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OMNISEAL SOLUTIONS™ WHITE PAPER

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Going Beyond In The Medical Devices Industry: Advanced Materials With USP Class VI Certification Standard

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Going Beyond In The Medical Devices Industry: Advanced Materials With USP Class VI Certification Standard

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Abstract

Omniseal Solutions™ is a global engineering leader with over 65 years of historical legacy, relentlessly dedicated to the design and manufacture of precision sealing and material solutions that protect critical applications in the most demanding environments. For life science applications, Omniseal Solutions™ provides components and materials that test purity in pharmaceuticals, diagnose disease to provide vital treatment, protect surgical devices for lifesaving procedures, and support home health mobility to better quality of life. Our life science teams around the world are relentlessly dedicated to collaborating with our customers to design creative solutions with unique tailored material formulations in order to allow their use in an extensive range of applications with challenging requirements: broad temperature, large pressure range, wide chemical compatibility, biocompatibility, and especially certification for extreme conditions.

The focus of this technical white paper is to illustrate the advantages of receiving USP Class VI certification in terms of high performance, safety and trust for medical devices. This certification is regularly a requirement for medical devices to be approved for use in the United States and since materials are tested for biocompatibility, it is most likely that they are then given the "medical grade" designation. This white paper will provide an overview of the USP Class VI certification, including the requirements, tests, and processes involved, as well as its importance to the medical device industry. Additionally, this paper will discuss the challenges that the medical device industry faces in meeting the USP Class VI standards and how these challenges can be addressed with our solutions and expertise.

The Importance of Biocompatibility Within The Life Science Industry

In today's healthcare sector and especially within the life science industry, material biocompatibility is a vital component of medical device safety. ***How do biomaterials interact with our human bodies and how does this impact the clinical success of medical devices we use every day (e.g., pacemakers, continuous glucose monitors, syringes, ultrasound scanners, and prosthetics)?*** As a result of these life impacting influences, the medical device industry continues to be one of the most strictly regulated sectors.

That is one of the reasons medical device manufacturers need to unconditionally consider the regulatory requirements of their medical devices as well as account for complicated variables associated with these interactions. Therefore, for all types of medical devices and biopharmaceutical manufacturing, biocompatibility testing is essential.

1. The components of any medical device must be confirmed to have no harmful reactions or long-term bodily effects caused by chemicals within plastic materials or trigger undesirable biological reactions within a patient.
2. The components of any medical device must also be verified for human usage in order to test for any possible adverse physiological impact or hazardous reaction due to the complexity of the enormous system in the human body.

The most relevant certification procedure for biocompatibility testing is USP Class VI and can be used in a wide range of medical applications. Material selection in medical devices has always been a challenging task for the designer and engineer; however, one priority that can be agreed upon is USP Class VI certification.

The USP Class VI Certification: Tried, True & Tested

What is USP Class VI certification?

United States Pharmacopeia (USP) Class VI is the biocompatibility test most used in the medical device industry. A scientific and non-profit organization, USP oversees the safety for all healthcare products manufactured and sold in the U.S. and 140 other countries. As the official public authority in this sector, USP's standards are used to inform decision-making at the U.S. Food and Drug Administration (FDA), publishing test instructions for plastic, polymer and elastomer materials.

Materials are divided into one of six classifications based on their unique function as well as other considerations such as the amount of patient contact time (short, protracted, or permanent). The most restrictive designation—and hence the one that is most helpful for medical applications—is USP Class VI. Among USP classes, Class VI materials meet the toughest testing requirements.

Why is USP Class VI testing considered a widely accepted certification in the medical device industry?

In efforts to reduce variance and boost performance, today's clients are demanding more material knowledge and consistent procedures due to rapidly evolving technology and rising regulatory requirements. When using materials that meet USP Class VI standards, there is generally a higher quality level of assurance as well as better acceptance with the FDA and USDA since materials should substantially lower the chance of patient injury or elevated stress due to a toxic material interaction. As a result, substances that do adhere to USP Class VI requirements are extremely desirable to manufacturers of medical devices.

