



Rx-360

*The International Pharmaceutical
Supply Chain Consortium*

Our History, Mission & Corporate Social Responsibility

History

- **2008:** Heparin adulteration incident
- **2013:** Rx-360's Joint Audit Program® launched
- **2023:** Rx-360 celebrates the beginning of our 15th year of serving the pharmaceutical industry

Mission Statement

To protect patient safety by sharing information and developing processes related to the integrity of the healthcare supply chain and the quality of its materials.

Corporate Social Responsibility

As a nonprofit, Rx-360 contributes to member organizations' corporate social responsibility efforts, aiding them to operate in an economically and socially sustainable manner.



Since our Founding, We've Worked With Pharmaceutical Companies in Over 30 Countries, Across the Globe

Countries

North America

- Canada
- United States of America

Latin America

- Brazil

Africa + Middle East

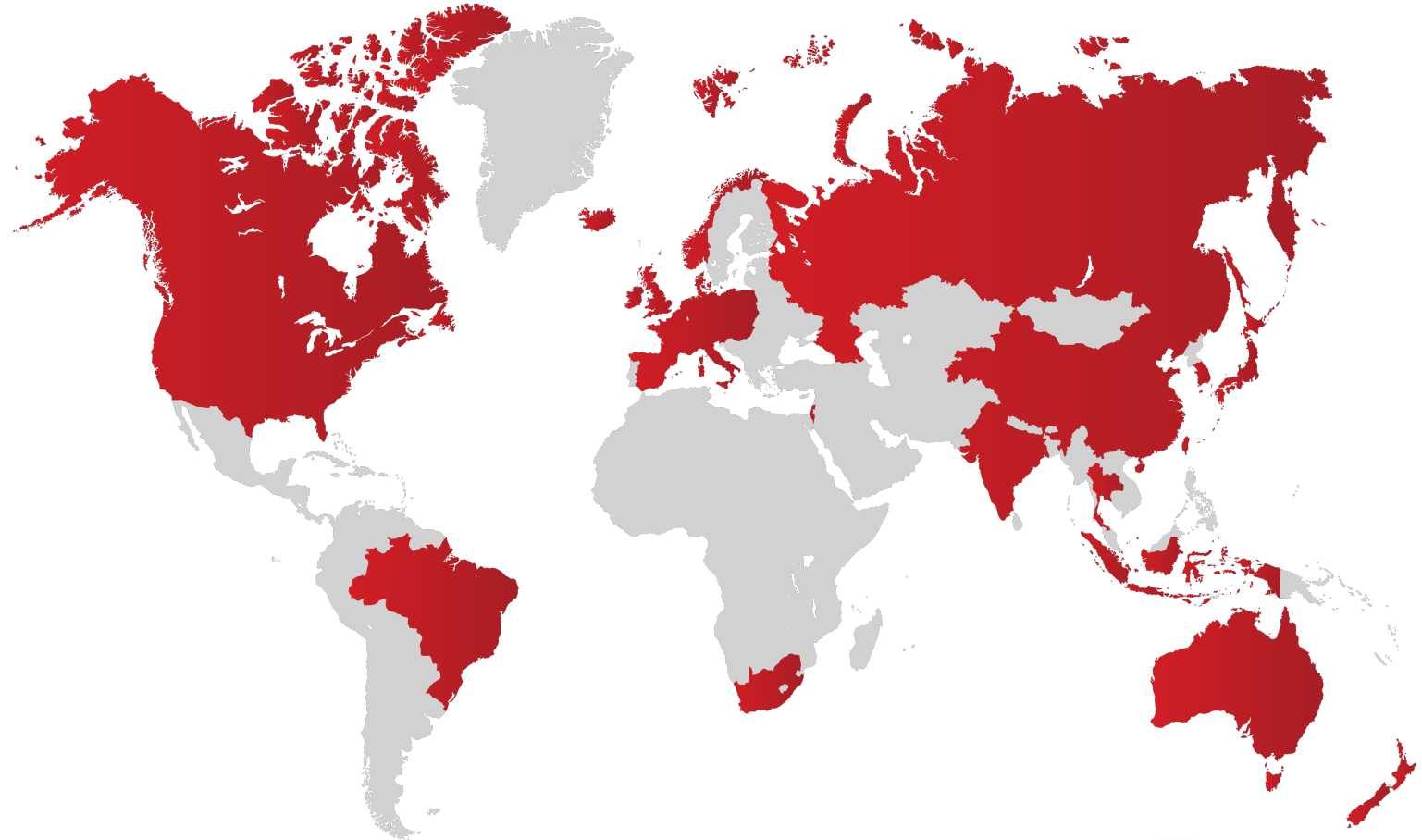
- Israel
- South Africa

Asia Pacific

- Australia
- China
- India
- Indonesia
- Japan
- New Zealand
- Singapore
- South Korea
- Taiwan

