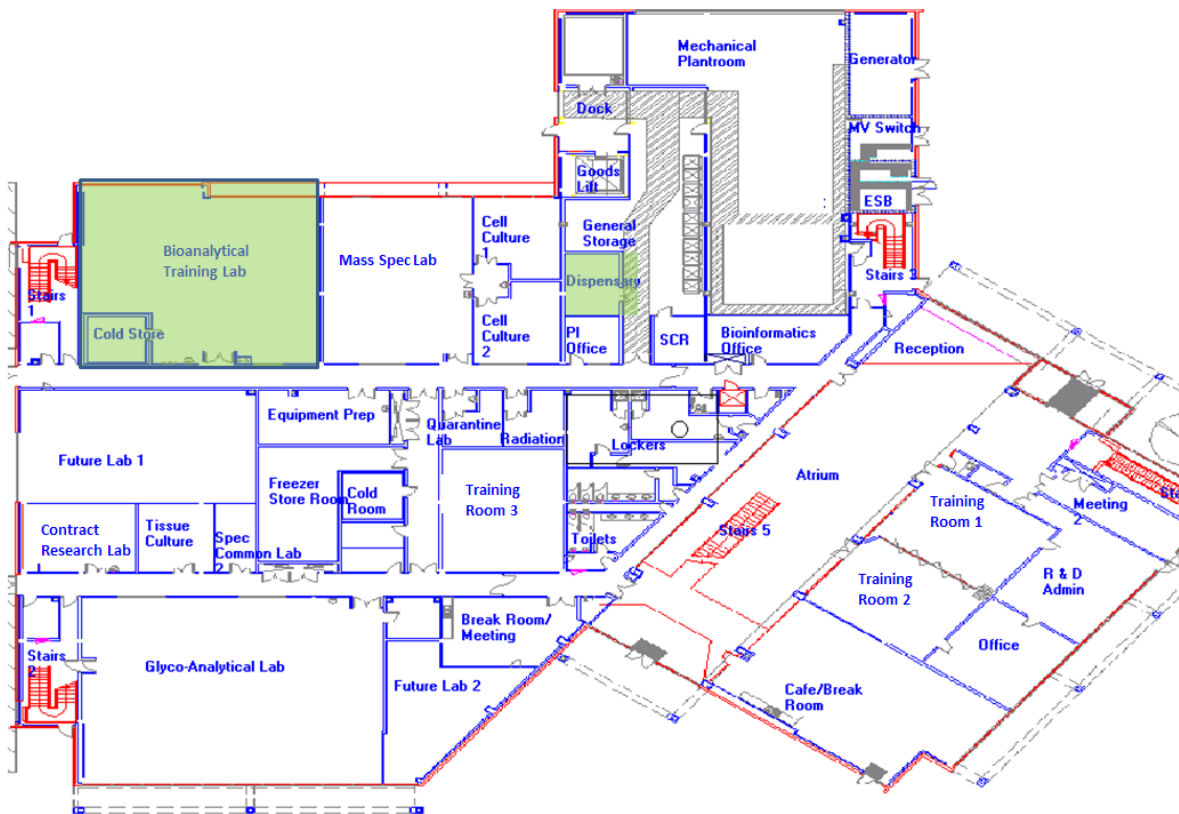
- Ready To Process Wave 25 x2
- XDR-50
- XDR-200 x2
- ÄKTA Ready x2
- ÄKTA ready gradient
- ÄKTA Ready Flux
- RTP Bin 500 x3
- RTP Bin 200 x7
- ReadyKart x2

