



# All US Manufacturing

- Contract Lyophilization
- Contract Injectables
- WFI Quality Water
- Ultra-Pure Tankless Water Systems



# WHO WE ARE AND WHAT WE DO

At HANS Scientific™, 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 Scientific™ 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.

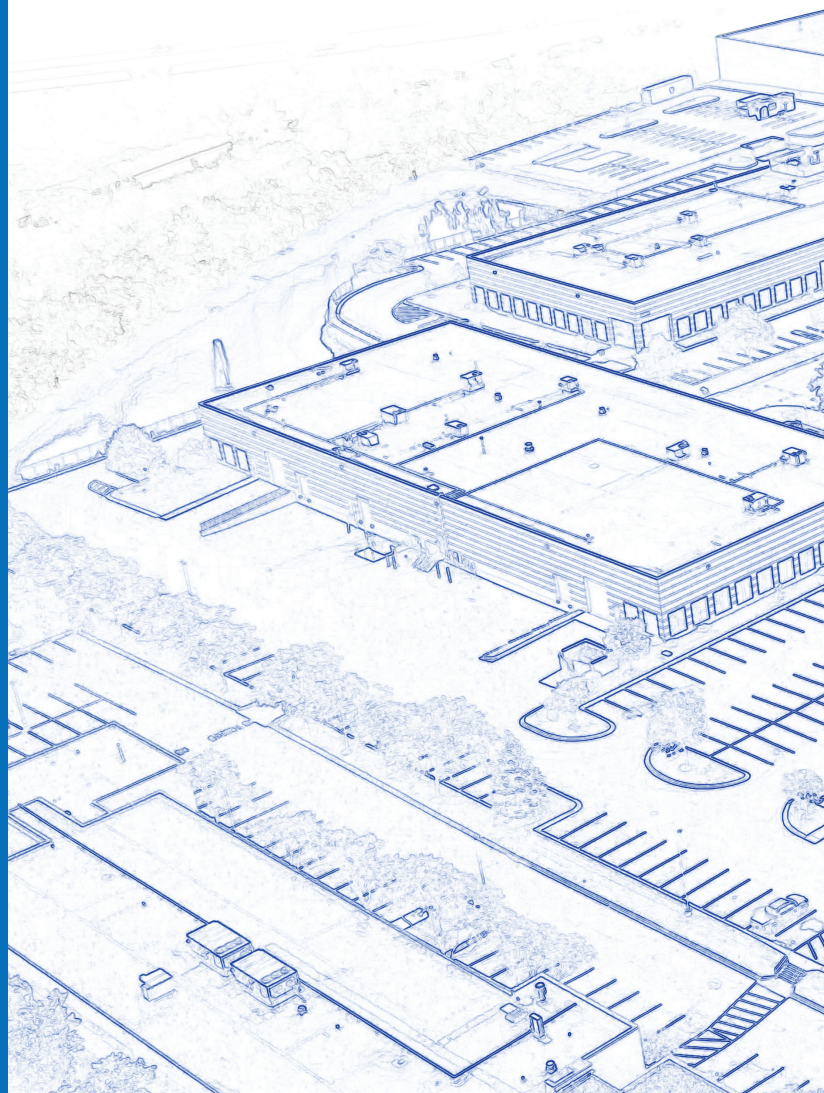
Whether you're sterilizing surgical instruments, purifying process water for cleanroom manufacturing, or require aseptic lyophilization services, we focus on ready availability of our products and services to help eliminate and reduce downtime. All our solutions meet or exceed the strictest industry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



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**HANS  
Scientific™**

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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™ WFI Quality Water