Europe

- Austria
- Belgium
- Czech Republic
- Denmark
- France
- Germany
- Hungary
- Iceland
- Ireland
- Italy
- Netherlands
- Norway
- Poland
- Russia
- Scotland
- Slovenia
- Spain
- Sweden
- Switzerland
- United Kingdom



Rx-360 Membership at a Glance



“Rx-360 is like an active neighborhood watch group that focuses on keeping the supply of medical products safe for patients worldwide. I am thankful that my company and so many of our peer and supplier companies are committed to working together on Rx-360’s supply chain integrity mission on behalf of our patients.”

Eric Berg
Director, Quality Assurance
Amgen

*This depicts a snapshot of Rx-360 membership and may not contain all members as logos are only used with permission



Membership Value & Opportunities

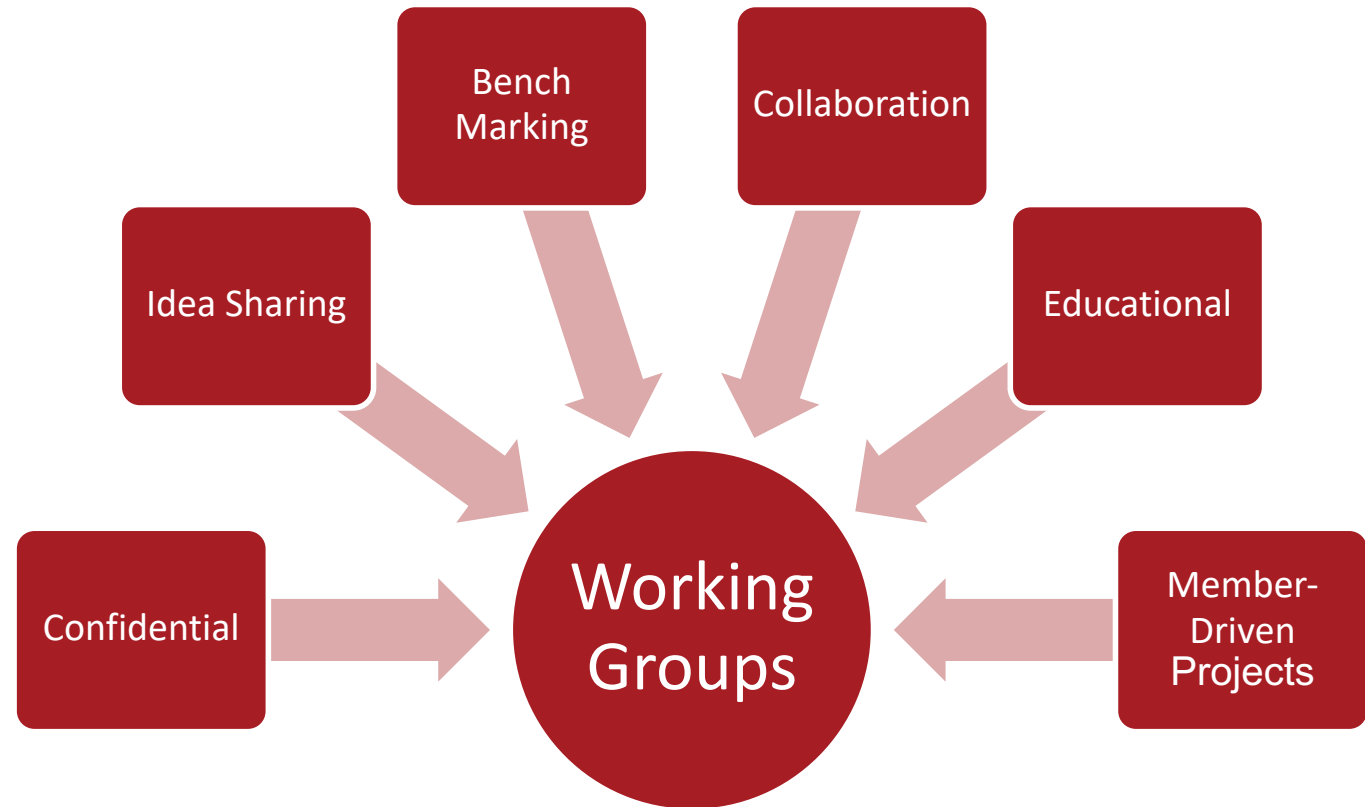
Rx-360 Membership Value & Benefits



Additional Benefits:

