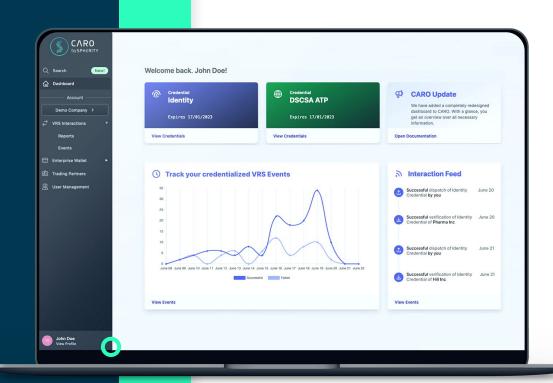


## Welcome to CARO

Spherity's solution to authenticate direct and indirect trading partners in the U.S. pharmaceutical supply chain in real-time.





## A VRS plug-in to meet DSCSA requirements for ATPs

#### Situation

The U.S. Drug Supply Chain Security Act (DSCSA) requires pharmaceutical manufacturers to verify and exchange serial numbers of prescription drugs within 24 hours **exclusively** with authorized trading partners (ATPs).

## Challenge

There are more than 60,000 supply chain participants potentially interacting in product verification processes who must confirm each other's ATP status.

Currently there is **no automated mechanism to validate** Board of Pharmacy or FDA-issued licenses to verify the ATP status of counterparties.

#### **Compliance Gap**

GLNs do not solve this problem. GLNs have been discovered that were not active or not associated with the requesting entity. GLNs also do not inform about authorized status. Additionally, there is no proof that a provided GLN actually came from the expected trading partner.

## Solution CARO closes the gap

- Respond in **real-time** to DSCSA-relevant product verification requests after confirming ATP status
- ☐ CARO is already integrated into existing supply chain infrastructure so you don't need IT expertise
- Save compliance overhead costs through **automated** processes
- ☐ Be audit-ready with complete ATP interaction records
- Communicate securely with indirect Trading Partners using trusted channels
- Exploit ATP credentialing for Tracing and other future processes



CONCEPT



## Credentialize existing licenses or registrations

#### **Credentialing Process**

#### Step 1

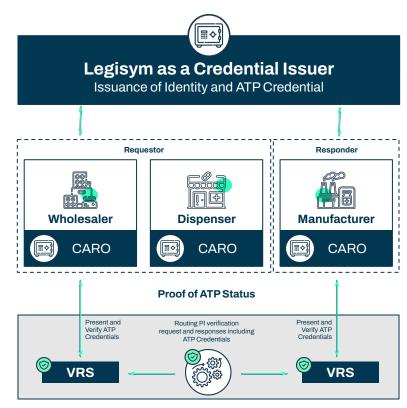
Unique enterprise identifier established.

#### Step 2

Identity and ATP credentials based on your current licenses or registrations assigned to you through Credential Issuer integration.

#### VRS plug-in

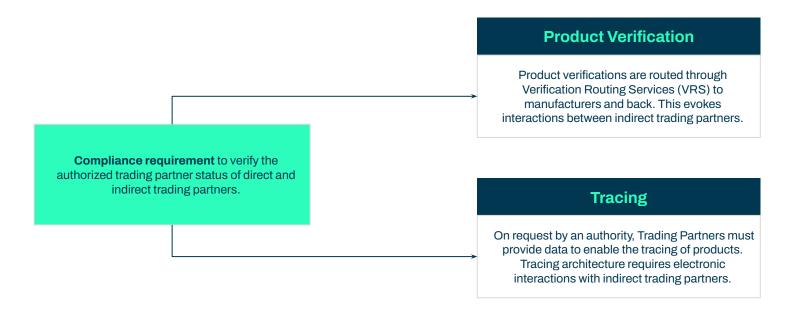
- CARO integrates with your service provider to take the technical burden off your shoulders.
- Your service provider will be able to handle your own and your counterparty's credentials to prove ATP status automatically.







## Three ways to explore and use CARO







## Verifiable Credentials to authenticate indirect trading partners



### Benefits for trading partners

Wholesaler

 Compliant and recorded ATP checks in every product verification

Repackagers

- Identity and ATP credentials can be used for product verification and tracing requirements
- Establish trusted and compliant communication channels with previously unknown trading partners

### Standards and specifications

- Spherity adopts the architecture designed by the Open Credentialing Initiative (OCI).
- Our solution meets <u>PDG blueprint requirements</u>.
- ✓ GS1 US has integrated usage of Verifiable Credentials in their Messaging Implementation Guideline
- ✓ Close collaboration with HDA working group for VRS

Dispenser



## **CARO - Credentialing of ATP for Regulatory Observance**





## Simplicity

Acquire your Identity and ATP credentials from our fully integrated Credential Issuer Legisym without any technical effort or additional contracts.



#### Interoperability

CARO is interoperable with all OCI-conformant service providers. Every OCI-conformant credential can be verified.



## Efficiency

Automated ATP status verification avoids DSCSA-related overheads and enables real-time responses.



#### Reusability beyond DSCSA

Verifiable Credentials can automate license checks in any commercial interaction, e.g. Order-to-Cash or Drop Shipments.



**VALUE** 



# Combining Spherity's Digital Wallet and Legisym's Credential Issuer capabilities automates compliance processes



#### **DSCSA**

#### **Product Verification**

VRS and Trading Partners attach ATP Credentials to PI Verification messages.

#### **Tracing**

Integrating credentials in Trace requests and response messages.

Current focus

#### Commercial

#### **Order-to-Cash**

Improve accuracy and compliance by credentialing DEA registrations, shipment addresses and schedules.

#### **Drop Shipment**

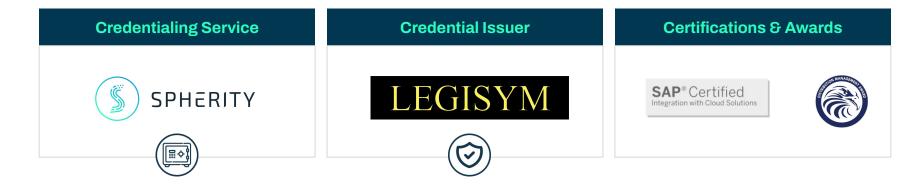
Verify shipment to location certificates and automate compliance checks prior to shipments.

**Innovation Projects** 





## Spherity's SAP-certified solution enables ATP compliance in VRS interactions and is available as a service



#### **Dave Mason**

Supply Chain Compliance and Serialization Lead



"We were able to increase our level of compliance with DSCSA.

All I had to do was sign up with Spherity and tell my VRS that I want to use credentialing.

I encourage all trading partners to add credentialing to their roadmap for compliance."





## Find out more at **CARO.VC**

#### Contact

Georg Jürgens, <u>georg.juergens@spherity.com</u> Michael Rüther, <u>michael.ruether@spherity.com</u>

### **Managing Directors**

Dr. Carsten Stöcker, Dr. Michael Rüther USt-Id-Nr.: DE 316 157 015

Inhaltlich Verantwortlich gemäß § 10 Absatz 3 MDStV: Dr. Michael Rüther

#### Office

Spherity GmbH Emil-Figge-Straße 80 44227 Dortmund Germany

+49 (0) 231 968 197 60

Spherity Inc 127 West 30th Street, 9th Floor New York, NY 10001 United States

+18333700440