



All US Manufacturing

- Contract Lyophilization
- Contract Injectables
- Water for Injection (WFI)
- Ultra-Pure Tankless Water Systems



WHO WE ARE AND WHAT WE DO

At HANS Scientific,TM we were founded on a simple but bold mission: solve some of the world's most complex challenges through innovation and engineering excellence.

We've aggregated the best engineering breakthroughs to create the most innovative and efficient systems for the Pharmaceutical, Medical, and other Commercial/Industrial applications.

HANS ScientificTM specializes in

- Ultra-Pure, Water for Injection (WFI) quality water products.
- Innovative, Highly Efficient, Water Purification Systems.
- State of the art Pharmaceutical Contract Manufacturing Services.
- JV Pharma Partnerships.

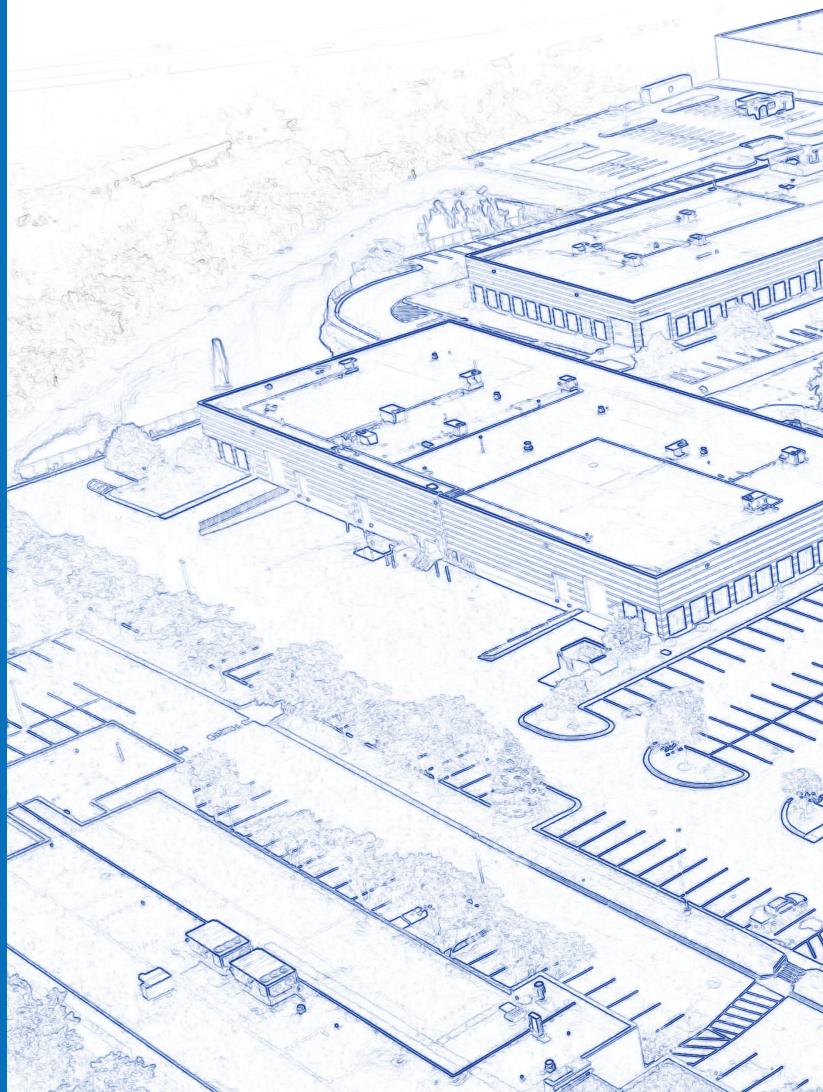
Whether you're sterilizing surgical instruments, purifying process water for cleanroom manufacturing, or require aseptic lyophilization services, we focus on ready availability of our products and services to help eliminate and reduce downtime. All our solutions meet or exceed the strictest industry standards and feature industry-leading efficiency.



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HANS
ScientificTM

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Product Overview

HANS Scientific™ operates a Michigan-based, advanced manufacturing campus serving the Pharmaceutical, Medical and Industrial communities. Our focus is on providing products and services that power speed-to-market for our clients. Whether it is specialty products such as our WFI quality water, or our contract manufacturing services, we concentrate on maintaining ready supply and available production capacity.



