Cleanroom services

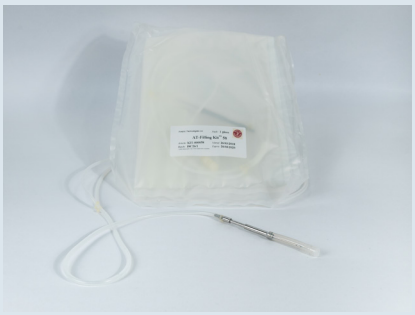
Member of SKAN Group

Custom single-use solutions for pharma and biotech companies

We leverage our joined innovative expertise in aseptic processes and production of single-use assemblies to offer you custom solutions that meet your needs.

Choose custom single-use assemblies and packaging :

- Optimized for complex pharmaceutical manufacturing
- Reduced product loss
- Smoother validation effort



Mastering the single use: more than 20 years of experience in custom cleanroom assemblies

Production of critical pharmaceutical ready-to-use assemblies, such as sterile single-use fluid path kits and aseptic connectors.

We take care of

- Design and prototyping of the assembly, including its packaging for bioprocess operation.
- Assembly and packaging of single-use components in qualified cleanrooms.
- Sterilization process validation (gamma-irradiation).
- Release testing, quality support and compliance documentation.

Maintaining
the cleanliness chain

ISO5 or ISO7 environment

Custom manufacturing by Aseptic Technologies minimizes the risk of particle contamination by ensuring ISO5 or ISO7 surrounding in operation while monitoring Grade C microbiological conditions.

Packaging

Custom assemblies are sterilized in double or triple packaging to ensure the cleanliness and sterility chain is maintained in addition to providing peace of mind for our customers.

- Optimizing the manufacturing processes
- Respecting most aggressive timelines
- Reducing validation efforts
- Validated to withstand H_2O_2 decontamination cycles (skanfog®)

Our services
to help you optimize your process

Development of customized single-use solutions

- Experienced manufacturing, quality, and logistic teams.
- Deep understanding of pharma and bioprocessing requirements.
- Modern ERP, robust quality system, productions released by internal QPs.
- Cleanroom capacity meeting highest pharmaceutical cleanliness standards.
- Grade A laminar air flow for critical operations.
- 700+ items managed in stock.
- 20+ approved suppliers.
- Product and packaging validation.
- Shipping and transport validation, as per ASTM/ISTA standards.
- Daily shipping, leading to over 2000 yearly shipments all over the world.
- Endotoxin validation according to USP 85.
- Particulates validation according to USP 788.

Production capacity
two dedicated production sites

Two production sites:

- ISO5 qualified cleanroom, T° controlled, RH monitored.
- ISO7 qualified cleanroom, T° and RH controlled and monitored.

SKAN Group sites
Cleanroom production sites in Belgium

Combined with:

Three storage sites (T° and RH monitored) for raw materials and finished products.
Two sites qualified for gamma irradiation.

Our quality certifications

ISO 9001:2015
Quality management systems.

ISO 15378:2017
Primary packaging materials for medicinal products.

Aseptic Technologies Rue Camille Hubert 7-9
5032 Gembloux, Belgium
+32 81 409 410, info@aseptictech.com

SKAN AG Kreuzstrasse 5
4123 Allschwil, Switzerland
+41 61 485 44 44, info@skan.ch

SKAN Stein AG Industriestrasse 3
4332 Stein, Switzerland
+41 62 885 03 00, info.stein@skan.ch

SKAN Deutschland GmbH Nickrischer Straße 2
02827 Görlitz/Hagenwerder, Germany
+49 358 223 789 0, de.info@de.skan.ch

SKAN US, Inc. 7409 ACC Blvd., Suite 200
Raleigh, NC 27617, USA
+1 919 354 6380, us.sales@us.skan.ch

SKAN Japan 5194-61 Katsuren-Haebaru Uruma-shi
Okinawa 沖縄県 904-2311, Japan 日本
+81 98 934 9922, jpskan@skan.ch

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