DATWYLER

WHITEPAPER

“P.E.R.F.E.C.T.” the Packaging Selection Process

A step-by-step path to building confidence in packaging component selection for injectable drugs

By: Gabrielle Gehron, Technical and Scientific Expert

Packaging decision-makers for injectable drugs understand how critical it is to select the right components for vials, cartridges, and pre-filled syringes. The stakes are high. The performance failure of stoppers, plungers and other elastomer components can pose serious consequences to patient health and compromise overall trust in the company for years to come.

That's why Datwyler has developed the P.E.R.F.E.C.T. pathway for navigating drug packaging selection. It aims to simplify the decision-making process, offering guidance on key considerations at every juncture.

What does "P.E.R.F.E.C.T." mean?

Datwyler's acronym provides an easy way to remember the key criteria for parenteral packaging selection. It guides users through seven considerations, including:

- **P**articulate – The presence of foreign matter, such as fibers, dust, or dirt, can be harmful to patients and the drug manufacturing process. It is critical to keep drug packaging components free from sources of potential contamination. To do that, decision-makers must understand the categorizations, considerations, and compendia of particulate matter.
- **E**xtractables and Leachables – Migration of substances from a packaging component into a drug product can compromise formulation integrity. Advancing the chemical cleanliness of rubber components can help prevent potential contamination. To prevent migration of potentially harmful materials, decision-makers must know how to identify and analyze extractables and leachables.
- **R**egulatory – The regulatory requirements for injectable packaging continue to evolve, requiring biopharma professionals to keep up with the latest updates that impact the drugs they market. Complying with new and existing standards and requirements helps to mitigate risks, reduce costs, and ensure patient safety.
- **F**unctionality – Functionality looks different for every product type and application. From multipuncture vial stoppers to syringes with consistent gliding forces, evaluations can be designed by considering the individual parts and the overall goal of the system. This requires attention to details like break-loose, glide forces, stopper pop-up—and how certain storage conditions can impact performance.
- **E**ngineering Capabilities – Similar to machinability, this criterion analyzes the compatibility between drug

packaging components and the manufacturer's fill-finish lines. Components ought to work with efficient, high-performing lines, while minimizing potential disruptions. Together with component suppliers and machine manufacturers, companies can design and implement safe and effective lines.

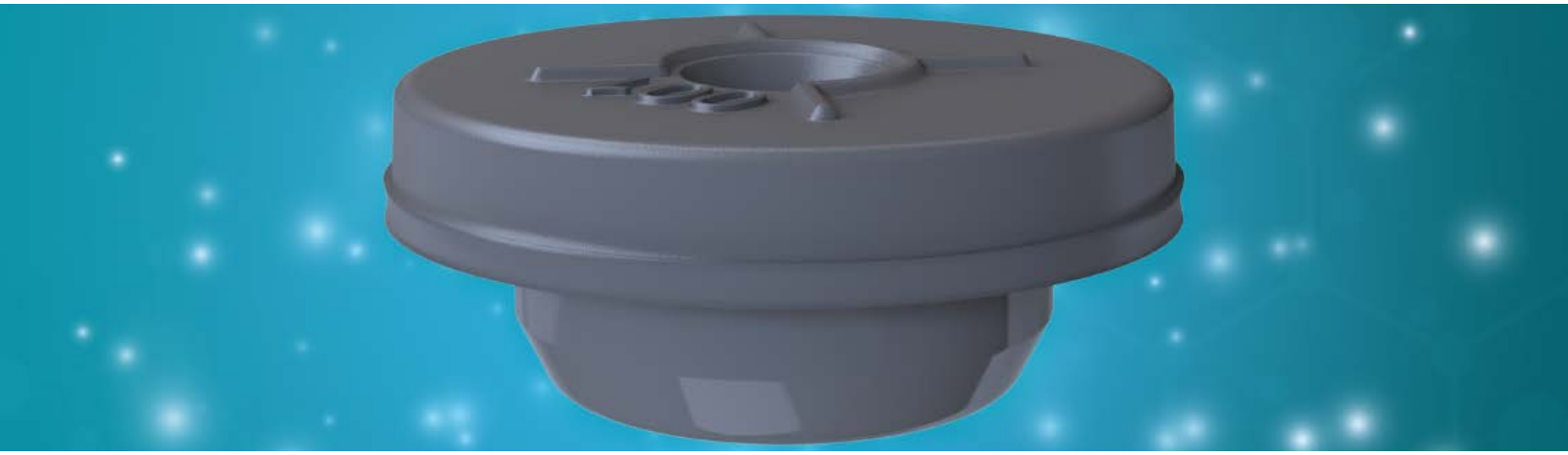
- **C**ontainer Closure Integrity – Once a vial, syringe, or cartridge has been filled with a drug product, no material should enter or leave the package until it is administered to a patient. This concept is measured through Container Closure Integrity (CCI) evaluations. A lack of CCI can result in wasted drug product, risks to patient safety, and a bad reputation for drug companies.
- **T**otal Quality – "Total Quality" refers to an overall assessment of the physical, chemical, and biological specifications agreed upon by the manufacturer and the recipient. This includes dimensional tolerances, wash and sterilization processing, and particulate, bioburden, and endotoxin limits.