HANS Scientific™ Water For Injection

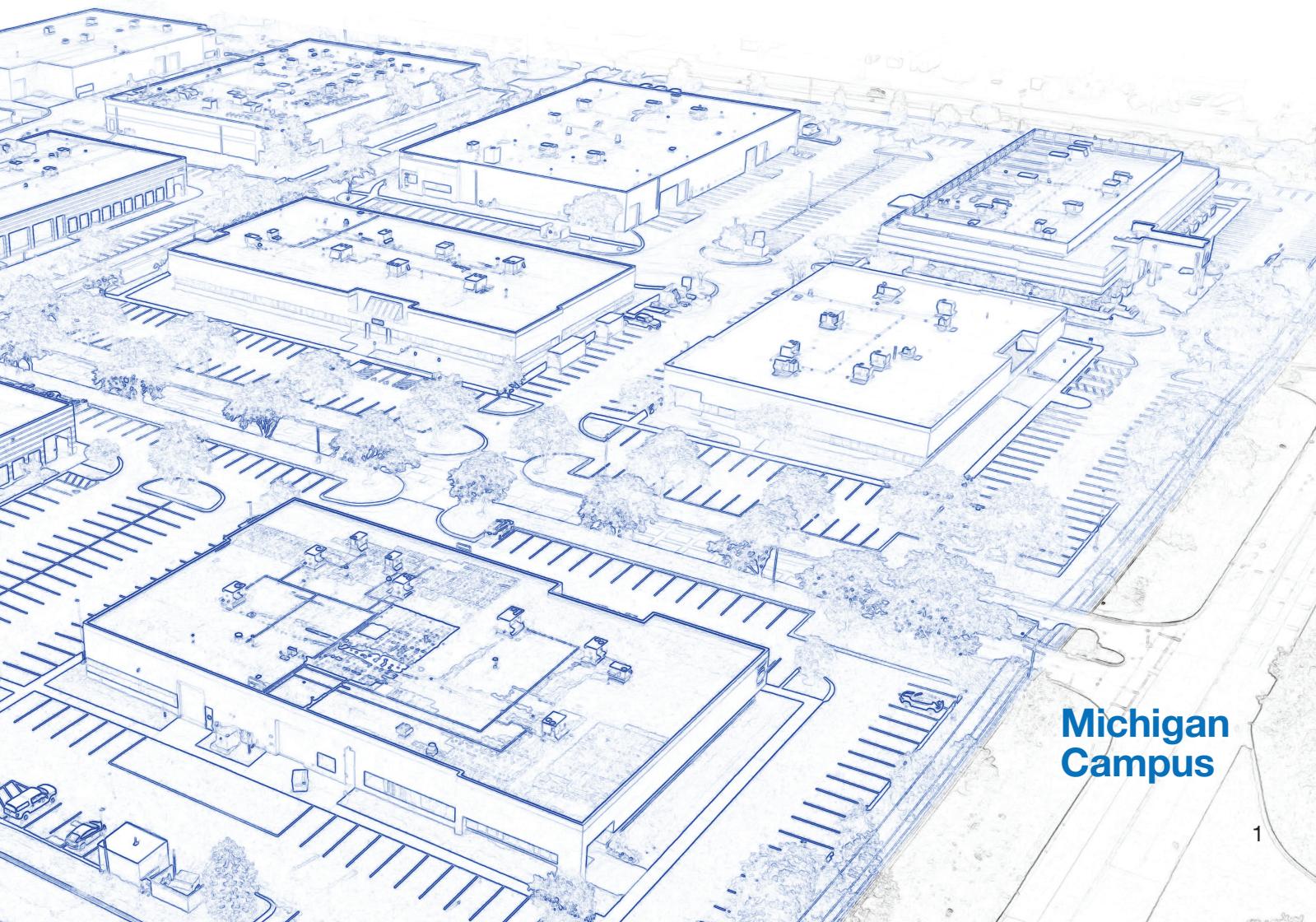
All grades of WFI water (Water for Injection, USP, Water for Injection, USP- Sterile, Water for Injection USP- Sterile/DNase/RNase Free & Rx grades) are produced on our proprietary, tankless, closed loop sterile water purification plant which features filtration that has pore size 1000x smaller than conventional Ultrafiltration. Exceeds stringent pharmaceutical water standards and is available in popular package sizes.