- Unique industry collaborations
- Member-Driven Special Projects
- White Paper Initiatives
- Industry Peer Networking
- Member Confidentiality

Rx-360 Working Groups



Developed *by* Members *for* Members

Topic-Focused Working Groups

Supply Chain Security Steering Committee: Identifies common gaps and opportunities to educate in the supply chain security and integrity.

Audit Operations Group: Provides guidance on all aspects of the Rx-360 Joint Audit Program.

Data Integrity: Develops processes, tools, and training to incorporate data integrity best practices.

Cell & Gene Therapy: Share best practices on how we approach cell and gene therapy suppliers while still in the clinical phase.

Legislative Guidances: Develops content and pathways for Rx-360 to engage with government authorities regarding these guidances.

Supplier Quality: Members from pharmaceutical companies and leading suppliers to the pharmaceutical industry.

Logistics Security: Logistics incidents that are security related involving pharmaceutical product.

Supplier Assessment Questionnaire Sub Team: The Rx-360 SAQ covers standard information that would be included in most supplier assessment questionnaires.

International Working Groups

Latin America: Concentrates on educational workshops in Spanish-speaking countries around GDPs & GMPs as well as supply chain issues specific to Latin America.

Africa & Middle East: Develops educational materials for use in Africa, to educate distributors in supply chain security.

Europe: Focuses on supply chain security in the European region. Topics covered may include BREXIT, COVID, Diversion, Parallel Trade, Issues with Turkey (diversion, counterfeit), Stolen product out of Italy, FMD and EFPIA.

Asia Pacific & India: Develops a vibrant network of regional/global companies, protects patient safety by sharing critical information, contributes to current Rx-360 workstream outputs with information specific to these regions, and influences regional regulatory activities to improve the transparency and integrity of the supply channels to protect patient health regionally and globally.

