

A close-up photograph of a laboratory setting. Several glass pipettes are positioned over a multi-well plate. The scene is illuminated with a strong blue light, creating a high-tech, scientific atmosphere. The focus is sharp on the pipettes and the wells they are positioned over, while the background is softly blurred.

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# SKAN Group AG Capital Markets Day

May 2025



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# Welcome to SKAN Capital Markets Day

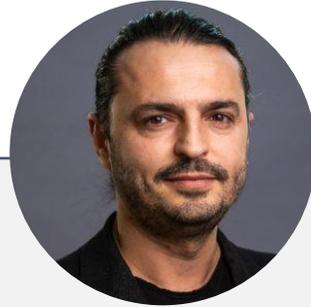
## Our speakers



**Thomas  
Huber**  
(CEO)



**Philippe  
Jérôme**  
(CMO)



**Burim  
Maraj**  
(CFO)



**Marina  
Häni**  
(CPCO)



**Thomas  
Zinn**  
(COAMS)



**Ralf  
Krämer**  
(CTO)



**Richard  
Denk**  
(Senior  
consultant)

# SKAN capital markets day

## Overview of presentations

| Time          | Topic                                       | Speaker         |
|---------------|---|-----------------|
| 09:00 – 09:10 | Welcome                                     | Thomas Huber    |
| 09:10 – 09:30 | Industry trends & SKAN strategy 2030        | Thomas Huber    |
| 09:30 – 09:50 | Growth path, margin expansion and targets   | Burim Maraj     |
| 09:50 – 10:10 | Competitive landscape & technology partners | Philippe Jérôme |
| 10:10 – 10:30 | SKAN culture & managing growth              | Marina Häni     |
| 10:30 – 10:50 | Q & A part I                                |                 |
| 10:50 – 11:10 | Coffee break                                |                 |
| 11:10 – 11:30 | Isolator technology & standardization       | Ralf Krämer     |
| 11:30 – 11:50 | GMP & regulatory compliance                 | Richard Denk    |
| 11:50 – 12:10 | Pre-approved services                       | Thomas Zinn     |
| 12:10 – 12:30 | Q & A part II                               |                 |
| 12:30 – 12:45 | Conclusion & wrap-up                        | Thomas Huber    |
| 12:45 – 14:00 | Flying lunch & facility tour                |                 |



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# SKAN Group AG Capital Markets Day

Industry trends & SKAN strategy 2030

Thomas Huber, Group CEO

May 2025

# Growth drivers for the biopharmaceutical market

## Growing chronic diseases



Demographic trends and live style of todays population are promoting chronic diseases

- Cancer
- Autoimmune diseases (Crohn's disease, ...)
- Metabolic diseases (diabetes, ...)
- Infectious diseases (influenza, ...)
- Neurological diseases (Epilepsy, ...)



## Progress in Biotechnology



Improvement in lab technology and computer science is speeding up the development process of new biotech drugs

- Genomics (identify disease associated genes)
- Proteomics (difference of proteins between healthy and diseased tissues)
- Bioinformatics (computational analysis of biological data)



## Growing field of applications



Growing number of available drugs that treat diverse numbers of diseases

- Personalized drugs
- Biosimilars
- Cell&Gene
- mRNA



The demand for injectable drugs will continue to grow structurally

# Growth drivers for isolators in fill-finish

## Complex molecules



**Complex molecules are difficult and expensive to produce**

- Sensitive in production
- Cannot be terminally sterilized
- Are typically of high value
- Dosing is key
- Injectable dosage form



## Sterility and correct dose



**Containment during manufacturing is key to keep the drug sterile and to protect the operator from harmful impact**

- Injectable drugs need to be sterile when administered
- Some of the molecules are harmful if exposed to manufacturing and health care personnel



## Isolator – technology of choice



**Isolator technology provides the highest safety over other technologies like RABS or clean rooms**

- Highly regulated (GMP)
- Safe aseptic environment
- Can adapt to sensitive drugs
- Provides operator and cross contamination protection



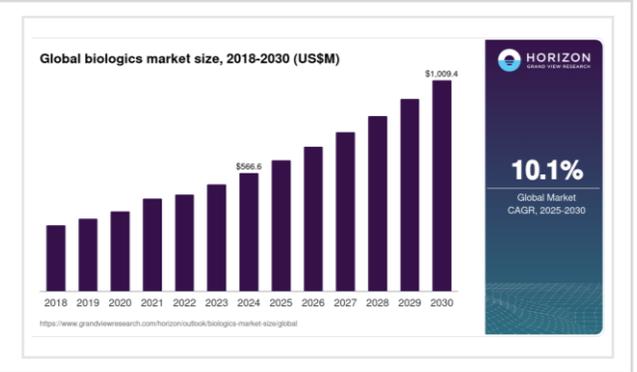
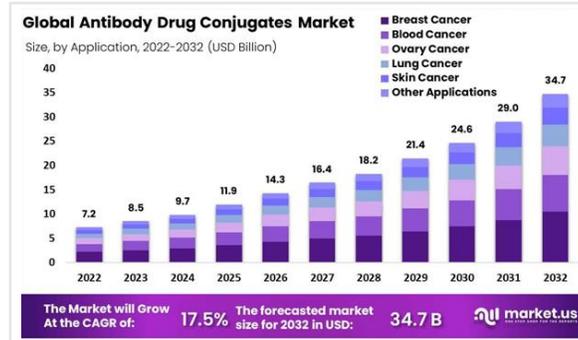
**Demand for isolators will grow with the industry and continue to replace older technologies**

# Resulting growth drives for SKAN



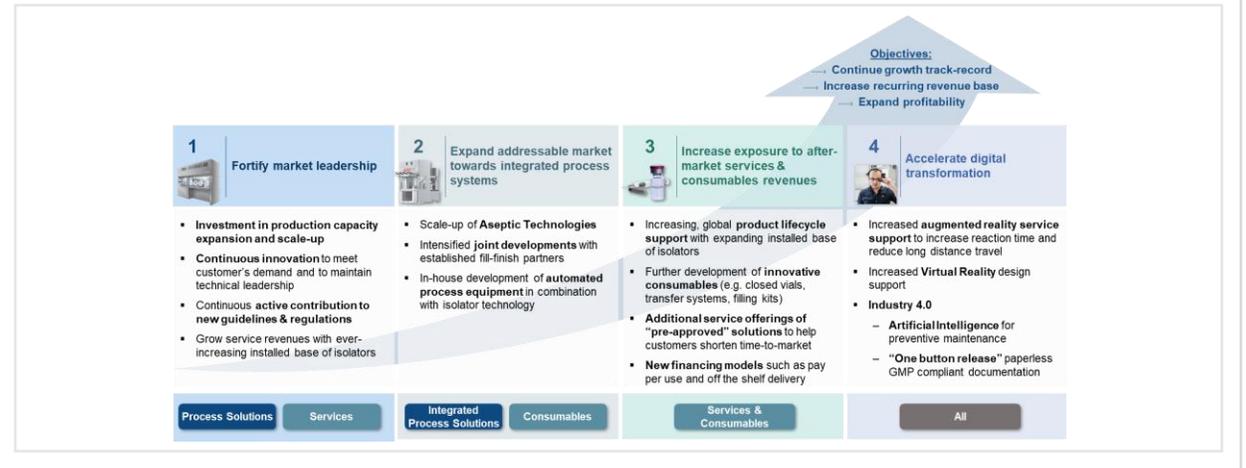
**Double digit growth of underlying biologics market.**

→ Supported by the growing number of molecules in development and clinical phases




**SKAN will continue to outperform the Bio-Pharma Market growth**

- The growing installed base provides a growing opportunity for services, spare parts and retro fits
- With robotics we are expanding within our niche
- By expanding to offering of consumables
- By providing new offerings (pre-approved-service)



# SKAN Strategy 2030



**SKAN's Strategy 2030 will continue to strengthen our position in the market**

Fortify market leadership in our core markets

Expand our offering within our niche with new processes and consumables

Stay inside our "niche" .... Culture – Quality – GMP

Increase customer attractiveness with new service offerings

**01**

**Fortify market leadership**

**02**

**Expand addressable market towards integrated process systems**

**03**

**Increase exposure to after-market services & consumables revenues**

**04**

**Accelerate digital transformation**





Culture

**CUSTOMER**

Safety and Trust

Business Drive

Quality

PROCESS

Pre-approved services

Innovation

Digitalization

CORE

Technology

GMP

**TOGETHER ALWAYS ONE STEP AHEAD.**

The background of the slide is a close-up photograph of a laboratory setting. Several glass pipettes are positioned over a multi-well microplate. The scene is bathed in a cool blue light, with some wells containing a pinkish-purple liquid. The focus is sharp on the pipettes and the wells they are positioned over, while the rest of the plate and the background are softly blurred.

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# SKAN Group AG Capital Markets Day

Growth path, margin expansion and targets

Burim Maraj, Group CFO

May 2025

# SKAN's growth path

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1 **Excellent track-record with consistent above-market growth**

2 Persistent **structural growth factors** fuel the **continued strong performance**, reflected in **double-digit growth rates**

3 **Net sales growth** underpinned by a **strong core business** and further **accelerated by strategic initiatives**

4 **Margin expansion** by **integrated process solutions** and new high margin **services and consumables**

5 Committed to significantly **invest in innovation** to **fortify market- and technology leadership**

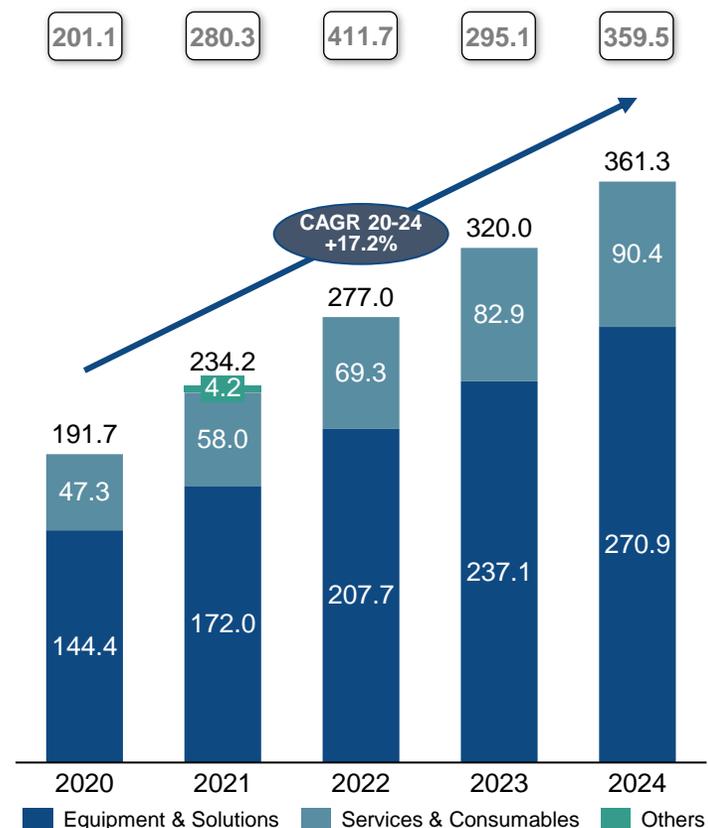
6 **Financial targets and guidance**



# Excellent track-record with consistent above-market growth and increasing profitability

## Net sales & order intake

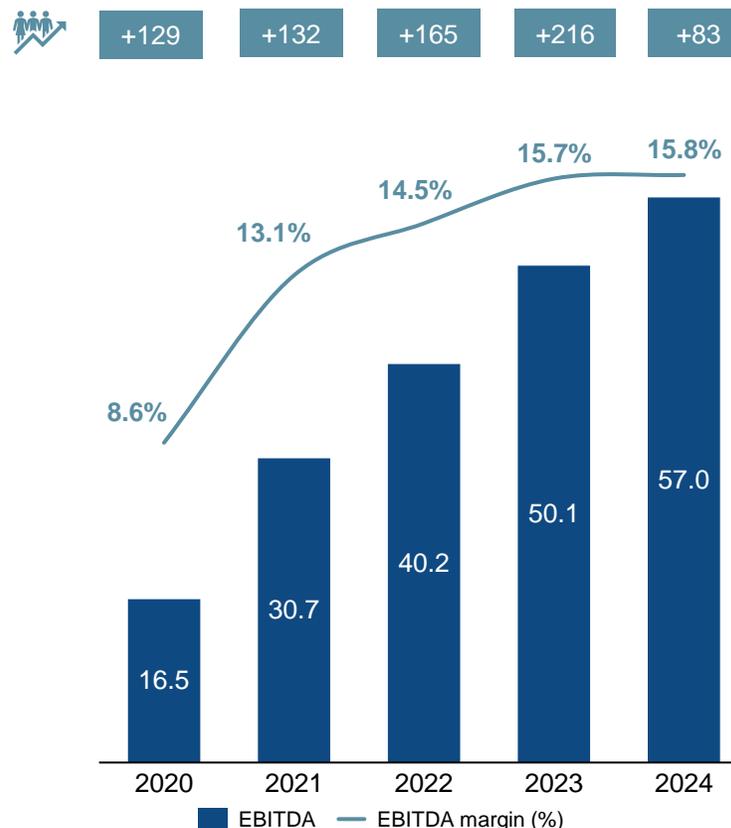
(CHFm)



