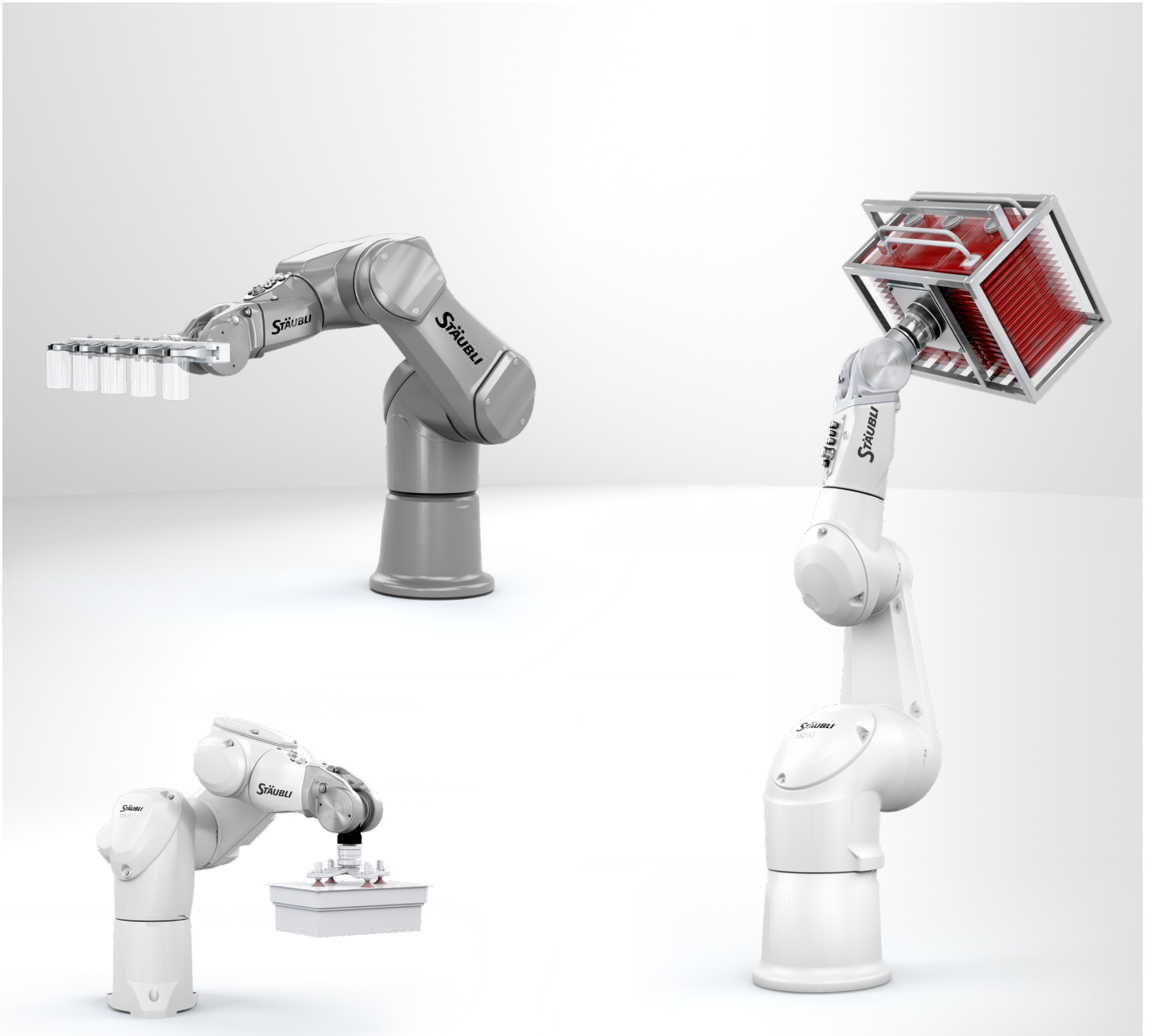


FAST MOVING TECHNOLOGY

STÄUBLI

Pharma offering - One range for each Pharma Grade

Robotics | Experts in Man and Machine



PHARMA OFFERING

Specific need, adapted solutions

In General industry, Robotics arm is usually defined according reach, payload and speed requirement for the cycle time of the production. In Pharmaceutical factory, there are additional features to take into consideration which are cleaning, decontamination process and agents, and for cleanroom class of the environment.

