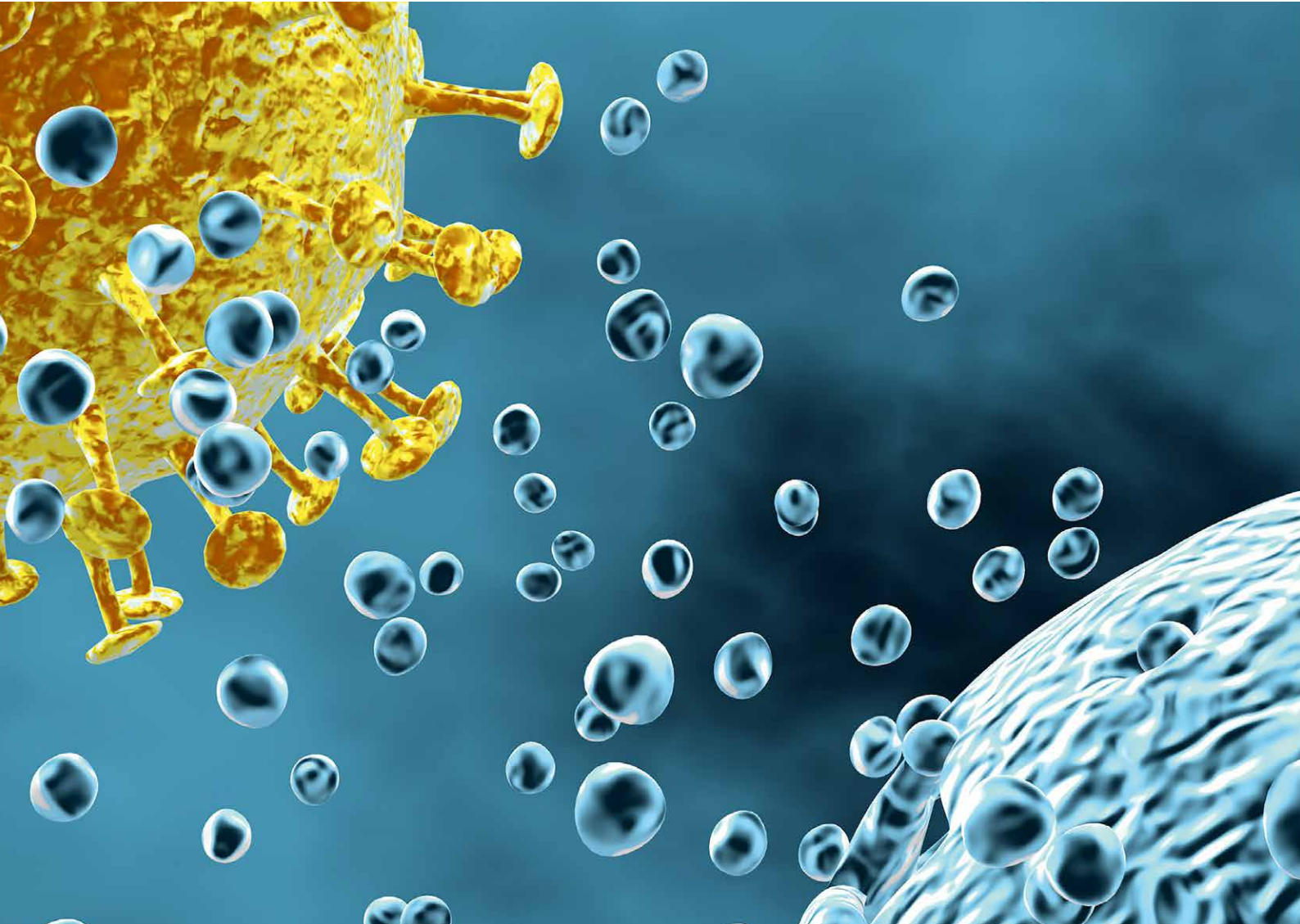


SKAN

Cell and Gene Therapy ATMPs

Cellana Isolators

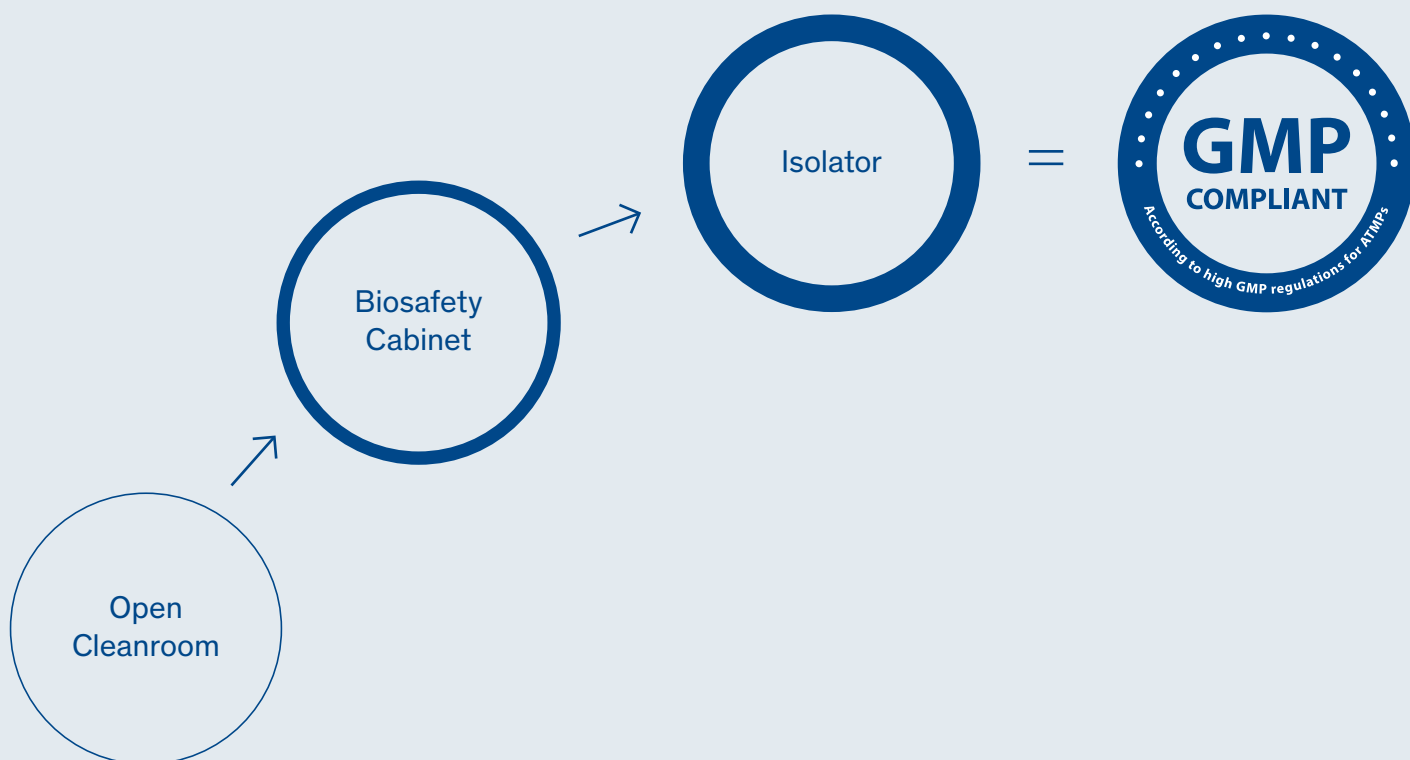


Key Steps to achieve Best Process Quality in Cell and Gene Therapy

Advanced therapy medicinal products (ATMPs) are fast-growing fields in modern medicine. ATMPs comprise innovative and sophisticated medicines to treat a variety of human disorders and genetic diseases.

It is critical to invest in manufacturing processes for these products to be compliant with cGMP regulations for the preparation and aseptic filling of sterile therapeutics for clinical and commercial use.

Choose Quality:
Highest cGMP solution for ATMP products



1 Explore an isolator for ATMP processes



“My primary concern is protecting my process. Isolators provide a much higher level of **contamination control**. We partnered with SKAN due to their CGT process knowledge and in-depth experience with H_2O_2 with our sensitive biological products.”



“Looking at life-cycle costs, it is a fact that the additional capital investment in isolators resulted in dramatic savings in facility and operational costs. It was easy to justify with a quick **return on investment** analysis.”



“Cellana isolators are a **green solution** that save energy and adopt advanced technologies to reduce waste and pollution.”