□ Order intake

## EBITDA

EBITDA (CHFm) and EBITDA margin (%)



Rounding differences may occur

(1) Defined as reported EBIT / (Total Assets – Short-term Liabilities)



**Consistent, above-market net sales growth** (+17.2 CAGR 2020-2024)



**Strong revenue visibility** based on order backlog of CHF 318.3m as of end of 2024



**Margin expansion** following important development costs and personnel ramp-up



**High ROCE** <sup>(1)</sup> despite important investments (2024: 21.5%)



**Current net cash position and solid cash flow generation** to finance future investment needs



**Structural negative working capital**

# «...four – three – two – one» ignition and lift-off!

**EBITDA  
~4x**

**Net sales  
~3x**

**FTE's  
~2x**

**No.  
#1**

## Structural key drivers of SKAN's growth course

Century of biology /  
Injectables



Growth of  
(bio)- pharma



Personalized medicine



Technology shift



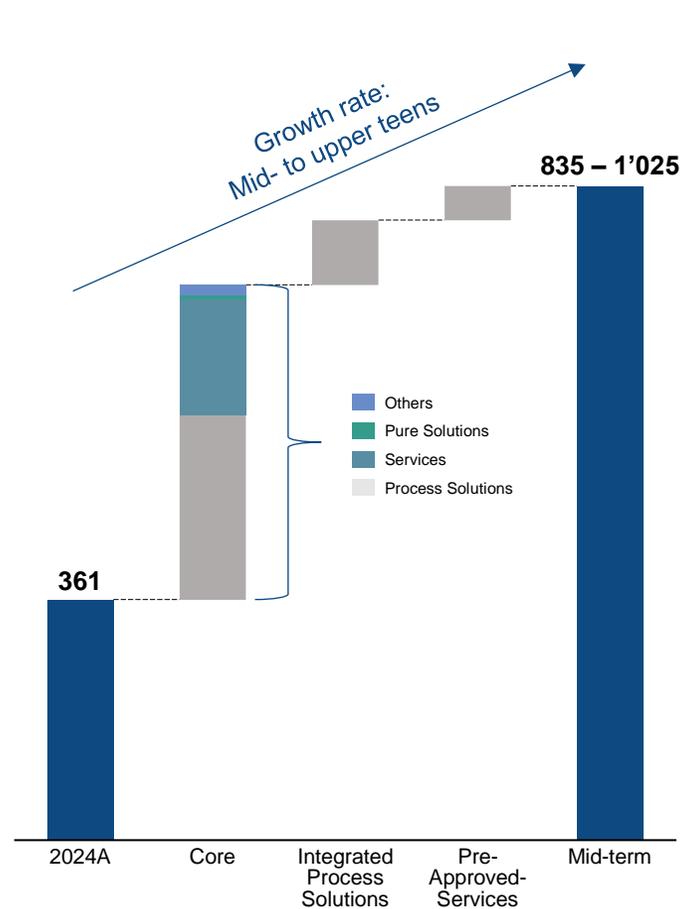
Regulatory  
environment



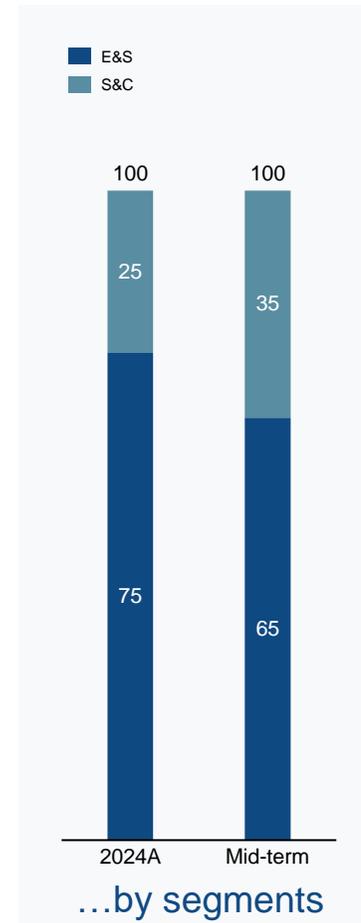
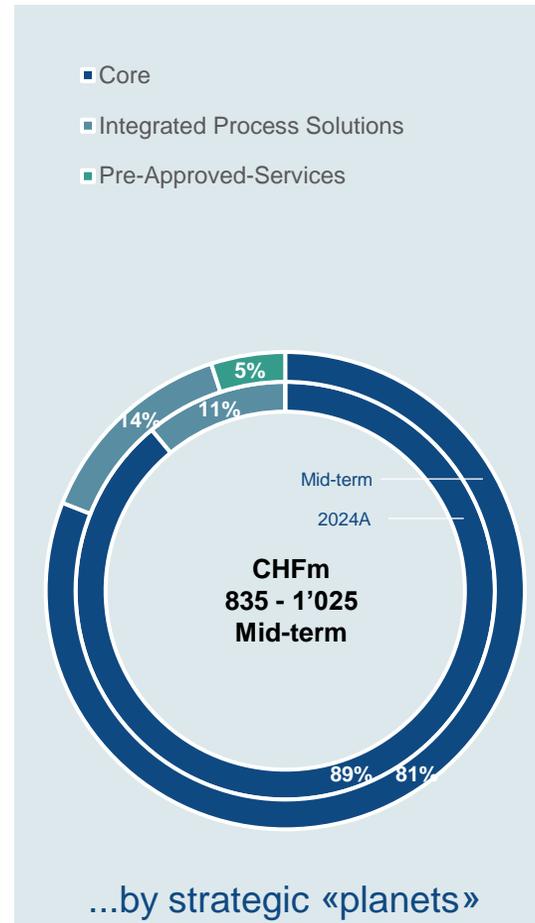
Expand market leadership & remain....

# Net sales growth underpinned by a strong core business and further accelerated by strategic initiatives

Growth contributors <sup>(1)</sup>  
(CHFm)



Net sales by strategic planets & reporting segments  
(in % of total net sales)

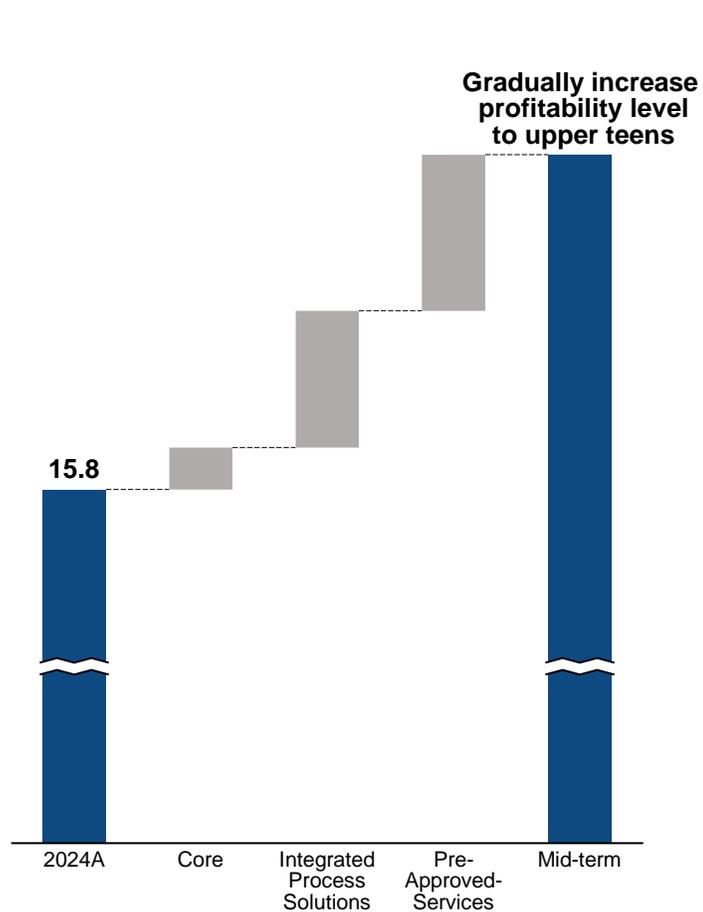


## Comments

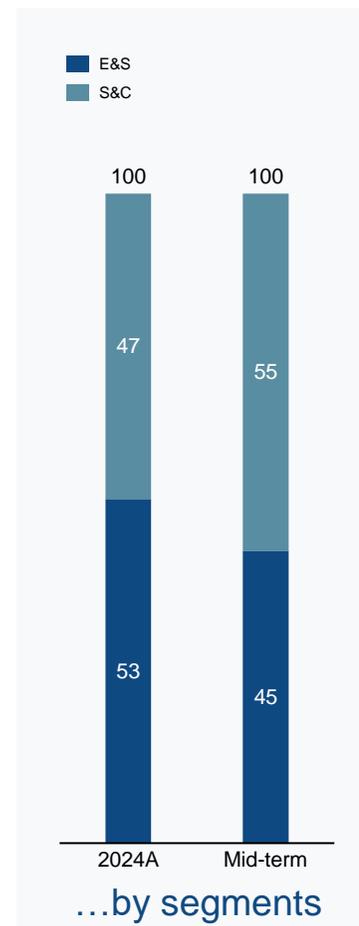
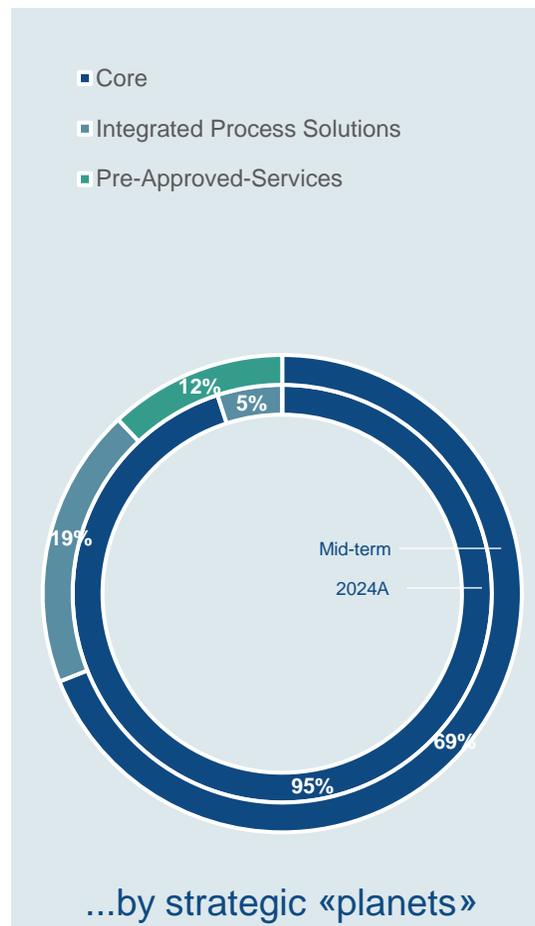
- Strategic goal: balanced revenue mix to reduce volatility and ensure consistency.
- Core business:
  - Double-digit project growth expands the installed base – unlocking scalable, high-margin service revenues.
  - Service business outpaces project growth – fueled by an expanding installed base and strong retrofit demand
  - Trade business grows at a single-digit rate but remains strategically vital – providing early access to innovations.
- Integrated Process Solutions & Pre-Approved Services as strategic initiatives – after targeted investment, positioned to deliver substantial revenue contributions.

# Margin expansion by integrated process solutions and new high margin services and consumables

EBITDA margin contribution <sup>(1)</sup>  
(in % of net sales)



EBITDA by strategic planets & reporting segments  
(in % of total EBITDA)

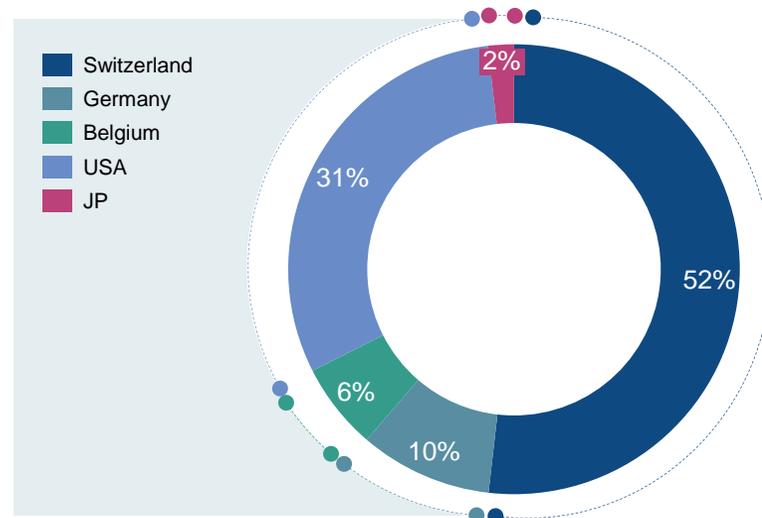


## Comments

- Strategic goal: drive >50% of EBITDA from scalable recurring revenues (Services & Consumables)
- Key margin drivers:
  - Accelerated growth of the high-margin consumables business
  - Cost leverage in other operating expenses
  - Increased standardization in assemblies and processes to boost core business efficiency
- Scalable, high-margin revenues from Pre-Approved Services and Integrated Process Solutions
- Recurring after-sales and revenues driven by a growing installed base