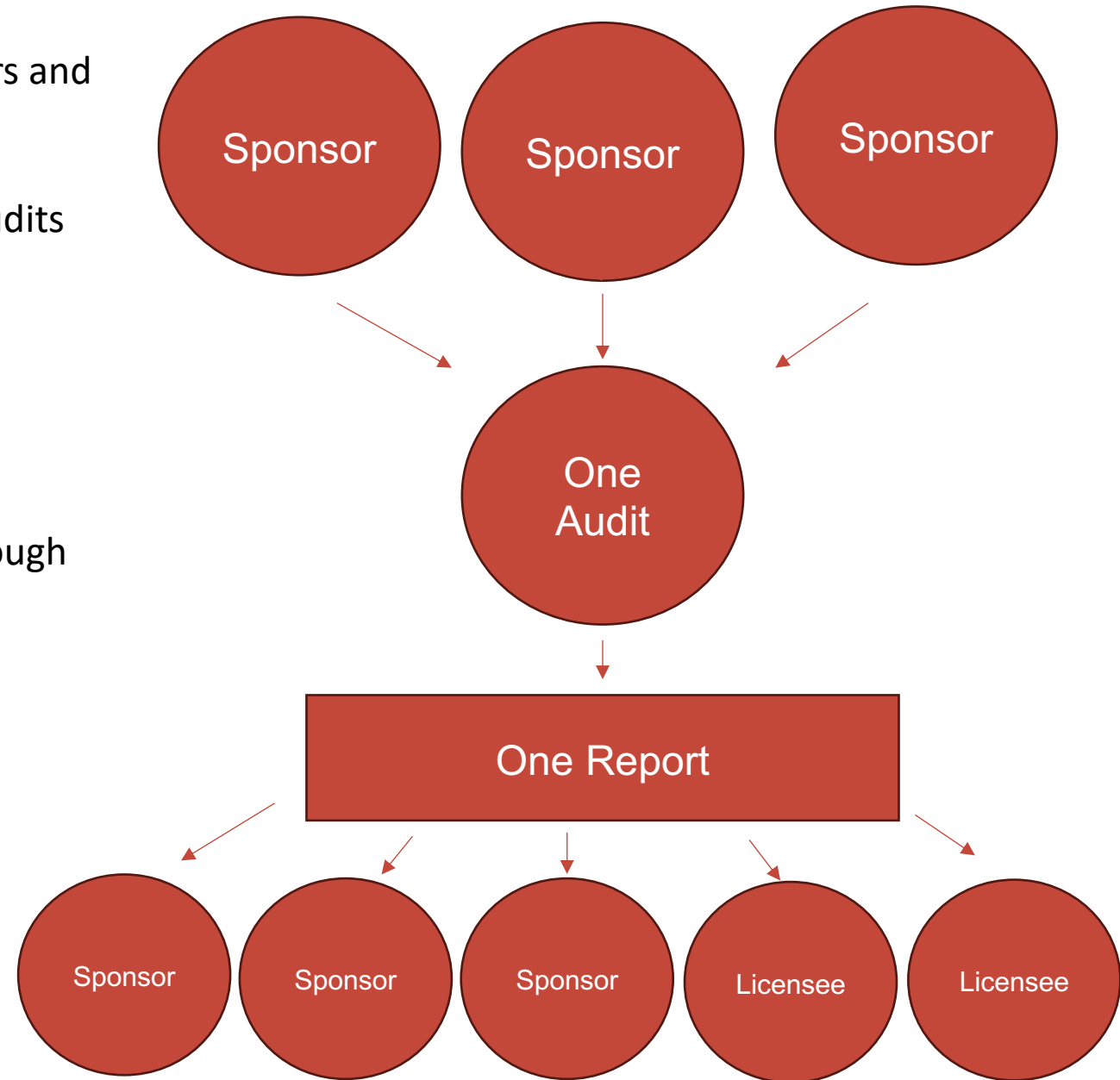


Rx-360 Joint Audit Program[®]

Rx-360 membership includes Pharmaceutical Manufacturers and Suppliers around the world.

The Rx-360 **Joint Audit Program**[®] reduces the number of audits that must be performed and hosted.

- ✓ Multiple companies can sponsor a single audit together, confidentially.
- ✓ The same audit report leveraged to more customers through confidential licensing.
- ✓ Auditee maintains control of recipients.
- ✓ All co-sponsors and all licensees receive the same audit document package.



Audit Checklists

API (ICH Q7, EUV.4 GMP Part II, EMEA/410/01)

Excipients (ISO 9001, ISO 17021, NSF/IPEC/ANSI 363-2016 WHO-TRS 885 Annex 5, IPEC PQG GMP)

Basic Chemicals/Raw Materials (ISO 9001)

Primary Packaging (ISO 9001, ISO 15378, PIC/S GMP Part 1)

Single-Use Systems (ISO 9001, ISO 14644-2)

Supply Chain Security (TAPA TSR/FSR, DSCSA)

*Airport

*GDP – Warehouse and Distribution

*Manufacturer

*Transportation

*Warehouse and Distribution Security

Supply Chain Security elements included with every audit: (C-TPAT, CR 203, 210, 211, EU GDP 94/C63/03, IPEC, ISO 9001, ISO 13485, ISO 2800, WHO-GDP)

Contract Laboratories (ISO 17025)

Medical Devices (ISO 13485)

Coming Soon:

IT Software (FDA 21 CFR Part 11, GAMP 5)