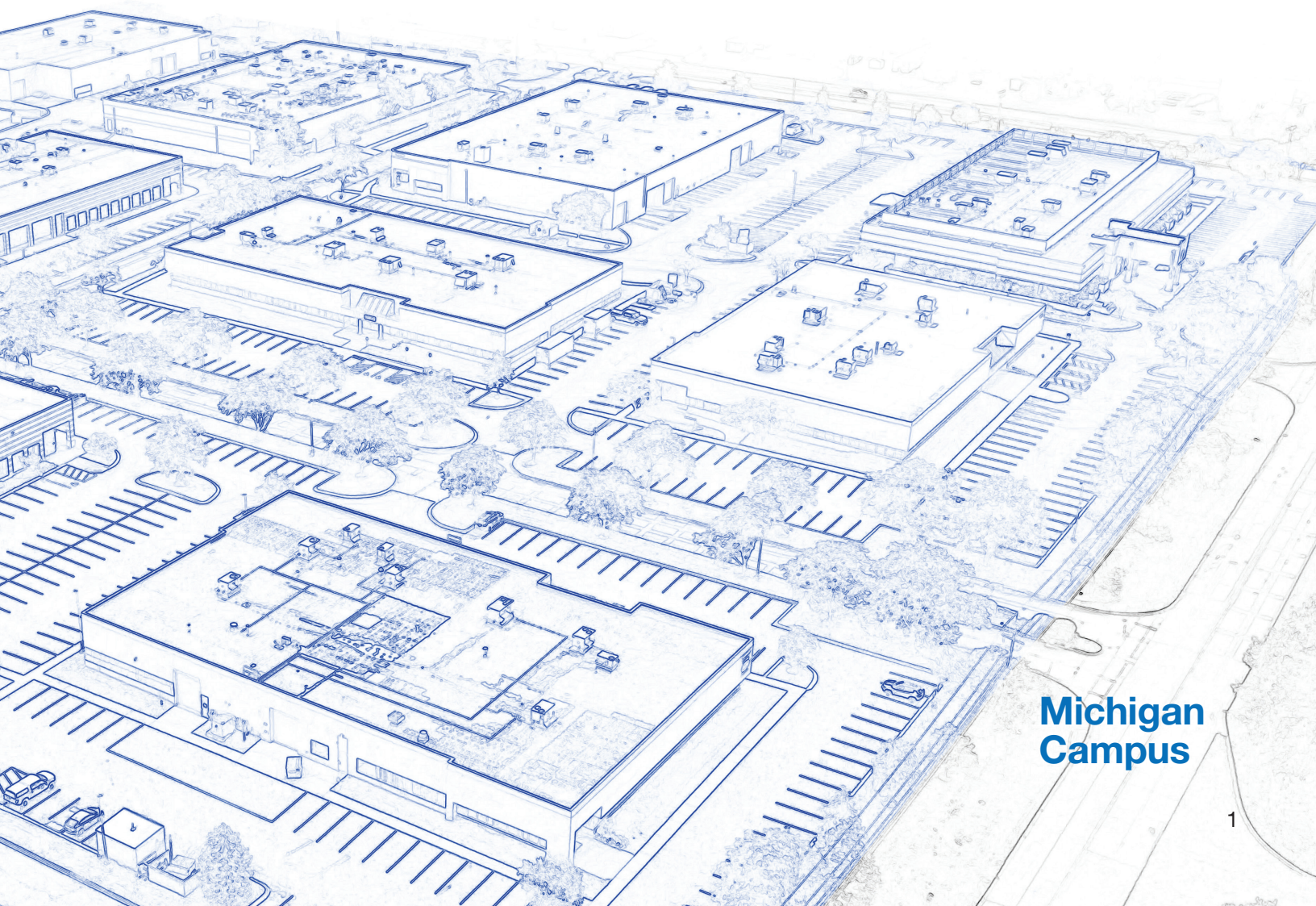
All grades of WFI Quality Water (Water for Injection, USP, Water for Injection, USP- Sterility tested, Water for Injection USP- Sterility tested/DNase/RNase Free & Rx grades) are produced on our proprietary, tankless, closed loop sterile water purification plant which features filtration that has pore 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.



**Michigan  
Campus**

# HANS SCIENTIFIC™ WFI

The NEW STANDARD  
in WFI Quality Water

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 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 with 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
- 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

## Why choose HANS Scientific™ WFI

- High-volume production capacities
- Short lead times
- Private Label Packaging available
- WFI Quality Water in both 20L and 200L bioprocess bag containers



## Meets or exceeds USP standards and monograph requirements

- FDA-registered and cGMP compliant 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