# SKAN continues to invest significantly in its future growth

## Investment split by regions



## Further capital allocation

### M&A Vision and Objectives

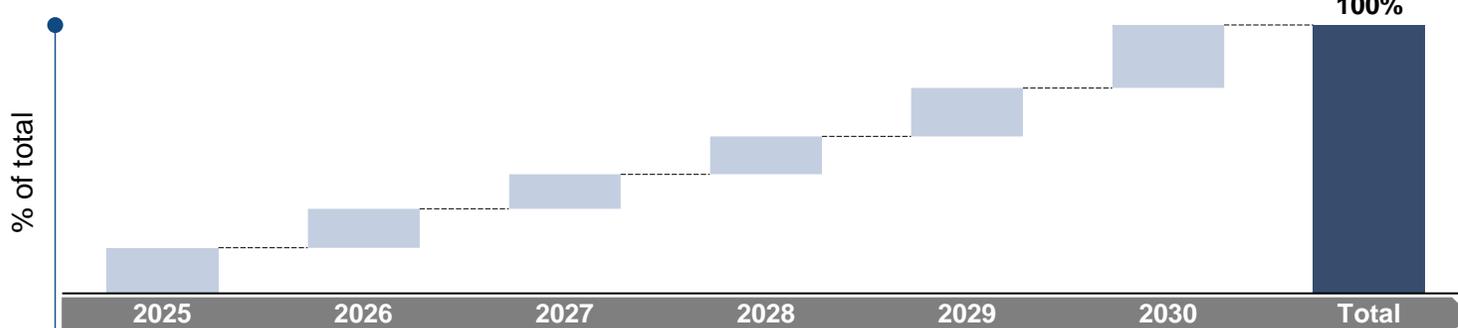
**Opportunistic M&A strategy** mainly based on the following pillars:

- Scaling the consumables business
- Strategic entry into Robotics & Digitalization
- Margin uplift
- High-barrier niche markets with growth potential

**7 – 8%<sup>(1)</sup> of net sales**

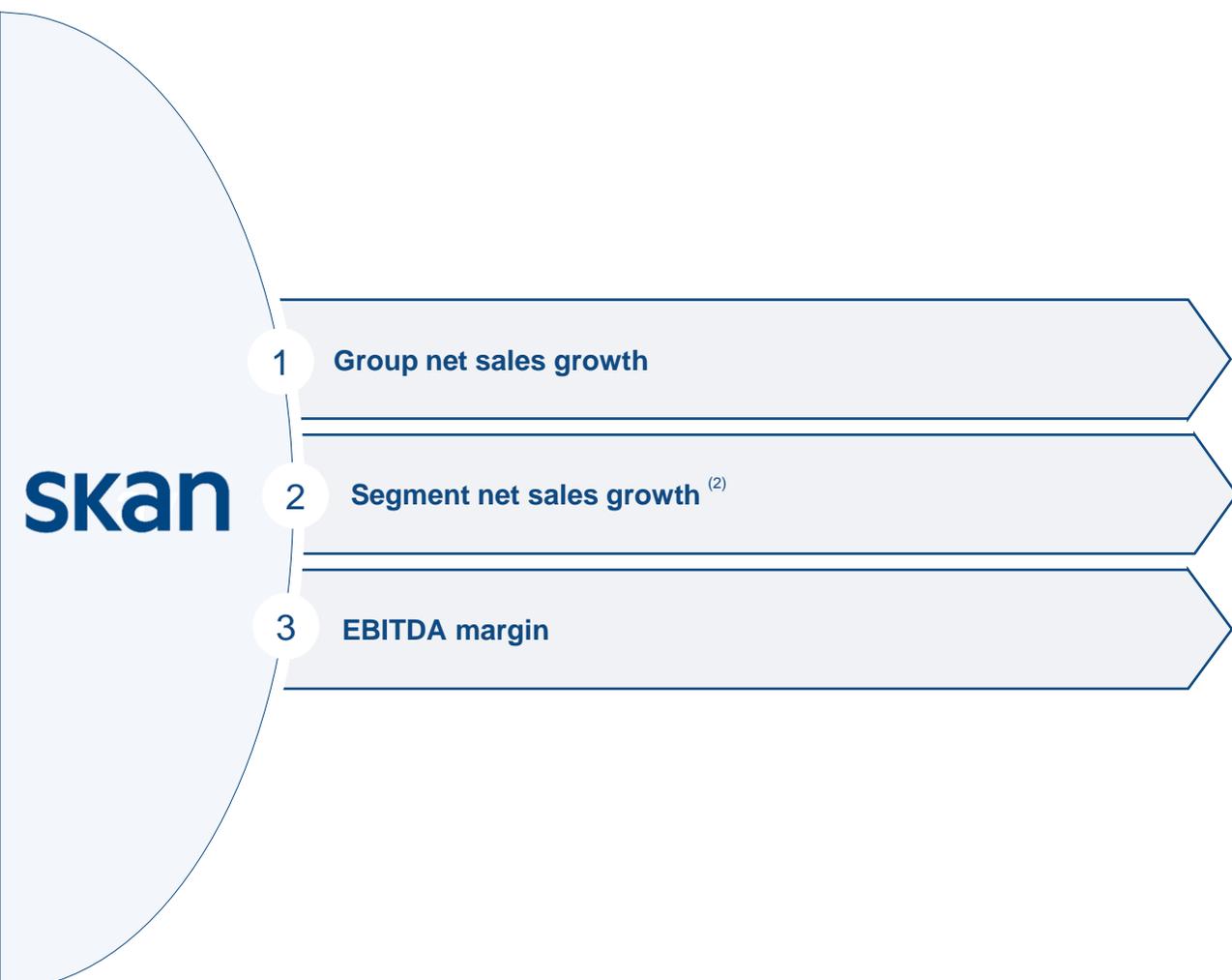
**Investment in Innovation to fortify market and technology leadership**

## Planned investments over the mid-term<sup>(2)</sup>



- SKAN is **committed to invest significantly in its future growth beyond the mid-term guidance.**
- Main investments:
  - Pre-Approved-Services incl. expansion within existing facilities
  - Central Hub in Germany to streamline material flows across the supply chain
  - Expansion production capacity for closed vial technology
  - Expansion production capacity in US
- Further potential expansion of Pre-Approved-Services in other regions considered with a positive impact on financials beyond mid-term plan.
- With maintenance capex at around 3% of net sales, SKAN demonstrates a low level of capital intensity, highlighting the efficiency and scalability of its business model.
- We are confidently funding our **strategy and organic growth** plans through consistently strong **self-generated cash flows.**

# Financial targets and guidance



## 2025 Guidance <sup>(1)</sup>

## Confirmed Mid-term Targets

|              |   |
|--------------|---|
| Mid-teens    | Mid- to upper teens   |
| E&S      S&C | E&S      S&C  |
| 14 - 16%     | Gradually increase profitability level to upper teens in the mid-term. Potential for further increase beyond mid-term period. |

The background of the slide is a close-up photograph of a laboratory setting. It features several glass pipettes with blue tips, positioned over a multi-well microplate. The scene is bathed in a cool blue light, with some wells containing a pinkish-purple liquid. The focus is sharp on the pipettes and the immediate wells, while the background is softly blurred.

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# SKAN Group AG Capital Markets Day

Competitive landscape and technology partners

Philippe Jérôme, Chief Sales and Marketing Officer

May 2025

# SKAN's leadership position is underpinned by high entry barriers and compelling value proposition

| Entry barriers   | SKAN's value proposition  | Key purchasing criteria         | skan |
|--|---|---------------------------------|------|
|  <b>Technological edge</b>                        |  <b>Mastery of difficult to replicate know-how on highest-performance isolators</b>  | Product quality / reliability   | ✓    |
|  <b>Stringent regulatory environment</b>          |  <b>Process warranty regarding all regulatory (e.g. FDA, EMA, Swissmedic) required qualifications &amp; timeline</b>                   | Brand reputation                | ✓    |
|  <b>Mission criticality of aseptic processes</b> |  <b>Swiss brand, engineering &amp; reputation provide trust in isolator safety</b>  | Validation process support      | ✓    |
|  <b>Lock-in effect</b>                          |  <b>Large installed base of isolators and leading global services incl. tech transfer &amp; consumables across product lifecycle</b> | Aftersales service / proximity  | ✓    |
|  |   | Relationship / track record     | ✓    |
|  |   | Delivery time / reliability     | ✓    |
|  |   | Customisation capabilities      | ✓    |
|  |   | Innovation and R&D capabilities | ✓    |
|  |   | Breadth of product offering     | ✓    |
|  |   | Price / TCO                     | ✓    |

Decreasing relative importance ↓

# Technological edge & innovation

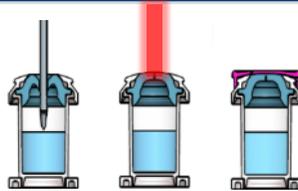
Fabrication know-how



Electron beam transfer



Filling technology



HVAC engineering & air flow modelling



GMP documentation & qualification of equipment



Automation & digitalization expertise



Chemical know-how on cleaning validation



Microbiological & H<sub>2</sub>O<sub>2</sub> know-how on surface decontamination



Decontamination cycle down to 3 minutes

- **Simplicity in the design** for fast start up
- **Robust technology** for longer production availability

- **Continuous active contribution to new guidelines & regulations** (ISPE, PDA, ISO) for smooth acceptance

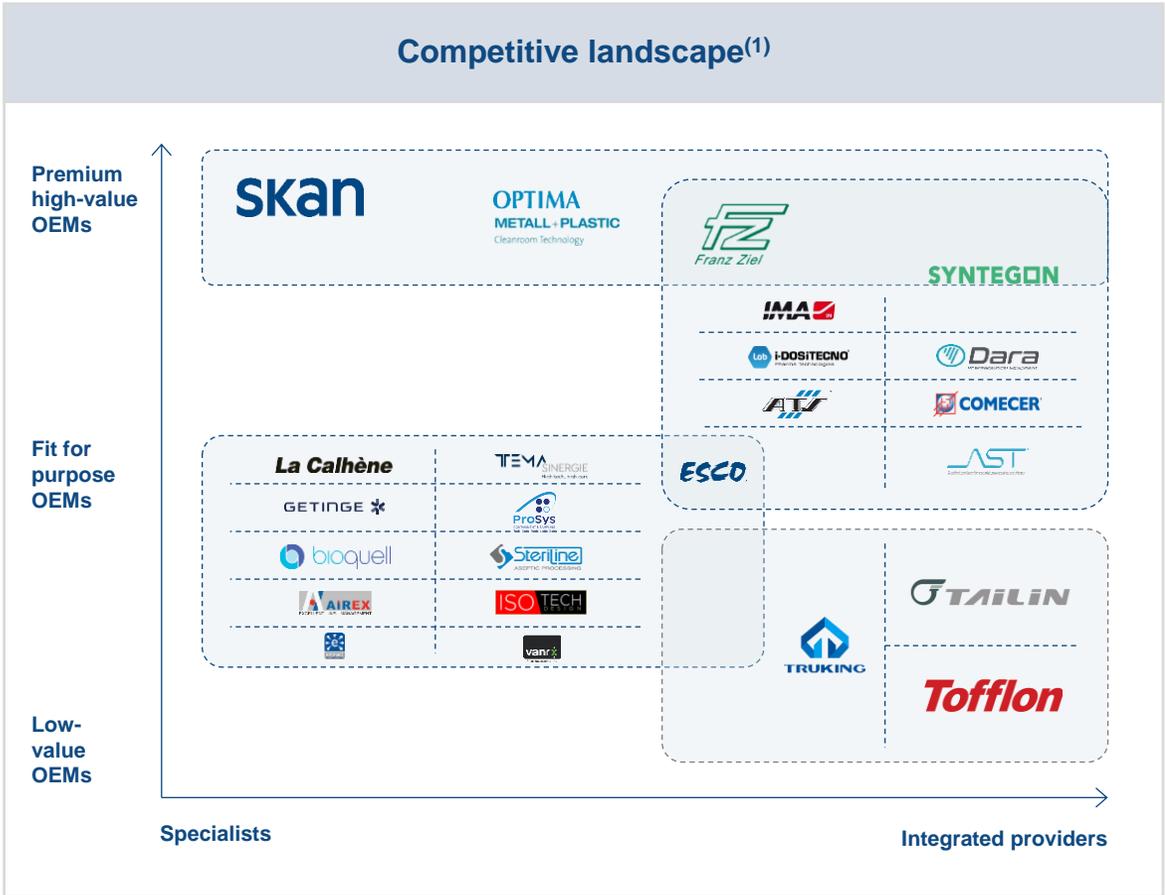
- **More than a product, an approved solution !!**

# Highest quality & service support

- Holistic aseptic processing **expertise**
- «**SKAN like**» expectation
- Automation of the process to **reduce human intervention**
- **Improved interaction system** to **facilitate the use** and maintenance of the equipment
- In-depth skilled employee for the **process understanding and quick response**



# SKAN is focused on high value isolators, in particular the premium high-value segment of the market



|  |  |
|--|--|
| <p><b>Premium high-value players</b></p>         | <ul style="list-style-type: none"> <li>→ Offer best-in-class high value isolators and complementary accessories</li> <li>→ Have formed partnerships to provide integrated solutions</li> <li>→ <b>SKAN Market share: 35 %</b></li> </ul> |
| <p><b>High-value integrated players</b></p>      | <ul style="list-style-type: none"> <li>→ Integrated or specialized OEMs challenging in certain segments of the high value market</li> <li>→ <b>SKAN Market share: 25%</b></li> </ul>   |
| <p><b>Specialized isolator manufacturers</b></p> | <ul style="list-style-type: none"> <li>→ Offer their products at lower prices and are not considered high value</li> </ul>   |
| <p><b>Low-value integrated players</b></p>       | <ul style="list-style-type: none"> <li>→ Integrated OEMs based in lower cost countries</li> </ul>  |

(1) SKAN Group AG Capital Markets Day

# Trusted and long-standing relationships to a broad base of partners



Solutions for filling and sealing different containers such as syringes, vials or cartridges

**INTEGRA filling line isolator**  
Robocell, Flexfill



Production lines for processing of bottles, vials, ampoules, cartridges and disposable syringes

**VarioSys filling line isolator**  
Combisys, Smartline



Machinery and advanced process technology supplier for the food, beverage and pharmaceutical sectors



Packaging of pharmaceutical products in blisters, bottles, and cartons

**Containment for blister filling machines**



Manufacturer of freeze-drying systems

**Aseptic loading & unloading of lyophilizers under isolator technology**



Processing of web materials, as well as dosing & inhalation technology

**Liquid dosing in GMP-compliant design for aseptic filling**



Customized process equipment for the sterile production of pharmaceutical equipment

**Sterile processing equipment for stopper supply**



# Future outlook & innovation initiatives

## Robotics and data management for integrated aseptic manufacturing



**Flexible solutions** for a range of **aseptic process** handling applications



Automated robotics offer a high level of **processes robustness**, i.e. more reproducible and accurate



Robotic systems offer **significant time efficiency advantages** vs. traditional methods translating into much faster production times



Reduce the amount of human contact involved in a production process, therefore **minimizing the risk of human contamination in a batch**



The background of the slide is a close-up photograph of a laboratory setting. Several glass pipettes are positioned over a multi-well microplate. The scene is bathed in a cool blue light, with some wells containing a pinkish-purple liquid. The focus is sharp on the pipettes and the wells they are positioned over, while the rest of the plate and the background are softly blurred.