With the process defined, each step can be explored in detail, letter-by-letter.

(P) Particulate

Particulates can include any foreign substances, such as fiber or dirt. Large, visible particulates pose the highest risk, as they can have the most severe medical and regulatory implications. Even in the cleanest of cleanrooms, a minute level of particulate should still be assumed to exist, and it can find its way into controlled drug products through a variety of avenues – including primary packaging components. While the presence of particulate is unavoidable, it can and should be reduced and mitigated as much as possible.

According to an analysis of Federal Drug Administration (FDA) recall data[1] , contamination, such as by particulate, microbiological contaminants, or chemical contaminants, is the leading reason for drug recalls. These contaminates likely stem from elements like glass delamination, undispersed active pharmaceutical ingredient (API), unfiltered drug product, or from the component manufacturing process. Simply put, particles pose a huge dilemma in drug manufacturing.



Size

Size can be considered in a variety of ways and particulates are often categorized into two groups: visible and subvisible particles. A particle is measured by its longest dimension. ISO 8871 defines "visible" particulate as those above 25 µm. Smaller particles are called "subvisible".

Many companies break size into even more precise groupings. Datwyler assesses the following size ranges:

2-5 µm
5-10 µm
10-25 µm
25-50 µm
50-100 µm
>100 µm

Material and Origin

Another way to categorize particulate is by material, which may be identified via visual inspection or through lab analysis. According to a Datwyler survey that analyzed quality data from component manufacturers and pharmaceutical companies, cellulose from paper is believed to make up 60.9% of particulate contamination in injectable products. Other commonly recognized materials were polyester (at 9.7%), silicone (3.8%), polyamide (3.2%), polypropylene (2.7%), and hair (2.1%).

Once you know the material, it is important to consider the origin. Inherent, intrinsic, and extrinsic particles can be classified based on how fixed they are in the rubber component. If they are merely on the surface of the product, they are considered "loose." If they are partially or fully stuck beneath the surface of the product, they are "embedded." Determining if the particle is loose or embedded can hint at the stage in the manufacturing process at which the particle may have been introduced.

[1]Buntz, B. (2023, April 20). 5 core trends in drug recalls: An analysis of 2022 and Q1 2023. Pharmaceutical Processing World. Retrieved March 20, 2024, from https://www.pharmaceuticalprocessingworld.com/drug-recalls-2022-2023-contamination-sterility-concerns/.