The basic questions to ask are : How clean the robot should be? How cleanable the robot should be? And how decontaminable the robot should be?

While robots installed within most critical Grade A / Isolator became mandatory, and reinforced by revised regulation for risk of contamination, and robots installed in end of line non classified were the easiest to integrate, there is now bigger opportunity for in between area.

Moreover, the emergence of biotherapy that turns into scale up phasis enlarges the specter of automation.

Obviously, Stäubli confirms its leadership and expertise on pharmaceutical industry with its new robotics pharma offering.



Sebastien Lagarde
Global Marketing Leader of Pharma & Medical devices

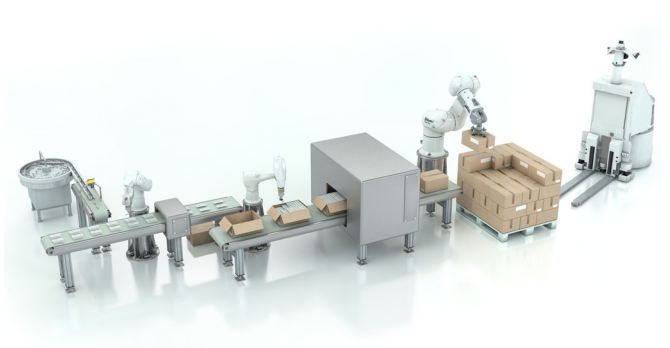
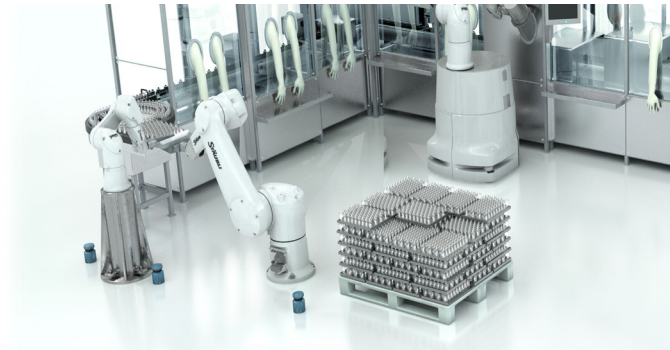
“Because there is not only Aseptic and non Aseptic rooms in pharma factory, Stäubli Robotics is offering a complete and flexible range of robot according hygienic requirements of the environment ”



PHARMA OFFERING

Pharma factory area

A pharma factory is divided into several areas that require different specifications in terms of cleaning processes and particle emissions. Stäubli defines four levels of requirements.



Level 1: Clean, highly cleanable, highly decontaminable
Isolator - Grade A (ISO5): Very critical areas dedicated to aseptic filling operations where the product is exposed to the open air (syringe filling, open vials, cap installation.)

- Highly monitored fill/finish process lines of high potency and toxic drugs
- Highest hygienic standards in design, material and components
- Regular VHP decontamination

Level 2: Clean, highly cleanable, decontaminable
RABS, freeze dryers and autoclaves - Grade A/B (ISO 5): Preparation area, filling and aseptic distribution. This class constitutes the immediate environment of a class A work zone.

- Auxiliary processes around isolators
- Hygienic design required
- Requires sometimes lower VHP concentration rates, liquid H₂O₂ cleaning tissue or decontamination by agent with different properties

Level 3: Clean and cleanable
Secondary packaging - Grade C (ISO 6/7): Controlled atmosphere areas for less critical stages of sterile drug manufacturing

- Inspection and individual packaging
- Easy to clean design
- Regular need of alcohol disinfection (Isopropanol (IPA) or Ethanol)

