

Mirko Müller
Leipzig | Fraunhofer IZI

Training- and educational concepts for GMP

Department of Cell and Gene Therapy Development

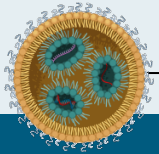
Organization



Prof. Dr. Dr.
Ulrike Köhl
Head of Institute

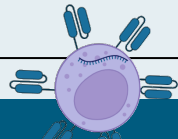


Department
Cell & Gene Therapy Development
Head: PD Dr. Stephan Fricke



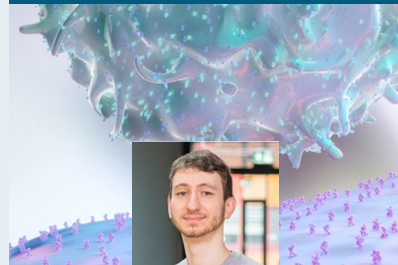
Cell & Molecular Biology

Dr. Sandy Tretbar
Dr. Ulrich Blache



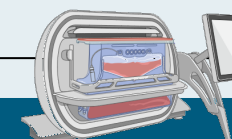
NK Cell Technology

Dr. Dominik
Schmiedel



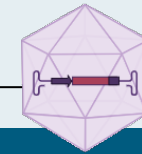
in vivo Models

Nadja Hilger
Dr. André-René Blaudszun



GMP Development

Dr. Anna Dünkel
Dr. Paul Franz



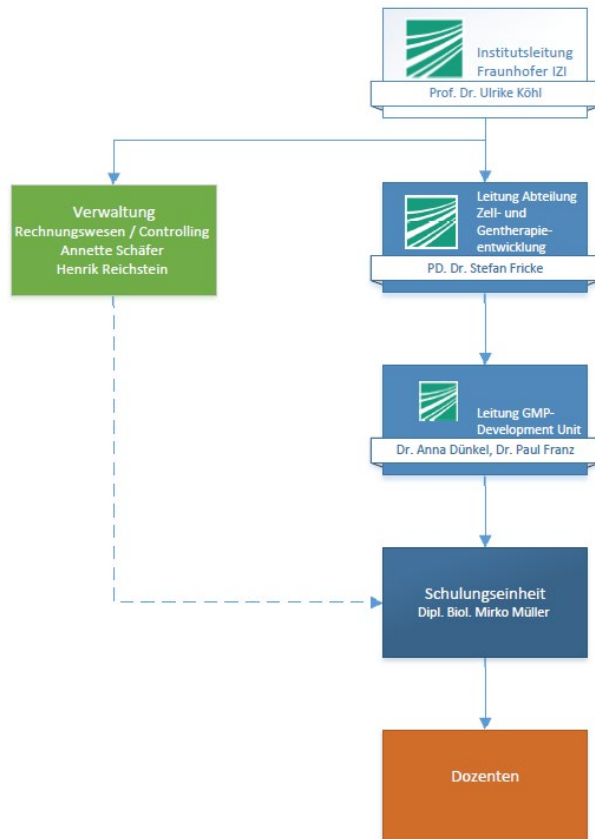
GMP Biopharmaceuticals

Thomas
Schmid



Department of Cell and Gene Therapy Development

Education and training unit / certification for employment promotion



AZAV

Akkreditierungs- und Zulassungsverordnung Arbeitsförderung



CURRENT ACTIVITY

Since 01/2022: Training officer and research associate in the GMP Process Development / ATMP Design department, **Since 02/2016:** Quality assurance in the project: "Novartis" of the GMP Cell and Gene Therapy department, Fraunhofer Institute for Cell Therapy and Immunology (IZI) in Leipzig, Germany

Fraunhofer-Gesellschaft, Institut für Zelltherapie und Immunologie IZI Leipzig		
	Qualitätsmanagementhandbuch (QMH) Schulungseinheit	Dok-Nr.: QMH-AZAV-V01
<h3>Qualitätsmanagementhandbuch Schulungseinheit</h3> <p>Abteilung Zell- und Gentherapie Entwicklung, Fraunhofer-Institut für Zelltherapie und Immunologie IZI, Perlickstr. 1, 04103 Leipzig</p> <p>Beschreibung des implementierten Qualitätsmanagementsystems in Übereinstimmung mit dem 3. Buch Sozialgesetzbuch (Akkreditierungs- und Zulassungsverordnung Arbeitsförderung -AZAV)</p>		