Detection Methods

USP <788> defines two methods for the determination of particulate matter: Light Obscuration and Microscopic Particle Count Test. Light Obscuration, used for both visible and subvisible particles, involves passing a sample through a controlled light source. Using a Particle Counter instrument, the amount of light blocked or obscured by particulate matter is measured and recorded. Microscopic Particle Count Testing involves visually inspecting a sample using a microscope to detect and quantify particulate matter. It is generally used for visible particles that may not be effectively measured by Light Obscuration.

Reducing Particulate Risk

Particulate risks can be different with different applications. Most commonly, injections come in three forms: Intravenous (IV), Intramuscular (IM), Subcutaneous (SC). One less-common route of administration is Intraocular (IO), also called Ophthalmic Injections. These highly specific injection routes present their own unique risks associated with particulate. As the eye is a very small, sensitive part of the human body, particulate must be especially limited. USP <789> addresses this explicitly, saying that "ophthalmic solutions should be essentially free from particles that can be observed on visual inspection" and recommending the Light Obscuration Particle Count Test or Microscopic Particle Count Test.

Overall, particulate is a critical consideration when choosing an elastomeric closure for a pharmaceutical injectable. The presence of particulate can lead to wasted product, decreased faith in the brand, and can even harm patients. For these reasons, particulate should be limited in every possible way.

(E) Extractables & Leachables

Extractables and leachables (often referred to as "E&L") are essential considerations in drug packaging. In this context, the term "extractables" refers to substances inherent to the rubber formulation which can be pulled out of components over time. "Leachables" refers to substances from rubber components which migrate into a drug product under normal storage conditions, specific to the pharmaceutical with which they are paired.

Using these definitions, we can see that a company which produces rubber components should have full knowledge of potential extractables, as they are inherent to the ingredients used in the creation of a rubber product. Leachables, however, are specific to the interactions between a single rubber formulation and a single drug product. Therefore, leachables must be evaluated for every individual combination thereof.

Risks of E&L

When considering E&L, the following goals should be targeted:

- The drug product does not lose any efficacy due to E&L.
- The drug product does not become dangerous to the patient due to E&L.
- Any substances formed in a reaction between the drug product and the packaging are not harmful to the patient.

A toxicologist may be employed to analyze shelf life leachables data and its potential risks to a patient. Any risks present must be multiplied by recommended dosage over a given period of time; therefore, something given once or rarely (like a vaccination) might have a different threshold for leachables than a daily (or multiple-times-daily) injection such as insulin. Indeed, different patient populations (such as infants, the elderly, or those with immunodeficiencies) may require different safety considerations as well. A third factor is route of injection; an intramuscular injection, for example, may have a different tolerance for leachables than an injection into an eye.

Taking into account the leachables observed while the product is on stability, the dose and frequency of the injection, the patient population, and the route of administration, each drug product can be individually evaluated for E&L risk.

Spray and Film Coatings

One way to minimize E&L is to use a stopper or plunger with a spray or film coating. This provides a physical barrier between the drug product and the rubber formulation, helping to decrease interactions between the two (and any undesirable substances that could result).

(R) Regulatory

Every country has laws. In the pharmaceutical packaging sector, relevant laws are put forth by government bodies assigned to protect the health and safety of their citizens. International guidelines also play a part in standardizing these regional laws.

It is important to differentiate between institutions that help to set standards and institutions that enforce standards. Typically, the enforcing institutions are the ones that receive applications to allow pharmaceuticals to be made commercially available in their markets. For example, a drug may be USP-compliant in the United States, but it will be submitted to the FDA for approval – and the FDA will be the institution to investigate, should any documentation be awry.

