



THE AUTOMATION PARTNER FOR LIFE SCIENCES COMPANIES

The background of the slide is a blue-tinted photograph of a pharmaceutical manufacturing facility. In the center, a white robotic arm is positioned over a large stainless steel tank. The facility is filled with various pieces of equipment, pipes, and tanks. Overlaid on the right side of the image is a network of white hexagons connected by lines. Inside several of these hexagons are white line-art icons: a syringe, a vial, a test tube, and a tablet labeled '100 MG'.

# Your Pharma Projects Our Proven Automation Solutions

ASEPTIC PROCESSING • COMBINATION PRODUCT SOLUTIONS • CUSTOM AUTOMATION

Few industries are as challenging as life sciences, the pharmaceutical sector in particular. Manufacturing processes can be highly complex and compliance with regulatory requirements can be challenging. The assurance of product quality and a robust supply chain are critical to success. As product teams adjust to increases in demand, changes in product portfolio, new product launches, and shifting business priorities, the selection of appropriate partners with subject matter expertise has never been more important.

ATS is a leading global automation solutions provider with over 40 years of experience in a variety of industries including pharmaceuticals. **Our products and services support the entire pharma manufacturing process from material intake to finished and packaged product.** Whether you require a customized system, a standard piece of equipment, or a fully integrated production line, our life sciences group of companies is here to support you. Let's talk about your project management, design/build, integration, validation, training, and post-project requirements. We are your Partner for Life.



*The pharma manufacturing process can be complex and CGMP compliance challenging.*

*With our portfolio of life sciences-focused companies, ATS has solutions that complement the pharma manufacturing process... from end to end.*

- Molding & forming**  
**Sorting & washing**  
**Depalletizing**
- Drug discovery**  
**Process development**  
**Biopharma processing**  
**API & HPAPI processing**  
**Decontamination & sterilization**  
**Aseptic formulation**
- Feeding & material handling**  
**Dispensing**  
**Filling**  
**Assembling**
- Monitoring**  
**Inspection**  
**Testing**
- External vial washing**  
**Labelling & marking**  
**Containers**
- Cartoning**  
**Palletizing**  
**Specialty packaging**



## COMPONENT PREPARATION

Many pharma and medical technology processes begin with preparation of components. Glass syringes, for example, generally require the **forming** of glass tubing into syringe bodies. Glass vials may require **washing and drying**. Components like safes for radiopharma or stoppers and caps for vials may require special handling for **induction** into isolators or containment spaces. Product parts supplied in bulk may need **singulation** and **orientation**, while parts that are supplied in trays need to be unstacked and unloaded for subsequent processing. Working with a partner with specialist knowledge in these processes ensures quality from beginning to end.



Sorting & washing

Molding & forming

Depalletizing

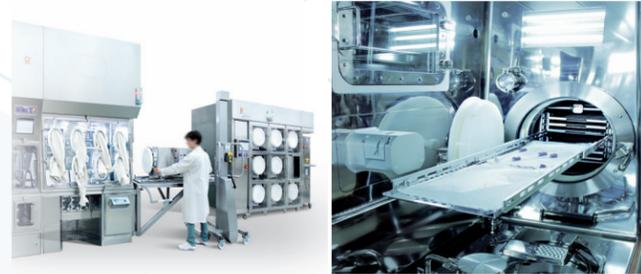
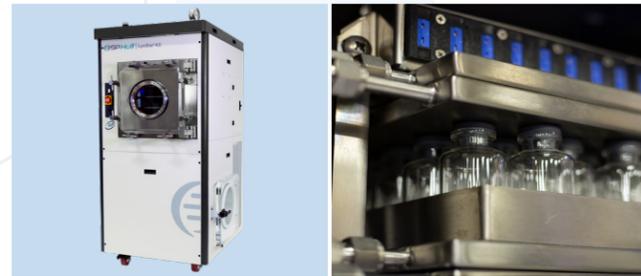


## DRUG FORMULATION

Mitigating the risk of microbiological contamination and product adulteration, and protecting the operator are critical considerations associated with API, HPAPI, and drug formulation. **Isolators and automated processing** offer solutions by creating a safe, aseptic environment that maintains separation between product and people.

Processes like mixing of different substances including excipients and active ingredients, managing living cells for R&D or production purposes, and preparing high potency products in part or in full, can be safely integrated into isolators. **Manual and automated tooling** installed within the isolator can improve efficiency and quality. Freeze **drying** liquid products in vials can increase product stability and reduce cold chain requirements. **Lyobead** formats are ideal for precise dosing, reduced wastage, microfluidic applications, bulk storage, personalized medicine opportunities, etc.