2 Adopt the best proven technology

Integrate lab and process equipment into your ATMP solution

Everything you need to control and operate your ATMP process is here. Advanced process and lab equipment can be integrated directly into your Cellana isolator, creating a true process solution within a fully compliant manufacturing platform.



AT Liquid Transfer Port

Perform safe material transfers

Aseptic transfer of supplies, equipment, buffers, media and most importantly, living cells, is a key function for your aseptic processing isolator. Choose the right transfer solution to address your limited time window, product sensitivity, quality or special process constraints from a selection of proven technologies with expert guidance.



SARA: Safe and RAPid Decontamination airlock



- 1. Microscope
- 2. Particle counter / Air sampler
- 3. CO₂ incubator
- 4. Centrifuge



Ultra Fast Decontamination RTP

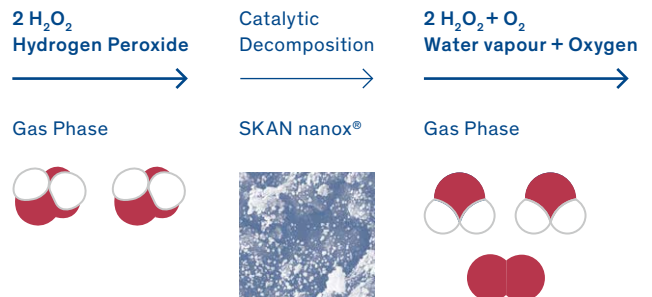
skanfog® automated decontamination

A fully automated and integrated decontamination system creates your compliant Grade A aseptic environment to protect your product, personnel and process. skanfog® H₂O₂ decontamination technology was developed by expert scientists with the fastest cycles in the industry to maximise your production efficiency and quality.



Patented nanox® catalyst technology

SKAN's patented catalyst technology was developed to provide rapid cycle performance, but also eliminates waste streams and costly facility integration. Low-level sterilant residuals which can impact cell viability can be minimised or eliminated with innovative transfer systems that reduce risk while maintaining process control and efficiency.



3 Select the right isolator solution: Cellana

The Cellana Isolator family represents SKAN's 50+ years of experience in aseptic processing isolators. cGMP knowledge and process expertise are combined to safely provide patients with your Cell & Gene Therapy products.