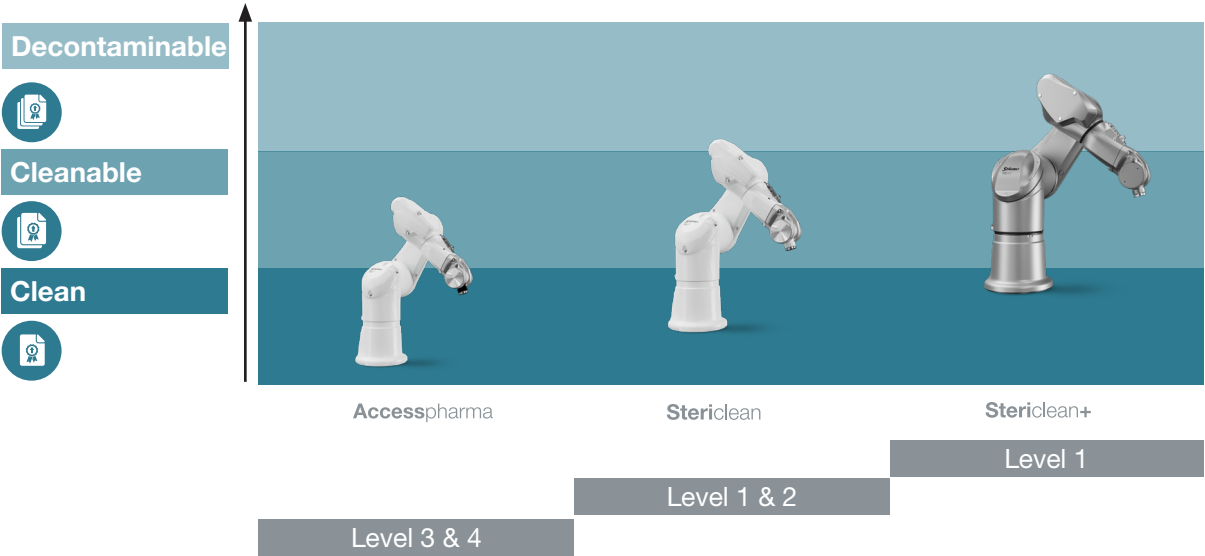
Level 4: Clean (and still cleanable)
Final packaging - Grade D/E & CNC (ISO 8): Secondary packaging activity, less critical manufacturing stage.

- Conditioning, cartoning & palletizing
- Pharma look robot - White robot
- Lower cleaning requirement

PHARMA OFFERING

A whole range to fit with all area

Robot in the industry is defined according payload, reach and speed. In pharma, three additional factors are also taken into account: clean, cleanable and decontaminable features. Consideration of the environment and cleaning process operated for the equipment is essential. Stäubli offers flexible solution into these various areas.



Dedicated industrial robots for each pharma grade environment

Documentation Package
Initial set of manuals and reports relating to clean, cleanable and decontaminable features.

- Clean**
The robot is tight and does not emit particles.
- Cleanable**
The cleaning of the robot (clean mapping) and its chemical compatibility (H₂O₂, Isopropanol (IPA), etc.) is validated.
- Decontaminable**
The robot has an hygienic design, resistant to microorganisms with quick and easy decontamination of its surface with VHP.

Customer benefits

- Stericlean+**
 - Made for isolator
 - FDA compliant materials
 - Highest hygienic design
 - VHP compatible

- Stericlean**
 - Proven accross the year
 - Full range H₂O₂ compatible
 - Pharma coating on arm

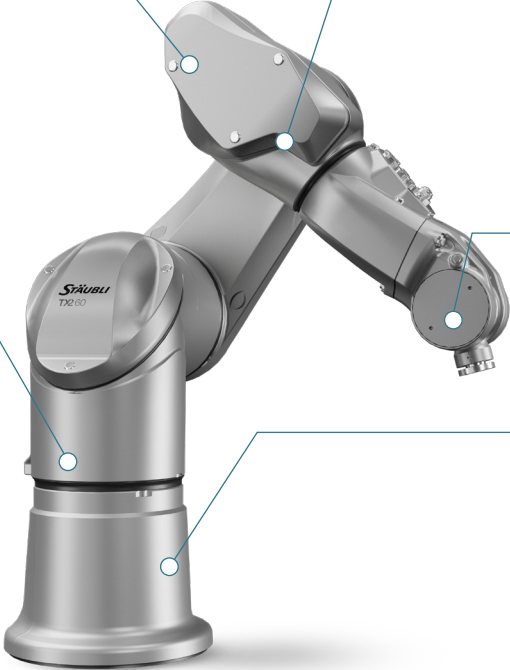
- Accesspharma**
 - Designed for intermediate cleanability
 - Guarantee alcohol (Isopropanol (IPA)) compatible