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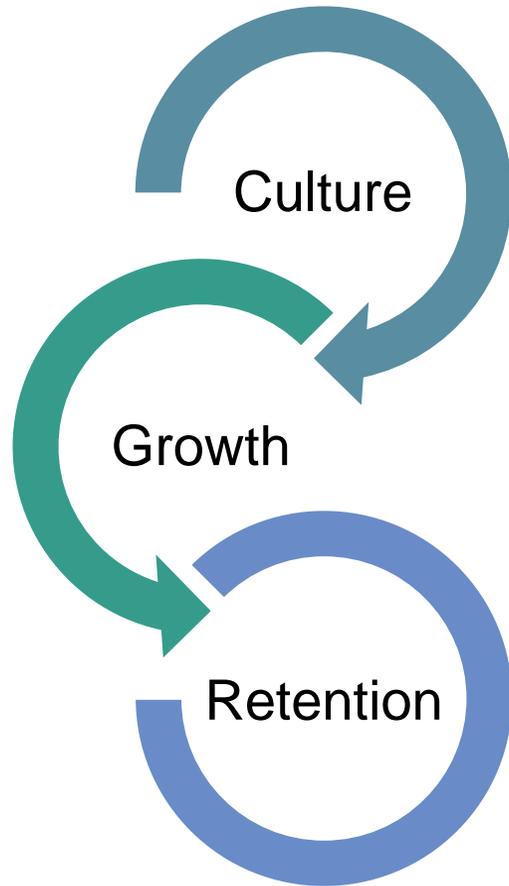
# SKAN Group AG Capital Markets Day

SKAN Culture and Managing Growth

Marina Häni, Chief People & Culture Officer

May 2025

# SKAN culture and managing growth



# The unique SKAN culture as a success factor

Culture is not a buzzword - it is our strategic advantage. It empowers growth, fosters innovation, and creates loyalty. At SKAN, we have made it our mission to nurture this culture, because we know:

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**Companies don't build culture - people do!**

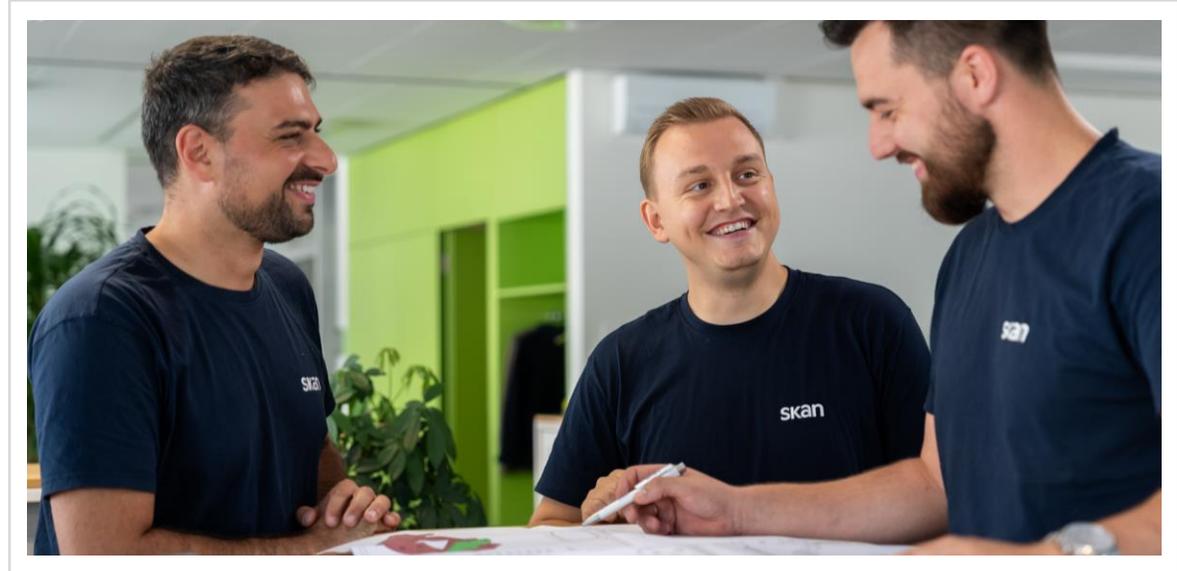


# SKAN culture

At SKAN, we look for people **who fit our culture** - not just the job description. Our work culture plays a decisive role in fostering motivation, collaboration, and commitment. It's what attracts people who bring both the technical skills and the right mindset.



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# Our values and culture



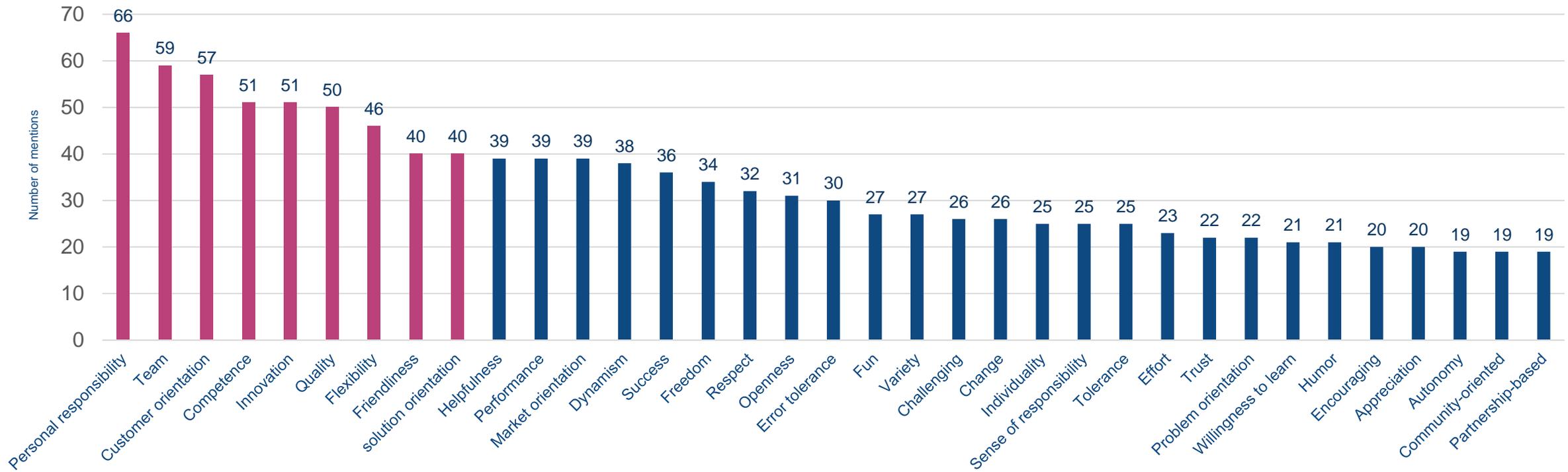
The image displays a grid of 12 icons, each representing a specific value or cultural aspect of the organization. The icons are arranged in three rows and four columns. Each icon is accompanied by a text label below it.

- Team-oriented: An icon of three stylized human figures with their arms raised.
- Individual responsibility: An icon of a single stylized human figure holding a document.
- Development: An icon of a human head profile with gears inside.
- Hands-on: An icon of two stylized human figures shaking hands.
- Independence: An icon of a single stylized human figure holding a document.
- Friendly working atmosphere: An icon of two stylized human figures sitting at a table.
- Solution-oriented: An icon of a single stylized human figure with a lightbulb above their head.
- Flat hierarchy: An icon of two stylized human figures with an equals sign between them.
- Attractive employment conditions: An icon of a single stylized human figure holding a document and a coin.
- Ambitious: An icon of a single stylized human figure with arms raised.
- Diversity: An icon of a group of stylized human figures in various colors.
- Agility: An icon of a stylized human figure in a dynamic, jumping pose.



# SKAN culture survey - What our employees say

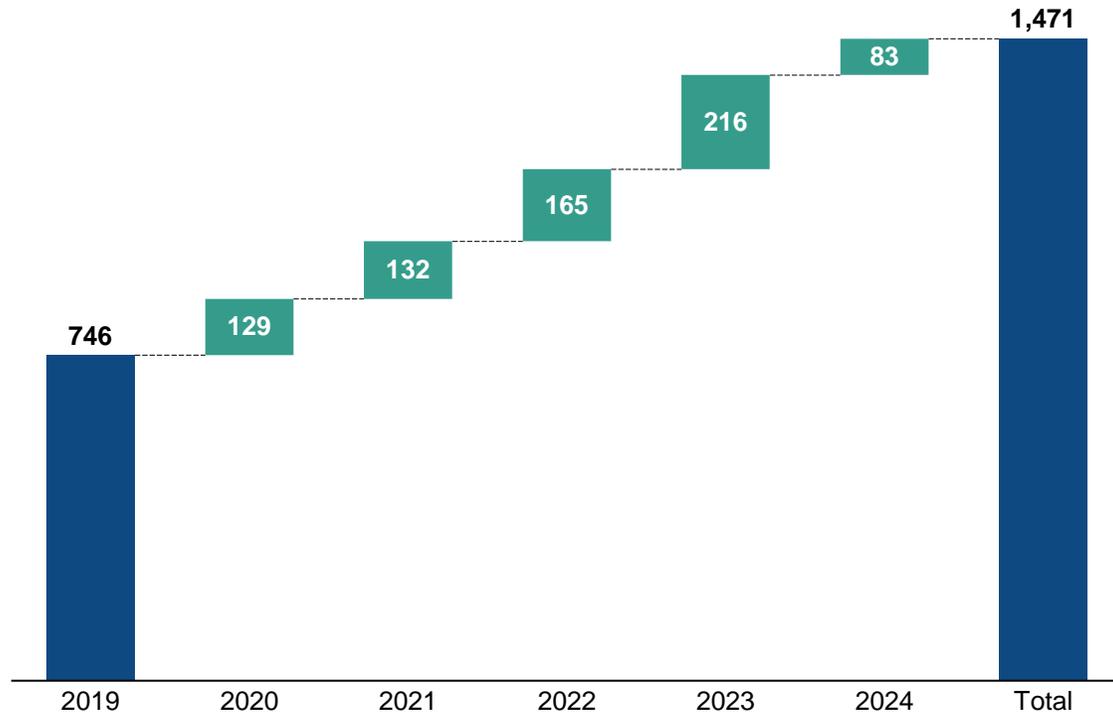
Survey results on SKAN`s corporate culture



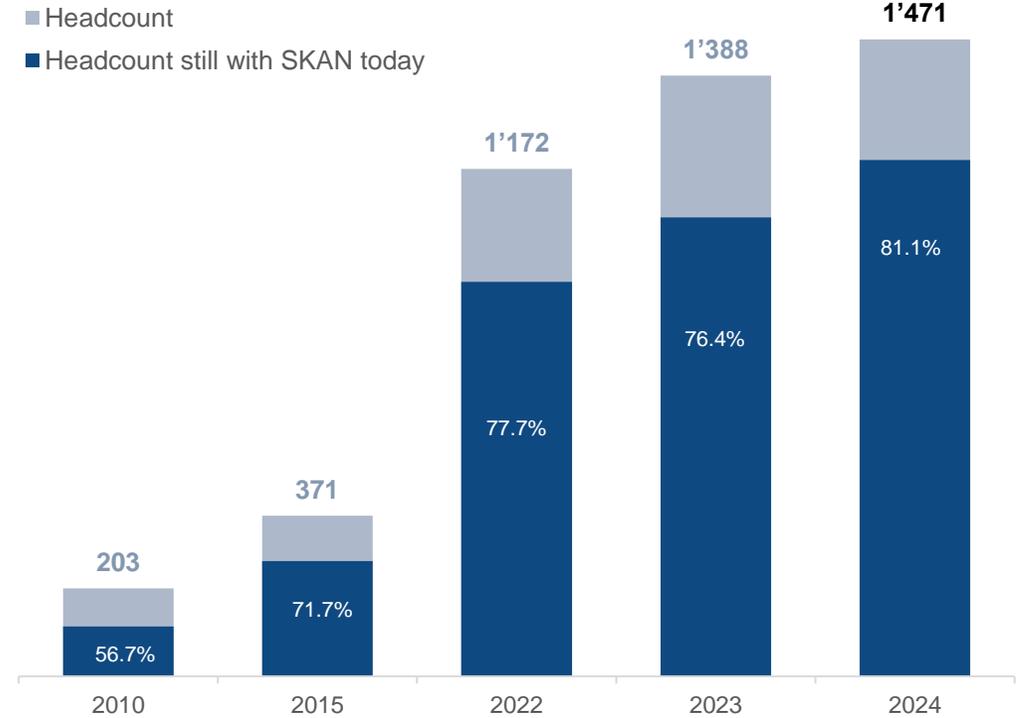
# Empowering growth through dedicated people



Ø 145 new colleagues/year



Loyal, increasing workforce <sup>(1)</sup>



(1) All figures as of December of respective year and exclusive of temporary workers.

