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SKAN Group AG Capital Markets Day

May 2025

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Welcome to SKAN Capital Markets Day

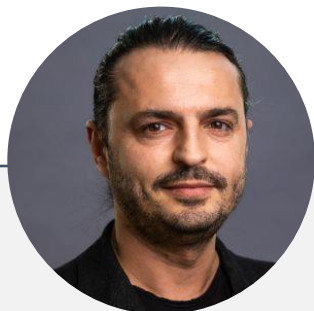
Our speakers



**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, ...)

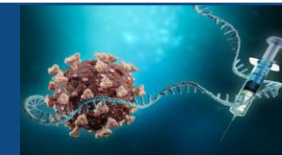
Progress in Biotechnology



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



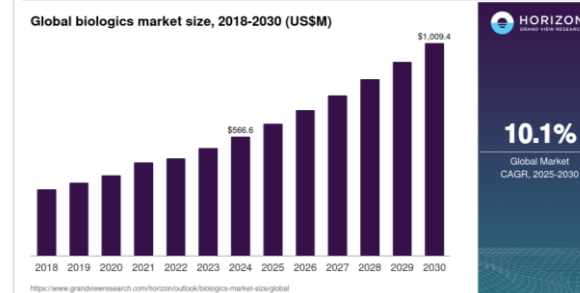
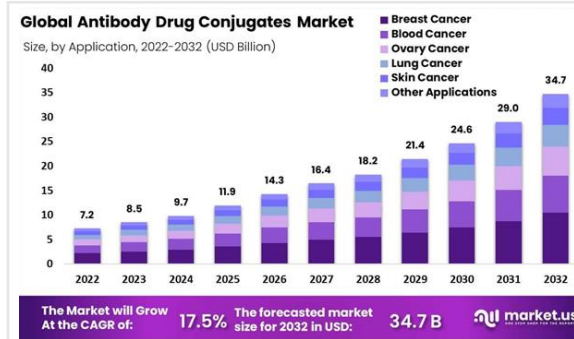
Demand for isolators will grow with the industry and continue to replace older technologies

Resulting growth drives for SKAN



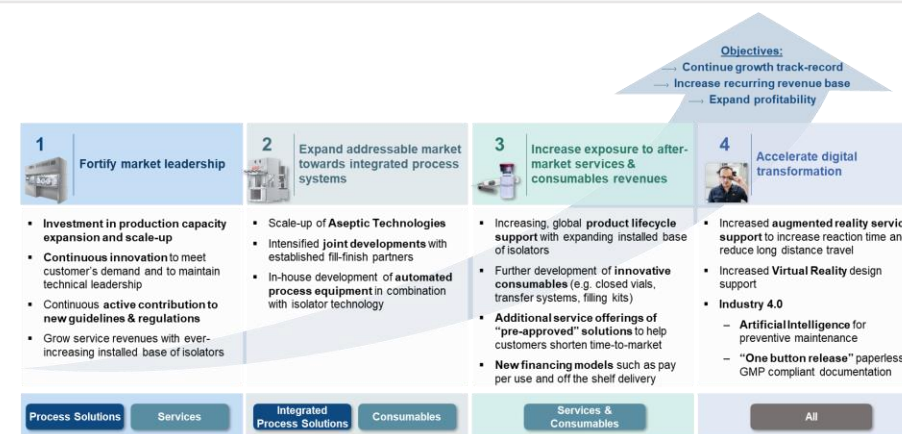
Double digit growth of underlying biologics market.

- 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.

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Growth path, margin expansion and targets

Burim Maraj, Group CFO

May 2025

SKAN's growth path

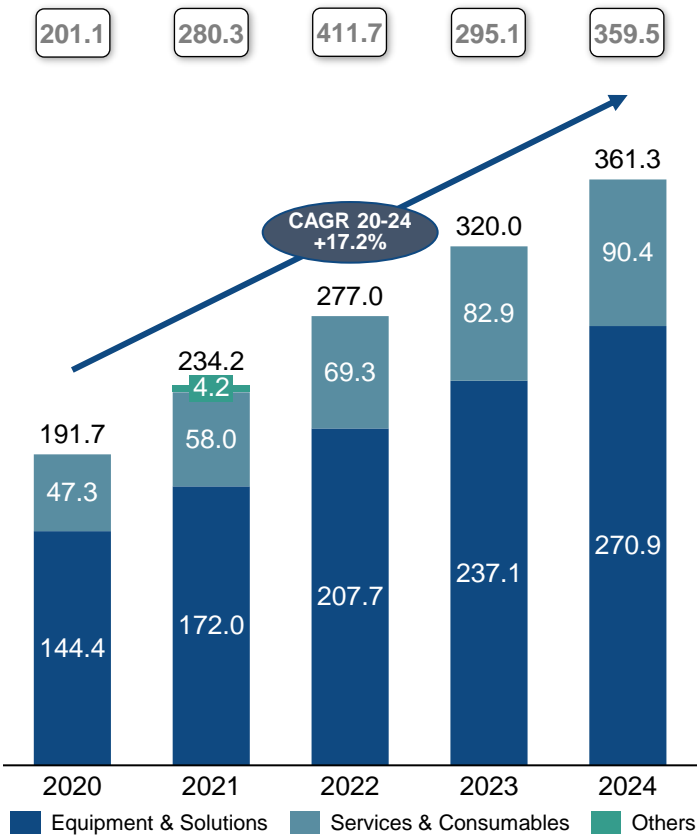
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- 1 **Excellent track-record with consistent above-market growth**
- 2 **Persistent structural growth factors fuel the continued strong performance, reflected in double-digit growth rates**
- 3 **Net sales growth** underpinned by a **strong core business** 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**



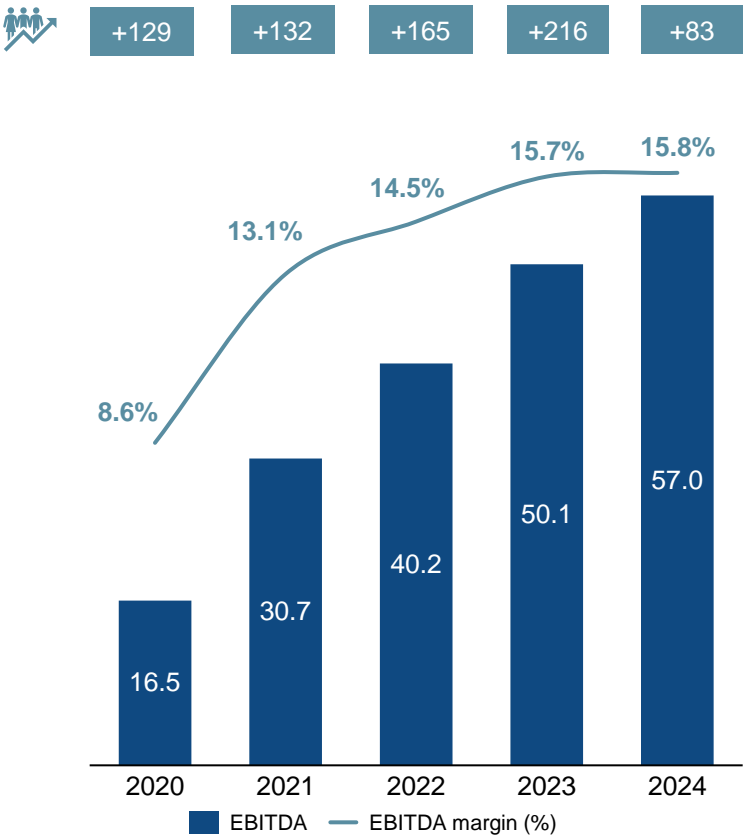
Excellent track-record with consistent above-market growth and increasing profitability

Net sales & order intake
(CHFm)



□ Order intake

EBITDA
EBITDA (CHFm) and EBITDA margin (%)



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 ⁽¹⁾ 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

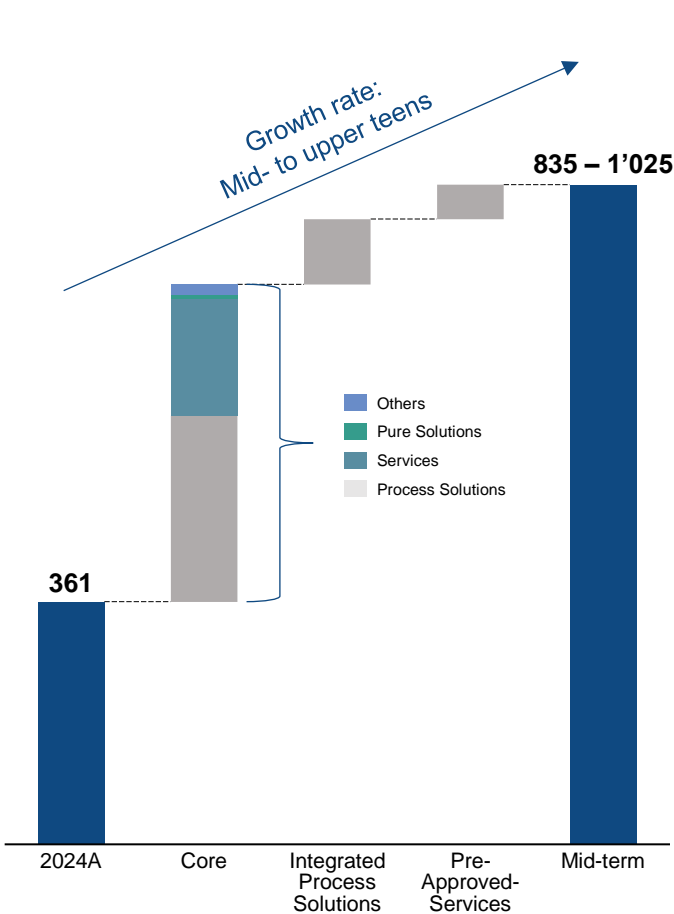


Expand market leadership & remain....