Whether your need is custom or standardized, our life sciences products and solutions can deliver turnkey systems for automated and aseptic drug formulation processes.



Drug discovery

Process development

Biopharma processing

API & HPAPI processing

Decontamination & sterilization

Aseptic formulation



## MANUFACTURING

Environmental requirements for a product inform automated manufacturing design decisions. Thus, experience and expertise in **aseptic and contained environments** and manufacturing automation ensure that the quality, craftsmanship, and **CGMP compliance** of manufacturing systems are appropriate for your product.

Life sciences products assume a variety of forms and presentations, each with a unique set of processes and requirements. For some products, **standardized solutions** may be appropriate, while other products may require **purpose-built solutions**.

ATS has automated and integrated many manufacturing and assembly processes including those for products with stringent environmental and sterility requirements, suitable for different ISO classification needs. From **picolitre dispensing to combination product assembly**, we have an automated solution to suit your product and process.



Feeding & material handling

Dispensing

Filling

Assembling



## QUALITY CONTROL

The quality of your finished product is critical to success. Automated systems that incorporate in-process monitoring, testing and quality control solutions help to deliver this goal.

From sensors to measurement systems, ATS works with you to identify the appropriate checks and verifications so that the operating environment, process steps, and in-process and finished product meet your defined requirements.

Our **vision systems** perform demanding attribute inspections, from text accuracy and legibility to **high speed lyocake inspections**, and even **dispense volumes for drops in flight**, and maintain image libraries for **traceability** purposes. Collected data and **reports can be accessed in real time** and used to fine tune operations and for electronic batch record purposes. And if you need in-process or finished product samples for quality control purposes, we will include in our design the ability to safely retrieve the samples while maintaining complete traceability.



Inspection

Monitoring

Testing



## PRIMARY PACKAGING

The majority of pharmaceutical products require some kind of primary packaging ranging from bottles and vials for solid dosage formats to tubes for medical ointments to glass or plastic containers for liquid drugs. These include vials, ampoules, cartridges, pre-filled syringes, and IV bags. Depending on the product, this packaging step may be performed within a contained environment like an isolator or RABS. In some instances, the exterior of the primary package may require washing after the packaging process to ensure that there is no harmful exposure to someone handling the container. Labelling or marking is an essential step for identifying the product for compliance and traceability.

For those unique primary packaging scenarios, ATS can offer **standard equipment as well as customized systems**. For products that have not been automated previously, ATS can design and build or **integrate** our own and third-party solutions that meet your requirements and expectations.



Labelling & marking

External vial washing

Containers



## SECONDARY PACKAGING

From primary packaging, finished products may be placed directly into trays, clam shells, blisters, tubs, or pouches, and then sealed for integrity purposes. Some may undergo further packaging in the form of kits, or specialty packs like tubs or multi-pocket trays. Secondary cartoning and case packaging are generally the end of the line for any production process. There are many standard cartoning offerings including vertical, horizontal, and top load cartoners. But the secondary packaging design may require a custom design.

At ATS, we have built a reputation for providing the right solution for each customer's needs. Within our family of life sciences companies, we can deliver an automated solution to meet your product's **specific secondary packaging requirements, or an entire manufacturing line**.



Cartoning

Palletizing

Specialty packaging



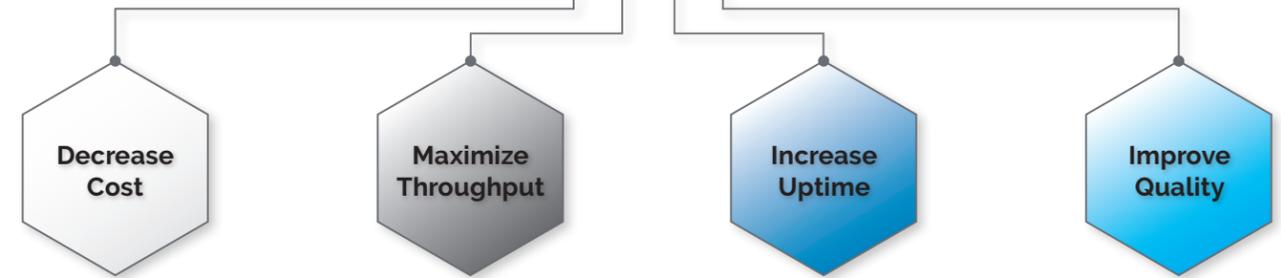
## GETTING THE MOST OUT OF YOUR MANUFACTURING DATA

In a world of Big Data, the challenge isn't how to collect machine performance, operation, and condition data, and product quality data. It is how best to make the data **available and friendly for use**. The **insights** from the data can decrease operational expenses, maximize throughput, increase uptime, avoid costly downtime, and improve quality.

