



DWK LIFE SCIENCES
DURAN WHEATON KIMBLE

READY-TO-USE & CUSTOM SOLUTIONS



DWK Life Sciences SALES PARTNER

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01 PARTICULATE CLEANING



Description

DWK Life Sciences offers reliable cleaning services for primary packaging components and labware. Using certified processes, components are cleaned with USP and WFI purified water and HEPA filtering, then packed in ISO certified 100/10 cleanrooms.

Components cleaned and validated to USP <788> and EP 2.9.19 microscopic particle counts are ready-to-sterilize or ready-to-use.

For select parenteral content, our particulate cleaning process can include an IPA or HCL pre-wash to remove any unbound salts on the interior surface.

Why partner with DWK Life Sciences?

✓ Convenience

- All products come with complete documentation and certification to meet regulatory requirements
- Capable of processing glass and plastic products
- Capable of processing closures and components

✓ Flexibility

- Water for Injection (WFI) rinse or cleaning
- USP purified water rinse
- Capable of processing large or small-volume containers
- Small to large volume processing and custom packing of primary packaging container closure systems

02 DEPYROGENATION



Description

Parenteral drug products must be manufactured to strict sterility guidelines using well-documented and validated aseptic processes. To meet this need, DWK provides our customers with glass vials prepared using validated procedures that ensure the removal of bacterial endotoxins to acceptable endotoxin limits (0.25 EU/ml). Each glass vial is subjected to high dry heat treatment and multiple WFI rinses to destroy pyrogens and vacuum packaged within an ISO clean room environment for terminal sterilization.

Why partner with DWK Life Sciences?



Convenience

- All products come with full documentation and certification to meet regulatory requirements
- Save time and money processing products in-house
- Receive ready-to-sterilize product
- Eliminates internal processing and validation steps to reduce cost and improve workflows



Flexibility

- Dry heat treatment or multiple WFI rinses
- Vacuum sealed for extended shelf life
- Capable of processing large and small-volume containers
- Small to large volume processing and custom packing of glass primary packaging containers

03 STERILIZATION



Description

Regulators expect drug manufacturers to consistently meet and demonstrate compliance with sterile manufacturing requirements to ensure the delivery of clean, sterile, and safe drug products into the medical marketplace.

DWK helps our customers meet this goal by preparing sterile glass vials and RTU products under validated processes, within a clean room environment, and with strict quality assurance procedures, assuring the delivery of RTU products certified sterile.

All sterile glass vials and RTU products are enclosed in vacuum-sealed sterile transport bags within a clean room to ensure safe entry into your aseptic operation. RTU products come with full documentation and certification.

Why partner with DWK Life Sciences?



Convenience

- All products come with full documentation and certification
- Receive ready-to-use product
- Single, double, or triple autoclave bag options available
- Eliminates internal processing and validation steps to reduce cost and improve workflows



Flexibility

- We offer steam heat, gas, and irradiation - the choice is yours!
- Vacuum-sealed for extended shelf life
- Small to large volume processing and custom secondary packing of glass vials and plastic primary packaging components, closures, stoppers, and seals

04 SURFACE TREATMENT

WHEATON® HydroSurface360™



Description

Surface treatment of pharmaceutical glass packaging is an established protection method for most parenteral content and certain APIs and excipients that may interact with the glass surface. While the hydrolytic resistance of Type I Borosilicate glass makes it a suitable containment solution for most applications, some liquids, when in contact with an untreated glass surface, pose a risk of glass delamination, excessive surface adhesion, and fogging.

HydroSurface360™ siliconization formulation has been carefully engineered to bond a REACH compliant Dimethicone to the glass surface. Resulting in siliconized vials designed to protect sensitive biologics, maximize extraction of viscous and protein-based content, and the ability to reduce content adherence to the glass surface. The resulting hydrophobic surface can also improve the formation of lyophilization cakes and elastomer closure fit.

Siliconized glass is validated, white room packed in coroplast trays, and shrink-wrapped for shipment with lot traceability documentation.

Why partner with DWK Life Sciences?

✓ Convenience

- Minimize the interactions between the product and container
- Siliconization ensures a higher restitution rate down to the last drop
- Silanization lubricates the vial and protects against alkalization

✓ Flexibility

- Silanization lubricates the vial and protects against alkalization
- Siliconization decreases the risk of glass delamination, excessive surface adhesion, and fogging
- Ammonium Sulfate protects against aqueous products that can react with alkali metal ions that are found in glass

05 CUSTOM PACKAGING



Description

DWK offers custom secondary packaging services leveraging industry and proprietary packaging expertise. Rely on DWK to help you design a customized solution tailored to your specifications and operational workflows.