The below table identifies the regulatory agencies who set and enforce standards in various regions:

Region	Standards	Enforcement
United States	United States Pharmacopoeia (USP)	Food and Drug Administration (FDA)
Canada	British Pharmacopoeia (BP)	Health Canada
Mexico	Mexican Pharmacopoeia (FEUM)	Federal Commission for the Protection from Sanitary Risks (COFEPRIS)
United Kingdom	British Pharmacopoeia (BP)	Medicines and Healthcare products Regulatory Agency (MHRA)
Europe (not UK)	European Pharmacopoeia (EP)	European Medicines Agency (EMA)
Japan	Japanese Pharmacopoeia (JP)	Pharmaceutical and Food Safety Bureau (PFSB)
China	Chinese Pharmacopoeia (YBB or ChP)	National Medical Products Administration (NMPA)
India	Indian Pharmacopoeia Commission (IPC)	Central Drugs Standard Control Organization (CDSCO)

Regulatory Risk

From 2020 to 2023, the pharmaceutical industry has seen an increase in FDA 483 warning letters, a notice where deficiencies were observed in quality systems or conditions that violate the Food, Drug, or Cosmetic Act in the United States. The notices were issued across several program areas, including biologics, devices, drugs, and veterinary medicine, underpinning the importance for drug and component manufacturers to verify that their processes are as clean and safe as possible as regulatory bodies become more stringent.

In addition to parenteral drug manufacturers maintaining alignment with regulations, suppliers must also comply with these regulations, and they can support their customers by providing parts that will be compatible with those regulations. By choosing a supplier that aligns with and prioritizes core regulations, drug manufacturers can be assured their products will follow the highest standards required.

(F) Functionality

Pharmaceutical elastomers do not operate by themselves (though some may work in a vacuum – pun intended). Rather, they operate within a system of components, typically including a glass or polymer container alongside a metal closure. Three common configurations include vials, syringes, and cartridges.

Each system (vial, syringe, cartridge) is assembled in a different way, and functions uniquely. Many factors affect functionality, including the elastomeric components, the glass or polymer components, the drug product, the administration of the drug product, and how all these factors work together to perform as a system.

Vial Systems

A vial system is composed of three main components:

- Vial, typically made from glass or a hard polymer.
- Stopper, typically made from rubber.
- Seal, typically made from aluminum and/or plastic.

Functionality of a vial system can be evaluated in the following areas:

- **Coring and Fragmentation** - The tendency of a stopper to allow chunks of itself to be cut out by a needle (referred to as "cores"), or to allow chunks of itself to be dislodged into the vial (referred to as "fragments").
- **Self-Sealing** – The ability of a stopper to maintain container closure integrity (CCI) after a puncture.
- **Multipuncture** – The ability of a stopper to be punctured multiple times without creating significant numbers of cores or fragments, and while maintaining resealability.
- **Penetration Force** – The amount of force required to insert a retrieval device – typically either a needle or a closed system transfer device (CSTD) – through a stopper.
- **Push-In** – The tendency of a stopper to be driven into a vial when a CSTD is applied.
- **Spike Retention** – A measure of a closed package's ability to be fully penetrated by a spike and to retain the spike during the product dosing time period.

Syringe Systems

A syringe system is composed of four main components:

- Plunger Rod, typically made from plastic.
- Plunger, typically made from rubber.
- Syringe Barrel, typically made from glass or a hard polymer.
- Needle, typically made from metal.

Functionality of a syringe system can be evaluated in the following areas:

- **Break-Loose Force (BLF)** – The force required for a plunger to move, after beginning in a motionless state.
- **Glide Force (GF)** – The force required for a plunger to maintain movement once it is in motion. This is often measured as a force over time, in which consistent glide force is key.
- **Plunger movement during transport** – The largest displacement from its original position experienced by a plunger during transport (or in conditions that simulate transport).

Cartridge Systems

A cartridge system is composed of three main components:

- Plunger, typically made from rubber.
- Cartridge Barrel, typically made from glass or a hard polymer.
- CombiSeal, typically made from a rubber component and a metal component.

Functionality of a cartridge system can be evaluated similarly to the functionality of a syringe.

(E) Engineering Capabilities

Similar to manufacturability, "engineering capabilities" evaluate how components move on a fill/finish line. For example, a component that is under-lubricated may stick to machining lines, resulting in a cessation of fill/finish until operators can resolve the issue. However, over-lubrication can result in excess residue on lines and in the end-product, creating unnecessary particulate.