DESIGN FEATURES

Stericlean+

Hygienic design

- FDA compliant coating
- VHP compatible
- Hygienic covers with FDA Compliant Static gaskets - USP Grade VI
- NSF H1 oil
- ISO 5 - Grade A



Improved tightness and cleanability

- FDA compliant dynamic Joint Sealing on all axis - USP Grade VI
- IP65

Hygienic wrist

- FDA compliant coating wrist

Smart design

- Encapsulated 6-axis arm enabled by hollow shaft drives, no external cables
- Vertical connection for integration through the base
- Attachment methods: 360° mounting possibility
- Patented JCS smart gearbox
- Unique and modular SIL3-PLe safety functionalities

Validation & Documentation Package relating to cleanliness, cleanability and decontamination

- D-Value
- Microbiological resistance
- H₂O₂ Desorption / Absorption test
- Cleanability Test with Riboflavin
- Surface roughness
- Chemical resistance with 13 cleaning agents

tested by skan

Stericlean+



MODEL	TX2-40 Stericlean+	TX2-60 Stericlean+	TX2-60L Stericlean+	TX2-90 Stericlean+
Load capacity	2 kg	4.5 kg	3.7kg	14 kg
Reach (between axis 1 and 6)	515 mm	670 mm	920 mm	1000 mm
Number of degrees	6	6	6	6
Repeatability - ISO 9283	± 0.02 mm	± 0.02 mm	± 0.03 mm	± 0.03 mm
Max cartesian speed	8.6 m/s	8.4 m/s	11.1 m/s	10.9 m/s
Weight	29 kg	52 kg	53kg	114 kg

Available options

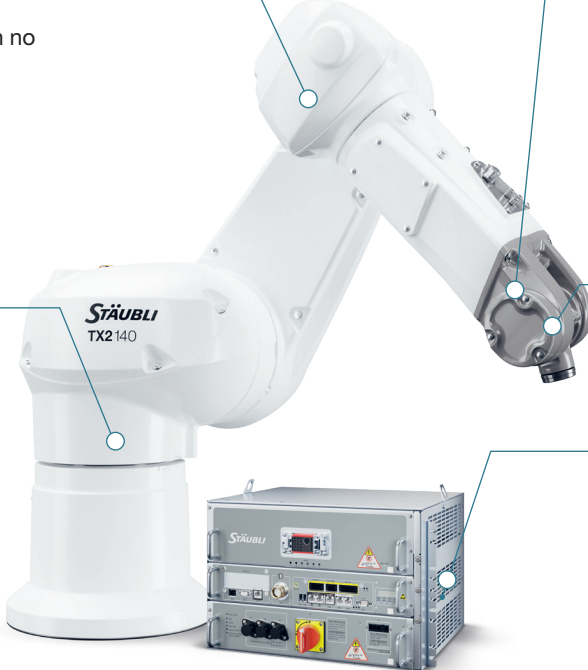
- Stericlean H₂O₂ harness
- Hygienic screwed caps or stainless steal caps

DESIGN FEATURES

Stericlean

Hygienic design

- Specific coating that allows H₂O₂
- Smooth surface
- Compatible with NSF H1 food oil with no loss in performance
- Sensitive parts in stainless steel



Improved tightness and cleanability

- Pharma compatible sealing on covers
- Screws in hygienic version
- IP65 for the entire arm
- IP67 on the wrist

Smart design

- Encapsulated 6-axis arm enabled by hollow shaft drives, no external cables
- IP67 for the entire arm with pressurization kit
- Vertical connection for integration through the base

Documentation Package as option

- Documentation relating to cleanliness and cleanability

Man robot collaboration

- Unique and modular SIL3-PLe safety functionalities
- High productivity and Man-Machine collaboration