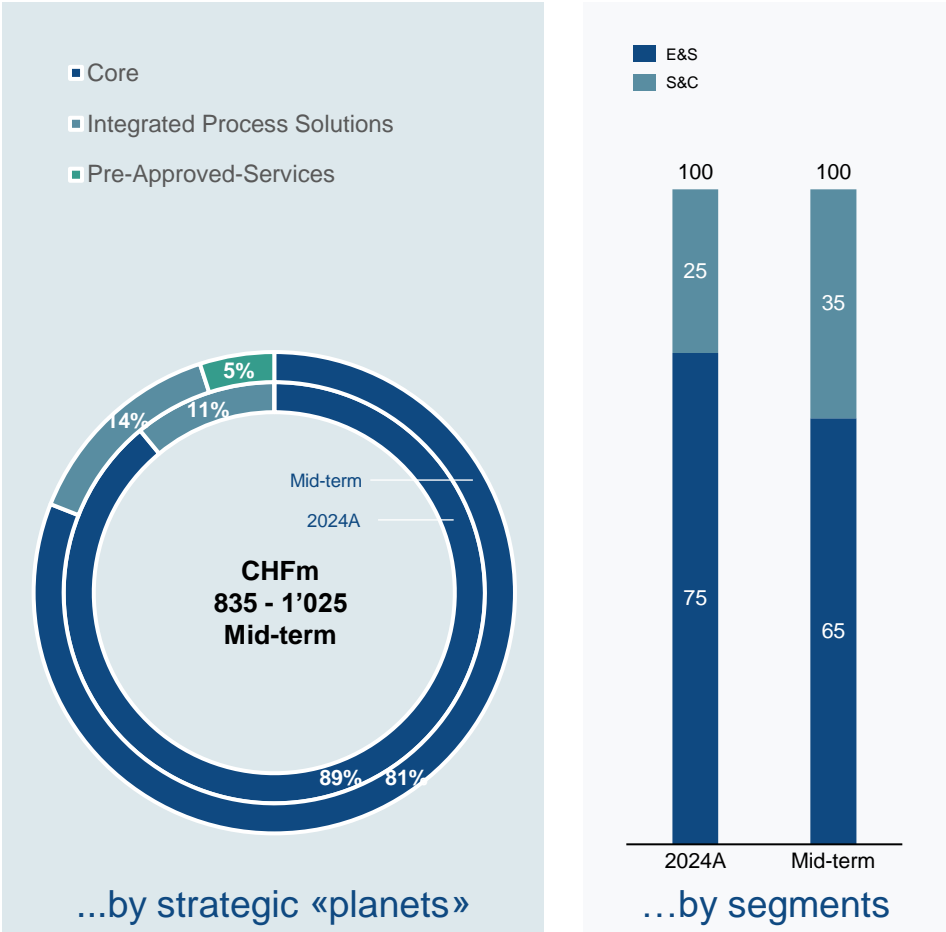
Net sales growth underpinned by a strong core business and further accelerated by strategic initiatives

SKAN

Growth contributors ⁽¹⁾
(CHFm)



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



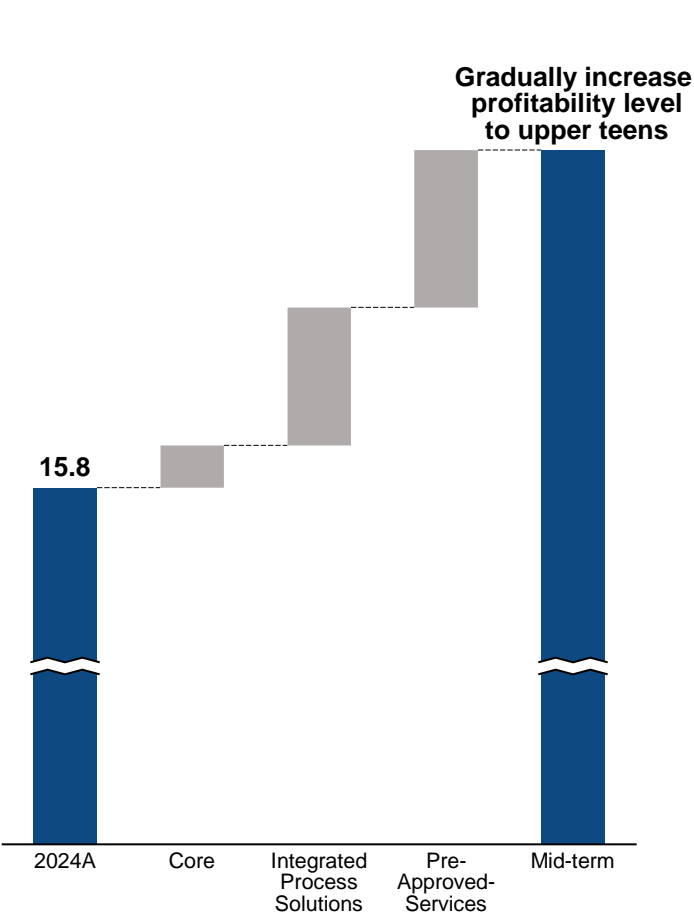
Comments

- 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.

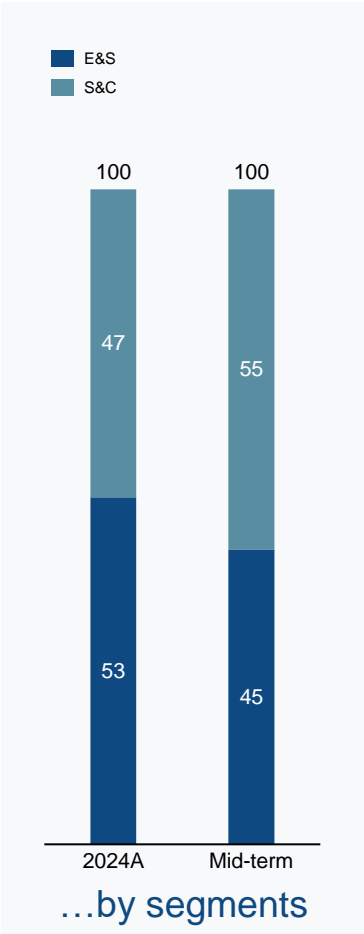
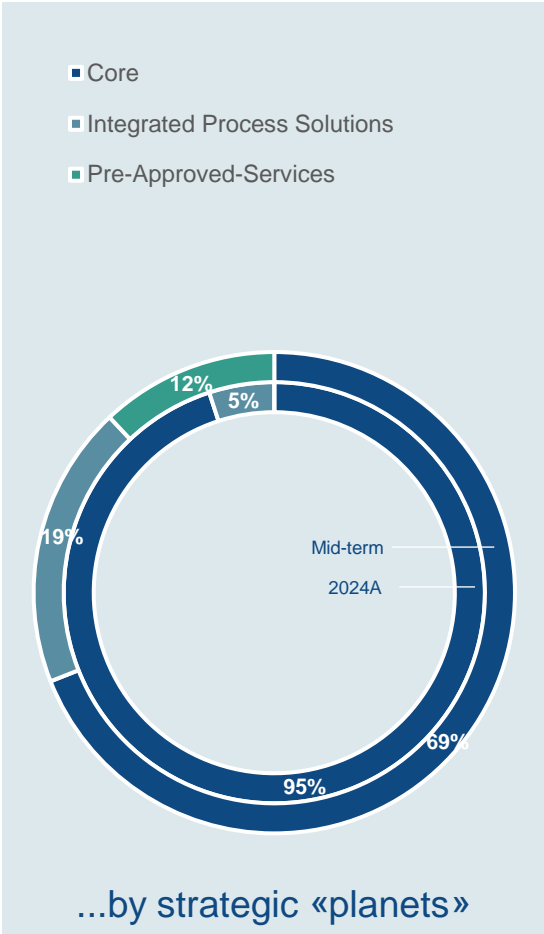
Margin expansion by integrated process solutions and new high margin services and consumables

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EBITDA margin contribution ⁽¹⁾
(in % of net sales)