<https://www.izi.fraunhofer.de/de/abteilungen/standort-leipzig/zell-und-gentherapieentwicklung/qualibiopharma.html>

<https://www.sprungbrettzumerfolg.de/unternehmens-berater-coaches/anleitung-zur-zertifizierung-nach-azav/>

Fraunhofer IZI - Education and Training Opportunities

„GMP & Sterile Training“ – A story of success



QualiBioPharma (QBP) *sponsored by Biosaxony Management GmbH*

Goal

To train jobseekers from outside the industry (or with previous experience) for employment in the pharmaceutical and biotechnological manufacturing industry.

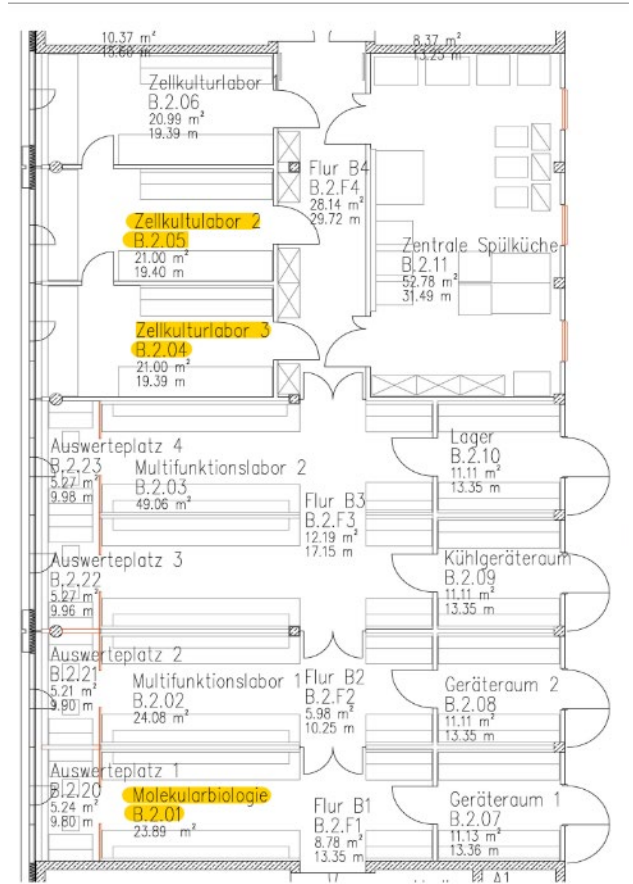
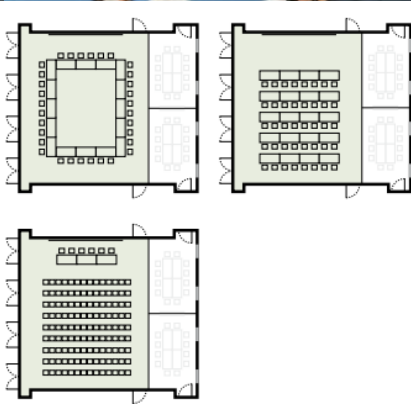
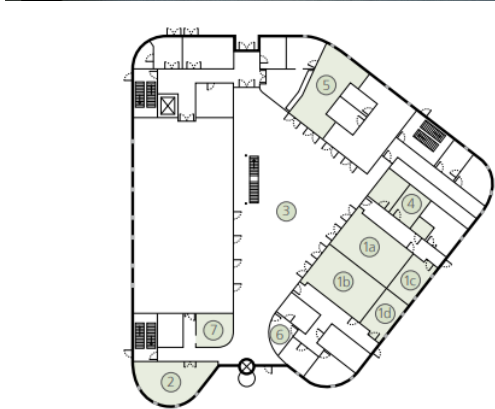
Achievements

After the first successful run in summer 2023, 67% of participants (8 out of 12) and 80% of graduates (8 out of 10) could directly be placed in new positions in biotech/pharma companies.



