# Robotics in aseptic drug manufacturing.

Life science / Pharmaceutical production / TX60 stericlean

**Challenge**

## Optimizing system safety in RABS and isolators

**Pharmaceutical manufacturing presents unique challenges. In order to enhance safety and quality, the industry has adopted Advanced Aseptic Processing (AAP) systems, using automation, robotics, machine vision and separative devices to prevent contamination.**

Separative devices include Restricted Access Barrier Systems (RABS) and isolators. Isolator-Barrier Systems and ANSI/RIA R15.06 (safety requirements for robot systems) all focus on restricting operator access to critical areas of machinery.

A RABS or isolator-based robotic system, implemented according to ANSI/RIA R15.06 standards, will provide a robot cell that meets requirements for Advanced Aseptic Processing in the pharmaceutical industry.

Aseptic isolator with a Stäubli Stericlean 6-axis robot arm.

**Solution**

## Advanced aseptic processing (AAP)

The Parenteral Drug Association (PDA) describes an Aseptic Process as “The process for manufacturing sterile products by which microbiological contamination is eliminated from the product and product contact surfaces protecting the product from sources of contamination. ”The challenge for drug manufacturers is to ensure that their manufacturing processes preclude microbiological contamination, particularly for injectable or parenteral drugs, which carry the highest risk.

While operators in cleanroom environments wear sterile garments, they remain the greatest contributor to contamination. A study by Whyte (Whyte, 1998) showed how activity affects particle generation rates with people wearing cleanroom gowning for particles 0.5um in size:

- Sitting motionless: 500,000 particles per minute
- Sitting with head, arms and body movement: 1,000,000 particles per minute
- Walking at 2 mph: 5,000,000 particles per minute

Advanced Aseptic Processing (AAP) utilizes automated technologies such as robotics and physical barriers to eliminate operator intervention with the process, product containers and surfaces. The key is to maintain absolute control of contamination sources.

**Technical features TX60 stericlean**

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|---|---|
| **Degrees of freedom** | 6 |
| **Nominal load** | 3,5 kg |
| **Maximum load*** | 9 kg |
| **Reach** | 670 mm |
| **Repeatability** | ± 0,02 mm |
| **Cleanroom standard: ISO 14644-1** | Class 4 |
| **Arm mounting options** | Floor / wall / ceiling |
| **Stäubli CS8 series controller** | CS8C |

* With specific configuration.



**Results**

# Robotics in aseptic processing

Aseptic manufacturing is a highly repetitive activity requiring a high degree of reproducibility to produce a high quality product. Robots are the ideal platform for such highly accurate and repeatable operations. Further, they generate extremely low particulate levels, and can operate in environments where humans cannot.

To further advance the use of robotics in AAP, Stäubli Robotics developed the TX series stericlean and HE 6-axis robot arms, which are suitable for sanitizing with isopropyl alcohol and bio-decontamination with sporicidal agents and vapor phase hydrogen peroxide (VPHP).

ANSI/RIA R15.06-1999 robot safety compliant RABS unit.

Robots offer one particular advantage over traditional aseptic machinery: flexibility. They are completely adaptable, and can be reprogrammed with minimal investment if an application or container format changes.

Tool changer technology, widely used in other industries but largely untapped in pharmaceutical applications, allows the robot to quickly couple and decouple end of arm tooling to perform operations that cannot be performed on a single tool.

## Robot safety equals product safety

The combination of Isolator-Barrier technology with robot safety requirements ensures that critical zones are protected during aseptic manufacturing. With isolator-integrated robots, the isolator walls become a safety fence encircling the robot. Light curtains detect operator presence at the glove port(s), and access door(s) are electrically interlocked.

In a RABS application, these safety devices can be used systematically through the machine control architecture to mitigate contamination risk during open door interventions. This would prevent interventions from taking place or manufacturing to resume unless certain conditions are met.

AseptiCell filling system with Stäubli stericlean or HE robots.

They key to Advanced Aseptic Processing is absolute control of all sources of contaminants, most importantly the human element. Robotics and isolator-barrier systems are core technologies in this regard. A properly integrated robot system combined with an isolator-barrier system offers a flexible robotic cell that meets the strictest of regulatory standards. The many layers of protection provided by isolated robotics offer superior control over ingress of contamination and thereby protect product quality and minimize risk.