**Illuminate™ Manufacturing Intelligence** is ATS' smart manufacturing system that makes sense of the data generated by your essential machines, lines and processes that power and propel your manufacturing operations. It connects your entire team to the production floor in real time to enable informed and timely intervention and decision. It makes your data accessible.



### illuminate™ MANUFACTURING INTELLIGENCE



- Improve equipment efficiency, yield, and lifespan through predictive maintenance
- Respond to issues quickly and unlock hidden performance
- Decrease cost through integrated statistical process control provisioning
- Keep the operational team informed and engaged to drive greater operational efficiency through real-time notifications

- Capture real-time OEE intelligence across lines, machines and locations for performance diagnostics and troubleshooting
- Identify production trends for top- down, bottom- up continuous improvement
- Achieve continuous manufacturing improvements and production line sustainability with data -to- decision in minutes

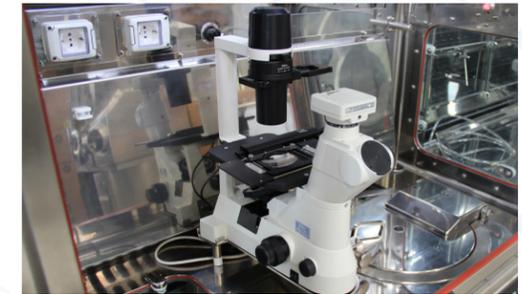
- Mitigate down time risk by tracking individual cycle counts on: wear parts, consumables, long-lead items or repairables
- Be prepared with color-coded early warning reminders and alerts
- Capture maintenance log reports or repair events to support: future failure analysis, equipment performance improvements, and continuous enhancement of the work management system

- Sustain product quality through synchronous and asynchronous processing
- Gain visual insight with live stream video of production root cause analysis, and troubleshooting issues
- Increase control and communication with integrated visual KPIs
- Facilitate visual machine learning on parts and product quality control inspection - decreasing hours of operator visual monitoring, performance fatigue, and quality faults

## CONTAINMENT TECHNOLOGY

Some pharmaceutical products require protecting – to ensure patients are not harmed by a contaminated product, or to ensure your team is not harmed during manufacturing. These protective environments range from **classified rooms to RABS and isolators**, and in some instances shielding with lead walls. The right solution for you and your product is going to depend on a number of factors including initial investment, operational costs, flexibility, and the hazard posed to or by your process and product.

ATS has the know-how to design and manufacture isolators and aseptic automation that meet current CGMP guidelines. Using a combination of isolation technology, custom automation solutions, and off-the-shelf process equipment integrated in a single unit, we can deliver in terms of ergonomics, safety, performance, and validation.



## ISOLATORS BY COMECER



### Integrity

Our isolators provide a safe and contained space in which there are no transitions to interrupt the cleanliness chain. The integrity of your process is not put at risk. Your product will only be exposed to the environmental grade you specify.



### Flexibility

Our isolators can be easily disinfected between batches. With demonstrated effective VPHP technology, you can transition from one product to the next quickly and reliably.



### Traceability

Our isolators are fully computer-controlled and able to support compliance with CFR 21 Part 11. Environmental and process variables are monitored AND recorded with two goals in mind: compliance with process requirements, and traceability to every batch produced.



### Quality

By design, isolators provide improved cleanliness assurance – removing the human element eliminates the greatest contamination source. Further, by constraining the isolator's working envelope, we are better able to control the environmental variables (T, RH) for improved process stability.