Stericlean



MODEL	TS2-40/60/80/100 Stericlean	TX2-40 Stericlean	TX2-60/L Stericlean	TX2-90/L/XL Stericlean	TX2-140 Stericlean	TX2-160/L Stericlean	TX2-200/L Stericlean
Load capacity	8.4 kg	2 kg	4.5 kg 3.7 kg	14 kg / 12 kg 7 kg	40 kg	40 kg / 25 kg	170 kg 110 kg
Reach (between axis 1 and 6)	460 mm 620 mm 800 mm 1000 mm	515 mm	670 mm 920 mm	1000 mm 1200 mm 1450 mm	1510 mm	1710 mm 2010 mm	2209 mm 2609 mm
Number of degrees of freedom	4	6	6	6	6	6	6
Repeatability ISO 9283	± 0.01 mm ± 0.01 mm ± 0.015 mm ± 0.02 mm	±0.02 mm	± 0.02 mm ± 0.03 mm	± 0.03 mm ± 0.035 mm ± 0.04 mm	± 0.05 mm	± 0.045 mm	±0.045 mm ±0.055 mm
Cycles per minute (4 axis) Max cartesian speed (6 axis)	240 ppm 220 ppm 200 ppm 170 ppm	8.6 m/s	8.4 m/s 11.1 m/s	10.9 m/s 11.1 m/s 11.6 m/s	9,5 m/s	10.3 m/s 12.3 m/s	12 m/s 14 m/s
Weight	38 kg / 39 kg 40kg / 41 kg	29 kg	52 kg / 53 kg	114 kg 117 kg 119 kg	250 kg	260 kg 265 kg	980 kg 1000 kg

DESIGN FEATURES

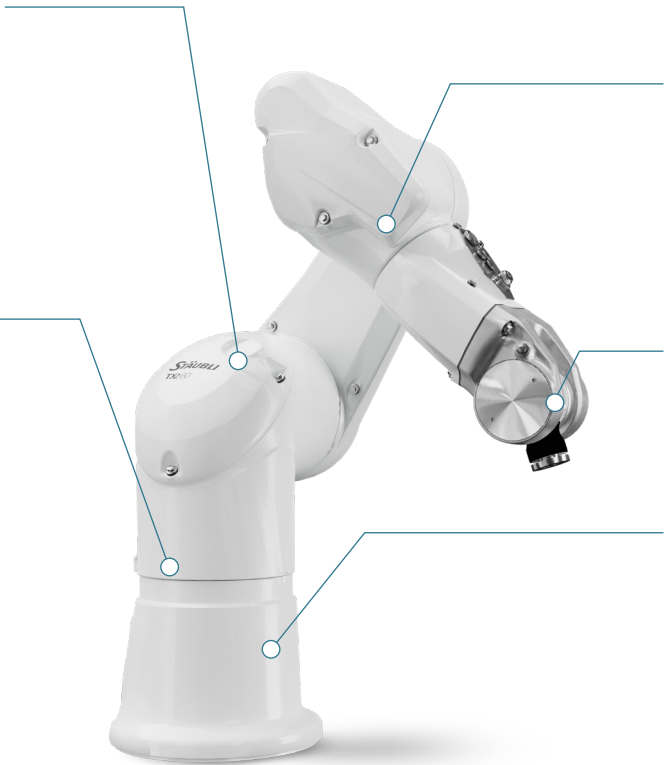
Accesspharma

Intermediate level of cleanability

- Isopropanol (IPA) resistant coating
- Hygienic screws
- ISO Class 5 according ISO14 644

Smart Design

- Encapsulated 6-axis arm enabled by hollow shaft drive, no external cable
- Flexible integration with vertical and horizontal connection
- Attachment method 360° mounting possibilities
- Patented JCS smart gearbox
- Unique and modular SIL3-Plc Safety functionalities



