more expertise. customized solutions. reliably supplied.
your specialized sterile manufacturing challenges, our tailored solutions.

With our parenteral delivery platforms, we create solutions for your most difficult aseptic fill challenges around pre-filled syringes and blow/fill/seal technology. The combination of our extensive drug and biologic manufacturing, filling and packaging capabilities ensures that we can offer tailored, modular options for each of our customers and supply their products to market reliably.

ADVANCED STERILE DOSING SOLUTIONS
OPHTHALMIC, RESPIRATORY, BIOLOGICS & ORAL LIQUID
BLOW/FILL/SEAL TECHNOLOGIES
ADVASEPT® GLASS-FREE INJECTABLE TECHNOLOGY
PRE-FILLED SYRINGE SOLUTIONS
FLEXIBILITY FOR LARGE & SMALL MOLECULE PRODUCTS
MARKET-LEADING EXPERTISE WITH ADVANCED ASEPTIC BLOW/FILL/SEAL TECHNOLOGY

We have proven expertise in providing customized solutions from development through commercialization. Our innovative technology delivers dosing solutions for the ophthalmic, respiratory, biologics, sterile and oral liquid markets.

MARKET-LEADING EXPERTISE WITH ADVANCED ASEPTIC BLOW/FILL/SEAL TECHNOLOGY

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BRINGING BETTER TREATMENTS TO MARKET

As the leading provider of blow/fill/seal technology solutions, our offerings are wide in scope and usage. We are proud to use this unit- and multi-dose delivery platform to solve our customers’ unique product challenges.

Development Expertise

Our experts will work with your products from pre-formulation through commercial scale.

Completely Customizable

In-house container design and component insertion capabilities allow complete customization for unit-dose or multi-dose products without reliance on stock containers, for both traditional or complex unit dose solutions.

Flexibility & Capacity

We have a long history of successfully taking customers from development through commercialization, leveraging our scientific talent, operational flexibility and extensive capacity to solve unique challenges and reliably supply product globally.

LOWER YOUR PRODUCT’S RISK PROFILE

Combining our scientific expertise with the sophisticated automation behind blow/fill/seal technology and our relentless focus on quality, Catalent is committed to ensuring our customers’ success.

World-class Expertise

We have expertise working with complex products including eye emulsions, viscous suspensions and products that are light/oxygen sensitive.

Highly Efficient Process

Highly automated, minimizing component handling and pre-sterilization steps, allowing high per-run output and maximum process efficiency.

High Quality Output

Recognized by the USP as an advanced aseptic process for forming, filling and sealing containers. Process features minimal operator interface and limited product exposure time, thus helping minimize risk.

BLOW/FILL/SEAL PROCESS

BLOW/FILL/SEAL is the combination of three major processing steps: 1) CONTAINER MOLDING, 2) CONTAINER FILLING and 3) CONTAINER SEALING. WITHIN A SINGLE CONTAINED PROCESS, THE ADVANCED ASEPTIC PROCESS IS A HIGHLY AUTOMATED SYSTEM WITH MINIMAL OPERATOR INTERFACE. THE PLASTIC EXTRUSION AREA AND CRITICAL FILL ZONE (ISO.5) ARE DESIGNED AS PARTIALLY ISOLATED AREAS WITH LOCALIZED PROTECTION WHERE EXPOSURE OF THE PRODUCT AND CONTAINER TO THE ENVIRONMENT IS MINIMIZED.
PARTICULATE REDUCTION
We have developed a filling process that drastically reduces the risk of particulates.