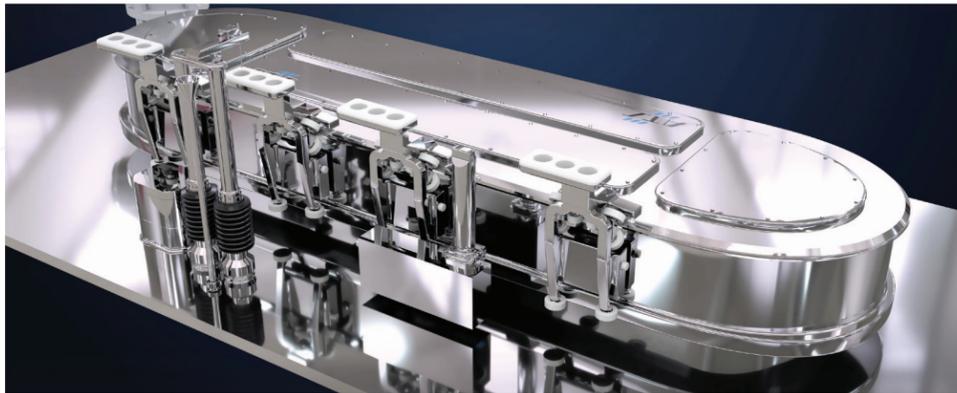
## AUTOMATED MANUFACTURING IN AN ASEPTIC ENVIRONMENT

The automated movement and manufacturing of products in an aseptic environment is challenging. How do you do this without introducing particulate, interrupting laminar flow, or creating serious disinfection challenges?

ATS has developed **SuperTrak PHARMA™**, the latest innovation in the SuperTrak CONVEYANCE™ family. It is a high performance, reliable linear motion solution designed for aseptic environments that enables synchronous and asynchronous processing on the same platform. This reduces repetitive tooling and overall footprint while delivering speed, precision positioning, acceleration/deceleration capability, flexibility, and programmability.

SuperTrak PHARMA™ has been tested at rest and in motion within a Grade A isolator. It successfully:

- met the particulate levels stipulated by ISO 14644.1 and EU GMP Annex 1,
- passed the riboflavin powder tests after washdown,
- met the acceptance criteria for effective decontamination with VPHP,
- did not disturb the unidirectional laminar air flow within the isolator, and
- demonstrated chemical compatibility with quats, ethanol, IPA and traditional sporicidals.



### PRODUCT SPECIFICATIONS

PRODUCT SPECIFICATIONS	VALUE
Materials	Stainless Steel 316L, Viton, PEEK, Ceramic
Loop Size	1m, 2m, or 3m plus turns; longer loops come with module build up
Loop Cover	Standard – individual sealed plates; Option – single piece cover with optional motorized lift
Maximum Speed	2.5 m/s
Acceleration	3G with 1 kg payload; 1G with 8.5 kg payload
Stop Repeatability	± 0.01 mm straight section; ± 0.025 mm turn section
Shuttle Payload	8.5 kg maximum
Shuttle Nests	Customized to suit product and process
Communication	EtherNet / IP, PROFINET, Powerlink, and EtherCAT
Power Consumption	10 W / section, 150-225 W / shuttle
Lubricants	Not applicable

## WALKING WITH YOU ON YOUR AUTOMATION JOURNEY

Your production project does not start the day you decide to invest in manufacturing systems, nor does it end once the newly acquired system is installed. At ATS, we want to support you **from R&D to product retirement**.

### PRE-AUTOMATION

Before you finalize your new product design or investment proposal, work with our pre-automation team to explore design options that will can improve manufacturability, the automated manufacturing options available to you, the cost of implementing and 'owning' a particular solution, and more.

- Manufacturing concept development and evaluation
- Simulation
- Prototyping
- Product and process development support
- Proof of principles studies
- Total Cost of Ownership (TCO) analysis
- CGMP review
- Validation

### AUTOMATION

From design/build to commissioning and validation, our teams will work with you to deliver a successful project. We will partner and collaborate with your team, soliciting your input, suggesting alternatives, training your staff, and more, to ensure the end result is more than a machine, it is a solution.

- Design – Mechanical & Electrical, and Software
- Automation products
- Integration
- Inspection and testing
- Commission and qualification
- Repetitive Equipment Manufacturing (REM)
- Date acquisition and MES

### POST AUTOMATION

Our design for maintenance culture, machine builder DNA and data-centric approach gives us a comprehensive understanding of the operation and maintenance of automated manufacturing systems and equipment. This reduces diagnostic effort and repair time, and allows us to prioritize actions to maximize help optimize ROI for our customers.

- Comprehensive lifecycle services portfolio
- Large, multidisciplinary work force
- ISO-certified service centers in Europe and North America
- Highly refined processes for testing and optimizing complex automaton systems
- Global footprint



## THE ATS FAMILY OF LIFE SCIENCES COMPANIES



**ATS Life Sciences** is an industry-leading, manufacturing automation provider to customers requiring CGMP compliance, performance, and reliability. Our innovative, turnkey systems address complex process, assembly, logistic and service problems. We have a world-class team, and an enviable portfolio of standardized and custom products, smart conveyance platforms, synchronous and asynchronous technologies, robotic solutions, and material handling systems.