Different components may experience different issues during fill/finish. Below, each component listed is accompanied by a common manufacturing issue, as well as related root causes and potential solutions.

Machining Serum Stoppers

Common Issue: Stickiness

- **Definition:** A condition in which elastomeric components cling to each other, and in which components are not easily separated by the progression of a fill/finish line.
- **Effect:** Excessive stickiness can lead to jams on a line and can result in undesirable amounts of human intervention required to separate components from each other.
- **Cause:** Rubber is inherently sticky. Without appropriate levels of coatings or films, components will stick together.
- **Solutions:** Adding coatings and films to the components, or using these throughout the fill/finish process, can help to abate stickiness. It is also possible to manually massage bags of product to try to alleviate coupling.

Machining Lyophilization Stoppers

Common Issue: Twinning

- **Definition:** When two stoppers physically entangle, typically involving the "legs" of a lyophilization stopper.
- **Effect:** Twinning can lead to jams on a line and can result in undesirable amounts of human intervention required to separate components from each other.
- **Cause:** The geometric design of the stopper can greatly contribute to the frequency of twinning.
- **Solutions:** Excessive twinning is typically solved by changing to a different stopper design or increasing the level of coating used.

Machining Vial Seals

Common Issue: Bulging

- **Definition:** The squeezing of rubber up and through the hole of the aluminum skirt of a vial seal after capping.
- **Effect:** Bulging gives an undesirable aesthetic for drug administrators prior to injection. This can cause them to fear that something is wrong with the product, leading to excessive disposal of otherwise "good" product.
- **Cause:** Excessive capping forces, potentially compensating for short skirt lengths.
- **Solutions:** Decreasing capping forces can help, potentially in combination with a longer seal skirt.

Machining Plungers

Common Issue: Forces, Friction, and Heat at High Speeds

- **Definition:** Increased forces, friction, and/or heat at the site of plunger placement.
- **Effect:** This can cause damage to the surface of the rubber component during placement, including to the film/coating (see below). High enough forces can cause vent tubes to "pop," often requiring human intervention. If this occurs with enough frequency, line times will suffer.
- **Cause:** Typically, high amounts of force (which can cause friction and high temperatures) occur at higher line speeds. Significantly high amounts of force can occur when there is not enough lubricity in a system.
- **Solution:** Decrease line speeds and/or increase lubricity of the system (for example, by introducing additional amounts of coating).

Machining CombiSeals

Common Issue: Short Skirts

- **Definition:** When the skirt length of an aluminum seal is too short to sufficiently cover the height of the compressed stopper flange while maintaining a secure latch under the lip of the vial.
- **Effect:** The effect of a too-short seal skirt may be lack of CCI, which is dangerous to the patient. Any systems without a proper seal should be immediately discarded.
- **Cause:** There are two main causes for a too-short skirt:
  - Improper fit between vial, stopper, and seal
  - Low crimping force
- **Solutions:** Depending upon which cause is most likely (or most easily remedied), solutions may include:
  - Changing component designs (including purchasing a seal with a longer skirt, a stopper with a shorter flange, or a vial with a shorter lip)
  - Increasing crimping forces (which will increase the compression of the stopper and push the seal skirt further down the vial lip)

Machine Testing

To ensure components will run successfully at a drug manufacturer's plant, newly purchased components must go through Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT.) While FAT requires the supplier to run a product through testing at the site where a filling machine is made, SAT requires testing at the drug manufacturer's final filling site. Both tests aim to mitigate problems on the final fill line at a drug manufacturer's site and address potential issues well before that stage. Companies who have established fill/finish lines may prefer to use components that will require only minor adjustments to their lines, when possible, across all their projects.