Fraunhofer IZI - Education and Training Opportunities

Education infrastructure – Rooms



Clean room

Facility example (inoperative for QBP training purposes)



class A / ISO-4.8

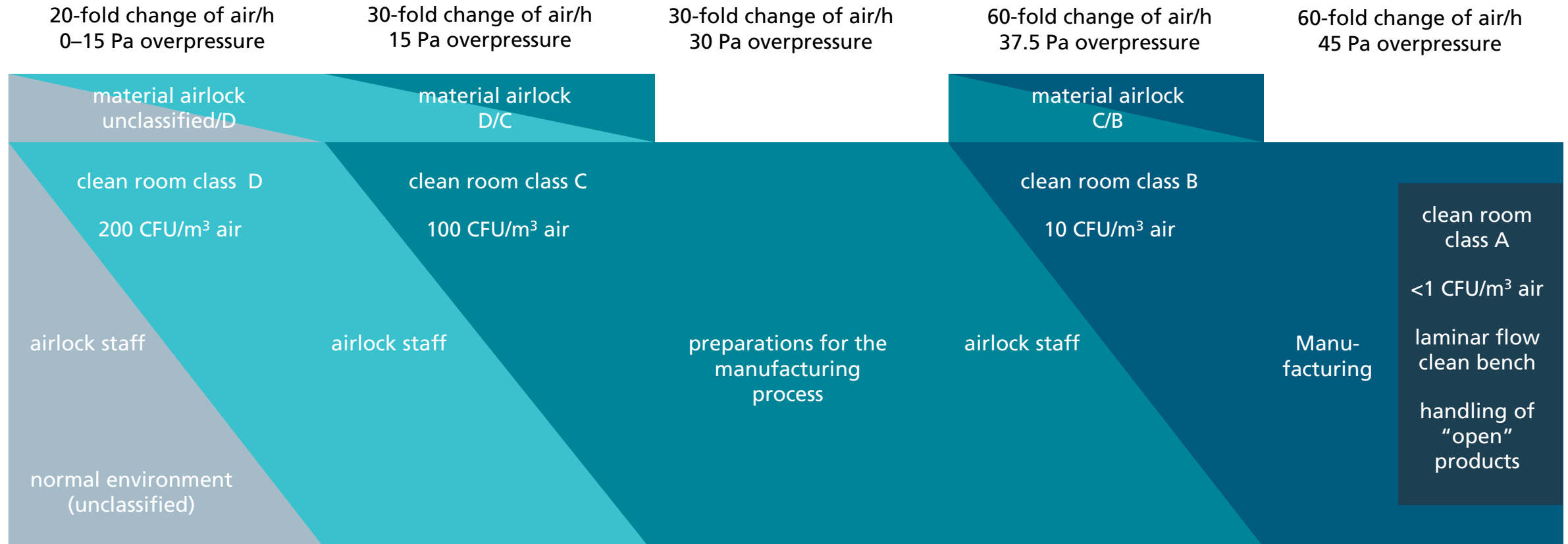
class B / ISO-5

class C / ISO-7

class D / ISO-8

Technical data of all facilities

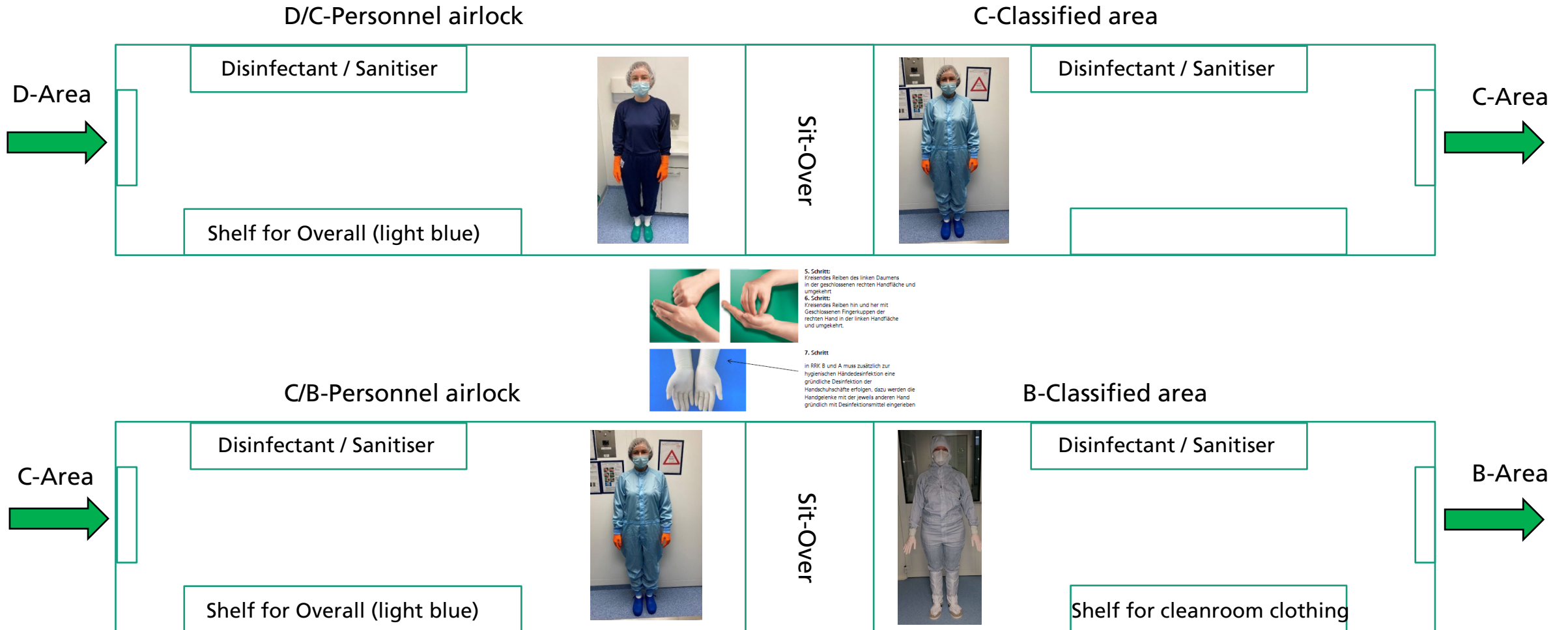
System of airlocks for staff and material / air filter fan unit and pressure system



All rooms / airlocks are equipped with filter fan units (FFU's) with H14 (HEPA) filters with 99.999 % retention of particles $\geq 0,3 \mu\text{m}$.

Example for Gowning and Personnel Airlock Training

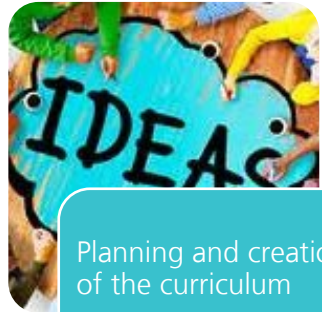
Training from Department GMP adapted for QBP



Encouraging Education & Training

Fraunhofer IZI - Example „QualiBioPharma“ course for (re)activation of specialists for biotech & pharma

From sketch to reality 2023



Planning and creation of the curriculum
provision of suitable personnel, material, devices and rooms



Theoretical course
Basics Biotechnology
Basics Immunology
Basics GMP



Practical course
Basics in laboratory work
Aseptic handling of cell material



Practical course
GMP conformal gowning and dressing
GMP related simulation of production and quality control



Support
generating and reactivating of new professionals for the local and (inter)national labor market



Fraunhofer IZI - Example „QualiBioPharma“ course for (re)activation of specialists for biotech & pharma