Since 1994, **BioDot** has been specializing in the development, manufacturing and customization of precision, high-throughput, low volume, fluid dispensing systems for point-of-care diagnostics, clinical diagnostics, and other life sciences. Our portfolio of ultra-low (picolitre) to low volume (nanolitre to microlitre) dispensing systems are used in research, development and commercialization of lateral flow tests, flow through tests, microfluidic devices, biosensors, immunoblots, and microarrays. We hold over 26 patents in the areas of low volume dispensing and novel applications.

Leveraging over 45 years of experience, **Comecer** is a leading provider of innovative, high-tech systems in the field of aseptic processing and containment for the pharmaceutical and nuclear medicine industries, specializing in isolation technology solutions for regenerative medicine and tissue engineering. Comecer equipment is made to enhance quality and safety of the pharmaceutical process in every step of the manufacturing chain. Comecer offers modular or customized isolators to best fit processes like drug compounding, aseptic vial and syringe filling, sterility testing, and to cell and gene therapy.

For over 35 years, **DF s.r.l.** has designed and manufactured washers and depyrogenation tunnels for the pharmaceutical industry. Other offerings include sterility test isolators, glove test systems, fill-finish lines in isolators for bags and vials, dry fog sterilization systems, and c-RABS.

In addition, we offer cassette and pallet load/unload systems as well as autoclave loading and unloading systems. All DF systems combine precision and reliability with safety and aseptic operation.

**IWK** has been focusing on efficient, precise, and attractive packaging of pharmaceutical and cosmetic products for more than 125 years. Our portfolio includes systems for tube feeding and filling, cartoning, collating, sorting, and handling. We also offer cobot systems for depalletizing and feeding needs. For pharmaceuticals, customers can rely on technical capabilities, resource capacity, high-performance reliability, and quality solutions.

Since 1986, **PA Solutions** has grown to be one of the leading providers of control systems and control systems solutions for the pharmaceutical and biotech industries. PA Solutions covers the entire production chain from API production to packaging. Key services include the design of control and process control systems, engineering of instrumentation control systems for process plants (EPCM), and the vertical integration of these systems into the overall corporate process systems.

**SP Industries** is committed to working with the global scientific community to improve the lives of people by supplying trusted products. SP is your single-source partner for CGMP aseptic drug manufacturing solutions, unifying workflows from freeze dryers and related process analytical tools, to end-to-end fill-finish equipment suitable for small batch production and larger-scale manufacturing. You will realize optimal results with our innovative life science equipment focused on controlling or even eliminating process variables. Our systems are intuitive and easy-to-use, taking care of your evaporation, thermal or humidity control needs, while you stay focused on the science. SP is also the manufacturer of labware and glassware so we can also support you from biopharma research and QA testing to clinical diagnostics, chemistry, environmental analysis, and materials science.

Choosing ATS is choosing a partner for life. From **project conceptualization to product maturity**, we can offer you an end-to-end partnership with the right mix of expertise. The combination of our know-how and technologies with your application will deliver **integrated and customized solutions** for pharmaceutical companies worldwide.

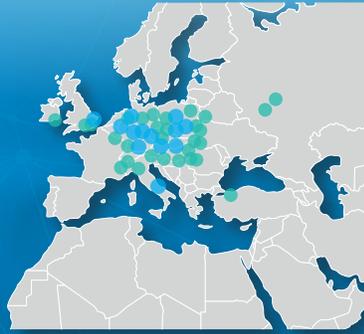
Connect with ATS or reach out directly to a specialist partner to begin the conversation.



LIFE SCIENCES COMPANIES



WOODBRIDGE  
 CAMBRIDGE  
 WIXOM  
 ROLLING MEADOWS  
 LEWIS CENTER  
 PARSIPPANY  
 IRVINE  
 HILLSBOROUGH  
 WARMINSTER  
 STONE RIDGE  
 WAYNE



NEUWIED  
 KOBLENZ  
 LUDWIGSHAFEN  
 STUTENSEE  
 LUTHERSTADT WITTEMBERG  
 ZWICKAU  
 EDENBRIDGE  
 JOURE  
 ST. GEORGEN  
 CASTEL BOLOGNESE  
 INGOLSTADT  
 MUNICH  
 CHICHESTER  
 IPSWICH



TIANJIN  
 SAMUTPRAKARN  
 SHANGHAI  
 TAIPEI  
 SEOUL  
 MUMBAI  
 TOKYO  
 BANGKOK  
 JAKARTA

● Manufacturing Facilities  
● Offices

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