## Small Scale Training Labs:

1. Contamination Control
2. Cell Culture and Aseptic Techniques
3. Bench Scale Downstream
4. Bioanalytics
5. Dispensary



**Figure 2: NIBRT First Floor Training Labs (highlighted green)**



**Figure 3:** NIBRT Ground Floor Training Labs (highlighted green)

## 1. Contamination Control

- 7L Bioreactor x 3 (Applikon Biotechnology)
- Bio Console ADI 1025, x 2 (Applikon Biotechnology)
- Bio Controller ADI 1010 x 2 (Applikon Biotechnology)
- Biosafety Cabinet Dura Vertical S.D. 4 (BioAir)
- Biostat CultiBag RM Control Tower (Sartorius Stedim)
- Biostat CultiBag RM Rocker (Sartorius Stedim)
- Gas analyser 5200 MultiPurpose x 3 (Servomex3)
- Gas Supply Unit ADI 1026 x 2 (Applikon Biotechnology)
- Incubator HERACell 240i x 2 (Thermo Scientific)
- Masterflex Pump x 3 (Cole-Parmer Instrument Company)
- Microscope (Nikon)
- Sonicator FB15050 (Fisher Scientific)
- Sparkfree Refrigerator (Labcold)
- Tube Sealer Biosealer (Sartorius Stedim)
- Tube Welder Biowelder (Sartorius Stedim)
- Universal Oven 100-800 (Mettler)

- UniVessel SU 2L Bioreactor (Sartorius Stedim)
- UV 35W Validation Torch Klercide (Shield Medicare)
- UV 52W Cabinet KlerReveal (Shield Medicare)

## **2. Cell Culture and Aseptic Techniques**

- Bio-Profiler (NOVA BioMedical)
- Biosafety Cabinets x 6 (BioAir/ESCO)
- Block Heater (Stuart)
- Cedex Bio Analyser (Roche)
- Convection Oven (Mettler)
- Floor Mounted Centrifuge (Beckman Coulter)
- Fume Hood (Waldner)
- Hot Plate Stirrer (Fischer Scientific)
- Incubator (Thermo Scientific)
- Incubator Shaker (New Brunswick Scientific)
- Microreactor (PALL Micro-24)
- Microscopes (Inverted) x 5 (Nikon Eclipse/ VWR/ Motic)
- Minus 20 degrees Freezer (Labcold)
- Osmometer (Gonotec)
- Peristaltic Transfer Pump (Watson Marlow)
- Thermoshaker (Biometra)
- ViCell Cell Counter (Beckman Coulter)
- Vortex x 5 (IKA)
- Water bath (Grant)

## **3. Bench Scale Downstream**

- ÄKTA Crossflow UF/DF systems x 2 (GE)
- ÄKTA Explorer Chromatography Systems x2 (GE)
- Bench-top balances (ScoutPro)
- Conductivity meters X 5 (Mettler Toledo)
- Minimate Bench-top Ultrafiltration Units x5 (Pall)
- Peristaltic Transfer Pump x 5 (Watson Marlow)
- pH meters X 2 (Thermo Scientific)
- Small scale chromatography kits
- Vacuum pump for bench scale filtration



## 4. Bioanalytics

- Analytical Ultracentrifuge (Beckman Coulter)
- Auto Titrator (Metrohm)
- Autosampler (GE)
- Biacore (GE)
- Block heater (Eppendorf)
- Capillary electrophoresis (Beckman Coulter)
- Capillary electrophoresis (Agilent)
- Centrifuge (Thermo Scientific)
- Centrifuge x 2 (Eppendorf)
- Conductivity Meter x 2 (Jenway)
- Conductivity Meter x 5 (Mettler Toledo)
- Convection Oven (Mettler)
- Electronic Balance (Shimadzu)
- Electrophoresis gel tanks x 4 (Fischer Scientific)
- Power unit x 2 (A.A.Hoefler)
- Freezer x 2 (Labcold)
- Fridge Labcold
- FTIR (Thermo Scientific)
- Fume hood (Waldner)
- Heating mantel/stirrer x 4 (Stuart)
- Image Analyser (SYNGENE)
- Karl Fischer Titrator (Schott Instruments)
- Mass spectrometer x 2 (Waters)
- Osmometer (Gonotec)
- PCR (Eppendorf)
- pH meter (Mettler Toledo)
- pH meter x 2 (Thermo Scientific)
- Plate Reader (Perkin Elmer)
- Portable TOC Analyser (GE)
- Precision Scales (Fisher Scientific)
- RealTime PCR (Roche)
- Rocker (Stuart)
- Solo VPE (C Technologies)
- Speed Vac (Thermo Scientific)
- UPLC x 5 (Waters)
- UV Spectrophotometer (Jenway)
- UV Spectrophotometer (Hitachi)
- Vortex X 2 (IKA)