How is the USP Class VI certification assigned?

Assigned by the United States Pharmacopeia, the following are three in vivo biological reactivity assessments that are part of the USP Class VI testing:

1. Acute Systemic Toxicity (Systemic Injection) Test**:** Evaluates the toxicity and irritability of a chemical whether it is ingested, injected topically, or breathed;
2. Intracutaneous Test: Measures toxicity and localized irritation when the sample is in contact with live subdermal tissue (specifically, the tissue that the medical device is intended to be in contact with);
3. Implantation Test: Evaluates the toxicity, infection, and irritability of a substance implanted intramuscularly into a test animal over a period of days.

By passing these three tests, the material must not only show a very low level of toxicity, but it must also withstand a number of temperature assessments over predetermined lengths of time.

What are the material certification benefits?

Achieving USP Class VI accreditation can be highly advantageous in terms of operational functionality but also building trust. Suppliers whose products require a high level of biocompatibility can do so without adding extra time or cost. First and foremost, medical manufacturers need to produce parts with minute tolerances, extreme precision, and exacting specifications. Any technical advantage can make the difference in reducing waste, increasing profitability and boosting production.

Commonly recognized by manufacturers and engineers, a USP material certification has a qualified standing worldwide and enables a competitive level of investment, making it excellent for a wide range of medical components and essentially, their end users.

Our Advanced & Certified Material Solutions That Go Beyond

Omniseal Solutions™ offers a complete line of USP Class VI certified materials through our Rulon® and high-performance polymer solutions - intended to be used for the containment of fluids and suspensions during transportation, processing, incubation, storage and cryopreservation. Rulon® and polymer materials are proprietary material formulations and an excellent choice for cell culture as they offer permeability to oxygen and carbon dioxide, remain impermeable to water and are highly chemical resistant.

Due to our global presence as well as local resources, our business demonstrates rapid response and agility every day, developing precision solutions in a wide range of designs that most often require tight tolerances. Working closely with key life science customers, our Rulon® and material experts have acquired the knowledge to improve manufacturing processes. Not all materials fit all processes and understanding which material and which process fits best ensures that our team designs "right the first time," creating finished and reliable parts for our customers.

The following Table 1 includes several of our certified materials that are widely used in medical devices due to benefits relating to wear, friction, chemical compatibility, or extreme temperatures.

Table 1: Our Certified USP Class VI Material Solutions

Material Name	Certification	Feature & Benefit
Rulon® J	USP Class VI/FDA	Extremely low friction, with good performance against soft mating surfaces
Rulon® 641	USP Class VI/ FDA/EU1935/2004	Excellent load and wear characteristics
Rulon® 907	USP Class VI	Excellent all-purpose, high wear resistant material
Rulon® 1439	USP Class VI/ FDA	Perfectly suitable for immersed service with better wear characteristics than most other PTFE compounds
A09	USP Class VI	Recommended for long wear life under severe conditions
A12	USP Class VI	Excellent for dry running applications against soft surfaces
A20	USP Class VI	Low gas permeability and good cryogenic properties
A41	USP Class VI	Excellent all-purpose high wear resistant material
A46	USP Class VI/FDA/ EU1935/2004	Good wear resistant material against all stainless-steel counter faces
A47	USP Class VI/FDA/ EU1935/2004	Very good wear resistant material under wet or lubricated conditions
A66	USP Class VI	Excellent performance in hostile chemical environments

As shown in the above Table 1, there are 11 certified materials, which is unique in that most other businesses may only have three or four certified materials in their solutions portfolio. Why such a big gap? You need knowledgeable subject matter experts (SMEs) and experienced engineers who can find the right balance between cost investment / savings and the necessary protection for medical device manufacturers, especially when it involves patient harm, lawsuits, or FDA recalls. Currently, USP Class VI testing can be achieved with reasonable turnaround; however, a global business like Omniseal Solutions™ (who works with life science materials every day) gives partners a technology advantage, offering a robust level of biocompatibility without incurring additional time to market (TTM) or cost overspending.