Cellana-M



Cellana-L



Key Features

- Modular w/ Flex chamber
- Integrated design
- Short delivery

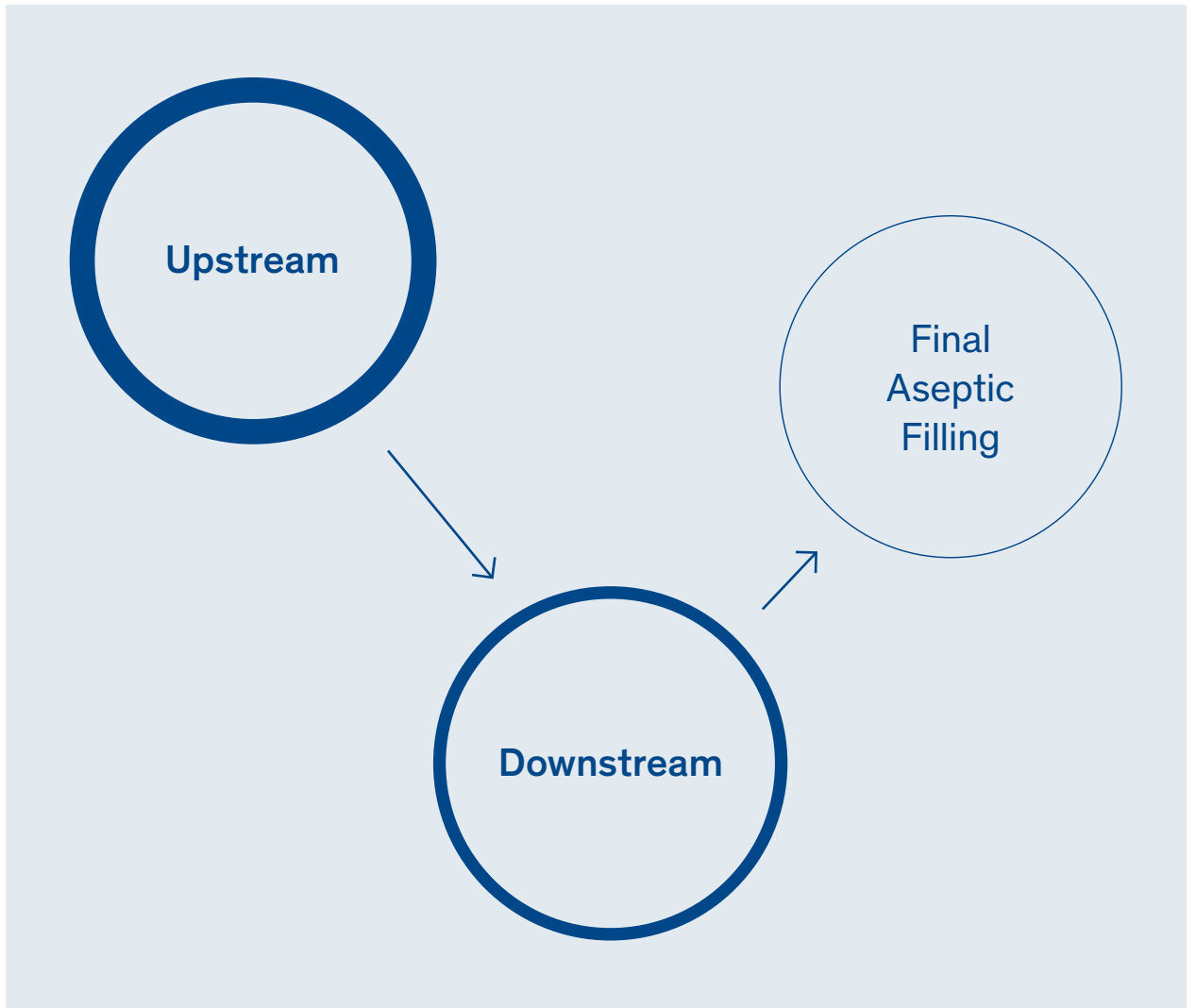
Key Features

- High flexibility
- Interchangeable modules
- Scalability and versatility

Main Features and Benefits

	M	L
FDA ISO 5/EU Grade A aseptic environment with unidirectional airflow	✓	✓
Integrated automated H ₂ O ₂ decontamination validated with expert process guarantee and SKANalytix support	✓	✓
Ultrafast decontamination transfer systems customised to your process	✓	✓
21 CFR Part 11 Compliant Controls and PC-based HMI with optional SCADA	✓	✓
Integrated centrifuges, CO ₂ incubators and lab equipment from multiple leading vendors	✓	✓
Optional potent compound and BSL-2 safety systems with proven technology	✓	✓
Free chamber design in prefabricated concept	✓	
Exchangeable L-flange modules for high-throughput mfg and unit operation exchange		✓

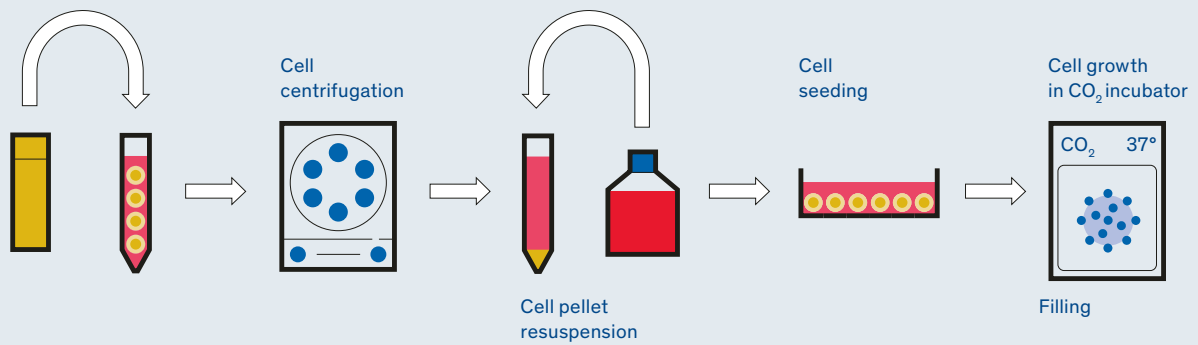
4 Apply the right solutions to your process