HANS Scientific™ Water Purification Systems

Highly innovative, modular systems that feature industry-leading water recovery rates and produce ultra-pure water that meet or exceed Pharmaceutical and Medical industry standards. HANS® systems are designed to eliminate system shut down for common maintenance through failsafe engineering and modularity. Unlimited scalability for the largest, most complex applications.

HANS Scientific™ Contract Manufacturing Services

Our injectable medicines plant features two high capacity Fill/Finish lines with terminal sterilization as well as one fully aseptic fill line with available high capacity Lyophilization. The plant has our innovative WFI suite integrated which eliminates production downtime caused by supply issues. Final inspection is performed using an automated particle scanner to allow 100% lot inspection of critical parameters including container closure, oxygen content, glass defects and others.



HANS SCIENTIFIC™ WFI

The NEW STANDARD in Water for Injection

At HANS Scientific™ is committed to creating a positive impact in the pharmaceutical, biopharmaceutical, life science, and healthcare sectors. Our purpose is providing an uninterrupted and reliable source of Sterile Water for Injection (WFI) and WFI Quality Water with high volume capacity to meet our customers' supply chain requirements.

New, state-of-the-art manufacturing plant

To best serve our customers, a new state-of-the-art production facility, including, ISO 7 Cleanrooms and ISO 5 automated filling stations, was built. Following cGMP guidelines, the facility gives us the size and flexibility to reduce supply chain lead times and meet growing market demand.



- High-output production facility
- Production capabilities from 10mL glass vials (Sterile WFI) to 200-liter drums (WFI Quality Water)
- On-site analytical testing analysis to ensure the highest quality assurance standards
- Eliminates the risk of contamination by using proprietary membrane technology and CSF (continuous sterile filtration) water recirculation without the need for storage tanks.
- Third Party tested & certified water system to the new IGC376 standard



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**Water for
Injection (WFI)**

Why choose HANS Scientific™ WFI

- High-volume production capacities
- Short lead times
- Private Label Packaging available
- Sterile WFI in 10mL Type 1 Borosilicate Glass vials.
- WFI Quality Water in both 20L and 200L bioprocess bag containers



Meets or exceeds USP standards and monograph requirements

- FDA-registered cGMP manufacturing facility
- U.S. Pharmacopeia (USP<1231>)
- ISO 13485:2016 Registered
- The only water purification system that has been tested and certified to the new IGC376 standard

Commonly Used For

- Cell Culture
- Chemical Mixing
- Sterilizing Medical Instruments (added to autoclaves or steamers)
- Cleaning/Rinsing medical equipment (before sterilization)
- Laboratory/Research Use
- Cleaning of the clean room/equipment
- Further Manufacturing
 - Cosmetics
 - Drug Manufacturing
 - Food & Beverage



Sterile Water for Injection, USP

10mL Vial			
Test	Test Method	Specification	Units
Conductivity	USP <645>	<25	µs/cm
Particulate Matter	USP <788>	Meets requirements	N/A
Endotoxins	USP <85>	<0.25	EU/mL
Sterility	USP <71>	No growth	N/A
TOC	USP <643>	<24	mg/L

FOR DRUG DILUENT USE ONLY. Contains no antimicrobial or other added substance. Sterile, nonpyrogenic. Use only if clear and seal is intact and undamaged. Do not give intravenously unless rendered nearly isotonic. Use promptly; discard unused portion.

Product Specifications

Classification		WFI Quality Water Grades			Options
Test	Test Method	Water for Injection, USP**	Water for Injection, USP-Sterile	Water for Injection, USP-SterileDNase/RNase Free	Size
Conductivity @25 C (µs/cm)	USP <645>	≤ 1.3	≤ 1.3	≤ 1.3	20L / 200L Bag
TOC (mg/L)	USP <643>	≤ 0.5	≤ 0.5	≤ 0.5	20L / 200L Bag
Endotoxins (EU/mL)	USP <85>	<0.25	<0.25	<0.25	20L / 200L Bag
Sterility	USP <71>	*	No Growth	No Growth	20L / 200L Bag
DNase/RNase Free	Fluorometric Assay	*	*	No Detected	20L Bag

MEETS USP MONOGRAPH FOR WATER FOR INJECTION AT POINT OF FILL. NOT INTENDED FOR PARENTERAL ADMINISTRATION. WFI QUALITY WATER IS INTENDED FOR FURTHER MANUFACTURING OR RESEARCH USE. NOT FOR DIAGNOSTIC USE OR DIRECT ADMINISTRATION INTO HUMANS OR ANIMALS.