Tightness and Cleanability

- IP65 for the entire arm
- IP67 on the wrist

Standard wrist

- Incolored Anodized wrist

Documentation Package

- Documentation relating to cleanliness and cleanability

Accesspharma



MODEL	TS2-40/60/80/100 Accesspharma	TX2-40 Accesspharma	TX2-60/L Accesspharma	TX2-90/L/XL Accesspharma	TX2-140 Accesspharma	TX2-160/L Accesspharma	TX2-200/L Accesspharma
Load capacity	8.4 kg	2 kg	4.5 kg 3.7 kg	14 kg / 12 kg 7 kg	40 kg	40 kg / 25 kg	170 kg 110 kg
Reach (between axis 1 and 6)	460 mm 620 mm 800 mm 1000 mm	515 mm	670 mm 920 mm	1000 mm 1200 mm 1450 mm	1510 mm	1710 mm 2010 mm	2209 mm 2609 mm
Number of degrees of freedom	4	6	6	6	6	6	6
Repeatability ISO 9283	± 0.01 mm ± 0.01 mm ± 0.015 mm ± 0.02 mm	±0.02 mm	± 0.02 mm ± 0.03 mm	± 0.03 mm ± 0.035 mm ± 0.04 mm	± 0.05 mm	± 0.045 mm	±0.045 mm ±0.055 mm
Cycles per minute (4 axis) Max cartesian speed (6 axis)	240 ppm 220 ppm 200 ppm 170 ppm	8.6 m/s	8.4 m/s 11.1 m/s	10.9 m/s 11.1 m/s 11.6 m/s	9,5 m/s	10.3 m/s 12.3 m/s	12 m/s 14 m/s
Weight	38 kg / 39 kg 40kg / 41 kg	29 kg	52 kg / 53 kg	114 kg 117 kg 119 kg	250 kg	260 kg 265 kg	980 kg 1000 kg

PHARMA OFFERING

Main applications

Accesspharma



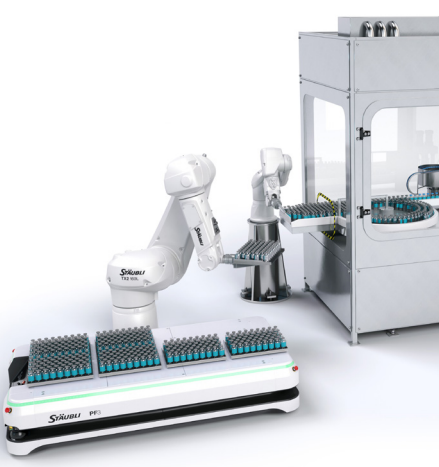
- Inspection
- Blistering
- Labelling
- Cartoning
- Palletizing
- Loading/Unloading machine
- IMM Unloading
- Consumable feeding
- Pipetting



Stericlean



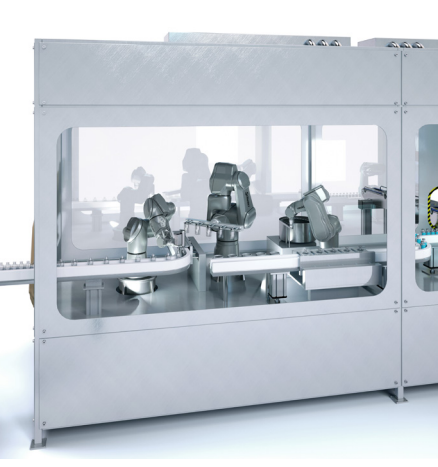
- Crimping / Assembling
- Tube handling
- Washing
- Loading / unloading freeze dryer
- Loading autoclaves
- Akylux box handling
- Cell culturing process management
- Cell & gene therapy process
- Bio printing



Stericlean+



- Filling
- Denesting
- Renesting
- Bag and TUBs opening
- Weighing
- Transferring
- Capping
- Stopper handling



PHARMA OFFERING

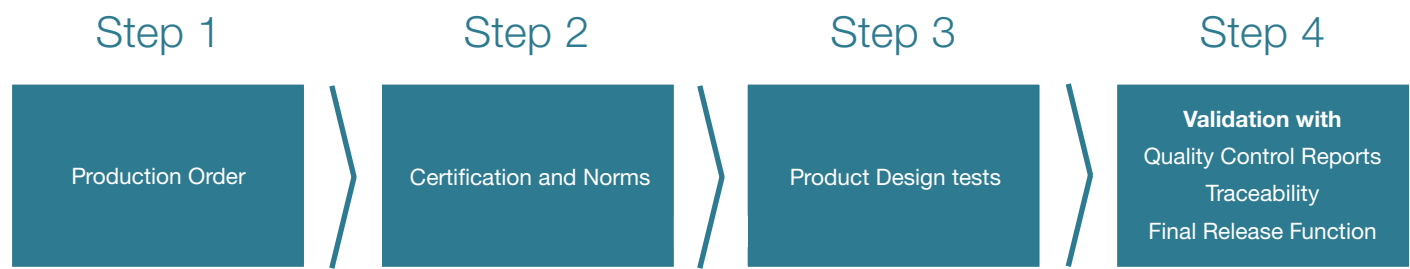
Validated robots for the pharma environment