DWK's secondary packaging services are turnkey and inclusive of assembly, kitting, custom configurations, and cleanroom packaging. We can even protect your products in secondary packaging branded with creative visuals and graphics using eco-friendly materials to support your sustainability initiatives.

Whether you are interested in protecting wares during transport and warehousing or improving workflows, consider DWK's custom secondary packaging services. We can help you to streamline your supply chain management through single sourcing of containment systems formatted to your secondary packaging requirements.

Why partner with DWK Life Sciences?

Convenience

- Engineering and design support
- Custom packaging in a variety of specific configurations
- Inventory management and drop shipment capabilities
- Closures may be affixed in a cleanroom environment or packaged separately

Flexibility

- Individual or multi-unit cleanroom bags
- Single or double bagged, twist tie bags, multi-unit clean room and heat-sealed bags
- Shrink wrap, anti-static corrugated polypropylene trays, stainless steel trays, partitions, shelf packs

06 BARCODING & LABELING



Description

We are driven to improve how work flows. We leverage our expertise in custom marking to help you identify and track critical assets and inventory to improve your processes, performance, and control.

DWK Life Sciences can produce custom bottle labels and customize primary packaging components with alpha/numeric, barcode, and graduations. Custom markings can be applied to plastic and glass containers, and closure components to support traceability, positive identification, and anticounterfeiting of packaged content.

Primary packaging components can be delivered with pressure sensitive, custom marking, ceramic, and screen labeling to ensure data elements remain adhered to the container, read correctly every time, and are durable enough to withstand severe environmental conditions.

Why partner with DWK Life Sciences?

✓ Convenience

- Increase productivity by freeing up time spent weighing and barcoding
- Reduce valuable lab space devoted to weighing and barcoding projects
- Sequence management ensures no duplicate barcodes

✓ Flexibility

- Custom alpha/numeric barcode sequencing available to fit your application
- Choice symbologies: Code 39 and 128, 2D Matrix Code, QR Code, Interleaved 2 of 5
- Materials: Pressure sensitive, ceramic or direct mark

07 CUSTOM INSPECTION



Description

DWK offers custom inspection services leveraging industry and proprietary packaging expertise.

Through hands-on **manual** visual inspection and resorting, DWK assures products meet your most demanding cosmetic and conformance specifications. Allowing you to deliver the highest quality packaged product having visual appeal and being safe for use, and with minimal disruption to your **operations up to and including fill process**.

DWK's inspection services are turnkey and can be combined with resorting, reselection, assembly, kitting, custom packing configurations, and clean room packaging.

We can help you to streamline your manufacturing process, identify manufacturing issues, and reduce costs associated with time-of-fill rejection.

Why partner with DWK Life Sciences?

Convenience

- Identify non-conforming products
- Pre-fill quality control reduces time-of-fill rejection
- Controlled classification & separation
- Tailored, actionable reporting

Flexibility

- Custom AQLs levels
- Visual defects and structural anomalies
- Color consistency and surface finish
- Durometer & Compressibility
- With or without disassembly
- ISO Class 8 Clean Rooms

READY-TO-USE AND CUSTOM SOLUTIONS

We at DWK Life Sciences focus on simplifying workflows, sourcing, and meeting your unique requirements. We understand the complexities associated with packaging parenteral and sterile drug products. Our offering of ready-to-sterilize (RTS) and sterile ready-to-use (RTU) primary packaging components ship complete with a Certificate of Analysis (COA), lot control, and traceability documentation.

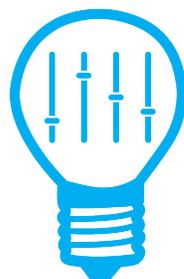
RTS and sterile RTU components can streamline your operation, allowing direct entry into your filling environment. Our ready-to-use offerings are available in small batch packs and large production run configurations. Other custom solutions include surface treatments to improve hydrophobicity, bar coding for traceability, and secondary packaging designed for your production environment.

We structure our secondary packaging to eliminate problems and maximize efficiencies. Our primary packaging components are offered in standard, case, bulk, and pallet quantities, with various custom secondary packaging configurations. Whether you want to make changes to materials, pack quantities, or labeling, we welcome your customization requests.



READY-TO-USE

RTS and RTU components are prepared to directly enter the drug production process



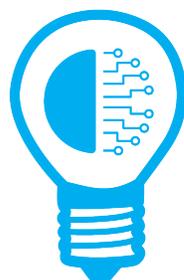
CUSTOMIZATION

We can process, prepare, label, and package components to your specifications



REDUCE RISK

All components are prepared using validated processes, meet industry standards, and include a COA



SIMPLIFIED SOURCING

DWK can provide glass and plastic primary packaging systems unprocessed, RTS, and RTU



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