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HEUMANN ENVIRONMENTAL

MEETING BIOLOGIC DRUG STANDARDS WITH A HIGH SURFACE FINISH SPRAY DRYING SYSTEM

HIGH TAPS IN ACTION: MASTERING HIGH SURFACE FINISH CHALLENGES

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PRECISION FABRICATION FOR BIOLOGIC DRUG MANUFACTURING

The rise of biologic drugs, made from living proteins and genes, has increased demand for pharmaceutical systems that go beyond conventional cleanliness standards. The organic makeup of these medications, such as Humira, Enbrel, Breztri, and Tremfya, heightens the risk of spoilage, and requires extreme diligence during production. To meet these elevated standards, a pharmaceutical client producing one such biologic drug, turned to Heumann Environmental Company (HEC) for a precision-engineered spray dryer system.

AT-A-GLANCE: BUILT FOR COMPLIANCE, SURFACE INTEGRITY, AND DESIGN ACCURACY

- **ASME Code Stamped and CE Certified**

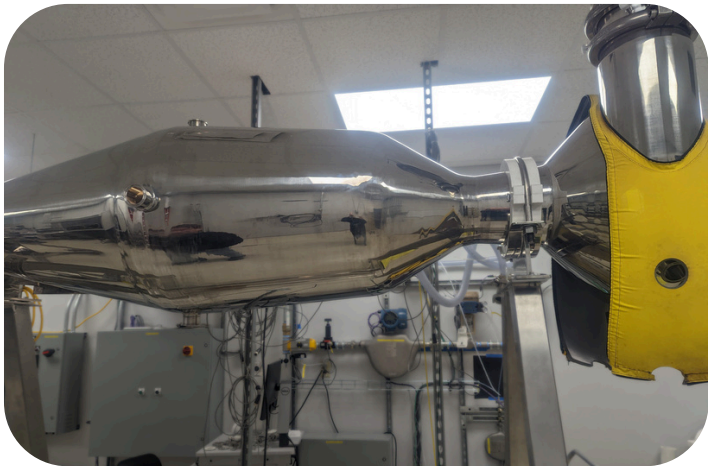
  Fabricated to ASME Section VIII, Division I standards and CE certified for 145 psig at 300 °F with full PED documentation.

- **Ultra-High Surface Finish**

  Interior and exterior surfaces polished to Ra <10 µin and electropolished for cleanability and product integrity.

- **Inside-Out Assembly for Internal Surface Access**

  Constructed from the inside out to allow internal polishing and match validated prototype geometry, ensuring consistent particle performance without regulatory rework.



THE CHALLENGE

HEC has spent the last decade supporting biologic manufacturing with custom spray drying and high efficiency cyclone recovery systems. In this case study, a pharmaceutical client selected HEC for our proven ability to design and fabricate ASME Code stamped and CE certified systems with complex geometries and elevated sanitary standards, critical for meeting both regulatory and product integrity requirements. Engineered to meet these stringent specifications, the vessel was fabricated from SA-240 316 stainless steel with ultra-high surface finish and assembled section by section to allow full internal access during polishing. The result is a precision-built, sanitary-grade system now in active use producing biologic medications.

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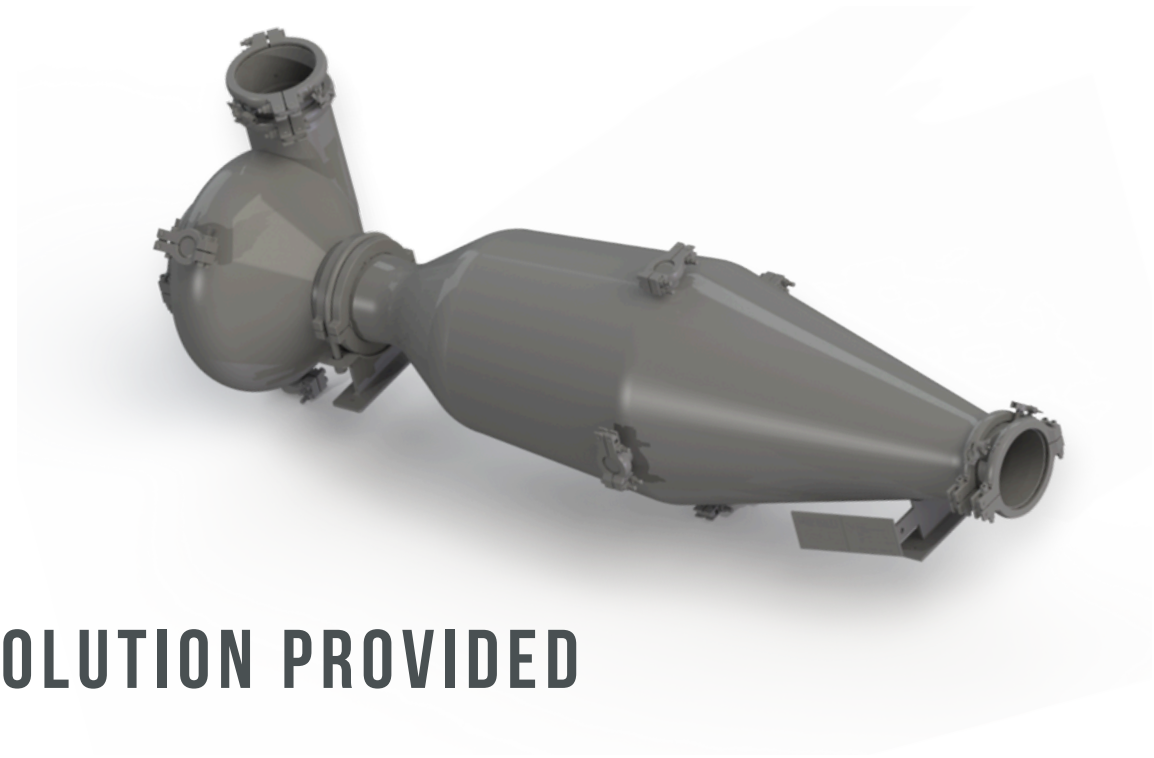