*Not Specified, Not Required, Not Applicable or No Limit

**Meets USP Monograph at Point of Fill

HANS SCIENTIFIC™ WATER PURIFICATION SYSTEMS

HANS Scientific™ has reinvented every aspect of traditional Water Purification Systems. From failsafe components to industry leading RO water recovery rates, our systems are engineered to operate efficiently and intelligently. HANS Water Purification systems have the most 3rd party certifications in the industry. Whether you need ultra-pure water for optimized agriculture, or medical grade sterile water, our systems are designed to produce it efficiently, reliably, and with significantly reduced maintenance burden.

Efficiency, Modularity, & Cutting-Edge Engineering

- Full system and element design allow for up to 95% water recover rates. Variable pumps and high efficiency elements minimize electric load.
- All system modules can be independently serviced without the need to take the entire system off-line. Each of our module designs is space-efficient, freeing up room for other critical items.
- Individual media and membrane chambers are configured in parallel to maximize flow rates and improve media & membrane longevity.
- HANS Scientific™ Water Purification systems feature intelligent component monitoring and controls that adjust to fluctuating levels of TDS, water pressure and flow rates.
- Tankless system design significantly reduces potential for bacterial growth.



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**Water Purification
Systems**

Parallel Configuration of Media
for optimal flow and efficiency



Purification Module

Modular Space, Efficient Configuration



Less than 8 sq ft per Module

Real time remote data

All HANS Scientific™ water solutions are WIFI compatible and provide the data your business needs – like water usage, pressure, TDS levels and filter life. All this data is on each module's data screen, and it's delivered in real time to a mobile device.



Custom Engineered & Designed Components for any Application

- Multi-Stage Failsafe Booster Pumps
- Calcite Purification Modules
- Pre-Filtration Purification Modules
 - Softener, Carbon, Sediment, Iron/Arsenic
- Anti-Scalant Modules
- High-Capacity, High Efficiency RO Modules that can be configured in parallel for unlimited scalability.
- UV Disinfection Purification Modules
- Chemical Injection Modules

Example System Configurations



Failsafe Booster Pump



Quad RO Module with Integrated Surge Tank



46,000 Gallons Per Day System



115,000 Gallons Per Day System



460,000 Gallons Per Day System



1,000,000 Gallons Per Day System

Certifications



ASSE
ASSE – 1087
ASSE LEC 2006-2019-POE (Point of Entry) RO Systems
ASSE/IAPMO IGC 376-2023
California Registered #3882
CSA B483.1

CSA C22.2#68:2018- Motor Operated Appliances
NSF 61 / CSA B483.1
NSF 53
NSF 244
NSF 372 (Ca AB1953)
UL-979- Water Purification Appliances



CMO SERVICES LYOPHILIZATION & ASEPTIC FILL



Lyophilization Powers Innovation

Lyophilization offers a powerful advantage for sensitive products by extending stability, increased preservation, and easing reconstitution. The freeze-drying process removes moisture while protecting the product's structure and potency, making it easier to store, transport, and reconstitute — without compromising efficacy. It's a trusted solution for ensuring long-term reliability across pharmaceuticals, diagnostics, and biologics.



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**CMO
Services**

Our Distinct Advantage

Integrated On-Site WFI System – High Capacity – Speed to Market

At HANS Scientific,TM our Lyophilization Suite is integrated with our proprietary, tankless Water for Injection (WFI) system—engineered for ultra-pure water production. This integration means no production delay or interruption due to inconsistent supply of WFI sterile water. Our Lyophilization Suite is fully aseptic from fill to finish, including cleaning processes (CIP, SIP) which are automatic and eliminate manual intervention. The suite features a high capacity, ALUS vial racking system for maximum cycle throughput. As a final step, we utilize a particle spectrometer for assurance of purity, sterility and seal integrity. Our mission is to increase speed-to-market for our partners with our state-of-the-art, high capacity lyophilization services.