Proper guidance from material suppliers will certainly help you navigate through challenging regulations and complex testing. All testing is done by an independent (third-party) laboratory and being certified for this large selection of materials shows that our business has taken the time and care on behalf of our customers.

Why do we have such a wide range of materials for the life science industry? You may not be aware that one of our polymer materials goes way back to the **Industrial Age when a pioneer, Ezra Dixon**, patented a metal bearing used on machines for spinning cotton yarn. The bearing became the global standard for this modest but nevertheless critical part. This relentless dedication to improve the performance of a simple mechanical component became the groundwork for the Rulon® fluoropolymer solutions you see today.

Rulon® Material's Proven Pedigree: Global History & Longevity

The Rulon® material and name became more visible in the early 1950s when Rulon® A, the first blended PTFE-material was developed by Omniseal Solutions™. Since this time, we have been the only provider of genuine Rulon® blended PTFE-filled materials, with hundreds of formulations created by our technical experts. The material is quite adaptable and diverse, used as bearings, piston rings, cup seals, wear components, and many other critical elements for many industries.

Our Rulon® and polymer materials are commonly used for life science, industrial, food and beverage (canning), and pharmacopoeia applications as they offer low coefficient of friction, high wear life, excellent abrasion resistance, chemical inertness, and the ability to operate in extreme temperature and pressure ranges. As part of the top tier in the high-performance plastics pyramid, our Rulon® fluoropolymer compounds complement our other polymer solutions, Omniseal® and Meldin®, ensuring that customers have the best of the polymer world.

With excellent wear resistance, friction control, superior chemical and corrosion resistance, low weight, and last but not least USP Class VI certification, our advanced materials provide our customers with the technology advantage that will position them at the forefront in the medical device world of tomorrow.

Due to Omniseal Solutions™ testing the Class VI materials from several of our worldwide plants, we ensure that the complete supply chain is available globally. This provides convenience and readily available access to our medical grade materials. Quality control is also ensured as formulations are unique to our business and cost-efficient for customers. During production, each new material batch is tested for quality in order to ensure that the mechanical property of the material meets material specification. Tensile strength, elongation, specific gravity, hardness and visual tests are conducted. During the production of the materials, all moulding and sintering parameters are controlled and checked towards our high-quality standards.

Verification by third-party testing confirms that our materials will handle challenging conditions in various medical devices. **Certificates are available for these life science applications – contact us!**

Biocompatibility At Work: A Closer Look At Some of Our Life Science Applications

One example of a USP Class VI requirement is for bioreactors that utilize flat blade impellers to rotate pharmaceutical manufacturing and require unique designs depending upon speed and chemical resistance. In bioreactor equipment, there are two components that Omniseal Solutions™ provides as both a seal and bearing option. These bearings and seals must be able to meet aseptic standards and biocompatibility.

1. Rulon® materials meet USP Class VI requirement to provide both chemical resistance and biocompatibility along with self-lubricating properties for bioreactor processes.
2. Rulon® 1439 has characteristics suitable for the application such as abrasive chemical resistance, excellent performance in high speeds, self-lubrication and long wear life.

Pharmaceutical Bioreactor Application Using Omniseal Solutions' Polymer Materials (Read Our Bioreactor Case Study)

Another example where biocompatible materials were required involves small mini motors that are implantable for a limited time and used to provide human fluid dynamics for improving medical illness. The motor is encased; however, the seal components protect internal electronics from ingress of bodily fluids. By requiring USP Class VI materials, this ensures biocompatibility and patient safety. In this application, our A12 polymer material was used due to its excellent wear resistance, dry running and moderate to high-speed service against soft or hard metals. The seal was tested to application requirements and passed longevity, chemical resistance, leakage and continuous running.

In surgical devices, our A46 polymer material is used for its wearability against stainless steel surfaces with required speed and rpm functionality. In addition, the material is beneficial due to its small or minimally invasive dimensions and repeatable autoclave resistance, which protect power source/electronics.