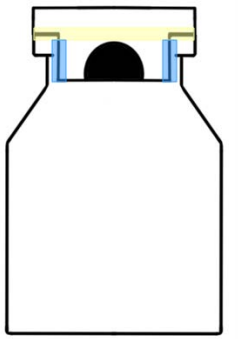
(C) Container Closure Integrity

Container Closure Integrity (CCI) can be defined as "the prevention of transfer of material into or out of a container closure system." In a system with good CCI, potential contaminates will not be able to enter the system, and pharmacological material will not be able to exit. Each of the three systems below (vial, syringe, cartridge) should be able to achieve CCI once the rubber component has been added and should be maintained throughout the shelf life of a system. This is achieved in different ways for each configuration.

Evaluating CCI in Vial Systems

There are two circumstances in which a vial's CCI must be evaluated. The first includes only the vial and the stopper; the second also includes a capped seal. Once a vial has been stoppered, nothing should be able to enter or exit the system. However, this is much easier to guarantee once a seal has been capped onto the system.

When a vial is stoppered, it is possible that it will not be capped immediately. In this case, CCI must be ensured until a seal can be properly capped onto the system. When considering only a stopper and vial, two important areas of contact include the "Land Seal" (below, yellow) and the "Valve Seal" (below, blue). The land seal is the area on the bottom of the stopper flange that meets the top of the vial lip. The valve seal is the area of the stopper plug that meets the inner neck of the vial.



Interference fit is measured in the valve seal area and can predict CCI performance. To evaluate interference fit, the dimensions of the stopper plug and the inner vial neck must be known. Comparing these two numbers, it is possible to determine how much the stopper will need to compress to fit into the vial. Too much required compression can result in the stopper not fitting in the vial, or "popping out," which can result in loss of CCI. Too little compression, and CCI may not be achieved at all.

Once a seal has been capped onto the system, the pressure applied to the stopper helps to guarantee CCI is maintained at the land seal as well. However, this is only true if a proper fit between seal, stopper, and vial is achieved. To evaluate "stack-up," or the dimensional compatibility of these three components, the height

of the vial lip, the height of the stopper flange, and the length of the seal skirt are needed. This, together with the expected percent compression of the stopper flange, can determine whether a proper fit is found.

Evaluating CCI in Syringe and Cartridge Systems

Syringes and cartridges both utilize rubber plungers to obtain CCI after filling with drug product. As with vials, interference fit is an important criterion for assessing whether a given system is expected to work well. For syringes and cartridges, the important dimensions include the inner diameter of the barrel and the outer diameter of the plunger. As the rubber plunger compresses in the barrel, the percent of interference can be assessed.

The size of the plunger is critical to the function of the syringe or cartridge system. If the plunger is too small, CCI may not be achieved. If the plunger is too large, it may not fit in the barrel, or may cause excessively high break-loose forces.

Methods for CCI Evaluation

CCI can be evaluated using methods considered either "deterministic" or "probabilistic". Deterministic methods are more repeatable and predictable. Probabilistic methods, while popular historically, incorporate some level of randomness. USP <1207> states that "deterministic leak test methods are preferred over probabilistic methods". Below, methods of each type are listed:

- **Deterministic Methods**
  - Vacuum Decay
  - High Voltage Leak Detection (HVLD)
  - Oxygen Headspace
  - Helium Leak
- **Probabilistic Methods**
  - Dye Ingress

(T) Total Quality

The term "quality" can refer to a certain aspect, caliber, or agreed-upon standard. In this context, quality refers to measures of a product's physical, chemical, or biological state that are previously agreed upon by manufacturer and recipient. A deviation from this agreed-upon state can result in action by the recipient, manufacturer, or both.