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

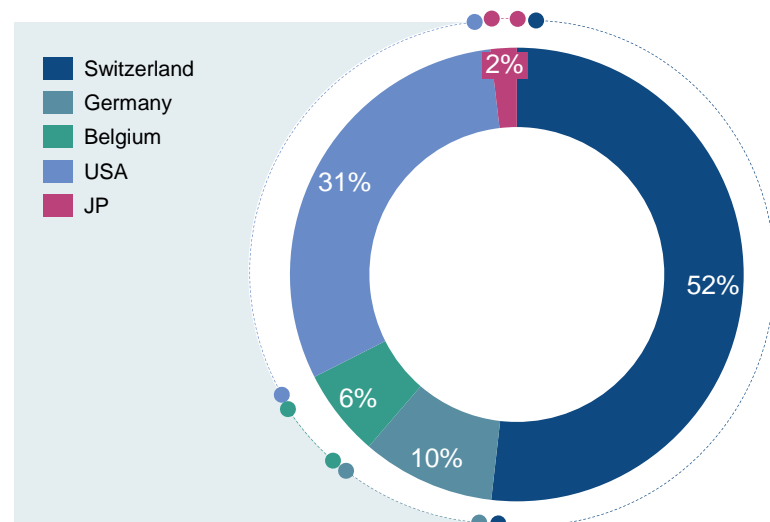


Comments

- 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

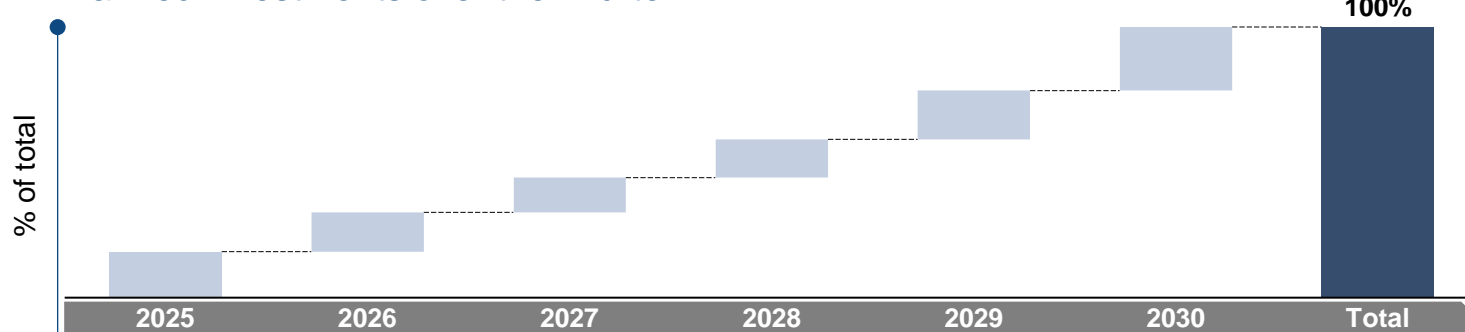
Opportunistic M&A strategy mainly based on the following pillars:

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

7 – 8%⁽¹⁾
of net sales

Investment in Innovation
to fortify market and
technology leadership

Planned investments over the mid-term⁽²⁾



- 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



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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
 Technological edge	 Mastery of difficult to replicate know-how on highest-performance isolators	Product quality / reliability	
 Stringent regulatory environment	 Process warranty regarding all regulatory (e.g. FDA, EMA, Swissmedic) required qualifications & timeline	Brand reputation	
 Mission criticality of aseptic processes	 Swiss brand, engineering & reputation provide trust in isolator safety	Validation process support	
 Lock-in effect	 Large installed base of isolators and leading global services incl. tech transfer & consumables across product lifecycle	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

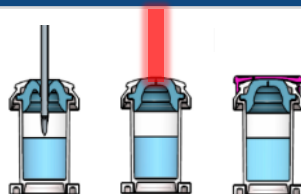
Fabrication know-how



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 & H₂O₂ 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

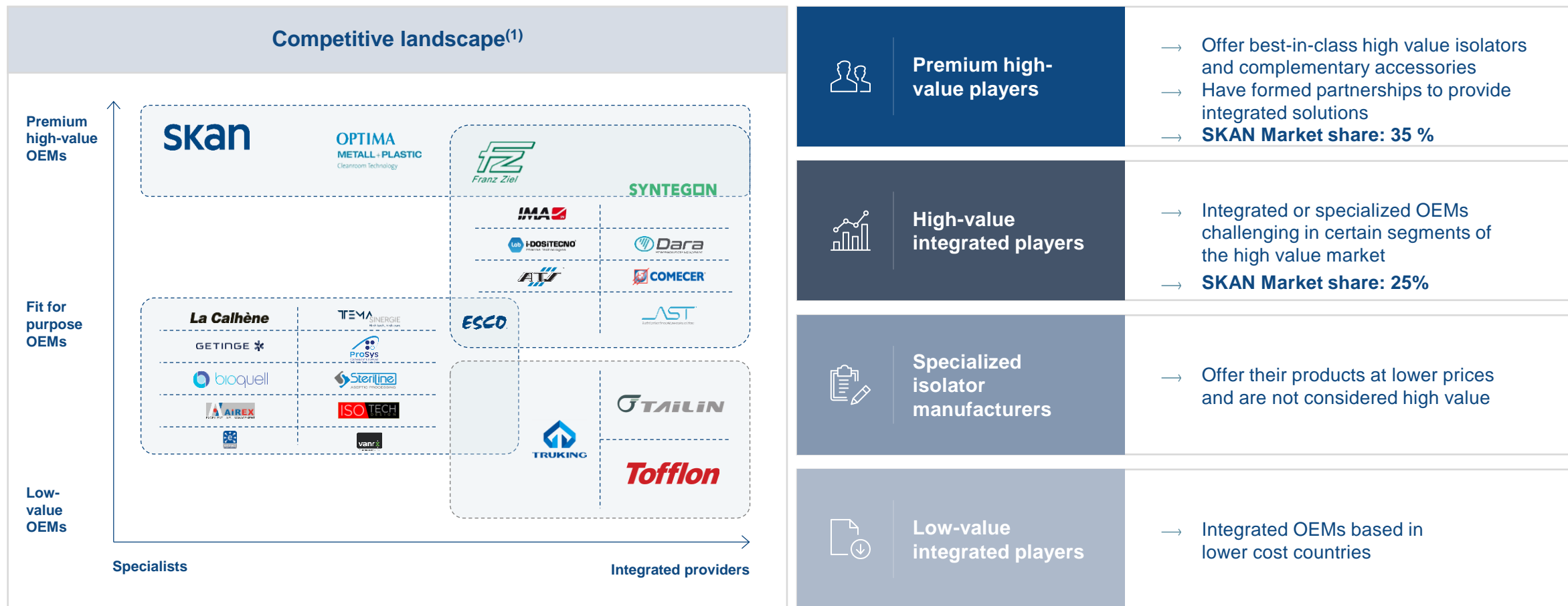
- **More than a product,
an approved solution !!**

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



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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**



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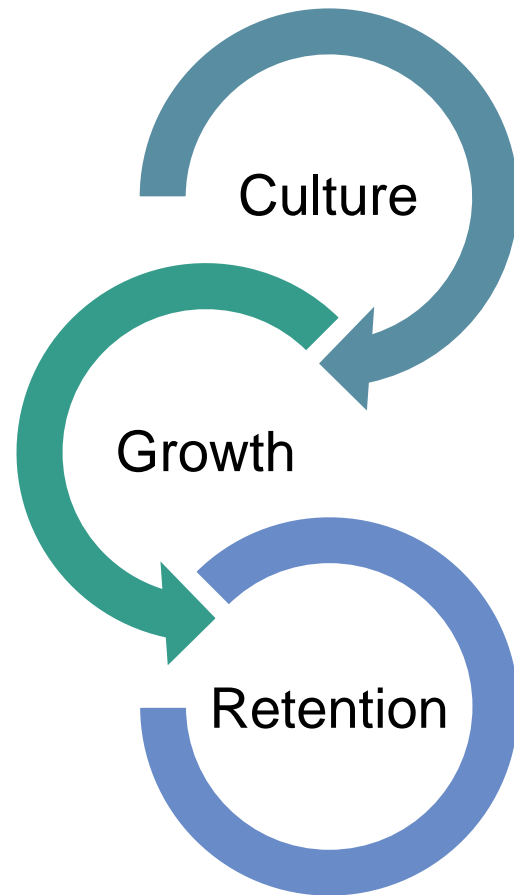
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SKAN Culture and Managing Growth

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:

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.