REDUCTION OF PARTICULATES COMPARED TO THE STANDARD AND THE INDUSTRY

<table>
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<th>&gt;10 µM PARTICLES</th>
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- Limits Set by USP General Chapter <788> for Small Volume Parenterals using Light Obscuration Particle Count Test Method
- Results from USP <788> particulate matter testing from 295 ANDAs covering 406 lots of drug product
- Results obtained from Catalent’s Advanced Aseptic Filling Process

EXTENSIVE DOE EVALUATION 32 DIFFERENT PROCESSING PARAMETERS
AVERAGE PARTICULATE COUNT ACROSS ALL 32 SAMPLE SETS (385 SAMPLES)

PROVEN TECHNOLOGY FOR GLASS REPLACEMENT

24 MONTH STUDY COMPARING A mAb IN GLASS AND ADVASEPT®

- Limits Set by USP General Chapter <788> for Small Volume Parenterals using Light Obscuration Particle Count Test Method
- Results from USP <788> particulate matter testing from 295 ANDAs covering 406 lots of drug product
- Results obtained from Catalent’s Advanced Aseptic Filling Process

EXTENSIVE DOE EVALUATION 32 DIFFERENT PROCESSING PARAMETERS
AVERAGE PARTICULATE COUNT ACROSS ALL 32 SAMPLE SETS (385 SAMPLES)

CUSTOMIZED OPTIONS FOR COMPLEX TREATMENTS
Advanced aseptic processing that delivers an innovative glass-free delivery for injectable drugs. With our diverse range of parenteral delivery platforms and proven expertise in specialized manufacturing challenges, we can tailor a solution for your unique needs.

ADVASEPT™ TECHNOLOGY
An advanced aseptic filling solution for parenteral products. The ADVASEPT™ family of products provide a glass-free, primary packaging solution that reduces and even eliminates some of the most pressing concerns associated with traditional glass vials. ADVASEPT™ technology drives at the root cause of many of the manufacturing and quality issues facing today’s traditional vial filling process.

- Provides higher levels of quality assurance through automation and eliminating human intervention
- Eliminates glass management and removal of variables
- Drastic reduction of particulates
- Elimination of delamination and glass particles

ADVASEPT™ VIAL
Glass-free vials as a proven container closure for biologics.
- Standard container sizes of 10mL, 50mL, and 100mL
- Provides the tooling expertise to give container design freedom for multiple sizes
- Reliable and efficient alternative for the aseptic filling of IV Bags
- Proven technology for biologics

ADVASEPT™ LOCK
Security and functionality in a primary container closure system.
- A stopperless vial that provides a glass-free needleless withdraw of drug product to provide a safe and efficient delivery solution. This technology is easily opened and locks to luered syringes for a smooth withdraw of the liquid product.

CATALENT CAPABILITIES
- Integrated analytical capabilities to support the transition from glass to plastic
- Formulation and process design expertise
- Best-in-class quality system and reliable supply

Container Design Freedom
ADVASEPT™ technology offers unlimited potential with an endless number of possibilities, configurations, and combinations.

- Customizable and flexible delivery solutions with the sterility assurance of this advanced aseptic process
- Functionality can be added directly into the container with aseptic assurance provided by Catalent’s blow/fill/seal technology
- Design expertise can provide the features desired in an efficient manufacturing solution

Our expertise in the blow/fill/seal technology and in-house mold design capabilities can deliver unique primary container designs to provide your brand promise.

Reliably Supplied from Formulation to Fill/Finish
- Formulation and process expertise to simplify the complex formulas and deliver a process for commercial excellence
- Scalable manufacturing capabilities to provide the right size equipment for the stage of life cycle development.

KEY BENEFITS
- Lower the risk associated with parenteral filling
- Drastically reduce foreign particulates by 95%
- Eliminate delamination & glass particles
- Lower the cost of shipping & disposal
- Design freedom & flexibility
- Processing impact on biologic products

Discover more solutions with Catalent. Call: +1 888 SOLUTION (765-8846)  Email: solutions@catalent.com  Visit: www.catalent.com
INJECTION SYSTEMS
SAFER, MORE ACCURATE DOSING

Our expertise with specialized delivery technologies, such as auto-injectors and needle safety systems allows for convenient safe dosing. Catalent can perform assembly of syringes into auto-injectors or needle safety systems working with your preferred device partner.

As a market leader in sterile manufacturing, we offer an extensively customizable range of pre-filled syringe products, uniquely tailored for each customer.

EXTENSIVE RANGE OF PRE-FILLED SYRINGES

Our solutions offer increased efficiencies, accurate dosing, and convenient single-dose administration of your injectable products.