# Managing growth



Location advantage and global reach



Good candidate experience in the recruiting process culture as a key Factor in recruitment



In house active sourcing via LinkedIn



SKAN academy & onboarding



Strong employer branding and strengthening of the employer brand

# Talent acquisition – our differentiators



Unique SKAN culture



Modern working environment



Reconnecting with alumni



Training of apprentices and trainees



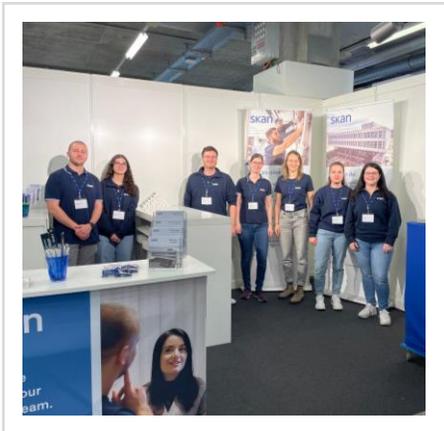
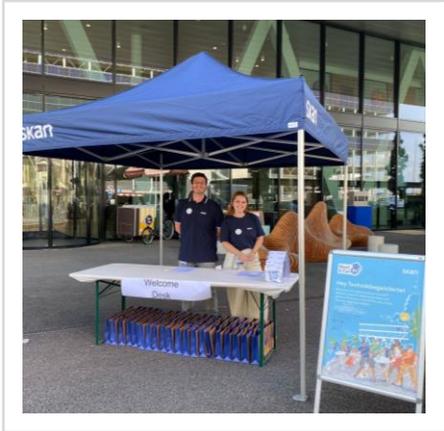
Fishing for friends

We had several appearances that strengthened our employer brand

- High-visibility events
- Job fair visits
- Meet & Eat
- Collaboration with universities



# Some impressions of our talent acquisition activities



# Environment Built for Innovation and Belonging



We design our physical and virtual working environment and continuously improve it to create a pleasant and productive working environment.



## The voice of our SKAN colleagues

“The open contact and helpfulness at all levels create a nice working atmosphere and make it a pleasure to work for SKAN. This atmosphere combined with the opportunity to help shape the future or it into your own hands makes SKAN unique as an employer.”

**Dr. Ing. Thierry Tchoumi**  
Director Project Management

“I enjoy working at SKAN because it offers me modern perspectives and the spirit for new challenges, from which I can grow and learn as a developer and as a person.”

**Corina Braun**  
VR/AR Application Developer

‘I enjoy the way we work together to make every project possible. Not only between members of the same team, but also with other colleagues from other departments. Even though we are a big company, we all take responsibility and make decisions.’

**Mauricio Contreras**  
Automation Engineer

# Retention – a key to sustainable growth

Hiring the right people is only one part. **Keeping them is just as important.**

- Attractive work environment
- Competitive benefits
- Employee engagement and feedback
- Career development
- Leadership development



# Benefits that strengthen our team and culture



Flextime



Homeoffice



Trainings at the  
SKAN Academy



Modern  
workplace



International  
team



Structured  
onboarding



Health &  
sport program



Employee  
discounts



Free drinks  
and fruits



Free work- and  
SKAN-wear



Celebrating  
success

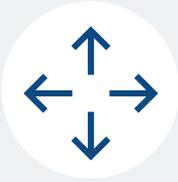
and more...

# Fostering engagement through open dialogue

We conduct regular employee surveys and actively respond to employee feedback. Their concerns are taken seriously and included in our decision-making processes.



# Career development



Internal mobility



First-time leadership



Continuous learning



# Leadership development



Management leadership program



Individual coaching



Focus on people



# Some impressions of our culture



A close-up photograph of a laboratory setting, featuring several pipettes dispensing liquid into a multi-well microplate. The scene is bathed in a cool blue light, with some wells containing a pinkish-purple liquid. The background is softly blurred, showing more lab equipment.

skan

# Questions & answers

May 2025



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Coffee break

May 2025

The background of the slide is a close-up photograph of a laboratory setting. It features several glass pipettes with blue tips, positioned over a multi-well microplate. The scene is bathed in a cool blue light, creating a professional and scientific atmosphere. The focus is sharp on the pipettes and the wells they are positioned over, while the rest of the background is softly blurred.

skan

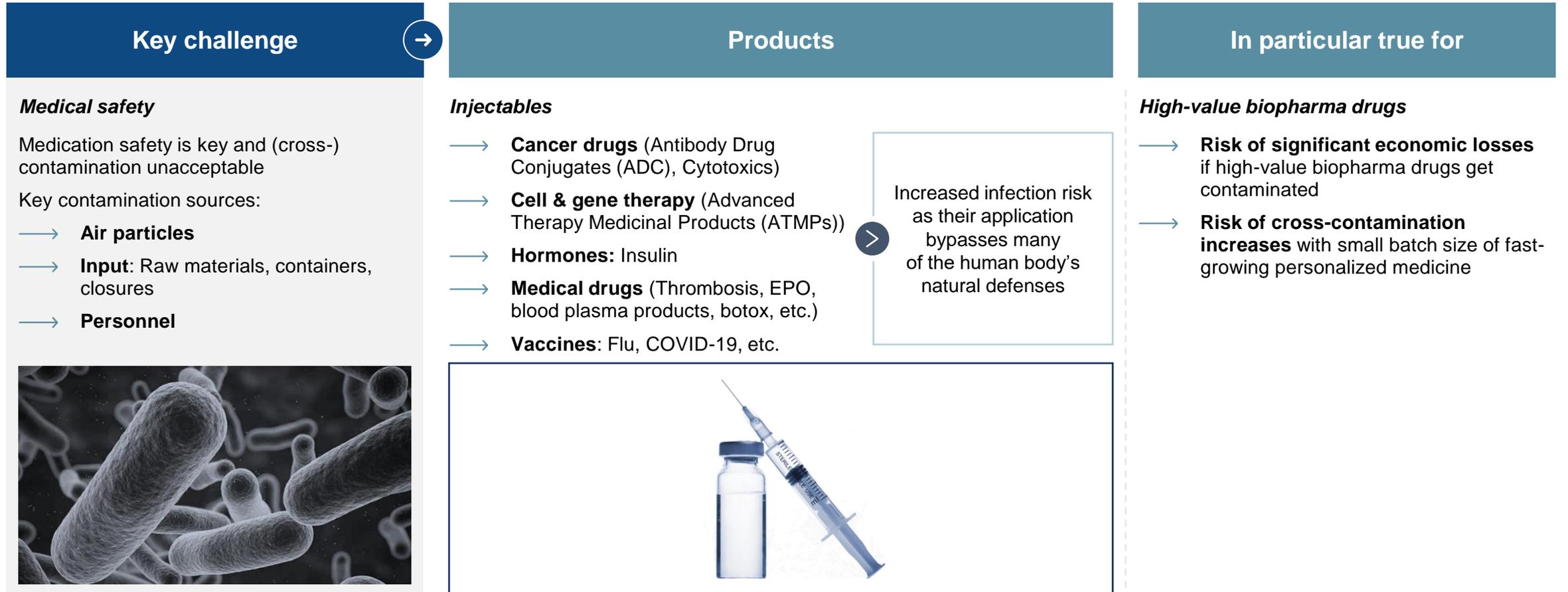
# SKAN Group AG Capital Markets Day

Isolator technology and standardization

Ralf Krämer, Chief Technology Officer

May 2025

# Key challenge for (bio-)pharmaceutical products



# Isolators – Mission critical for (bio-)pharmaceutical processes

## Solution: Medication sterility

### TRADITIONAL PHARMA

Pharma products mainly chemical based



#### CLEANROOM

- Filling / closing in cleanroom with terminal sterilization
- Inappropriate for complex biopharmaceuticals

Cleanroom environment

Terminal sterilisation

Raw materials procurement

Formulation

Fill-finish

Quality control

Packaging & shipping

↑ Sterilisation

Aseptic processing

### BIOPHARMA OF TODAY AND TOMORROW

New products mainly biotech-based (sensitive to heat and pressure)



#### ISOLATORS

- Filling/closing under aseptic conditions eliminating effectively all contamination risk
- Reduced cleanroom footprint and running costs and environmental-friendly
- Complex process results in high market entry barriers



**SAL 10<sup>-3</sup>**  
Probability of 1 in 1,000 of finding a non sterile unit

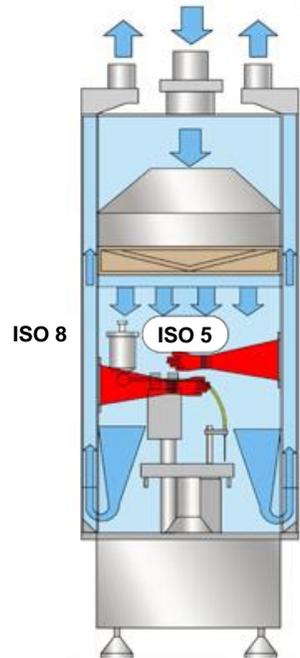


**SAL 10<sup>-6</sup>**  
Probability of 1 in 1,000,000 of finding a non sterile unit

Note: SAL = Sterility Assurance Level

# Isolator technology: What are isolators?

## Isolators create a fully controlled aseptic environment



- Isolators are **completely sealed systems**, separating operator and process area for **highest sterility assurance levels (SAL)**
- **Fitted with air handling systems** providing high efficiency particulate air (**HEPA**) in an **unidirectional flow pattern**
- **Positive pressure** to protect the work area from contamination, or **negative pressure**, to limit flow of hazardous particles to the operator

## Optimizing sterility to ensure patient safety



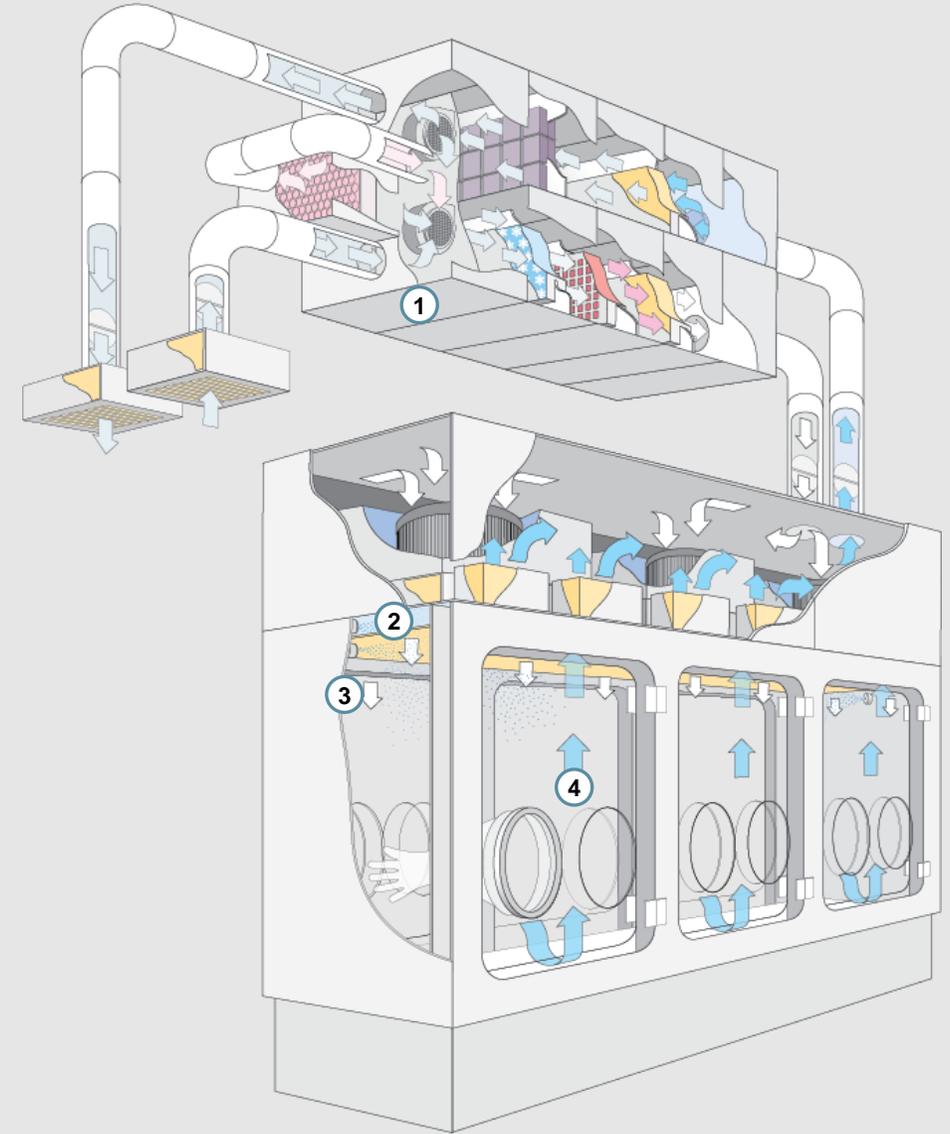
**Isolators** facilitate **meeting sterility standards for injectables** and other **complex molecule therapies** (such as **biologics** and **vaccines** which are too vulnerable for traditional heat sterilisation) to **ensure patient safety**