Second year / run 2024



Theoretical course
 Basics Biotechnology
 Basics Immunology
 Basics GMP



Practical course
 Basics in laboratory work
 Aseptic handling of cell material



Practical course
 GMP related simulation of production and quality control

Grundlagen Immunologie academy

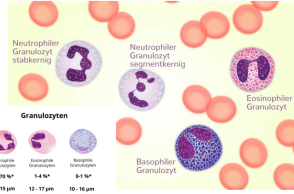
Granulozyten



Eosinophile Granulozyten
 Bekämpfung von Parasiten
 ‚major basic protein‘
 Rezeptoren für Komplement und Antikörper

Neutrophile Granulozyten
 Phagozytose von Mikroorganismen
 Antibakterielle Enzyme, Sauerstoffradikale
 Rezeptoren für Komplement und Antikörper

Basophile Granulozyten
 Freisetzung von vasoaktiven Substanzen
 Heparin, Histamin, Leukotriene
 Rezeptoren für Komplement und Antikörper



Why (what is) GMP?



- Drugs work in the smallest quantities.
- Bad medicines cannot be recognised by patients not be recognised by patients.
- Sick and weakened people take medicines.
- Would I take my manufactured medicine myself?

Medicines must be of high quality

Image source: <https://www.gmp-erfolg.de/legung-medizin-herstellung-biotechnik/>

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WP 8 – Encouraging Education & Training

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MUNI | CREATIC

GMP-in-a-box-devices for semi-automatic production and quality control (QC)

- Custom-made courses
- Hands on training
- Regulatory advice



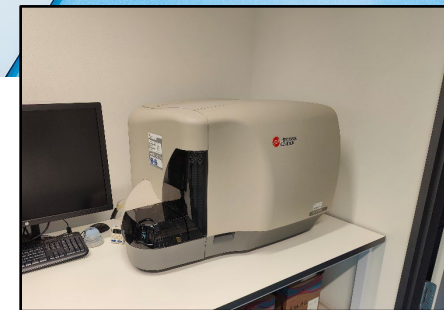
**CliniMACS
Prodigy®**
from Miltenyi Biotec



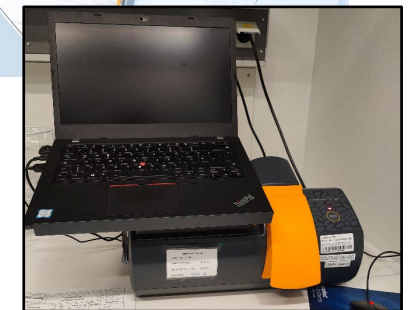
Cocoon® Platform
from Lonza



ADVA X3™
from ADVA Biotechnology



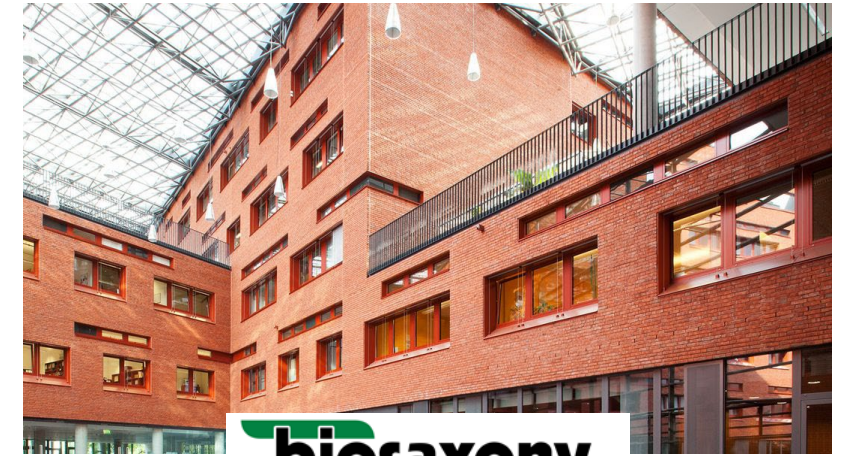
Navios® Ex (QC)
from Beckman Coulter



NC202® (QC)
from Chemometec

Outlook and the Future

virtual training and VR and dummy GMP facility



biosaxony



Source: [SaxoCell Shocase \(vr-bits.de\)](https://www.saxocell.com)

Thank you for your attention!