Safety Unlike multi-dose vials, pre-filled syringes require no preservatives which can trigger allergic reactions in some patients. Pre-filled single-dose syringes also reduce the likelihood of medication dosing errors.

Convenience Our pre-filled syringe solutions provide an accurate single dose of your drug product in a convenient, ready-to-use format.

Cost Efficiencies Each pre-filled syringe delivers a precisely measured dose, eliminating the overfill and wasted product associated with multi-dose vials – a significant cost savings for manufacturers and all customers.

Extractables & Leachables Our world-class analytical teams have performed controlled extraction studies on primary and secondary packaging components. Six leachables methods have been validated to cover analysis of any known extractable in the most common sterile formulations, providing a solution that saves time and money.

Stability Programs Industry leading expertise and a global footprint to support your projects.

Regulatory Consulting to support your product filings and get to market faster.

Customized Products in Ready to Fill or Bulk Syringes, we offer a range of pre-filled syringe sizes (0.5mL to 20mL), tops (luer, luer lock or with needle), graduation and aseptic/terminal sterilization.

Unique Filling Capabilities Including dedicated product lines for complex, highly viscous filling.

Flexible Capacity A global network with dedicated lines and capabilities to handle projects from the very small to the very large, up to 175 million units.

Integrated Services Fully integrated services including labeling, plunger rod insertion, blistering, and cartoning of injectable products. Expertise in manual and automated assembly of auto-injectors and syringe safety systems. On-site analytical testing and QP release.

VACCINES

We have a proven track record in fulfilling market requirements for high volume seasonal vaccines.

• Demonstrated capability to scale up in support of pandemic demand

• Global regulatory approvals

BIOLOGICS

• Innovators in Biologics and Biosimilar manufacturing

• Experience in handling and packaging complex products
INTEGRATED SERVICES, RELIABLE SUPPLY
Customized, integrated solutions to solve your most complex challenges, from development and delivery to manufacturing and packaging.

We are a global leader in customized integrated service solutions. Whether you need a single solution or an end-to-end partner, our team of scientific, regulatory, manufacturing and operations professionals can develop a tailored proposal that will put you on track to faster, more efficient drug development and commercialization pathways.

BIOLOGICS
We are your strategic partner for biologic drug development success. With our GPEXS™ technology for mammalian cell line development and our broad range of integrated services, we provide fast, seamless solutions from development to biomanufacturing, analytical, fill/finish and packaging.

ORAL & PARENTERAL DRUG MANUFACTURING
With over 80 years of manufacturing expertise, continuous innovation, consistent quality and reliable product supply, our global infrastructure of cGMP, FDA, EMA and locally accredited facilities can provide you with a tailored drug manufacturing solution.

ANALYTICAL SERVICES
From rapid testing of early candidates to new drug application/registration submission and post-launch, we have the broadest range of analytical testing services to accelerate your project with immediate resourcing and expert technical support. Our strong continuum of problem-solving expertise, state-of-the-art systems and proprietary technologies can support small or large molecule drug development needs.

CLINICAL SUPPLY SERVICES
As your clinical supply partner, we solve unique challenges to reliably supply clinical studies of all sizes and complexity. Our clinical supply services include clinical supply management and optimization, global comparator and reference product sourcing, manufacturing and packaging, specialty handling and cold chain solutions, clinical storage, distribution and returns management.

INTEGRATED PACKAGING
A broad range of packaging solutions can be integrated with our global manufacturing options for a tailored solution that helps optimize your supply chain, reduce cycle time and inventory levels, and simplify release and invoicing procedures for lower overall supply chain costs.

REGULATORY CONSULTING
With over 50 years of experience across a wide range of therapeutic areas for global markets, we help you maximize your product value with expert development solutions. From pre-clinical to life-cycle maintenance, we help ensure accurate, timely regulatory submissions, which can minimize development timelines and maximize the probability of success.

Discover more solutions with Catalent. Call: +1 888 SOLUTION (765-8846) Email: solutions@catalent.com Visit: www.catalent.com
more products.
better treatments.
reliably supplied.

Challenge us. Let us help you get your products to market faster, stay there longer, and be more successful. Catalent Pharma Solutions. We are the catalyst for your success.

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