**Superior bio-decontamination** compared to traditional cleanrooms & RABS<sup>(1)</sup> **place isolators at the forefront of future biopharmaceutical manufacturing**

# Isolator air handling (aseptic)

- 1 Air handling unit (AHU)
- 2 HEPA filter H14
- 3 Unidirectional air flow
- 4 Return air by double windows



# Isolator for aseptic filling of toxic products

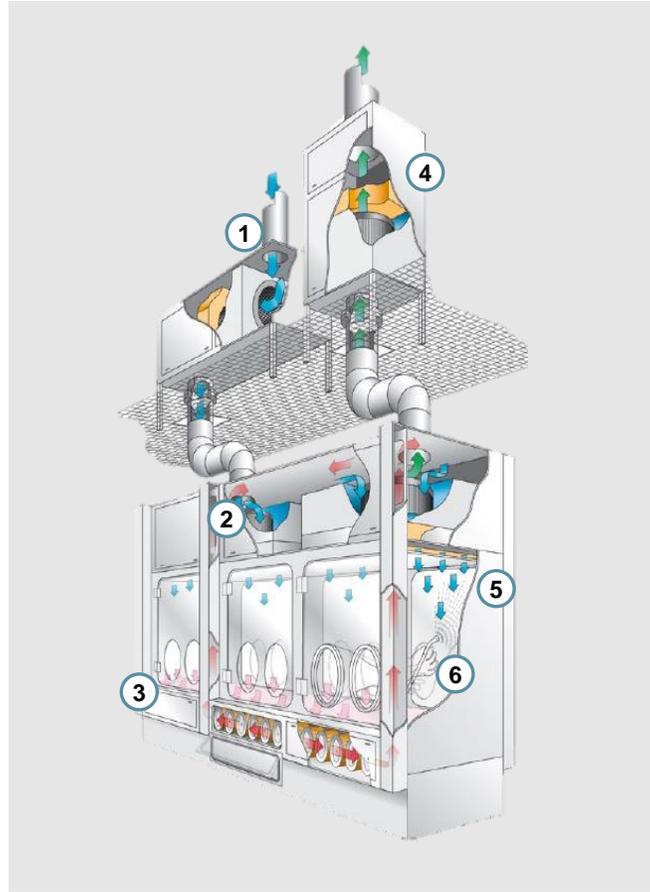
- 1 HEPA filtered inlet air from the room is treated (temperature, relative humidity, nitrogen atmosphere)

---

- 2 Simple and safe filter change system for personnel protection

---

- 3 Recirculation air flow with double window design



- 4 HEPA filtered exhaust system

---

- 5 Monitoring of air velocity, differential pressure, temperature & relative humidity as well as particle counting & microbiological monitoring

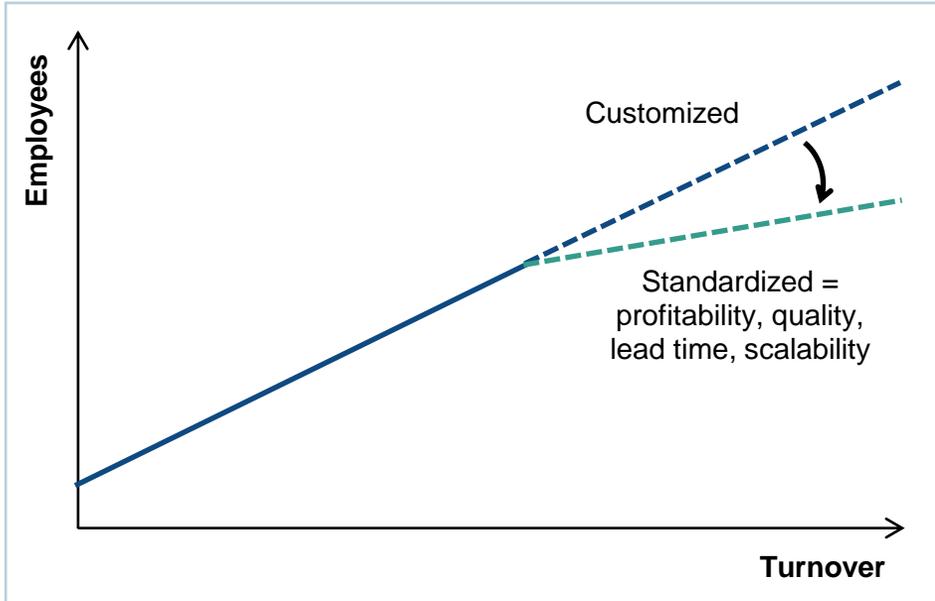
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- 5 Vertical, unidirectional controlled air flow

---

- 6 Isolator chamber washable with spray balls and spray wands

# Standardization to enable growth with less effort

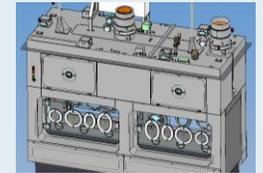


|             | Number of activities |
|-------------|----------------------|
| In pipeline | 25                   |
| Ongoing     | 36                   |
| Completed   | 37                   |

## Examples

### CAD template for toxic filling line

- Several hundred hours less MED per each customized project
- Quality improvement



### Reduce 630 wire types to 99

- Better purchase price
- Less supplier audits
- Less master data maintenance
- Less warehouse and logistics cost



### Automation catalogue

Document to discuss & decide with customer required functions at project start

- Avoid late modifications of SW and misunderstandings
  - expectation management
- Higher customer satisfaction



### Automate project execution for spectra

- Generate manufacturing BOM out of sales-options
- Automated 3D-Drawing generation
- Automated output for technical documentation and electrical engineering



# Automation catalogue

The image shows two overlapping document covers for SKAN automation standards. The left cover is titled "Thin Client topology" and dated April 2025. The right cover is titled "Secomea Gateway Remote Access Device" and dated January 2025. A blue arrow points from the right cover to a text box on the right.

SKAN automation standards for  
**Thin Client topology**  
April 2025

SKAN automation standards for  
**Secomea Gateway Remote Access Device**  
January, 2025

Currently 27 existing  
> to be continued

## Sales - Calc

| SPECTRA  |  | Yes |
|--|--|-----|
| <b>Combination (SPECTRA / SARA) with standard equipment</b>  |  |     |
| SPECTRA, SKANFOG, Catalyst, leak test, differential pressure sensor, temperature sensor, relative humidity sensor, filter differential pressure gauge, SKAN1 glow port round, suspension bar with hooks (4 long + 4 small), alarm lamp & horn, double floor 6 parts, Siemens or Allen Bradley PLC and HMI, integrated IP54 electrical cabinet, standard documentation, FAT, 12 or 24 months warranty |  | Yes |
| Option: Upgrade to toxic design to handle potent substances for SPECTRA and SARA (select one of two options)   |  | Yes |
| - Basic Package -> FIPA with cover for manual closing with tool (low cost version - FIPA opening and closing not integrated in HMI process steps: FIPA Cleaning not implemented)   |  | Yes |
| - Extensive package -> FIPA with cover and drive for automated closing   |  | Yes |
| Option: SKAN oval glove ports instead of SKAN round glove ports  |  | Yes |
| <b>SPECTRA SARA left</b>   |  |     |
| (SKANFOG, catalyst, leak test, differential pressure sensor, temperature sensor, filter differential pressure sensor, pull-out shelf at the bottom)  |  | Yes |
| Option: Additional pull-out shelf on top   |  | Yes |
| <b>SPECTRA SARA right</b>  |  |     |
| (SKANFOG, catalyst, leak test, differential pressure sensor, temperature sensor, filter differential pressure sensor, pull-out shelf at the bottom)  |  | Yes |
| Option: Additional pull-out shelf on top   |  | Yes |
| Control cabinet on the left side of the isolator   |  | Yes |
| Control cabinet on the right side of the isolator  |  | Yes |
| Option: Single wire labelling for CE (for UL, it's automatically included)   |  | Yes |
| Remote FAT (select days as usual)  |  | Yes |
| Additional FAT days (1 day is always included)   |  | Yes |
| <b>Communication Package</b>   |  |     |
| Basic communication package (always included)  |  | Yes |
| Option: Additional extensive communication package   |  | Yes |
| <b>Documentation</b>   |  |     |
| Project document language: always English  |  | Yes |
| User doc. & HMI language: standard: English, German, French, Dutch, Russian, Spanish, Hungarian  |  | Yes |
| User doc. & HMI language: (other languages)  |  | No  |
| Documentation (as built) required for US customers   |  | No  |
| <b>Control System</b>  |  |     |
| <b>Siemens</b>   |  |     |
| Local PC Solution: Siemens Simatic 57-1500   |  | Yes |
| Beckhoff Panel = PC + Zener, Alarm Log, Local & domain login (active directory), Events Log (Audit Trail), Monitoring (Trends recording)   |  | Yes |

## PL - Config. Plan

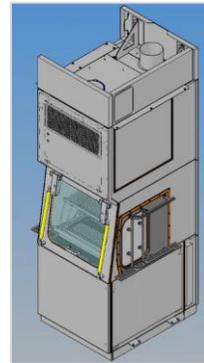
| Isolator configuration  |    | Alter |
|---|----|-------|
| Control cabinet (left/right)  | No |       |
| Airlock 3 (left/right)  | No |       |
| Airlock 4 (right)   | No |       |
| Chamber 1   | No |       |
| <b>General</b>  |    |       |
| SKANFOG® Flow decontamination system  | No |       |
| H <sub>2</sub> O <sub>2</sub> concentration: 35% (Standard)   | No |       |
| H <sub>2</sub> O <sub>2</sub> bottle size / manufacturer: 1 liter / Solvay (Standard)                               | No |       |
| Intake air from surrounding room  | No |       |
| Intake air from technical area  | No |       |
| Exhaust air back to the room via control cabinet  | No |       |
| External exhaust air to technical area  | No |       |
| Cover on the top for finishing to ceiling - Ceiling height: X mm  | No |       |
| WirelessGT device - Project no.: XXX-XXX-XXX<br>(Delivery scope separately listed in the configuration plan of WGT) | No |       |
| WirelessGT storage / charging holder on the side wall for 2 WGT   | No |       |
| FIPA 225 test bucket  | No |       |
| Warranty:   | No |       |
| 12 month (standard)   | No |       |

Seite 1

| Control cabinet  | Section | Option    | Yes |
|--|---------|-----------|-----|
| Must have:   |         |           | Yes |
| Control cabinet  | CC      | FLOW-GE-L | Yes |
| Dosing unit SKANFOG with 2 pumps   | CC      | FOG-3P-L  | Yes |
| Base cover to the floor for the left control cabinet   | CC      | BC0       | Yes |
| Ethernet connection on the PLC (Real time data, Read only)                                       | CC      | PLC-ETH1  | Yes |
| Options:   |         |           | Yes |
| Back cover for control cabinet left with exhaust air terminal filters F9                         | CC      | BWCC2     | No  |
| Back cover for control cabinet left with no exhaust air (Exhaust air back to CE control cabinet) | CC      | CE        | No  |
| CE control cabinet   | CC      | UL        | No  |
| UL control cabinet   | CC      | UL        | No  |
| No H2O2 TLV Sensor installed   | CC      | TLV0      | Yes |
| H2O2 TLV Sensor for the surrounding room, integrated in the control cabinet                      | CC      | TLV51     | No  |
| H2O2 TLV Sensor for the surrounding room, remote installation and wired with                     | CC      | TLV52     | No  |
| External H2O2 TLV signal provided by customer, only signal integration by                        | CC      | TLV3      | No  |
| Optional input voltage transformer - 3x200VAC to 3x400/230VAC 50/60 Hz                           | CC      | T1        | No  |
| Optional input voltage transformer - 3x240VAC to 3x400/230VAC 50/60 Hz                           | CC      | T2        | No  |
| Optional input voltage transformer - 3x480VAC to 3x400/230VAC 50/60 Hz                           | CC      | T3        | No  |