Scan to learn more about  
**WFI Quality Water**

## 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



## Product Specifications

| Product Description                                           | Volume        | Conductivity @ 25 C (us/cm )<br>Test Method:<br>USP <645> | TOC (mg/L)<br>Test Method:<br>USP <643> | Endotoxin (EU/mL)<br>Test Method:<br>USP <85> | Sterility Tests<br>Test Method:<br>USP <71> | Fluorometric Assay |
|---------------------------------------------------------------|---------------|-----------------------------------------------------------|-----------------------------------------|-----------------------------------------------|---------------------------------------------|--------------------|
| WFI Quality Water, USP                                        | 20L Bag       | ≤ 1.3**                                                   | ≤ 0.5                                   | < 0.25                                        | *                                           | *                  |
| WFI Quality Water, USP                                        | 200L Drum/Bag | ≤ 1.3**                                                   | ≤ 0.5                                   | < 0.25                                        | *                                           | *                  |
| WFI Quality Water, USP – Sterility Tested                     | 20L Bag       | ≤ 1.3**                                                   | ≤ 0.5                                   | < 0.25                                        | No Growth                                   | *                  |
| WFI Quality Water, USP – Sterility Tested                     | 200L Drum/Bag | ≤ 1.3**                                                   | ≤ 0.5                                   | < 0.25                                        | No Growth                                   | *                  |
| WFI Quality Water, USP – Sterility Tested<br>DNase/RNase Free | 20L Bag       | ≤ 1.3**                                                   | ≤ 0.5                                   | < 0.25                                        | No Growth                                   | None Detected      |

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 water, our systems are designed to produce it efficiently, reliably, and with significantly reduced maintenance burden.

## System components designed to handle a wide variety of conditions and work seamlessly together.

- Proprietary high efficiency, Quad RO units
- Proprietary pre-treatment modules maximize efficiency of RO membranes
- Chemical anti-scalant modules
- Electronic Deionization modules
- Proprietary Disinfection modules with 1000x finer pore size than ultra filtration and commercial UV sanitation as well as commercial grade UV bulbs
- Proprietary, multi-stage, failsafe booster pumps can be placed as required at any position in the train



Scan to learn more  
**Water Purification  
Systems**



Less than 8 sq ft per Module

## Reduce cost and complexity

### HANS Scientific™ Quad RO Module

- **Compact, Scalable Design** – 128 sq ft footprint with full top/side access for efficient servicing and seamless system expansion.
- **Extended Component Life** – Advanced design maximizes membrane and filter longevity (rated up to 25 million gallons).
- **Low Maintenance, Lower Cost** – Real-time monitoring engineered to streamline operations and significantly reduce maintenance burden.

## Mitigate compliance risk

- **Industry-Leading Certification** – Fully certified to ASSE/IAPMO IGC 376-2023, reducing validation timelines by months
- **Proven Water Quality Performance** – Handles up to 5x bio-burden and 7x TOC/endotoxin limits while consistently delivering 12–18 MΩ water
- **Engineered to Minimize Risk** – Tankless, continuous sterile filtration with advanced UV, RO, and 21 CFR Part 11-ready monitoring



## Speed to Market

- **U.S.-Based Fabrication & Installation** – Engineering, plumbing, and fabrication performed by HANS experts –no third parties
- **Streamlined Deployment** – Integrated, in-house execution accelerates installation timelines and reduces project complexity
- **Faster Validation** – Certified to ASSE/IAPMO IGC 376-2023, cutting months from WFI validation timelines

**Reduce complexity and cost while  
enhancing performance and compliance.**



**HANS Scientific™ systems are designed and fabricated in the U.S.,  
accelerating the time from concept to commissioned.**

## Medical and Pharmaceutical Solutions

All systems are custom configured based on water chemistry and usage requirements and can scale or adapt as operations evolve. Systems can be sized to deliver anywhere from 9-96GPM.



**ST-108 Compliant System**



**WFI Generation System**

ASSE/IAPMO IGC 376-2023 certification for entire system **speeds regulatory and validation process and timelines.**

## Commercial & Industrial Solutions

All systems are custom configured based on water chemistry and usage requirements and can scale or adapt as operations evolve. Systems can be sized to deliver anywhere from 9-720GPM.



HANS Scientific™ Water Purification Systems have the most 3rd party certifications in the market including California registration and IGC 376-2023 certification for the entire 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,<sup>™</sup> 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     |

\* Vial size and volume dependent

| 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            |

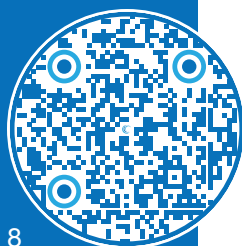
## Versatile Partnership Options

### 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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**HANS**  
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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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