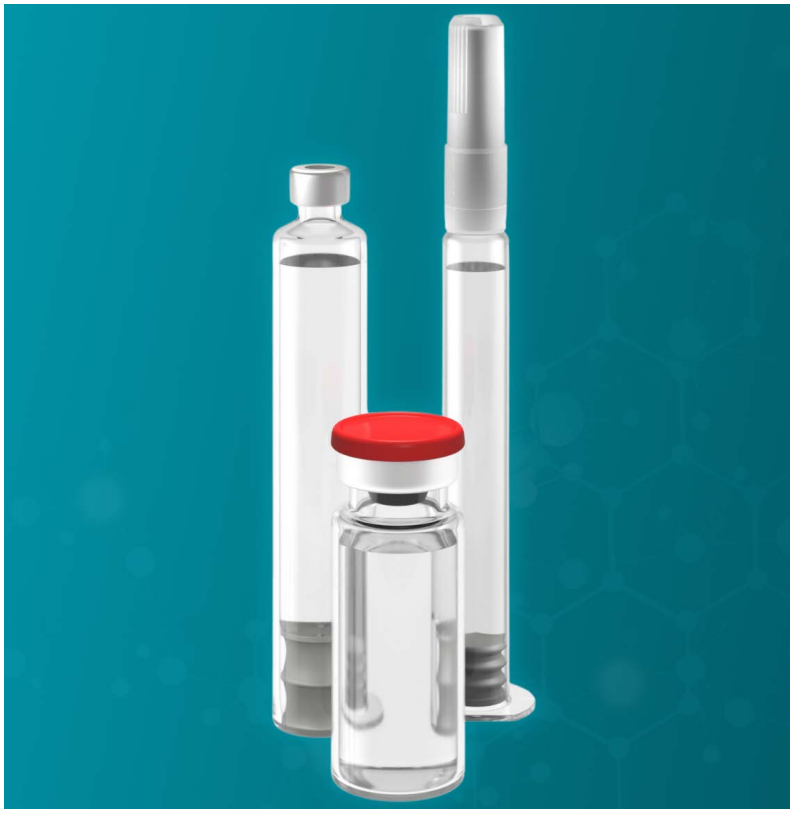
In considering the "total quality" of packaging components, one must consider physical, chemical, and biological quality, as well as compliance to Good Manufacturing Practices (GMP).

Physical Quality

The physical quality of a product is ruled by its mold. This creates the size, shape, and geometry of a product, all of which are detailed in the product's drawing. A drawing is a promise from the manufacturer of the physical quality of a component; drawings will contain nominal (or 'goal') dimensions, as well as tolerances within which the component must exist. Tolerances may be determined by the manufacturer (sometimes in collaboration with the recipient), but are guided by DIN-ISO 3302, "Tolerances for Rubber Molded Parts." Though it is possible and acceptable to deviate from the tolerances set by ISO, the default assumption for any tolerance-less dimension on a drawing is to refer to this standard.

Chemical Quality

Most elastomer manufacturers have documents defining the attributes of their formulations and coatings. Any that apply to a specific product should be provided



to purchasers. At Datwyler, Compound Data Sheets detail compliance information, identification information (such as ATR-FTIR spectra), and physical properties (such as hardness) for individual formulations.

Chemical quality deviations are rare, since formulation recipes are highly controlled. Amounts, ingredient origins, and processing steps are strictly followed (and sometimes automated to increase consistency) to maintain consistent products. The same is true of films and coatings, whether produced by the elastomer manufacturer or outsourced.

After manufacturing and coating, products will often undergo final treatments such as washing, steam sterilization, and/or gamma sterilization. These contribute to both the chemical and biological quality of a product.

Biological Quality

The cleanliness of parenteral products is commonly addressed in quality agreements. Three important criteria include Particulate (addressed in the first post in this series), Endotoxin, and Bioburden, all of which should be minimized as much as possible.

- Particulate - "Mobile undissolved particles, other than gas bubbles, unintentionally present in the solutions" (USP)
  - Compendia: USP <788>, USP <789>, USP <790>, EP 2.9.19, EP 2.9.20, JP 6.06, ISO 8871-3
- Bioburden - The number of bacteria living on a surface
  - Compendia: USP <61>, EP 2.6.12
- Endotoxin - Toxic heat-stable lipopolysaccharides released from a cell when the cell is destroyed; endotoxins are considered pyrogens.
  - Compendia: USP <85>, EP 2.6.14

Compliance

All companies, even those acting in accordance with the highest-level Good Manufacturing Practices (GMP) and in the cleanest environments, should assume that particle contamination, leachable materials, and under-performing packaging components are potential threats that can result in wasted time, money, and resources. However, if drug packaging components are produced in an environment designed entirely around quality control, these issues can be mitigated.