## PL/MED - Profile-CH

| #       | Baseline Chamber option                 | Baseline Chamber options               |         |
|---------|---|--|---------|
| 1380171 | OPT Luftkeimsammler Vorbereitung BG     | OPT active air sampler preparation CA  | AS3     |
| 1359258 | OPT Steriltest Milipore Vorbereitung BG | OPT Steriltest Milipore preparation CA | ST2     |
| 1346573 | OPT H2O2 LC Sensor BG                   | OPT H2O2 LC Sensor CA                  | 2G-LCS1 |
| 1334956 | OPT Verkleidung Mitte BG                | OPT Covering Middle CA                 | CMC1    |
| 1334969 | OPT Verkleidung rechts BG               | OPT Covering right CA                  | CRC1    |
| 1333643 | OPT Verkleidung links BG                | OPT Covering left CA                   | CRC2    |
| 1333500 | OPT H2O2 HC Sensor BG                   | OPT H2O2 HC Sensor CA                  | HCS1    |
| 1299740 | OPT Bodenblech 2 Türen BG               | OPT Bottom plate 2 door CA             | BP1     |
| 1299739 | OPT Bodenblech ohne Tür BG              | OPT Bottom plate without door CA       | BP0     |
| 1295044 | OPT Luftgeschwindigkeitssensor BG       | OPT Air velocity sensor CA             | AV1     |
| 1292555 | OPT Bodenblech Tür links BG             | OPT Bottom plate door left CA          | BPL1    |
| 1292130 | OPT Seitenwand Blind BG                 | OPT Side wall blank CA                 | Sw1     |
| 1274834 | OPT Regale hängend BG                   | OPT hanging shelves CA                 | SH1     |



Electro

Docu

Automation - Config

## PL/MED - SAP-DE

| Material                         | 1369525         | SPECTRA CHAMBER |
|----------------------------------|-----------------|-----------------|
| Werk                             | 2000            | SKAN DE         |
| Konfigurierbares Mat             | SPEC_4G_ISO_V03 |                 |
| <b>Merkmalsbewertung</b>         |                 |                 |
| Merkmalsbezeichnung              | Merkmalswert    | In...           |
| <input type="checkbox"/> 1301999 | JA              | (I)             |
| <input type="checkbox"/> 1302972 | 1,000           | (I)             |
| <input type="checkbox"/> 1306129 | 1,000           | (I)             |
| <input type="checkbox"/> 1313957 |                 | (I)             |
| <input type="checkbox"/> 1315990 | JA              | (I)             |
| <input type="checkbox"/> 320194  |                 | (I)             |
| <input type="checkbox"/> 320196  | JA              | (I)             |
| <input type="checkbox"/> 1324156 | JA              | (I)             |
| <input type="checkbox"/> 1324202 | JA              | (I)             |
| <input type="checkbox"/> 1324405 | JA              | (I)             |
| <input type="checkbox"/> 1324471 |                 | (I)             |

## Profile-DE

| #       | Baseline Chamber option                 | Baseline Chamber options               |         |
|---------|---|--|---------|
| 1359258 | OPT Luftkeimsammler Vorbereitung BG     | OPT active air sampler preparation CA  | AS3     |
| 1358542 | OPT Steriltest Milipore Vorbereitung BG | OPT Steriltest Milipore preparation CA | ST2     |
| 1346573 | OPT H2O2 LC Sensor BG                   | OPT H2O2 LC Sensor CA                  | 2G-LCS1 |
| 1334956 | OPT Verkleidung Mitte BG                | OPT Covering Middle CA                 | CMC1    |
| 1334969 | OPT Verkleidung rechts BG               | OPT Covering right CA                  | CRC1    |
| 1333643 | OPT Verkleidung links BG                | OPT Covering left CA                   | CRC2    |
| 1333500 | OPT H2O2 HC Sensor BG                   | OPT H2O2 HC Sensor CA                  | HCS1    |
| 1299740 | OPT Bodenblech 2 Türen BG               | OPT Bottom plate 2 door CA             | BP1     |
| 1299739 | OPT Bodenblech ohne Tür BG              | OPT Bottom plate without door CA       | BP0     |
| 1295044 | OPT Luftgeschwindigkeitssensor BG       | OPT Air velocity sensor CA             | AV1     |
| 1292555 | OPT Bodenblech Tür links BG             | OPT Bottom plate door left CA          | BPL1    |
| 1292130 | OPT Seitenwand Blind BG                 | OPT Side wall blank CA                 | Sw1     |
| 1274834 | OPT Regale hängend BG                   | OPT hanging shelves CA                 | SH1     |

| Material                         | 1369525         | SPECTRA CHAMBER |
|----------------------------------|-----------------|-----------------|
| Werk                             | 2000            | SKAN DE         |
| Konfigurierbares Mat             | SPEC_4G_ISO_V03 |                 |
| <b>Merkmalsbewertung</b>         |                 |                 |
| Merkmalsbezeichnung              | Merkmalswert    | In...           |
| <input type="checkbox"/> 1301999 | JA              | (I)             |
| <input type="checkbox"/> 1302972 | 1,000           | (I)             |
| <input type="checkbox"/> 1306129 | 1,000           | (I)             |
| <input type="checkbox"/> 1313957 |                 | (I)             |
| <input type="checkbox"/> 1315990 | JA              | (I)             |
| <input type="checkbox"/> 320194  |                 | (I)             |
| <input type="checkbox"/> 320196  | JA              | (I)             |
| <input type="checkbox"/> 1324156 | JA              | (I)             |
| <input type="checkbox"/> 1324202 | JA              | (I)             |
| <input type="checkbox"/> 1324405 | JA              | (I)             |
| <input type="checkbox"/> 1324471 |                 | (I)             |





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# SKAN Group AG Capital Markets Day

GMP and Regulatory compliance

Richard Denk, Senior Consultant Aseptic Processing & Containment

May 2025

# GMP requirements for sterile injectables



The Aseptic manufacturing for sterile Products is highly regulated and monitored



National and International Guidelines have to be adapted and are inspected routinely from national and international Regulatory Authorities.



# GMP requirements for sterile injectables

- Current good manufacturing practice cGMP for sterile pharmaceutical products EU GMP Annex 1 – All EU countries
- PIC/s Annex 1 – 54 global Member states
- WHO Annex 2 – remaining world
- This is the first time that there is a global almost harmonized guideline
- SKAN was involved service provider in the ISPE commenting team for the revision of Annex 1.
- Support on the published Annex 1 guideline



2.1 The manufacture of sterile products is subject to special requirements in order to minimize risks of microbial, particulate and endotoxin/pyrogen contamination. The following key areas should be considered:

- Facility, equipment and process should be appropriately designed, qualified and/or validated and where applicable, subjected to ongoing verification according to the relevant sections of the Good Manufacturing Practices (GMP) guidelines. The use of appropriate technologies (e.g. Restricted Access Barriers Systems (RABS), isolators, robotic systems, rapid/alternative methods and continuous monitoring systems) should be considered to increase the protection of the product from potential extraneous sources of endotoxin/pyrogen, particulate and microbial contamination such as personnel, materials and the surrounding environment, and assist in the rapid detection of potential contaminants in the environment and the product.



# GMP requirements

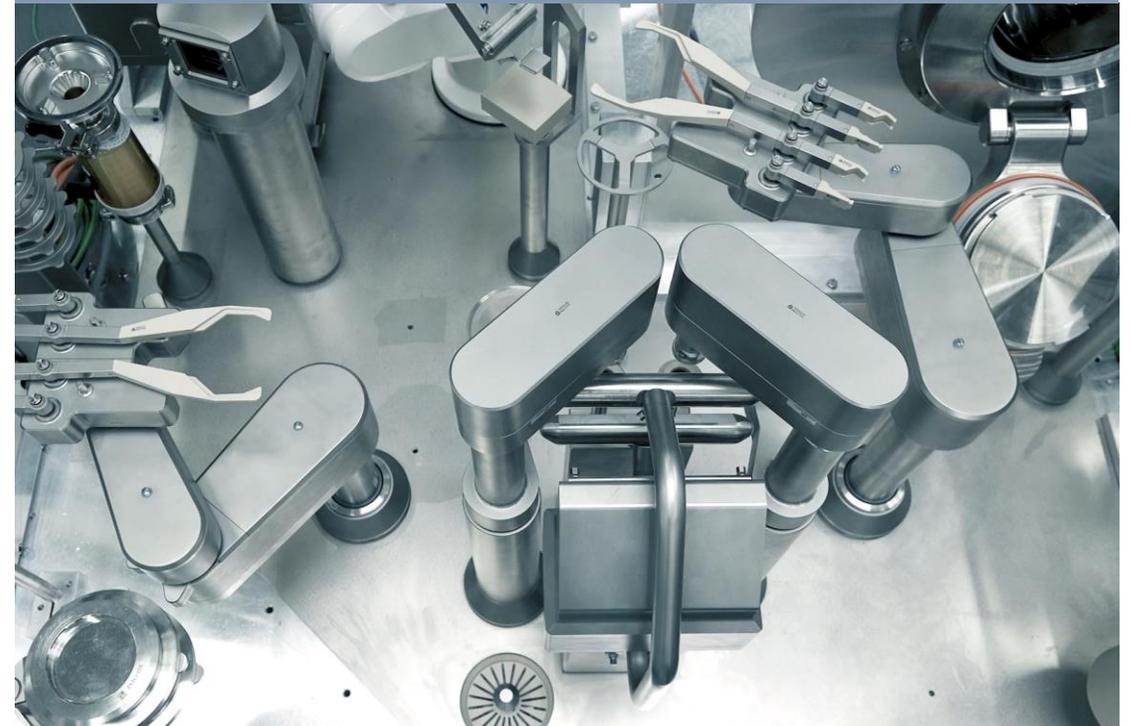
Barrier and isolator systems



Transfer as ebeam



Automation as robotics



# Shaping GMP standards – Trusted by inspectors worldwide



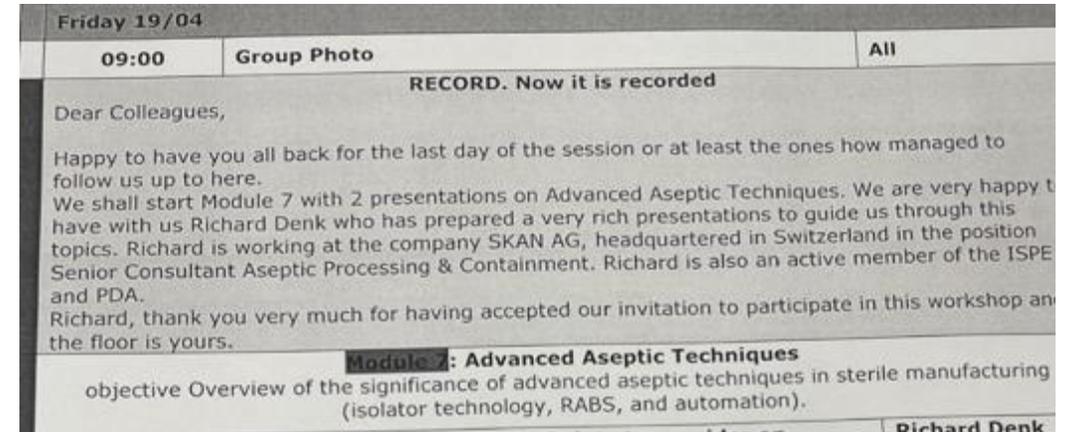
Sole industry presence at the 2024 EU/GMP Annex 1 training – reinforcing SKAN’s leading market position



Training on Annex 1 implementation and robotics – concise, high-impact format with expert interaction



Nearly 700 inspectors worldwide – on-site and virtual – engaged with SKAN’s expertise



# Shaping GMP standards – Trusted by inspectors worldwide



Leveraging its deep  
expertise, SKAN  
conducted additional  
inspector trainings for  
major health authorities



In October 2025, SKAN hosts the official  
GMP inspector training at its headquarters in  
Allschwil – strengthening its role as a trusted  
authority in regulatory compliance

# GMP requirements ATMPs cell and gene therapies

- Current good manufacturing Practice cGMP for ATMPs EU GMP annex 1 Part IV – All EU countries
- PIC/s Annex 2A – 54 global member states
- SKAN was involved as a service provider in the ISPE commenting team for the PIC/s Annex 2A for ATMPs



**EudraLex**  
**The Rules Governing Medicinal Products in the European Union**  
**Volume 4**  
**Good Manufacturing Practice**  
Annex 2A Manufacture of Advanced Therapy Medicinal Products for Human Use

## ANNEX 2A

### MANUFACTURE OF ADVANCED THERAPY MEDICINAL PRODUCTS FOR HUMAN USE

#### SCOPE

The methods employed in the manufacture of Advanced Therapy Medicinal Products (ATMPs) are a critical factor in shaping the appropriate regulatory control. ATMPs can be defined therefore largely by reference to their method of manufacture. For example, for gene therapy ATMPs, genetic modifications can be obtained through a variety of methods (e.g. viral & non-viral vectors, mRNA, genome editing tools). The genetically



# Why is this a strategic advantage for SKAN – today and tomorrow?



SKAN shares best practices with inspectors and regulators – demonstrating full alignment with current cGMP standards



Being known by regulators worldwide enhances SKAN's credibility – facilitating smoother inspections and enabling future business.