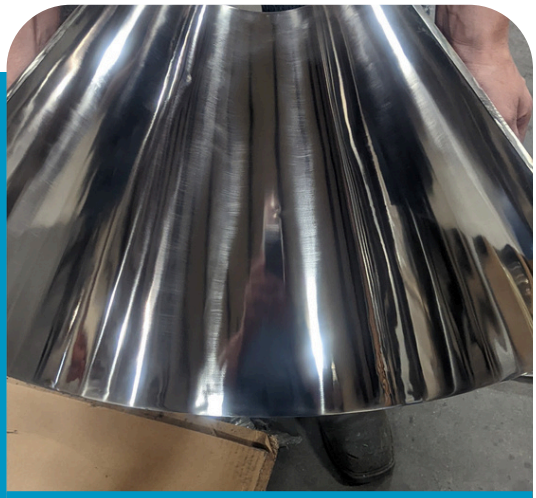
SOLUTION PROVIDED

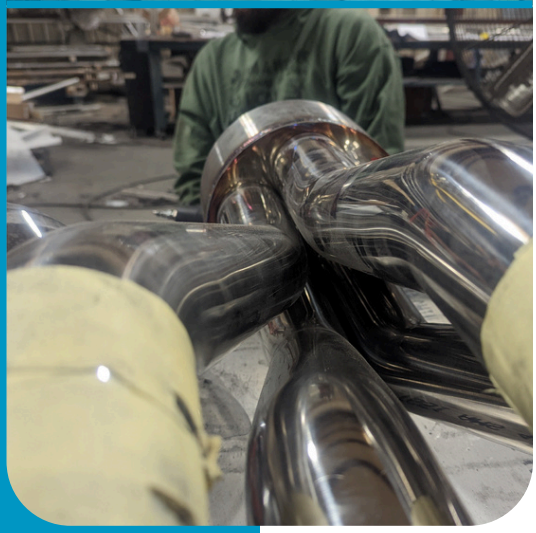
This ASME Code stamped, CE certified unit was rated for 145 psig to mitigate deflagration risk and required a highly specialized fabrication approach to meet ultra-smooth surface finish standards and complex geometry.

KEY SPRAY DRYER SYSTEM FEATURES

SYSTEM SPECIFICATIONS

- **MATERIAL OF CONSTRUCTION**: SA-240 316 STAINLESS STEEL
- **DESIGN PRESSURE:** 145 PSIG
- **SURFACE FINISH:** RA < 10 MICROINCHES (INTERIOR & EXTERIOR)
- **DESIGN TEMPERATURE:** 300 °F
- **PARTICLE SIZE:** PRODUCES ≈2 µM PARTICLES





ENSURING SANITATION IN INACCESSIBLE SPACES

The design constraints of this biologic spray dryer required a fundamental shift in how we approached fabrication and sanitation planning. With no internal manual access and no flanges allowed in the sprayer body, due to concerns over particle buildup and the additional thermal mass that pressure-rated flanges would introduce, we had to engineer the system for cleanability from the outset. These limitations necessitated not only an ultra-high surface finish but also a fabrication strategy that maintained strict sanitary standards while accommodating complex internal geometry.

