

AASTROM



Aastrom Biosciences *Copenhagen, Denmark*

ATMP Facility Sale
November, 2014

The site offers state of the art facilities that fulfilled the strict requirements of EU GMP for manufacture of sterile pharmaceutical products, including Advanced Therapy Medicinal (ATMP) products.



- Facility occupies 1,200 square meters with classified areas complying with EU GMP Annex 1 - grades A, B, C and D (ISO 5, 7 and 8)
- New clean room approved in 2012 by Danish Health & Medicines Agency (DHMA)
- Facility held the following licences issued by DHMA:
 - Tissue Establishment Licence
 - GMP Manufacturing Licence for chondrocytes

Internal engineering services include:

- Design of cell culture cleanrooms in compliance with ISO and Annex 1
- Expertise with handling of materials and methods
- Commissioning / start-up
- Certification and validation to current standards



Present equipment for cell cultivation process

Equipment in A/B area include:

- Biological Safety Cabinets (BSC) – Left photo
- Incubators – Middle photo
- Centrifuges – Right photo
- Continuous Particle Monitoring System (CPMS) ports used to collect non-viable particles in both Grade A and B environment - No photo
- Viable air monitoring in BSCs – No photo



Present equipment for cell cultivation process

Equipment in D and warehouse areas include:

- Pharma grade Refrigerators and Freezers – Top right photo
- Cryopreservation tanks – Lower left photo
- Warehousing



Programs Established for Controlling the Facility

The following programs are established:

- Environmental Microbiological Testing Program
 - Viable and Non-viable particles
 - Personnel
 - Facility
- Equipment Testing Program
- Clean Room Cleaning Program
- Sterility Assurance Program
- HVAC and HEPA Systems
- Building Management System (BMS)
- Facility Management System (FMS)

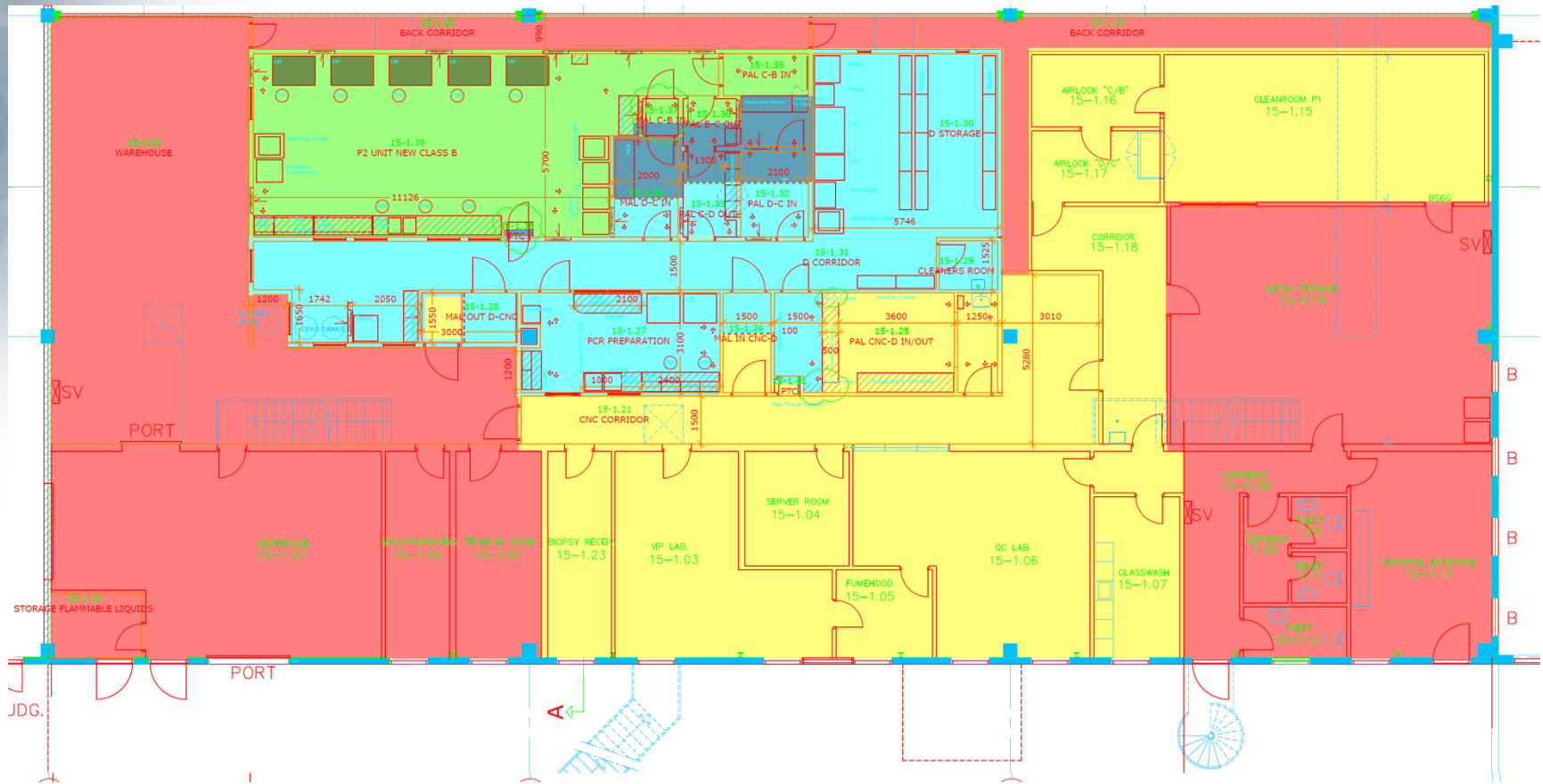


Quality Control Testing including:

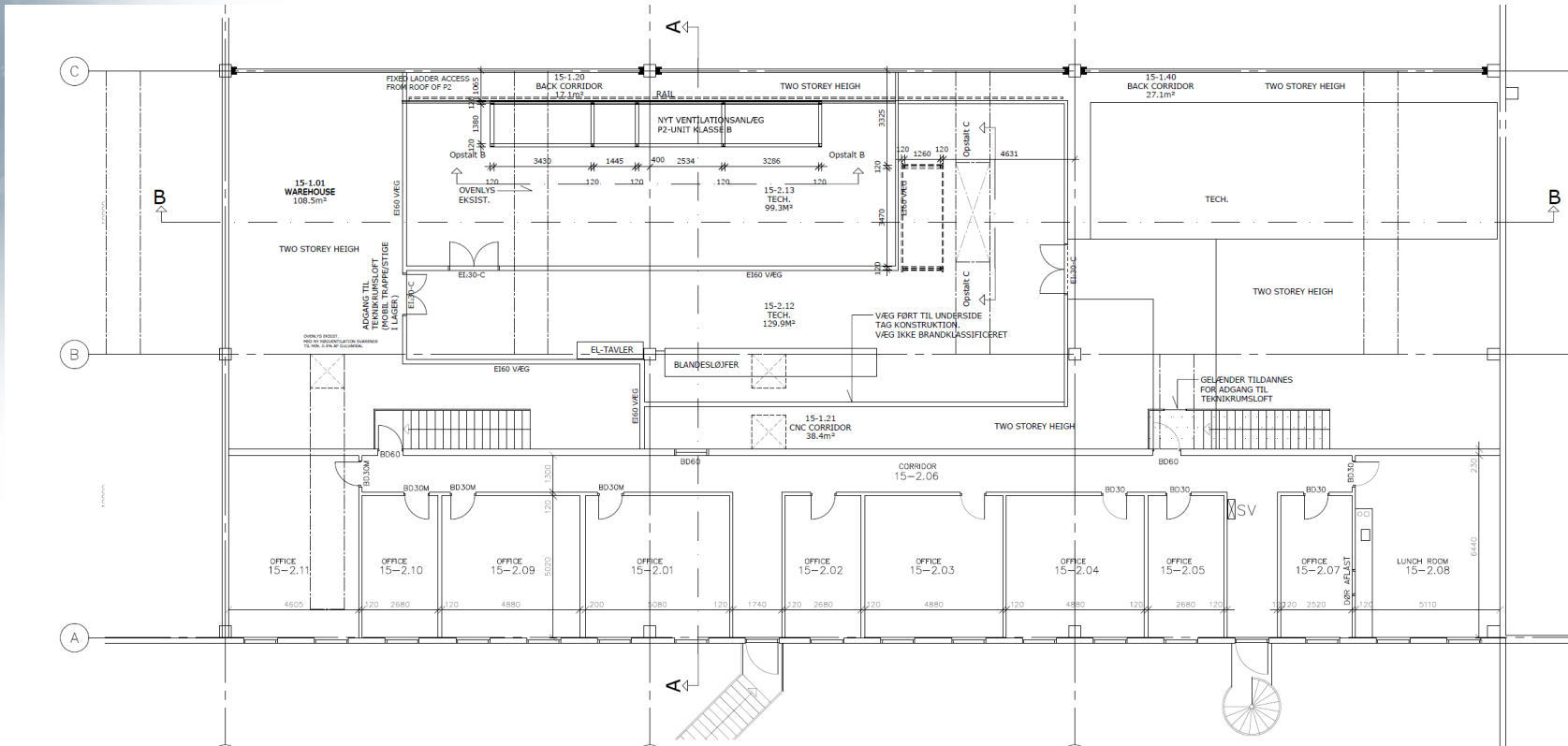
- Product Sterility
 - BacT/ALERT instrument used for sterility testing – Top right photo
- Endotoxin Assay
 - PTS instrument used for Endotoxin testing - Lower left photo
- PCR based assays including mycoplasma
 - Equipment used for PCR assays – Middle photo
- Spectrophotometer
 - Lower right photo



Copenhagen Clean Room/Supporting Areas Floor Plan



Copenhagen Office Facility 1st Floor Plan



- Lease Terms:
 - Can be terminated with 6 month notice on either October 1st 2015 (which is Aastrom's intent) or October 1st 2019
 - Deposit equals to 6 month's rent (at any time)
 - The rent is regulated with an increase of 3% every October
- Lease Expenses:
 - Lease payments per month: DKK 76,746.19 incl. VAT
 - Utilities (e.g. Common expenses on account (e.g. real estate tax, water, sewer) per month: DKK 11.000,00 incl. VAT
 - Heating costs on account per month: DKK 11.750,00 incl. VAT
 - Electricity at full capacity in both offices and cleanrooms (01-JUL-2013 to 30-JUN-2014), average cost per month: DKK 80.287,54 incl. VAT