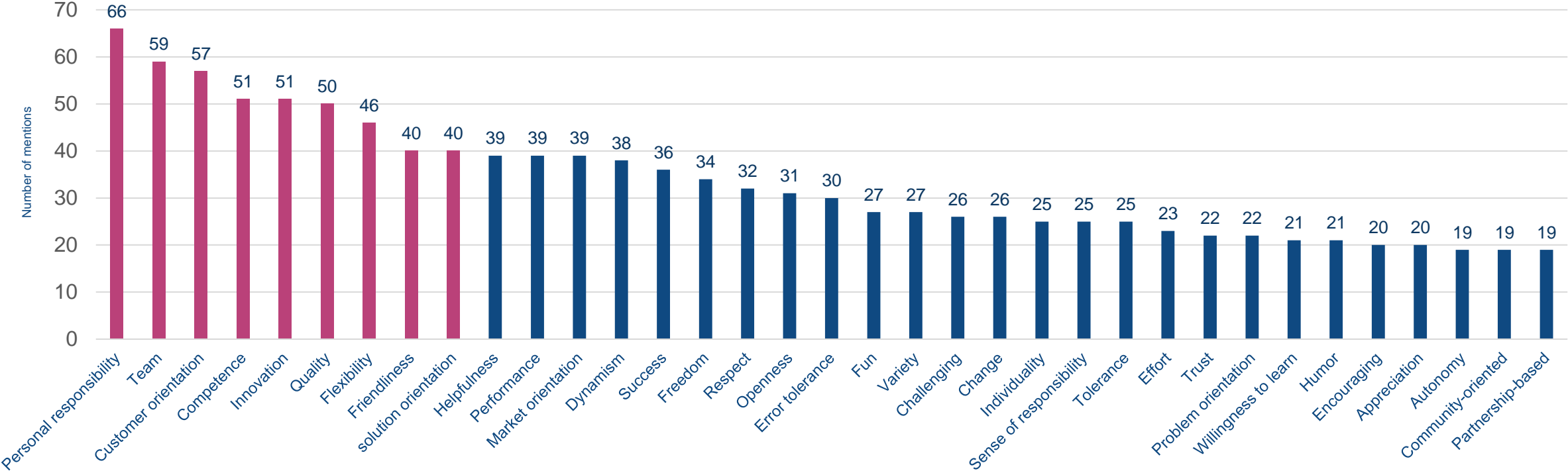


Our values and culture



SKAN culture survey - What our employees say

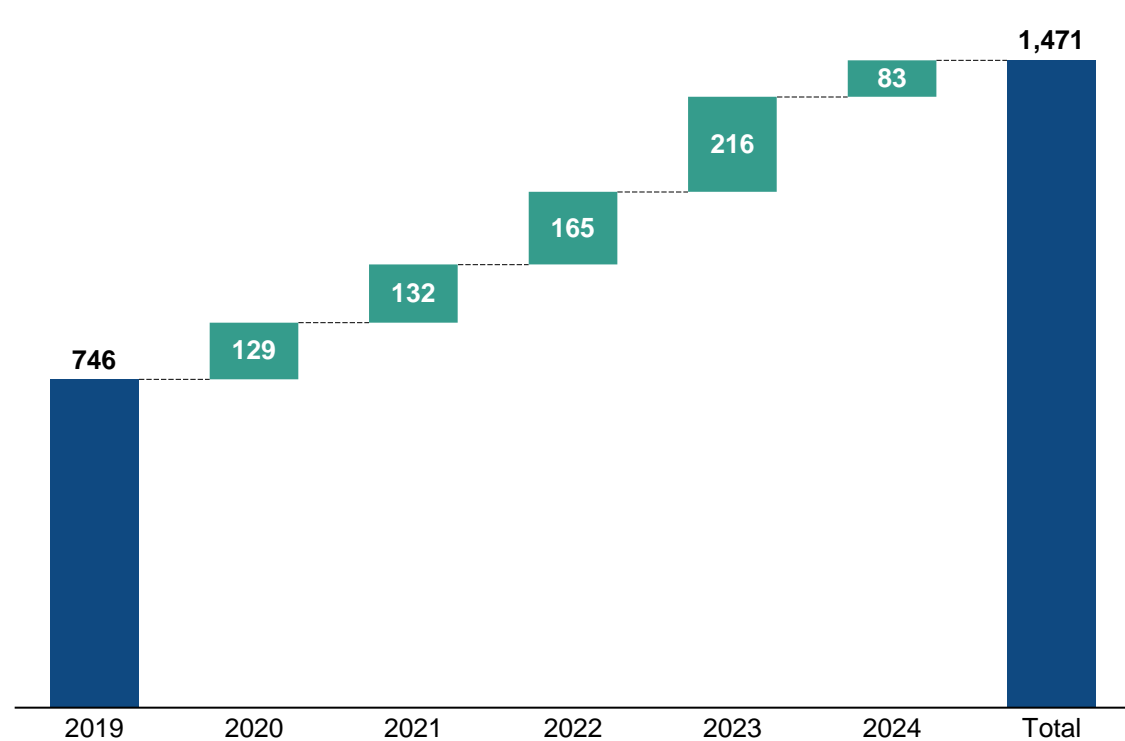
Survey results on SKAN`s corporate culture



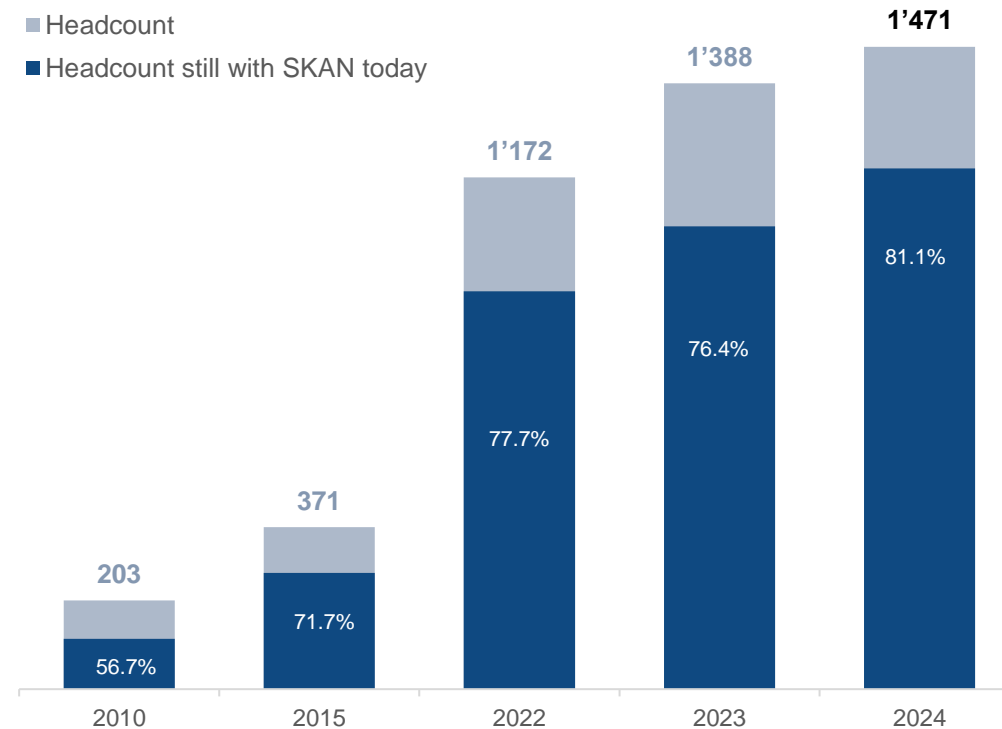
Empowering growth through dedicated people



Ø 145 new colleagues/year



Loyal, increasing workforce ⁽¹⁾



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 aquisition – our differentiators

 Unique SKAN culture

 Modern working environment

 Reconnecting with alumni

 Training of apprentices and trainees

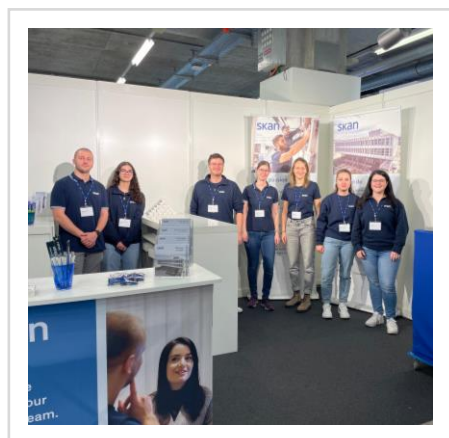
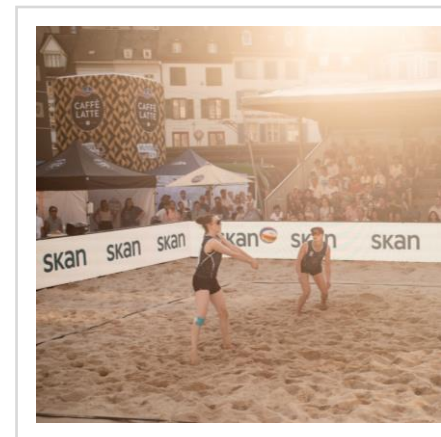
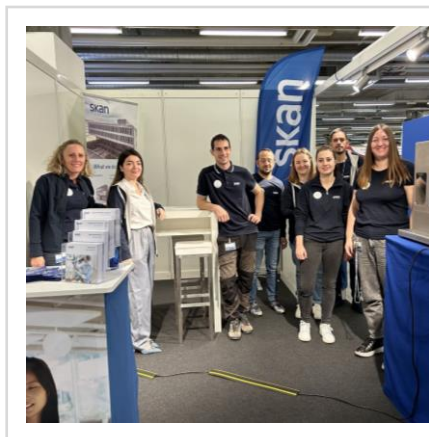
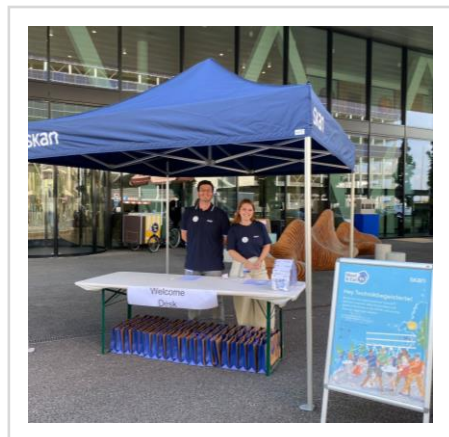
 Fishing for friends

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 aquisition 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.



SKAN



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



The background of the slide is a close-up, artistic photograph of a laboratory setting. It features several glass pipettes in the upper right, angled downwards towards a multi-well microplate. The microplate is filled with a liquid that exhibits a vibrant purple and pink fluorescence. The entire scene is bathed in a cool blue light, creating a high-tech, scientific atmosphere. The text is overlaid on this background.

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Questions & answers

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The background of the slide is a close-up, artistic photograph of a laboratory setting. It features several glass pipettes in the upper right, angled downwards towards a multi-well microplate. The microplate is filled with a vibrant pink liquid, which is out of focus, creating a bokeh effect. The entire scene is bathed in a cool blue light, giving it a high-tech, scientific feel.