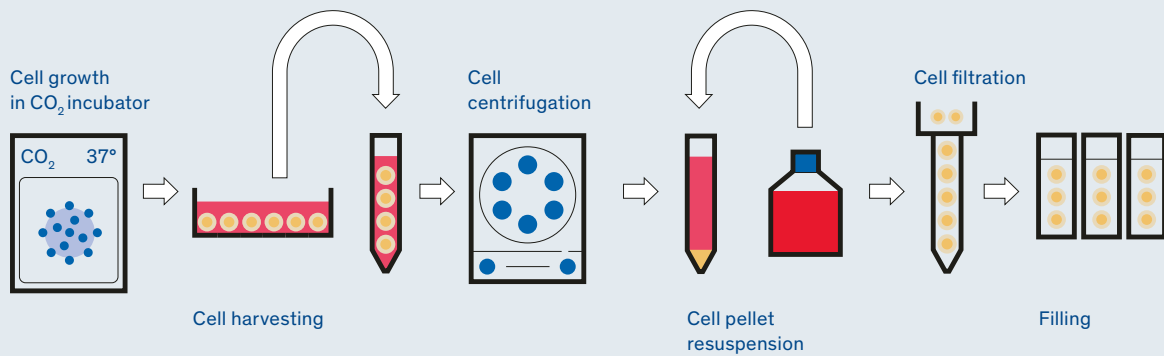
Example: Mesenchymal Stem Cell preparation

From cell thawing to cell harvesting and final downstream steps in Cellana-M

Cell thawing

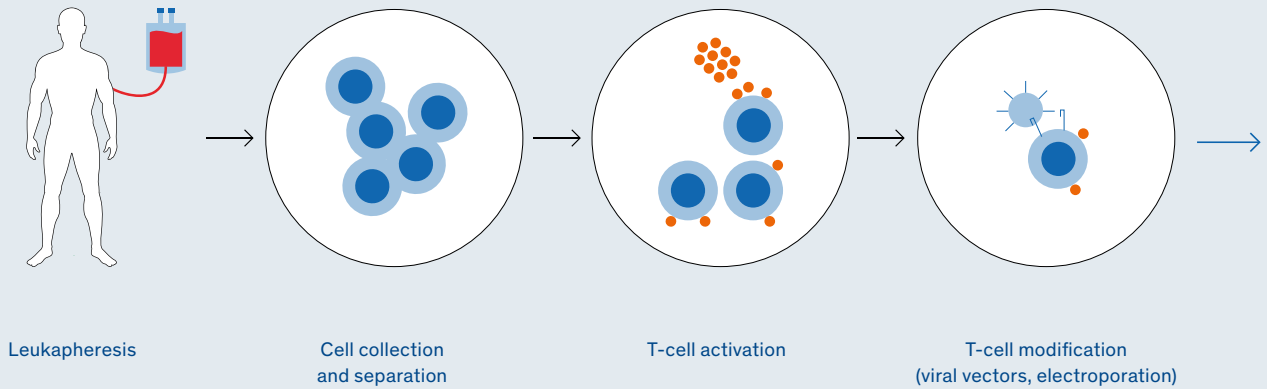


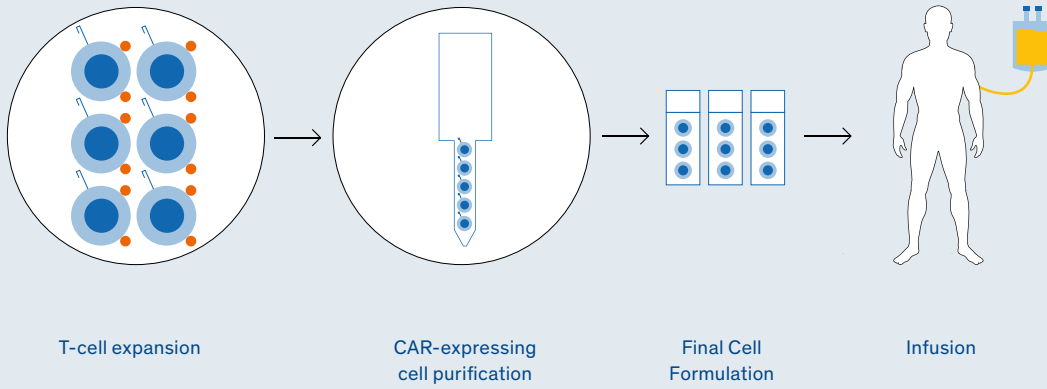
Cell harvesting and filling



Example: CAR T-cell therapy production

Step-by-step from aseptic leukapheresis bag transfer, gene editing and CAR T-cell separation to final cell formulation in a high-throughput Cellana-L isolator system.