We have QA and RA staff on site as well as biological and material testing labs onsite. With nearly unlimited capacity at our medical campus here in the US, we offer speed and economic benefits that are not found with overseas producers.



Registered and Approved

Our facility is ISO 13485:2016 Registered and cGMP compliant as well as FDA and State Registered.



Features

- Integrated, closed loop WFI suite producing high purity (14-18 megohm) water. No holding tanks to clean and risk introduction of contamination.
- High shear, closed loop compounding
- Fully automated line, including Wash, Depyrogenation, Fill, Lyophilization and Capping.
- Automated nitrogen vial purge before fill.
- Automatic loading & unloading (ALUS) system for Lyophilization chamber increases production efficiency and maintains aseptic conditions. ALUS also protects from high potency substances and accommodates low temperature loading (as required).
- Automated particle scanner for 100% lot inspection of oxygen headspace percentages, closures, defects, particles and other items. Significant time savings versus manual inspection.
- Integrated CIP (clean in place) and SIP (sterilize in place) systems
- Nitrogen generation system onsite to assure purity and supply
- Stability chamber for shelf-life validation
- Biological and material testing labs onsite to expedite lot validation testing
- QA and RA experts on-site
- On-site warehousing and labeling available.

Scan for
**Virtual
Plant Tour**



CMO Plant Capabilities and Capacities

- Integrated, closed loop WFI suite producing high purity (14-18megohm) water. Capable of producing all classes USP monogram WFI as well as sterile WFI products.
- High shear, closed loop compounding
- Fully automated line, including Wash, Depyrogenation, Fill, Lyophilization and Capping.
- Automated nitrogen vial purge before fill.
- Automatic loading & unloading (ALUS) system for Lyo chamber increases production efficiency and maintains aseptic conditions. ALUS also protects from high potency substances and accommodates low temperature loading (as required).
- Automated particle scanner for 100% lot inspection of O2 headspace %, closures, defects, particles and other items. Significant time savings versus manual inspection.
- Integrated CIP (clean in place) and SIP (sterilize in place) systems
- Nitrogen generation system onsite to assure purity and supply
- Stability chamber for shelf-life validation
- Biological and material testing labs onsite to expedite lot validation testing
- QA and RA experts on-site
- On-site warehousing and labeling available.
- On-Campus support and consulting for:
 - Engineering
 - Planning
 - Process design
 - Equipment Specifications
 - Building Specifications
 - Full Print packages
 - Construction
 - Program Management
 - Electrical Install
 - Plumbing Install
 - Infrastructure work
 - Equipment install
 - Equipment Validation
 - Procedures and Processes
 - FDA Documentation

Capacities

Line	Fill Suite / Terminal Sterilization Products	Vials/8hr Shift	24/7 Operation
Line 1*	Filling WFI or compounded injectables in 2/6/10/15/20/25R Vials	41,000	41,820,000
Line 2*	Filling WFI or compounded injectables in 2/6/10/15/20/25R Vials	41,000	41,820,000

* Lines can be operated simultaneously

Aseptic Fill Suite	Vials/8hr Shift	24/7 Operation
Aseptic fill of Compounded Injectables in 10/15/20/25R Vials	34,000	34,680,000

Lyophilization Capacity	Vials/Cycle	Annual @ 2 Cycles/Day
25R Vials	12,000	8,160,000
20R Vials	12,000	8,160,000
15R Vials	18,000	12,240,000
10R Vials	18,000	12,240,000

Versatile Partnership Options

Services Available Now

- Injectable Medicines Manufacturing
- On-site biological lab for validation testing
- On-staff QA & RA experts
- Labeling & Packaging
- Warehousing of finished inventory

Strategic Options

- Joint Venture Options on Generics
- Production partner for out-licensing arrangements
- Private label production
- Distribution in all US States
- Engineering/Design/Regulatory experts for accelerated build of new facilities

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INDUSTRIES WE SERVE



Commercial and Industrial Sectors

- Pharmaceutical
- Aviation/Transportation
- Government/Education
- Hotel/Retail
- Life Science/Labs
- Sports/Entertainment
- Food & Beverage Production
- Manufacturing/Industrial
- Engineering Firms



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