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Coffee break

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Isolator technology and standardization

Ralf Krämer, Chief Technology Officer

May 2025

Key challenge for (bio-)pharmaceutical products

Key challenge	Products	In particular true for
<p>Medical safety</p> <p>Medication safety is key and (cross-) contamination unacceptable</p> <p>Key contamination sources:</p> <ul style="list-style-type: none"> → Air particles → Input: Raw materials, containers, closures → Personnel 	<p>Injectables</p> <ul style="list-style-type: none"> → Cancer drugs (Antibody Drug Conjugates (ADC), Cytotoxics) → Cell & gene therapy (Advanced Therapy Medicinal Products (ATMPs)) → Hormones: Insulin → Medical drugs (Thrombosis, EPO, blood plasma products, botox, etc.) → Vaccines: Flu, COVID-19, etc. <div data-bbox="1403 566 1768 886"> <p>Increased infection risk as their application bypasses many of the human body's natural defenses</p> </div> 	<p>High-value biopharma drugs</p> <ul style="list-style-type: none"> → Risk of significant economic losses if high-value biopharma drugs get contaminated → Risk of cross-contamination increases with small batch size of fast-growing personalized medicine

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

skan



SAL 10^{-3}
Probability of 1 in 1,000 of finding a non sterile unit

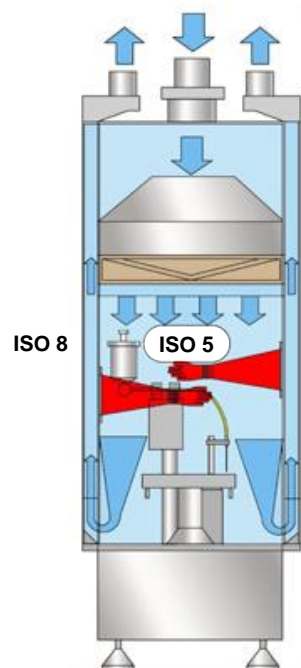


SAL 10^{-6}
Probability of 1 in 1,000,000 of finding a non sterile unit

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



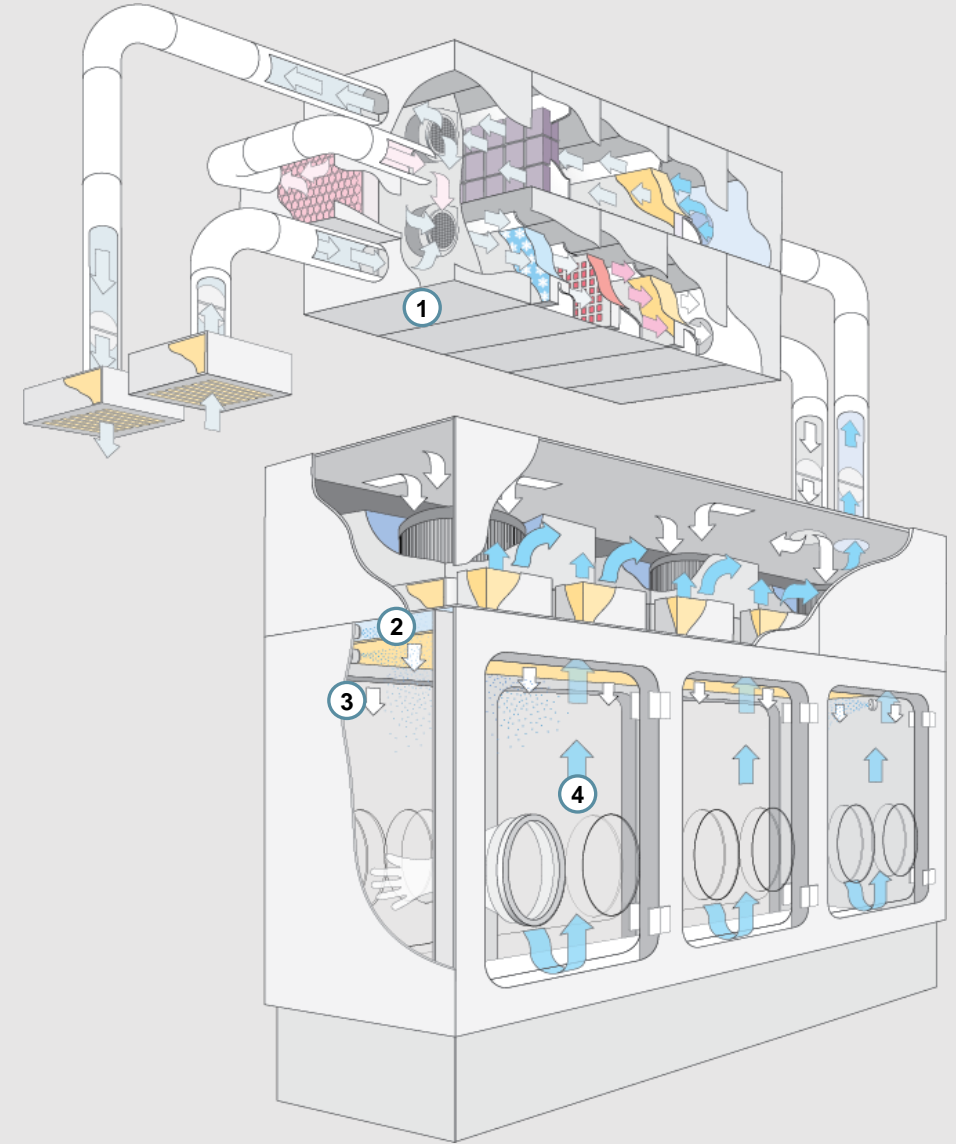
Isolators facilitate **meeting sterility standards for injectables** and other **complex molecule therapies** (such as **biologics** and **vaccines** which are too vulnerable for traditional heat sterilisation) to **ensure patient safety**



Superior bio-decontamination compared to traditional cleanrooms & RABS⁽¹⁾ **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

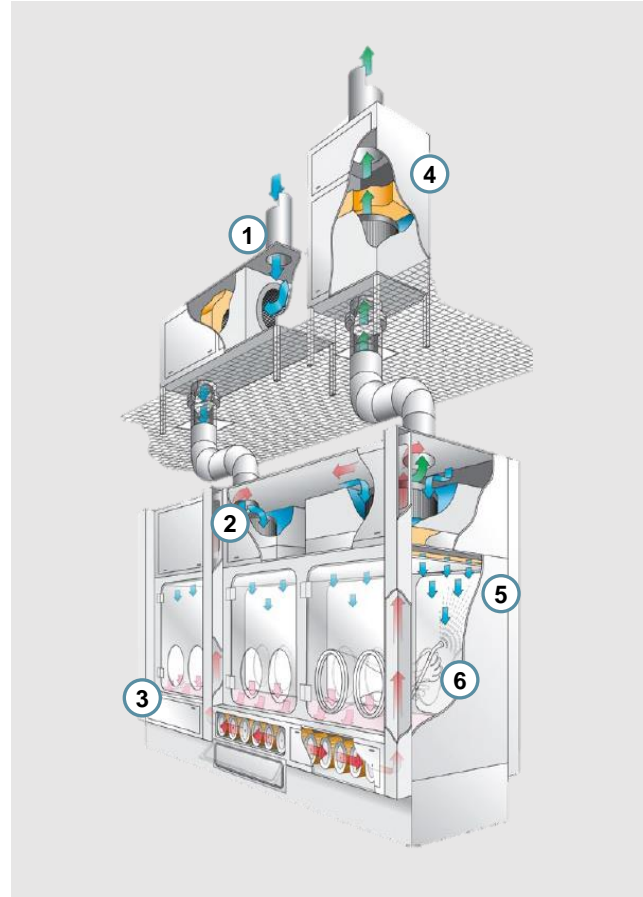
HEPA filtered inlet air from the room is treated (temperature, relative humidity, nitrogen atmosphere)

2

Simple and safe filter change system for personnel protection

3

Recirculation air flow with double window design



HEPA filtered exhaust system

4

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

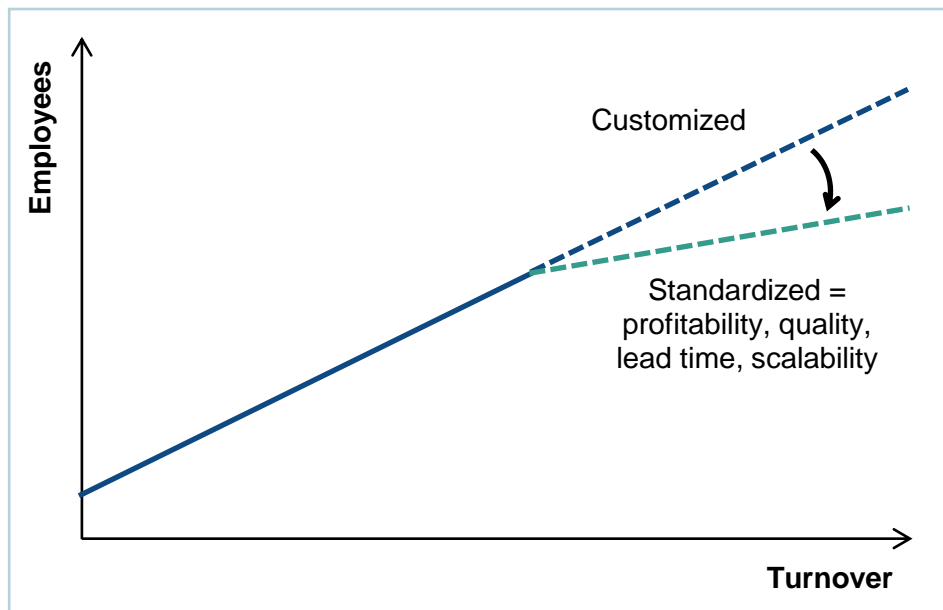
Vertical, unidirectional controlled air flow

5

Isolator chamber washable with spray balls and spray wands

6

Standardization to enable growth with less effort

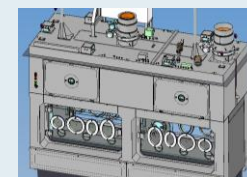


	Number of activities
In pipeline	25
Ongoing	36
Completed	37

Examples

CAD template for toxic filling line

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



Reduce 630 wire types to 99

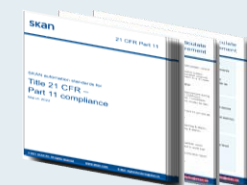
- Better purchase price
- Less master data maintenance
- Less supplier audits
- Less warehouse and logistics cost



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



Profile-DE

Automation - Config

✓

Material:

Werk:

Konfigurierbares Mat

Merkmalsbewertung

Merkmalsbezeichnung	Merkmalswert	In...
<input type="checkbox"/> 1301999	JA	<input type="button" value="N"/> <input type="button" value="I"/>
<input type="checkbox"/> 1302972	1.000	<input type="button" value="N"/> <input type="button" value="I"/>
<input type="checkbox"/> 1306129	1.000	<input type="button" value="N"/> <input type="button" value="I"/>
<input type="checkbox"/> 1313957		<input type="button" value="N"/> <input type="button" value="I"/>
<input type="checkbox"/> 1315990	JA	<input type="button" value="N"/> <input type="button" value="I"/>
<input type="checkbox"/> 1320194		<input type="button" value="N"/> <input type="button" value="I"/>
<input type="checkbox"/> 1320196	JA	<input type="button" value="N"/> <input type="button" value="I"/>
<input type="checkbox"/> 1320197		<input type="button" value="N"/> <input type="button" value="I"/>
<input type="checkbox"/> 1324156	JA	<input type="button" value="N"/> <input type="button" value="I"/>
<input type="checkbox"/> 1324202	JA	<input type="button" value="N"/> <input type="button" value="I"/>
<input type="checkbox"/> 1324405	JA	<input type="button" value="N"/> <input type="button" value="I"/>
<input type="checkbox"/> 1324471		<input type="button" value="N"/> <input type="button" value="I"/>

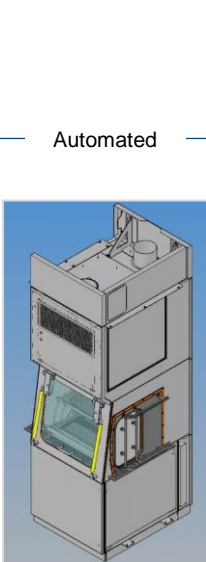
	Baseline Chamber option	Baseline Chamber options	
✱ 1350171			
▷ 1359268	OPT Luftkeimzähler Vorbereitung BG	OPT active air sampler preparation CA	AS3
▷ 1358542	OPT Steriltest Miljøre Vorbereitung BG	OPT Steriltest Miljøre preparation CA	ST2
▷ 1346573	OPT H202 LC Sensor BG	OPT H202 LC Sensor CA	2G-LC
▷ 1334956	OPT Verkleidung Mitte BG	OPT Covering Middle CA	CMC1
▷ 1334869	OPT Verkleidung rechts BG	OPT Covering right CA	CRC1
▷ 1338643	OPT Verkleidung rechts BG	OPT Covering right CA	CRC2
▷ 1333800	OPT H202 HC Sensor BG	OPT H202 HC Sensor CA	HCS1
▷ 1297490	OPT Bodenblech 2 Türen BG	OPT Bottom plate 2 door CA	BP1
▷ 1299738	OPT Bodenblech ohne Tür BG	OPT Bottom plate without door CA	BP0
▷ 1265044	OPT Luftgeschwindigkeitssensor BG	OPT Air velocity sensor CA	AV1
▷ 1292555	OPT Bodenblech Tür links BG	OPT Bottom plate door left CA	BP1L
▷ 1292130	OPT Seitenwand Blind BG	OPT Side wall blank CA	SW1
▷ 1274834	OPT Regale hängend BG	OPT hanging shelves CA	SH1

[illegible]

Spectra config tools

Sales - Calc

SPECTRA		Yes
Combination (SPECTRA / SARA) with standard equipment		
SPECTRA, SKANFOG, Catalyst, leak test, differential pressure sensor, temperature sensor, relative humidity sensor, filter differential pressure gauge, SKAN glow port round, suspension bar with hooks (4 long + 4 small), alarm lamp & horn, double door 6 parts, Siemens or Allen Bradley PLC and HMI, integrated IP54 electrical cabinet, standard documentation, FAT, 12 or 24 months warranty		
Option: Upgrade to toxic design to handle potent substances for SPECTRA and SARA (select one of two options)		
- 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		
SPECTRA SARA left (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
SPECTRA SARA right (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 is automatically included)		Yes
Remote FAT (select days as usual)		Yes
Additional FAT days (1 day is always included)		Yes
Communication Package		Yes
Basic communication package (always included)		Yes
Option: Additional extensive communication package		Yes
Documentation		Yes
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)		Yes
Documentation (as built) required for US customers		No
Control System		Yes
Siemens		Yes
Local PC Solution: Siemens Simatic S7-1500		Yes
Beckhoff Panel = PC + Zenon, Alarm Log, Local & domain login (active directory), Events Log (Audit Trail), Monitoring (Trends recording)		Yes



Automated



Electro

Docu

Automation - Config

	Baseline Chamber option	Baseline Chamber options	
1360171	OPT Luftkeimsammler Vorbereitung BG	OPT active air sampler preparation CA	AS3
1360542	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
1334869	OPT Verkleidung rechts BG	OPT Covering right CA	CRC1
1333643	OPT Verkleidung rechts BG	OPT Covering right CA	CRC2
1333600	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
1296044	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
1274934	OPT Regale hängend BG	OPT hanging shelves CA	SH1

PL/MED – SAP-DE

Material: 1360525 SPECTRA CHAMBER
Werk: 2000 SKAN DE
Konfigurierbares Mat: SPEC_4G_ISO_V03

Merkmalsbewertung

Merkmalsbezeichnung	Merkmalswert	In...
1301999	JA	(1)
1302972	1,000	(1)
1306129	1,000	(1)
1313957		(1)
1319990	JA	(1)
1320194		(1)
1320196	JA	(1)
1320197		(1)
1324156	JA	(1)
1324202	JA	(1)
1324405	JA	(1)
1324471		(1)

Profile-DE

	Baseline Chamber option	Baseline Chamber options	
1360171	OPT Luftkeimsammler Vorbereitung BG	OPT active air sampler preparation CA	AS3
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1296044	OPT Luftgeschwindigkeitssensor BG	OPT Air velocity sensor CA	AV1
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1292130	OPT Seitenwand Blind BG	OPT Side wall blank CA	Sw1
1274934	OPT Regale hängend BG	OPT hanging shelves CA	SH1

Material: 1360525		Werk: 2000	
Bezeichnung: SPECTRA CHAMBER		Beschreibung: SPECTRA CHAMBER	
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The background of the slide is a close-up, blue-tinted photograph of a laboratory setting. Several glass pipettes are shown in the foreground, angled towards a multi-well microplate. The microplate contains a pinkish-purple liquid in some of its wells. The lighting is dramatic, with strong highlights and deep shadows, creating a sense of precision and scientific activity.

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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



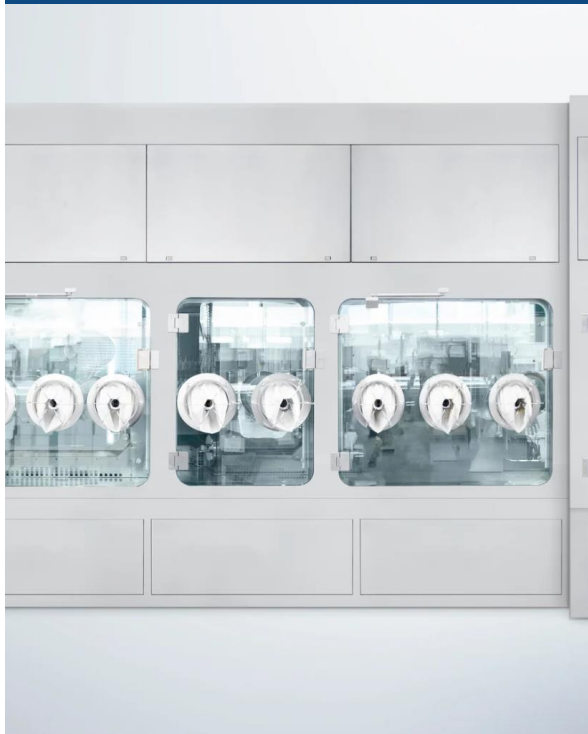
2.1 The manufacture of sterile products is subject to special requirements in order to minimize risks of microbial, particulate and endotoxin/pyrogen contamination. The following key areas should be considered:

- 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

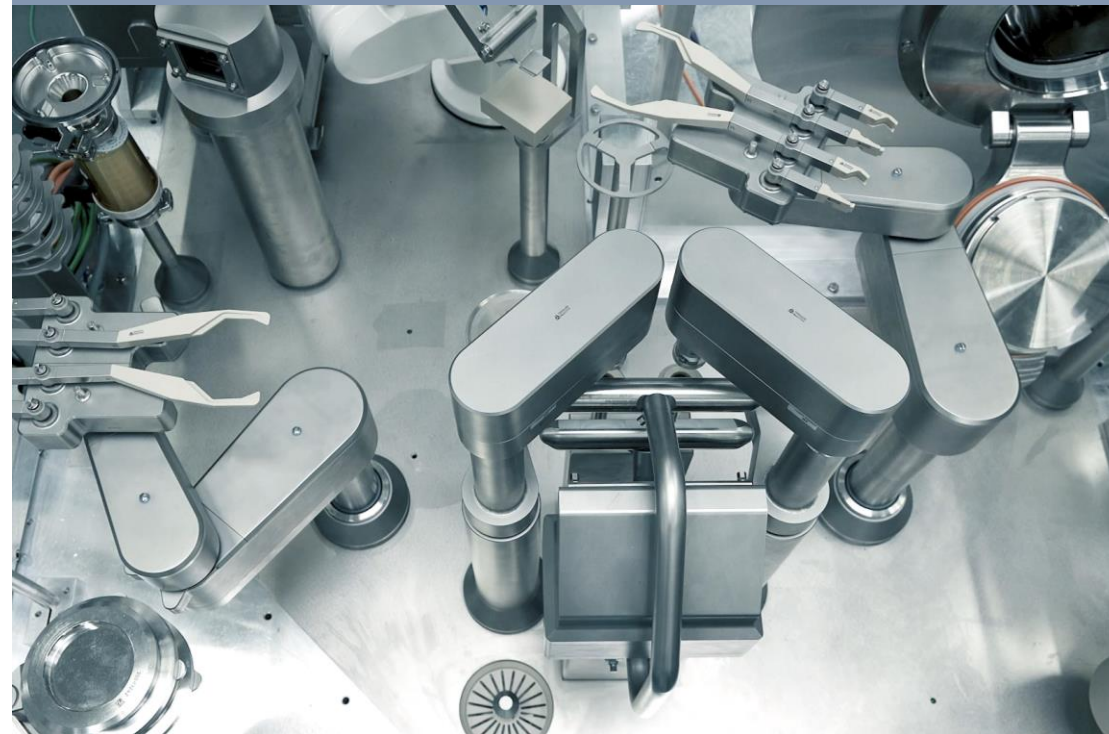
Barrier and isolator systems



Transfer as ebeam



Automation as robotics



Shaping GMP standards – Trusted by inspectors worldwide



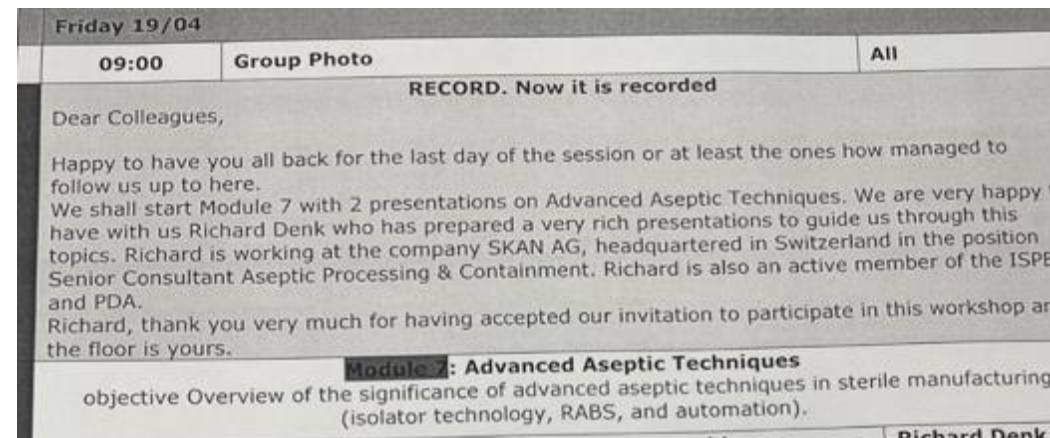
Sole industry presence at the 2024 EU/GMP Annex 1 training – reinforcing SKAN's leading market position



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.



The background of the slide is a close-up, blue-tinted photograph of a laboratory setting. Several glass pipettes are visible, angled downwards, with some dispensing a pinkish-purple liquid into a multi-well plate. The lighting is dramatic, with strong highlights and deep shadows, creating a sense of precision and scientific activity.

skan

SKAN Group AG Capital Markets Day

Pre-approved services

Thomas Zinn, Chief Officer Aseptic Manufacturing Services

May 2025

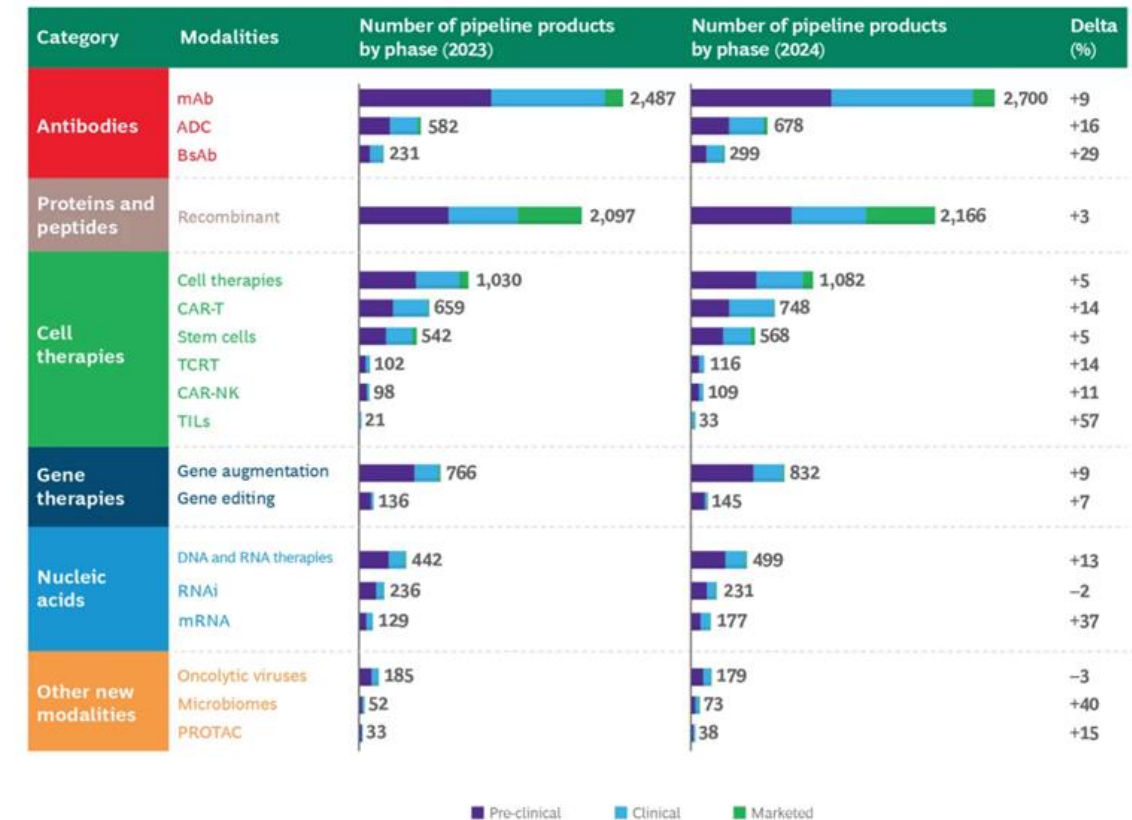
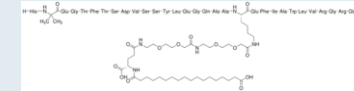
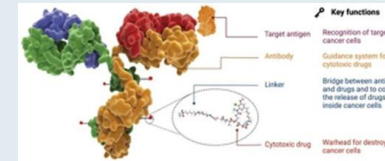
Shift toward injectable biotech drugs continues and drives need for aseptic process solutions



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**.