The robot used in these areas must be suitable and validated to operate. Stäubli offers a full range of validated robots including the documentation package that will be required to ensure compatibility, safety and consistency and ease the final acceptance of the whole machine.

To stay in line with these new requirements, Stäubli partnered with SKAN, the world leader in manufacturing isolator

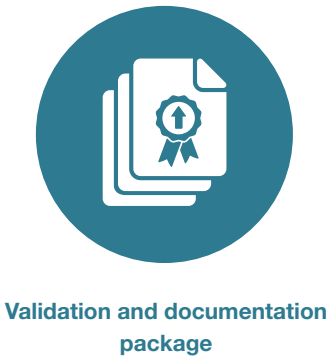
systems, and specialized in pharma and aseptic environments, in August 2021. “SKAN’s analytical services (SKANalytix) are helping Stäubli improve its aseptic robot design. They also provide robots with the much-needed validation and documentation package that clients ask for. We’ve done our homework,” smiles Rudolf M. Weiss, Stäubli’s Global Head of Life Sciences.

“Through our SKANalytix service, we provide our customers with analytical support for their questions and concerns around aseptic processing,” continues Gregor Hommes, Head of Research and Strategic Business Development at SKAN. “We offer studies around all aspects of isolators, and run tests regarding product, process and operator safety with regard to isolator and cleanroom technology.”



Customer benefits

- More transparency
- Compatible proof
- Save time for machine qualification documentation
- Support on your risk assessment
- More acceptance



In August 2021, Stäubli partnered with SKAN’s analytical services (SKANalytix) to improve the aseptic robot design and provide the much-needed validation and documentation package for the customers.

The Stericlean+ will be easily integrated in the pharma automation, thanks to its entire documentation that will support pharmaceutical industry for the Qualification of the whole machine.

“With a comprehensive and well-documented testing package, this also generates an added value for the pharmaceutical industry and ultimately patient-safety.” says Maximilian Mittelviehhaus, Research Manager, SKAN AG.

PHARMA OFFERING

A third party as witness

Decontamination process is key in pharma especially within isolator. Stäubli performed the main tests to validate the robot and material used and evaluate performance with various cleaning agents. Results of these tests are part of this package.

Stäubli
quality assurance

External tests

tested by
skan

=

An essential package for helping our customers building the integration master qualification and validation file

H₂O₂ (de)sorption

D-Value evaluation

Particles emission

Surface roughness

Tightness

Chemical Resistance

Cleanability mapping with Riboflavin

Microbiological Resistance

TESTED

3 steps for the right package

	Particles emission Tightness			Cleanability mapping Chemical resistance			Highest hygienic design Hydrogen peroxide performance Biological resistance		
Accesspharma	✓	✓	✓	✓					
Stericlean	✓	✓	✓	✓	✓				
Stericlean+	✓	✓	✓	✓	✓	✓	✓	✓	✓

PHARMA OFFERING

3 packages
4 levels requirements

Accesspharma

Level 3 & 4

- Alcohol compatible (Isopropanol (IPA))
- Qualified casting

Documentation Package included

Stericlean

Level 1 & 2

- Pharma coating on arm
- Compatible with H₂O₂
- Qualified casting

Documentation Package available

Stericlean+

Level 1

- FDA Compliant materials
- Optimal Hygienic design
- Validated robot
- Designed for isolator use and VHP

Validation & Documentation Package included

PHARMA OFFERING

A constantly evolving pharmaceutical offering



Sterimove
Cleanroom mobile robot



TX2-60 Stericlean+
with Hollow wrist option

Notes

[illegible]



● Stäubli Units ○ Representatives/Agents

Global presence of the Stäubli Group

www.staubli.com