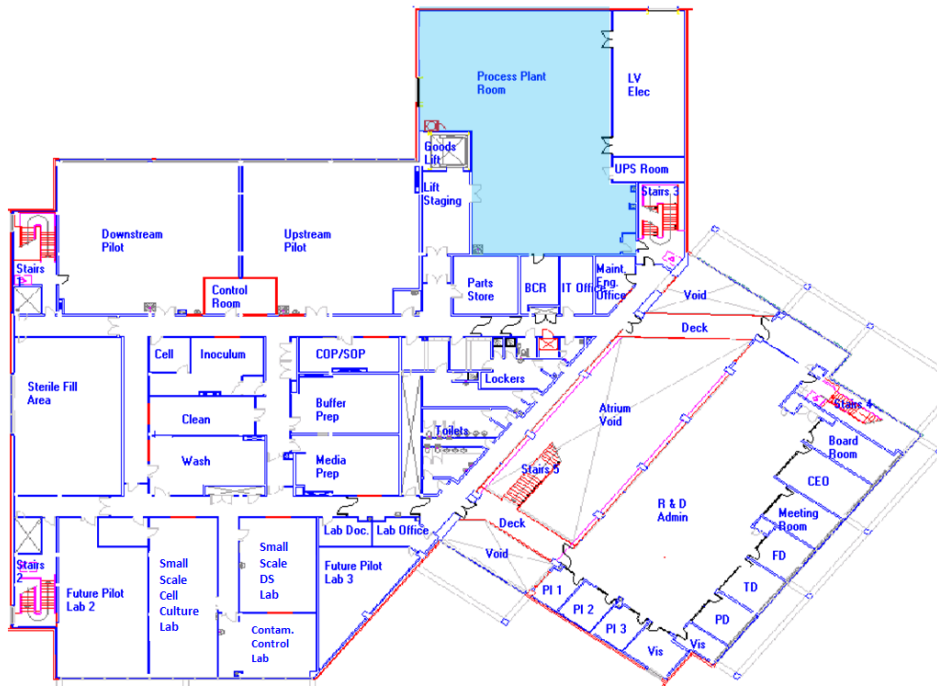
- Vortex (2)
- Water Bath (Grant)
- Western Blotting units x 4 (SCIE - PLAS)

## **5. Dispensary**

- Anemometer
- Down flow booth
- Non-Viable Particle Counter (Climet CL153 1 CFM )
- Non-Viable Particle Counter (Lighthouse Solair 3100+)
- Smoke Generator (DOP)
- Viable Air Sampler (Millipore)
- Watson Marlow Peristaltic Pumps x 2
- Weigh scales (Sartorius Stedim, ScoutPro)

## Clean Utilities

1. PUW system
2. CIP system
3. Clean Steam System
4. Plant/Process Air



**Figure 4:** NIBRT Clean Utilities (highlighted blue)

### 1. PUW System

- F270 50 µm cartridge filter
- Structural carbon polyglass filter with PE inner shell
- Structural water softener polyglass filter with PE inner shell
- Christ Aqua Ultrafiltration system (model no:sfp-2660)
- Testo Mat 2000 water hardness tester
- Endress and Hauser chlorine monitoring system
- Advance UV Inc. UV Disinfection unit
- Christ Aqua RO and EDI unit
- T560 PUW storage tank
- Thorton metler Toledo 5000 T.O.C
- Innovatec O3 Analyser and Generator
- Siemens PUW analysis

## **2. CIP System**

- Suncombe (x2) CIP 500l Storage Tanks
- Siemens multi-panel analysis

## **3. Clean Steam System**

- Telstar Clean steam generator and analyser

## **4. Plant and Process Air**

- Atlas COPCO quality solutions compressed air storage, analysis and filters.