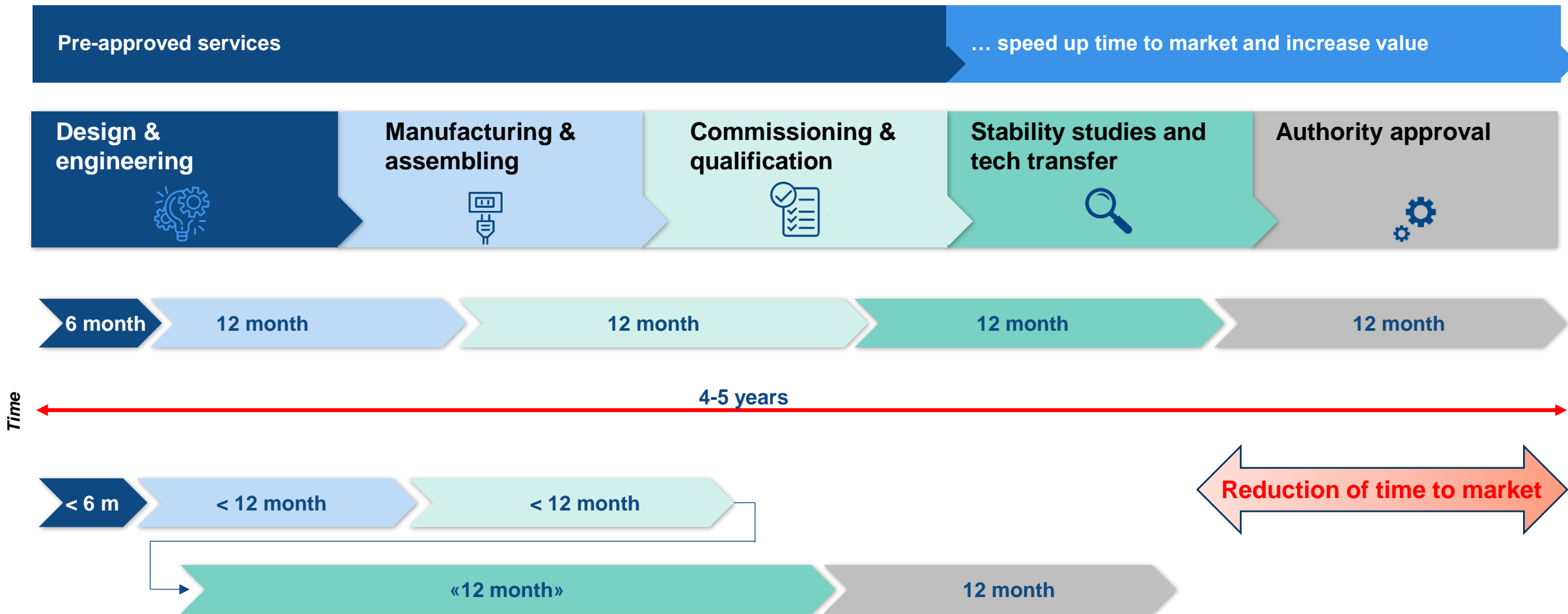
Key data

- **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

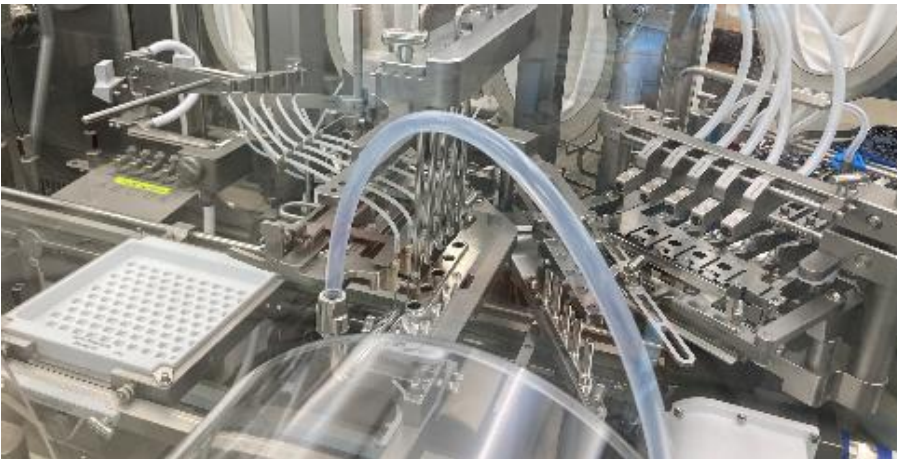


Accelerated go-to-market for our customers through pre-approved services – enabling faster access for patients

SKAN



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

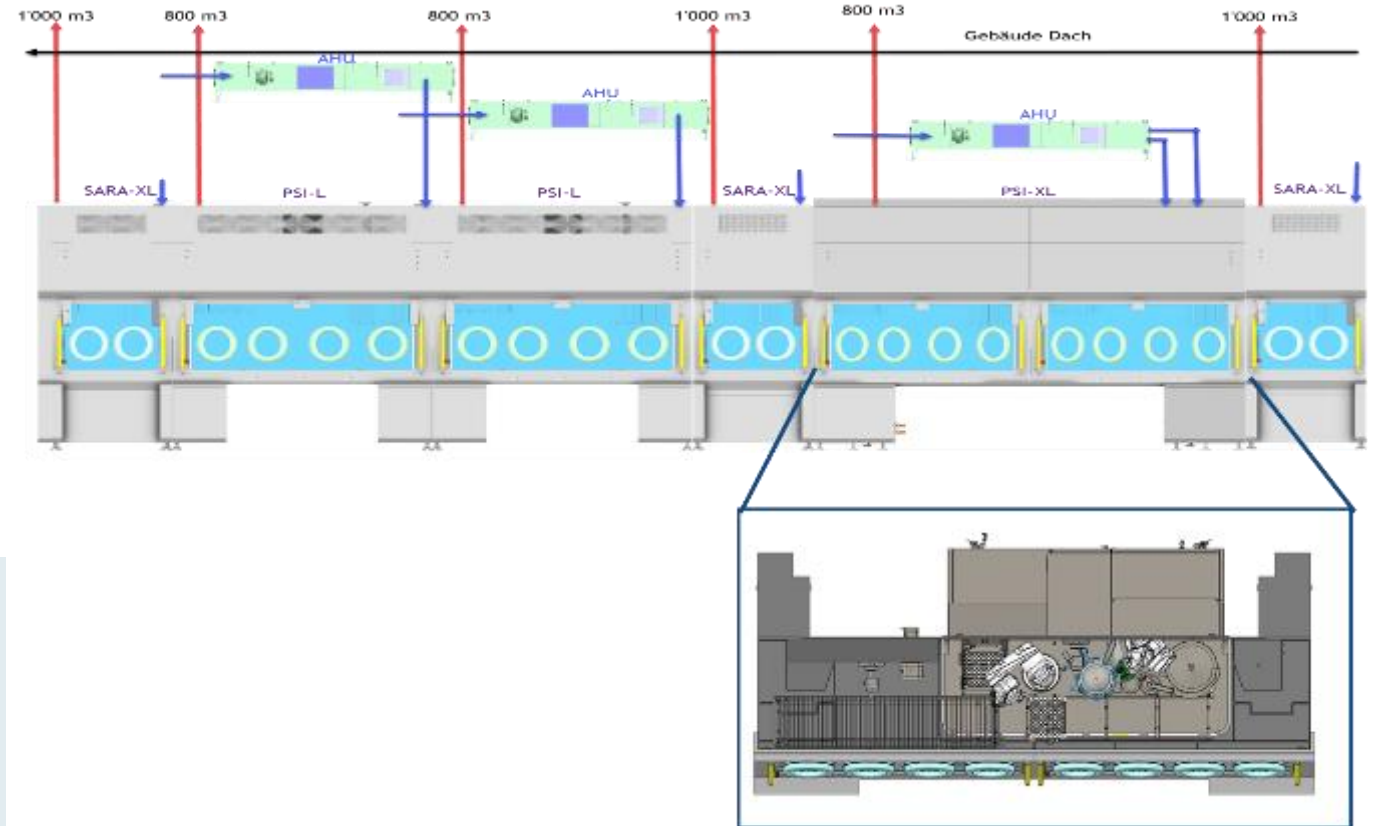


Manufacturing system for novel ATMP manufacturing



Flexible and state of the art design

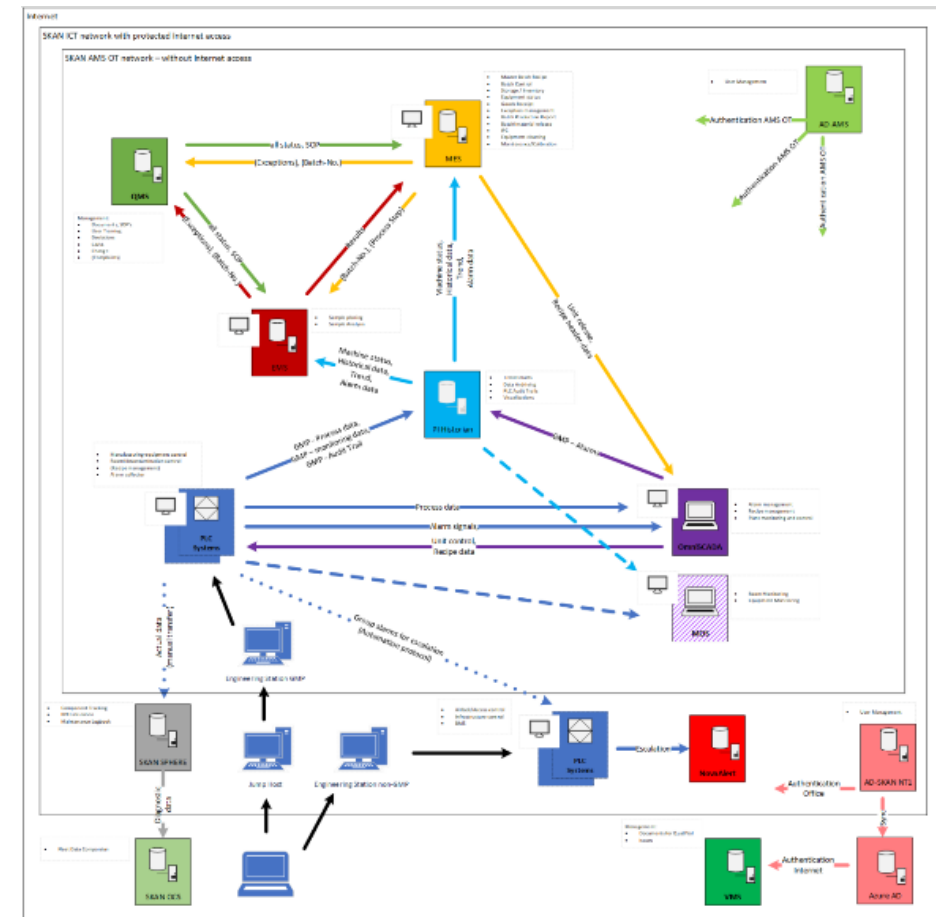
- to adapt to customer process needs
- to overcome current compliance weaknesses
- to ensure robust supply to patients



Fully integrated digital landscape enables full leverage of manufacturing data

Digital Operational Technology (OT) Landscape

- All GMP relevant data in digital form (paperless manufacturing)
- Limits for process parameters checked by system (review by exception)
- Information in «OT landscape» used for proactive functions («One Button Release»)



The background of the slide is a close-up, artistic photograph of a laboratory setting. It features several glass pipettes in the upper right, angled downwards towards a multi-well microplate. The microplate is filled with small, clear wells, some of which contain a vibrant pink liquid. The entire scene is bathed in a cool blue light, creating a high-tech, scientific atmosphere. The lighting is soft and diffused, highlighting the glass surfaces and the liquid within the wells.

skan

Questions & answers

May 2025

The background of the slide is a close-up, artistic photograph of a laboratory setting. It features several glass pipettes in the upper right, angled downwards towards a multi-well microplate. The microplate is filled with a vibrant pink or magenta liquid, which is in sharp focus in the foreground. The rest of the image, including the pipettes and the background, is softly blurred, creating a sense of depth. The overall color palette is dominated by cool blues and purples, with the bright pink of the liquid providing a strong contrast.

skan

Wrap up

May 2025



CUSTOMER

Safety and Trust

PROCESS

CORE

Quality

Business Drive

Innovation

Pre-approved services

Technology

Digitalization

GMP

Culture

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

May 2025

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