ULTRA HIGH SURFACE FINISH FOR BIOLOGIC INTEGRITY

To exceed stringent cleanliness standards, HEC polished all internal and external surfaces to Ra < 10 microinches, then applied a brief electropolishing step to passivate the stainless steel without removing additional material. The dryer was fabricated from a combination of sheet and plate-formed or rolled sections, custom metal-spun components, standard tri-clamp fittings, and precision-machined parts. Assembled section by section from the inside out, this approach ensured full polishing access prior to closure. This approach ensured that all product-contact areas met strict cleanliness standards despite the vessel's complex and enclosed geometry.

COMPLEX SHAPES AND CRITICAL GEOMETRY

The spray dryer's design had been extensively validated to produce precise particle characteristics, and any deviation, however minor, risked requiring requalification through stringent regulatory pathways. To maintain both functional performance and compliance, HEC precisely replicated the original geometry, fabricating the system section by section to ensure every contour matched the approved design.

RESULTS AND OUTCOMES

The successful delivery of this system demonstrates HEC's capability to integrate ASME-compliant pressure vessel design with precision fabrication, ultra-high surface finishing, and complex geometry, meeting the stringent sanitary and performance standards required for biologic drug manufacturing. Combining design, engineering, polishing, and quality assurance under one roof, HEC produced a fully certified system that is now in operation, supporting the production of high-purity biologic medications.

ENGINEERED FOR THE FUTURE OF BIOLOGICS

Biologic drug manufacturing requires tighter sanitary controls than standard pharmaceuticals due to the high risk of spoilage and contamination from living materials. These products are especially sensitive to residual buildup, making surface finish critical to product integrity, cleanability, and compliance.

This project shows that even highly complex systems can be fabricated to exacting standards while maintaining strict cleanliness and reliable performance, offering a scalable, compliant model for one of pharma's most demanding sectors.

- TEMPERATURE – ABRASION
  PRESSURE – SURFACE FINISH

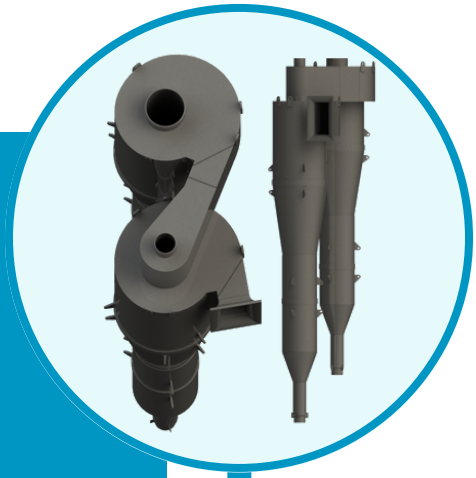
HIGH TAPS SOLUTIONS

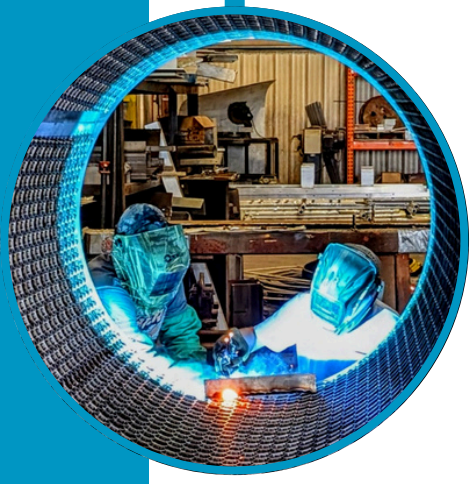
Biologic drug manufacturing pushes the limits of sanitary fabrication. In these systems, even microscopic residue can compromise batch integrity, trigger cross-contamination, and invite regulatory scrutiny. Cleanability isn't just a requirement, it's a design constraint.

That's why our High TAPS approach brings together pressure-rated design, ultra-high surface finish, and precisely fabricated geometry that supports cleanability and consistent performance. From spray dryers for biologics to cyclones for high-pressure gas systems, we build solutions that perform under extreme thermal, abrasive, and sanitary conditions. When failure isn't an option, High TAPS delivers performance that's engineered to endure.

WHY HEUMANN ENVIRONMENTAL?

At Heumann Environmental, we take a collaborative, custom-engineered approach to align each solution with your operational goals. Backed by decades of experience, we design high-performance systems that improve recovery, reduce emissions, and enhance sustainability, while ensuring compliance, reliability, and efficiency.





BEYOND OFF-THE-SHELF

EXPLORE MORE HIGH TAPS SOLUTIONS FOR EXTREME INDUSTRIAL CHALLENGES

Our ASME-certified fabrication facility adheres to AWS, IBC, and AISC standards with the ability to provide ASME or CE certifications as needed. We deliver solutions that meet the highest industry benchmarks across industries such as:

- OIL & GAS
- CHEMICAL PROCESSING
- PHARMACEUTICALS
- WOOD PROCESSING

DISCOVER HOW HIGH TAPS SOLUTIONS ARE ENGINEERED TO PERFORM.

LEARN MORE ABOUT HIGH TAPS →