Co-creating standards with global authorities.





skan



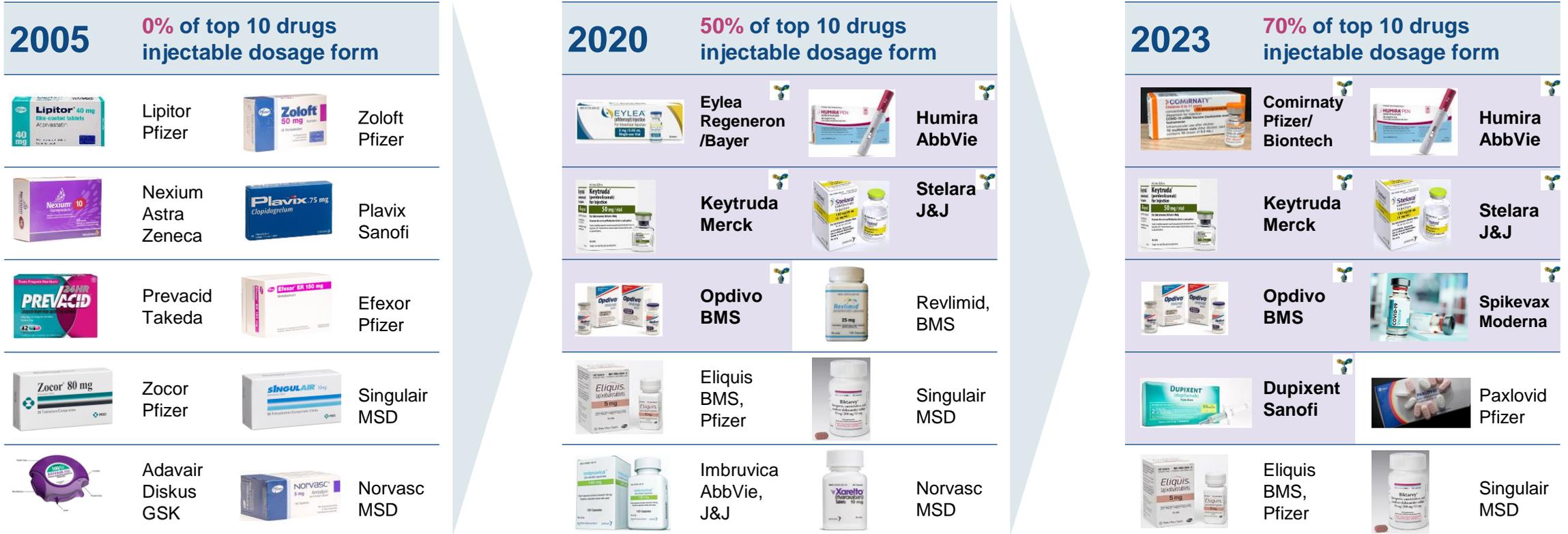
SKAN Group AG Capital Markets Day

Pre-approved services

Thomas Zinn, Chief Officer Aseptic Manufacturing Services

May 2025

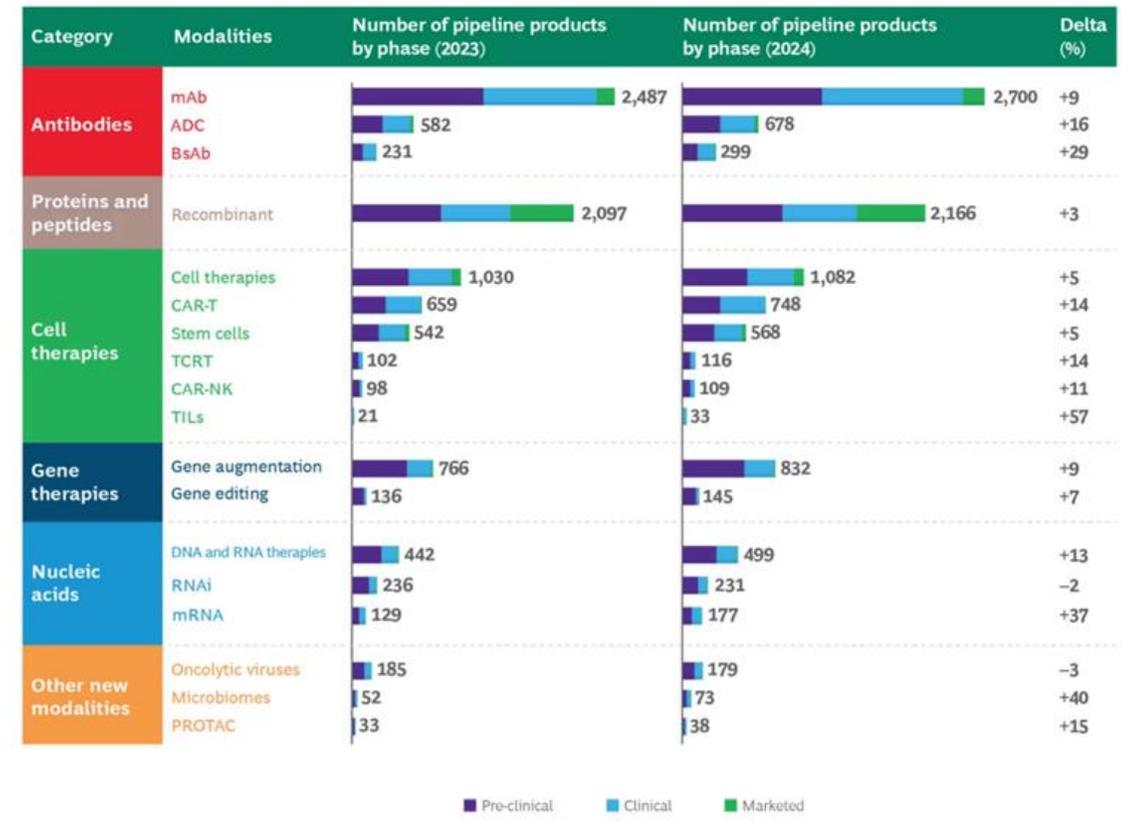
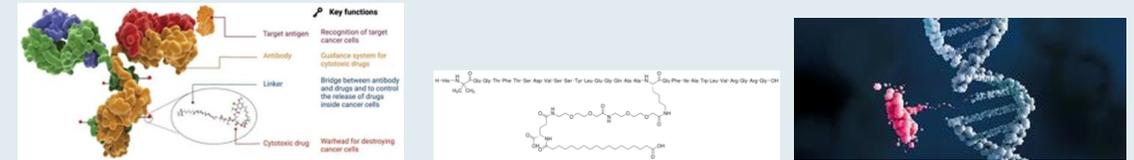
# Shift toward injectable biotech drugs continues and drives need for aseptic process solutions



# Pre-approved services

## Focuses on technology driven Services and Offerings for aseptic fill-finish

- In the “Century of Biology”, precision molecules are developed faster with higher success rates
- Pharma manufacturers require faster, more flexible supply chain solutions
- Innovators depend on reliable and future-ready technology partners
- Humans must master increasingly complex manufacturing environments
- Incubators needed for user-centric offerings and service models (e.g. test pilots)
- Fully integrated and pre-approved system solutions are essential
- SKAN provides all key elements – they “just” need to be brought together



Sources: Evaluate Pharma; BCG analysis.  
 Notes: ADC = antibody-drug conjugate; BsAb = bispecific antibody; CAR-NK = chimeric antigen receptor-transduced natural killer cell; CAR-T = chimeric antigen receptor T cell; mAb = monoclonal antibody; PROTAC = proteolysis-targeting chimera; TCRT = T-cell receptor therapy; TIL = tumor-infiltrating lymphocyte.

# Pre-approved services commercialization planned in H2/2026

- With **Pre-Approved Services**, SKAN will offer customers the possibility to **carry out their stability tests on our systems**.
- This will allow our customers to **shorten the time-to-market for a new drug significantly**.
- **Significant investments were made by SKAN** to develop pre-approved services.
- SKAN seeks **regulatory approval in Q1 2026** and intends **commercial production in H2 2026**.

## Key data

- **Equipment:**  
At start: filling equipment with potential to expand  
At full capacity: a wide range of products can be handled
- **Commercial use:**  
H2/2026E: Planned start of commercial use with successive increase in capacity utilization over several years until full capacity is reached



# Accelerated go-to-market for our customers through pre-approved services – enabling faster access for patients

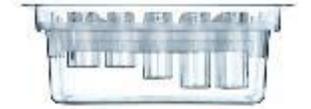


# Filling system for RTU primary pack with isolator and ebeam

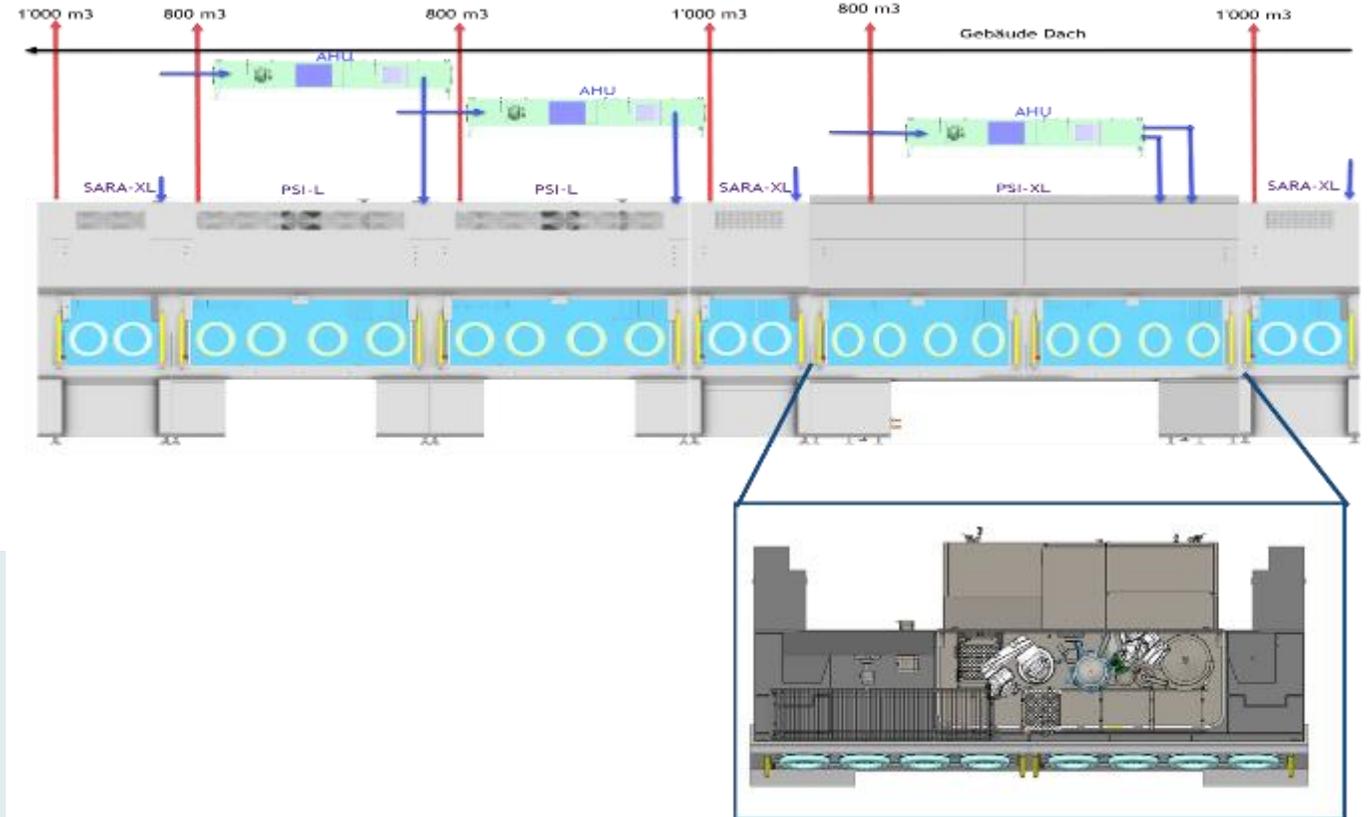


## Process

- Aseptic operation in grade A isolator
- Room grade C
- ebeam for introduction of RTU containers
- Inline sterile-filtration with PUPSIT
- RTP alpha/beta port systems
  
- Equipment
- Single use: direct product contact filling-kits,  
Connectors multi use: no direct product contact  
Format part, stopper bowl



# Manufacturing system for novel ATMP manufacturing



## Flexible and state of the art design

- to adapt to customer process needs
- to overcome current compliance weaknesses
- to ensure robust supply to patients



A close-up photograph of a laboratory setting, featuring several pipettes positioned over a multi-well microplate. The scene is bathed in a cool blue light, with some wells containing a pinkish-purple liquid. The background is softly blurred, showing more lab equipment.

skan

# Questions & answers

May 2025

A close-up photograph of a microfluidic lab setup. Several glass pipettes are positioned over a multi-well plate, dispensing liquid into the wells. The scene is illuminated with a strong blue light, creating a high-tech, scientific atmosphere. The liquid in the wells appears to have a pinkish-purple hue.

skan

Wrap up

May 2025



Culture

**CUSTOMER**

Safety and Trust

Business Drive

Quality

PROCESS

Innovation

Pre-approved services

Digitalization

CORE

Technology

GMP

**TOGETHER ALWAYS ONE STEP AHEAD.**

# Facility tour during lunch

- Four different groups depending the color on your name tag
- Start during lunch time
- Tour takes about 20 minutes

Enjoy your lunch!

Together always  
one step ahead!

Together always one step ahead

skan