One of our widely used Class VI certified materials is our Rulon® A09 - valued for long wear life under severe conditions. This material is used in liquid chromatography reciprocating piston pumps for long service life and reducing maintenance requirements. Our seals have handled up to 2 million cycles and have been resistant to the unique and often harsh chemicals analyzed in liquid chromatography laboratory equipment. The pumps utilize high operational pressure up to 20,000 psi (1400 bar) and above. Due to the high pressures utilized, critical sealing is necessary in the plunger pumps to ensure analysis accuracy.

Seals are critical as they solve challenges such as chemical resistance as well as friction and wear control. In many instances, biocompatibility is a growing necessity, especially in biopharmaceutical product manufacturing, where there has been the biggest growth in this market.

Omniseal Solutions' Technology Advantage

A technical and innovative sealing material company

Industry standard certifications are the outcome of prior genuine internal test results, highlighting Omniseal Solutions' capabilities to address complex issues that call for seals and materials that may interact safely with the human body.

The outcomes will empower engineers to confidently use Omniseal Solutions' sealing materials in a wider array of medical devices. Our polymers will speed up research because they are "conforming" materials. Our seals can help medical OEMs and tier suppliers achieve higher standards of device performance, dependability, and safety.

Critical industry proprietary materials

Our large proprietary range of materials allows us to deliver high performance and precision solutions to our customers with the highest quality certification standards level for a variety of application needs. Our cutting-edge materials maximize performance while guaranteeing component integrity in a variety of wear components, including precision bearings, piston rings, cup seals, and wear components with high specification compounds.

That is why Omniseal Solutions™ offers a wide variety of FDA and USP Class VI certified materials for the required biocompatibility. Without this technology advantage, sealing function will be unreliable, causing major production losses.

Standardization for highest quality certification

The Rulon® properties and subsequent benefits help Omniseal Solutions™ solve many of the challenges in the medical device industry. As such, we have become recognized experts in manufacturing processes in facilities all over the world due to our standardization processes strategy.

Conclusion

Biocompatibility is one of the most important factors in the Life Science industry to ensure that materials not only withstand the chemistry and environment, but they also do not affect the environment and our human body.

Omniseal Solutions™ is relentlessly dedicated to the protection of our customers and the patients they serve, which is why we are constantly adapting to changes in this industry market and stringent requirements. Our solutions portfolio that includes 500+ unique compounded materials is even more enhanced with our newly Rulon® and USP Class VI certified materials. Engineered for your unique needs, these materials have been thoroughly tested and validated by the USP Class VI requirements (a process that is quite intensive), which make these materials available now to our global customers and local ones since they are produced at multiple locations.

As discussed in this white paper, USP Class VI certification is critical and valued in the medical device industry:

1. **Safety**: Materials are tested for human use so they will not cause any negative effects. As a trusted partner in life science, Omniseal Solutions™ has invested our technical expertise, time and cost in order to offer a wide range of materials that meet USP Class VI requirements for various medical applications that impact patient care: bioreactors, surgical devices, and liquid chromatography reciprocating piston pumps.

2. **High Performance:** Materials that meet USP Class VI requirements will continually support medical device manufacturers who need reliability and cost-effectiveness. Omniseal Solutions' materials have undergone rigorous testing to ensure they meet the necessary requirements for biocompatibility, aseptic standards, wear resistance, and chemical resistance.

3. **Trust:** USP is an independent, scientific, nonprofit organization that has been around for 200 years, and using USP's standards guarantee that safety and quality control reach patients. Omniseal Solutions™ also has its own global history and longevity, with material pioneers from the Industrial Revolution. Through the years, we have continued to innovate, develop, engineer and collaborate so that our customers can continue to go beyond in this field.

Ultimately, the use of USP Class VI certified materials can improve production efficiency, reduce waste, increase profitability, and most importantly, ensure the safety of patients when using medical devices. Please contact **our life science experts** so we can help you go beyond!

Other Ways To Connect

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Connect on LinkedIn

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