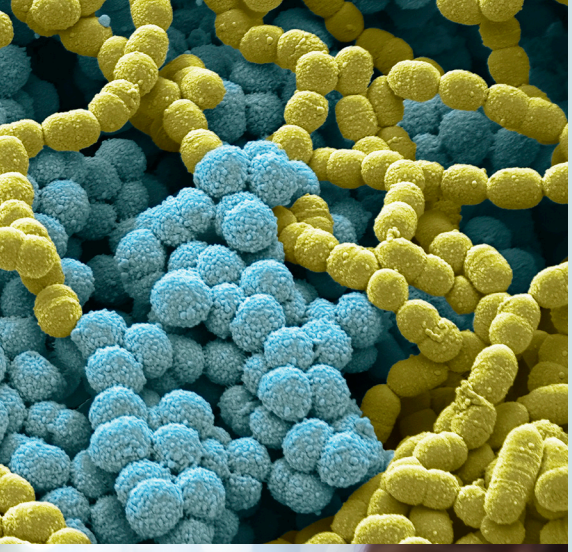


Cellana
for Cell and Gene Therapy

Solutions for Advanced Therapy Medicinal Products (ATMPs)

skan

SKAN, founded in 1968, is the world leader in aseptic isolators for the pharmaceutical industry. Innovative products, client specific solutions as well as an efficient global service organization have made SKAN a market leader and important partner of industry and research laboratories worldwide.

Cellana for cell and gene processes are specifically designed for handling cell cultures and the production of Advanced Therapy Medicinal Products (ATMP) in a GMP controlled environment. Isolators create advanced aseptic conditions, compliant with cGMP regulations for the formulation and aseptic filling of sterile therapeutics for clinical and commercial use.

Your needs:

- Aseptic controlled isolator to process autologous and allogeneic therapeutics for pre-clinical and human clinical use
- Fast transfers of biological materials in various containers (cell culture flasks, vials, cryo vials, bags, etc.)
- Gene manipulation by viral transduction
- Aseptic working conditions with highest sterility assurance
- Operator and patient safety
- Acceptance from cGMP regulatory authorities (US FDA,
- EU EMA and other global agencies)

Cellana solution:
Utilize a flexible and modular platform with proven isolator solutions that can be customized to your ATMP process. Work with SKAN experts who have experience in wide-ranging applications to:

Protect your…

- product from contamination
- process from direct human bioburden (the leading source of aseptic process contamination)
- personnel, operators and scientists from biohazards, potent or toxic compounds

Control and monitor your…

- environment (fully compliant, Grade A aseptic manufacturing area) with integrated particle counters and active viable air samplers
- process with a PC-based HMI, 21CFRPart11 compliant data handling and an advanced SCADA (Supervisory control and Data Acquisition)

Integrate your process equipment, such as…

- advanced and efficient H_2O_2 integrated decontamination process with rapid aeration
- incubators (RH, temperature, CO_2)
- centrifuges
- tabletop lab equipment
- single use disposables

Wide range of cell-related processes:
Ultra-fast material transfer with
skanfog® flash decontamination solutions

- ⟶ Cell vials
- ⟶ Cell culture flasks
- ⟶ Leukapheresis bags

Upstream procedures

- ⟶ Cell thawing
- ⟶ Cell isolation
- ⟶ Cell seeding
- ⟶ Cell culture (centrifugation and incubation)
- ⟶ Gene editing
- ⟶ Cell reprogramming and differentiation

Cell expansion procedures

- ⟶ Cell expansion (bioreactors, T-flasks, shaker flasks, multi-layer adherent systems)

Downstream procedures

- ⟶ Cell purification (cell purifier/separator)
- ⟶ Cell filtration
- ⟶ Cell concentration (cell bioprocessor)

Aseptic filling procedures

- ⟶ Crystal® L1 Robot Line – a specially designed robotic solution for safer fill & finish of cell and gene therapies in AT-Closed Vials®
- ⟶ Wide range of small-scale filling machines for cell vials,
  cell bags and AT-Closed Vials®
- ⟶ VarioSys® filling solutions for vials, syringes with bulk and nested RTU (ready-to-use) formats

Benefits of isolators over cleanrooms and biosafety cabinets:
Assure your process and product quality with a fully controlled environment.