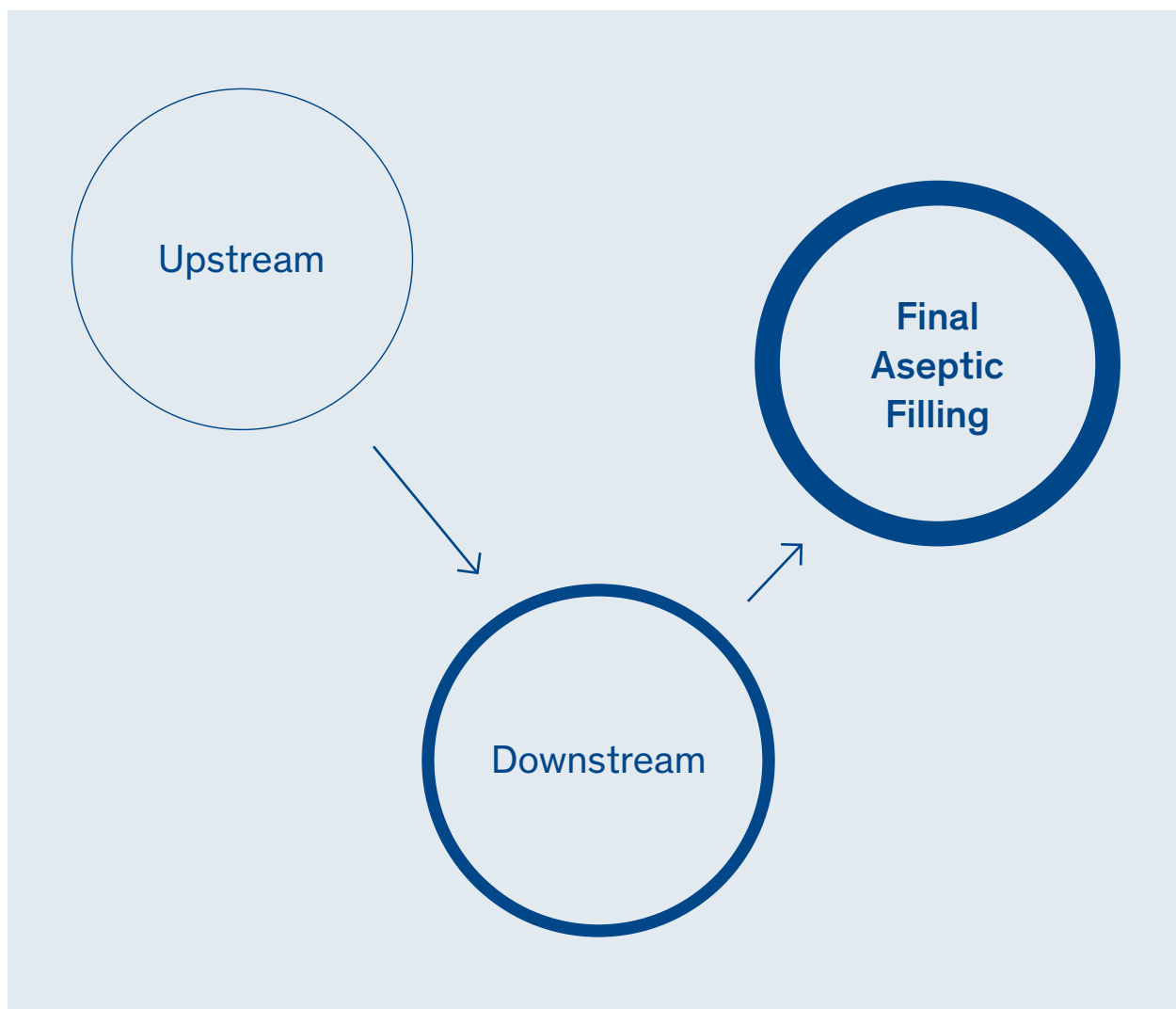




5 Implement Flexible Aseptic Filling



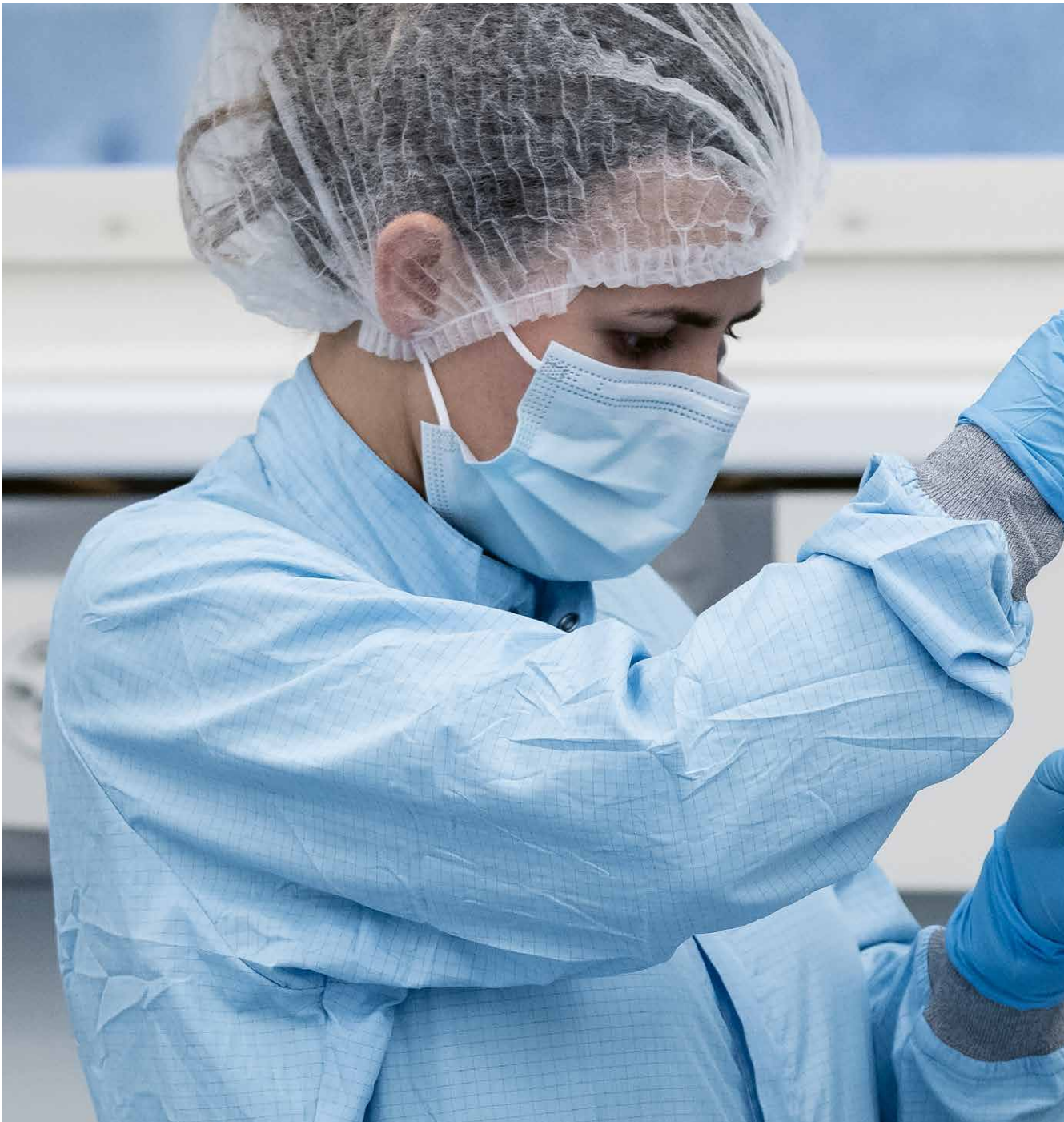
SKAN provides a wide range of fully-integrated isolator-based aseptic filling solutions. Cellana is your one-stop solution for manual to highly automated filling, including robotic systems.





6 Validate your process with Expert Support

The scientific method is the only approach for successful qualification of cGMP processes. Quality must be implemented in the design phase (QbD). SKAN's compliant regulatory strategy maintains your product quality at the highest level. We collaborate with our partners and share our experience to define the right isolator for your specific needs.



Utilise smart digitalisation solutions
SKAN integrates digital solutions for your process
control and automation needs



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