What's the Next Step?

In an environment awash with complications from the COVID-19 pandemic, increasing regulations, and higher quality standards, the pharmaceutical industry must continue to serve patients and caregivers. When drug manufacturers are better able to understand and evaluate their packaging components, they gain agency and confidence in their decisions. "P.E.R.F.E.C.T.-ing" the packaging selection process can be made easier by beginning with a dedicated checklist and partnering with reputable suppliers. By implementing these measures, pharmaceutical companies can achieve increased success and overcome whatever challenges still lie ahead.

Visit https://healthcare.datwyler.com/navigate-through-the-pharmaceutical-packaging-selection-process-with-confidence to learn more about Datwyler's P.E.R.F.E.C.T. drug packaging selection process or contact Datwyler's team at healthcare@datwyler.com to get started.

After manufacturing and coating, products will often undergo final treatments such as washing, steam sterilization, and/or gamma sterilization. These contribute to both the chemical and biological quality of a product.

Biological Quality

The cleanliness of parenteral products is commonly addressed in quality agreements. Three important criteria include Particulate (addressed in the first post in this series), Endotoxin, and Bioburden, all of which should be minimized as much as possible.

- Particulate - "Mobile undissolved particles, other than gas bubbles, unintentionally present in the solutions" (USP)
  - Compendia: USP <788>, USP <789>, USP <790>, EP 2.9.19, EP 2.9.20, JP 6.06, ISO 8871-3
- Bioburden - The number of bacteria living on a surface
  - Compendia: USP <61>, EP 2.6.12
- Endotoxin - Toxic heat-stable lipopolysaccharides released from a cell when the cell is destroyed; endotoxins are considered pyrogens.
  - Compendia: USP <85>, EP 2.6.14

Compliance

All companies, even those acting in accordance with the highest-level Good Manufacturing Practices (GMP) and in the cleanest environments, should assume that particle contamination, leachable materials, and under-performing packaging components are potential threats that can result in wasted time, money, and resources. However, if drug packaging components are produced in an environment designed entirely around quality control, these issues can be mitigated.

What's the Next Step?

In an environment awash with complications from the COVID-19 pandemic, increasing regulations, and higher quality standards, the pharmaceutical industry must continue to serve patients and caregivers. When drug manufacturers are better able to understand and evaluate their packaging components, they gain agency and confidence in their decisions. "P.E.R.F.E.C.T.-ing" the packaging selection process can be made easier by beginning with a dedicated checklist and partnering with reputable suppliers. By implementing these measures, pharmaceutical companies can achieve increased success and overcome whatever challenges still lie ahead.

Learn more about Datwyler's P.E.R.F.E.C.T. drug packaging selection process.

Learn more

Contact Datwyler's team at healthcare@datwyler.com to get started.

About Datwyler

Datwyler is focusing on high-quality, system-critical elastomer components and has leading positions in attractive global markets such as healthcare, mobility, general industry and food & beverage. With its recognized core competencies and technological leadership, the company delivers added value to customers in the markets served. With more than 20 operating companies, sales in over 100 countries and more than 7,000 employees Datwyler generates annual sales of more than $1,000 million. Within the healthcare solutions business area, Datwyler develops, designs, and manufactures solutions for injectable packaging and drug delivery systems to facilitate customers to create a safer medical environment of tomorrow. Looking back onto more than 100 years of history, Datwyler is a reliable partner, now and in the future! The company has been listed on the SIX Swiss Exchange since 1986 (security no. 3048677).

www.datwyler.com

DATWYLER