Better process control

- ⟶ Validatable, integrated H_2O_2 decontamination process (high performance skanfog® with patented NANOX® catalyst technologies)
- ⟶ Validated rapid aseptic transfers (no more “spray and pray”)
- ⟶ Secure enclosure with qualified Grade A conditions
- ⟶ Integrated monitoring and process equipment
- ⟶ Ergonomic design features

Reduced facility capital and operational costs

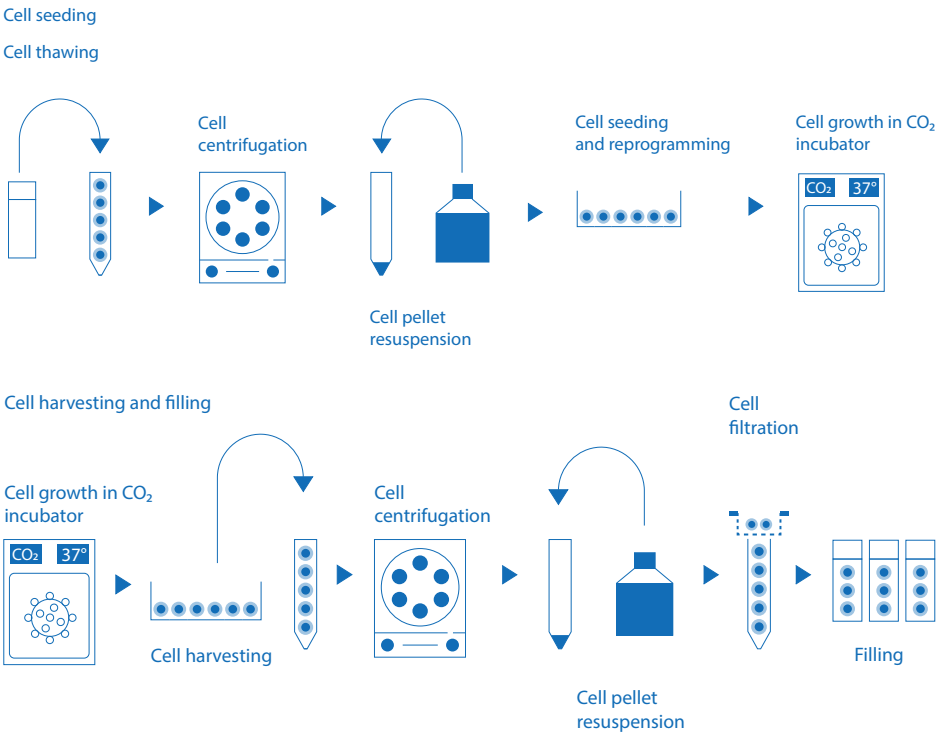
- ⟶ Less gowning, improved efficiency and better operator comfort
- ⟶ Less environmental monitoring – save time, supplies and sample processing
- ⟶ Less facility footprint – fewer airlocks, cleanroom construction and operation savings
- ⟶ Lower utility and HVAC costs – “go green” while saving money

GMP COMPLIANT
According to high GMP regulations for ATMPs

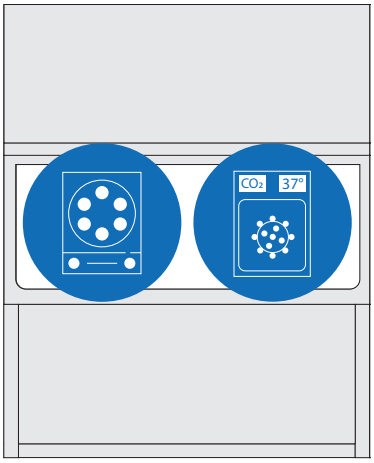
Trust SKAN experts to customize and adapt your process to an advanced isolator system

Case Study 1: Cellana-M

Cell therapy: Mesenchymal Stem Cells-based Therapy



- Cell washing and concentration in the built-in centrifuge
- Cell dilution in a fresh cell culture medium and seeding in a flask/vessel within the isolator
- Cell growth under controlled conditions of CO_2, temperature and relative humidity in the built-in incubator
- Cellular reprogramming and differentiation within the isolator
- Cell resuspension with the final formulation buffer
- Filling of the cells into vials

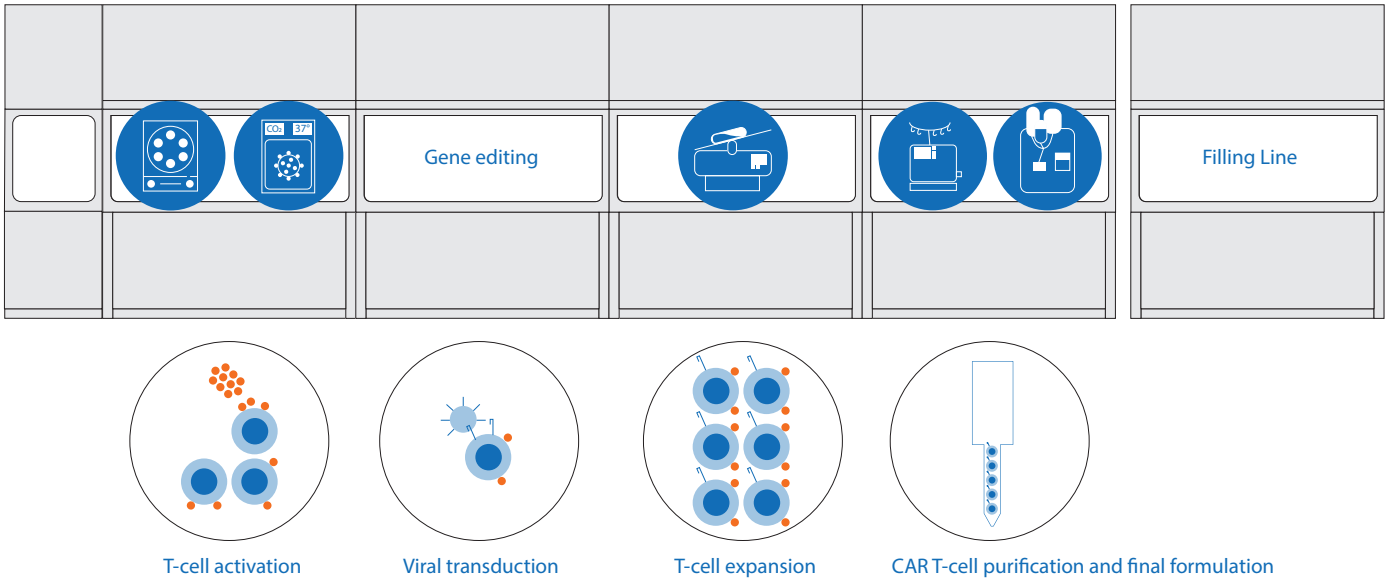


Ergonomically integrated incubator solutions

Variety of integrated centrifuge options

Case Study 2: Cellana-L

Cell and gene therapy: Chimeric Antigen Receptor (CAR) T-cell therapy



- T-cell washing and concentration in the built-in centrifuge
- T-cell activation in the built-in incubator
- Viral transduction with Chimeric Antigen Receptor (CAR) construct
- T-cell expansion in the bioreactor
- T-cell harvest and CAR expressing T-cells final isolation in automated cell processing systems

Consultancy – Excellence by Design

The ATMP and biological experts at SKAN can support you with the design of your process to achieve and guarantee excellence in process flow, ergonomics, automation, GMP compliance, process and operator safety.

Robotics can be integrated, if you wish to

- bring your production equipment to a cutting-edge standard
- increase the safety of the operators and the efficiency of your process
- integrate an automated process into an isolator
- guarantee sterile conditions and efficient decontamination

Perform manual or highly automated aseptic filling in an advanced, flexible and efficient SKAN isolator system with solutions from Aseptic Technologies – a subsidiary of the SKAN group:

AT-Closed Vial® technology by Aseptic Technologies: safe cryostorage with Crystal® M1, Pure M1 and Crystal® L1 Robot Line

AT-Closed Vial® - ready-to-fill closed vial, ensuring uncompromised Container Closure Integrity during cryogenic storage at different scale allowing rapid processing between formulation and freezing.

Facing the challenges of small or individualized batches, Crystal® Pure M1 combines a manual filling station for AT-Closed Vials® with isolator technology from SKAN.

Avoid the scaling-up bottlenecks with Crystal® L1 Robot Line, automatically processing up to 500 vials/hour.

Visit www.aseptictech.com to see the equipment in action.

For AT-Closed Vials®, manual or automated:

⟶ Filling by piercing

⟶ Laser re-sealing

⟶ Snap-fit capping

See www.aseptictech.com for additional details

Bulk and nested component aseptic filling with VarioSys®

Achieve maximum flexibility with a VarioSys® aseptic filling system. Ready to Use (RTU) components (vials or syringes) or bulk vials can be filled using the same or additional SKAN PSI-L isolator system chambers. Solutions are available from manual and semi-manual low speed systems for early stage clinical trials to automated and robotic systems for late stage clinical and commercial production quantities with our partner.
See www.variosys.com for additional details.

For Ready to Use (vials or syringes) or bulk glass:

- Debagging, delidding, delining, denesting – manual or auto tub handling
- Nested vial or syringe filling
- Bulk vials with glass
- Stoppering and capping
- Bag filling

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