Good Clinical Practice (GCP) Cell and Gene Therapy

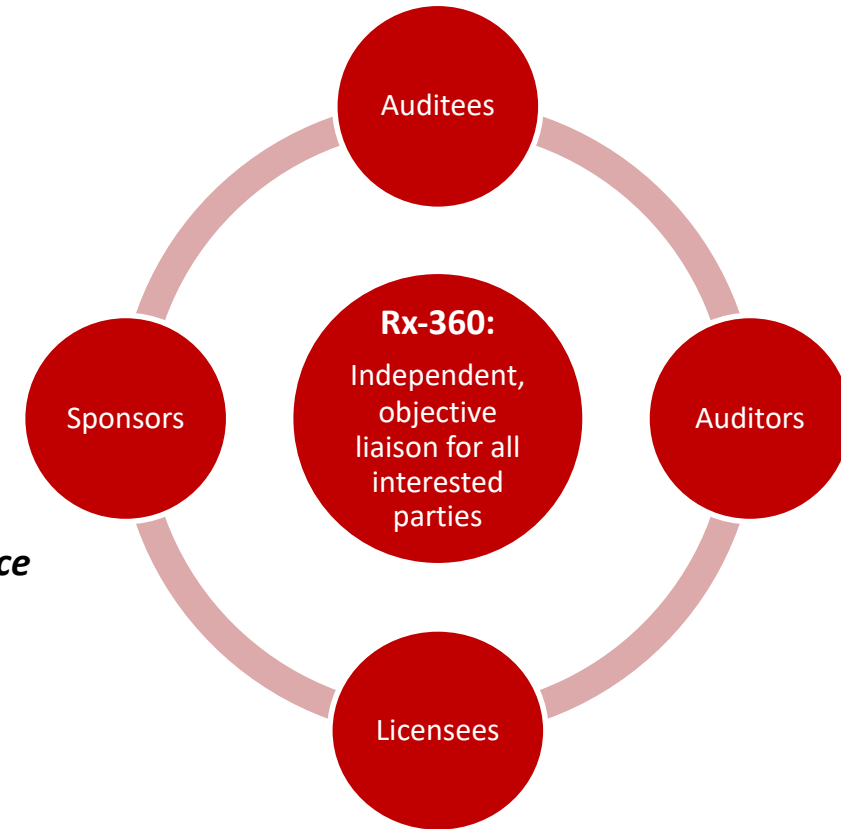
Member-developed audit checklists, based on industry standards

Joint Audit Program[®]

Program Utilization

- The **Rx-360 Joint Audit Program[®]** is open to members as well as non-members
- **Sponsoring:** your company participates in the planning process, through to closure
 - **Co-Sponsorship:** share the audit cost confidentially
 - **Sole-Sponsorship:** solely own the scope and timing
- **Licensing:** your company receives access to the documents after the audit

Easily manage suppliers through the convenience of utilizing existing reports
- **Hosting:** your company receives the benefit of leveraging a single audit for multiple customers



Confidentiality protection is a strict requirement of our program



Audit Scheduling & Execution



- Sponsor audit requests
- Rx-360 checklist (criteria) identified
- Audit cost quoted; co-sponsors may join (confidentiality)
- CDAs executed
- Audit dates secured
- Audit firm selection
- Collaborative agenda development
- Audit execution
- Review draft report (auditee and sponsor)
- Final report signed and issued to auditee & sponsors
- Audit added to Rx-360 Licensable Library
- CAPAs tracked to closure
- Closing letter issued

Industry Value through the Joint Audit Program®

- The burden on your internal resources is **reduced**
- Sponsor requirements recorded via **confidential** special requests
- Co-sponsorship **reduces** your audit cost
- Sponsor **review of draft** audit report
- **CAPA** follow up, through to closure, managed on your behalf
- The final deliverable is the complete audit document package, providing suitable **vendor controls**
- Real-time **communication** on status updates or changes
- From beginning to end, Rx-360 acts as the central liaison between all parties, **always protecting your confidentiality**

Joint Audit Program® Members-Only Benefits

- **50% discount** when licensing reports
- **Waived administrative fee** when sponsoring audits
- Opportunity to participate in confidential peer-led working groups, such as the **Audit Operations Group**
- Contribute to **Audit Checklist** development
- Automatic enrollment in **Credit Program**

Members-Only Credit Program

Money invested to sponsor an audit can be recouped as that audit report is licensed to others, through the accumulation of dollar-for-dollar credits, up to your sponsorship fee. Earned credits can be spent on additional audit sponsorships or licenses.

Real-Time Data on Credit Activity

- Semi-Annual reporting and upon request
- Statement sections display Pending, Earned and Used Credits
- Planning your audit ROI
- Reviewing Rx-360 audit utilization

Rx-360 Member Case Studies

Reducing Audit Burden on the Industry



Nearly
\$100,000

in Rx-360 Joint Audit Program Credits

"In just the last five years, GSK has accrued a massive number of credits, which we've applied to subsequent audits and licensable audit reports. It's a benefit that makes Rx-360 membership a no-brainer for us."

Gary Armstrong
Supplier Quality Compliance Manager, GSK



NewAge Industries, a member of Rx-360, is a leading independent, employee-owned manufacturer of fluid transfer systems that produces high-quality tubing, hose, fittings, clamps, and accessories and offers expert project guidance and services. NewAge Industries has tapped into the full potential of Rx-360's Joint Audit Program® by being a member of the consortium through sponsoring audits and leveraging Rx-360's Licensable Audit Report Library.

SAVINGS OF NEARLY
\$110,000
IN AUDIT EXPENSES



Delivering Industry-Leading Value

"The first audit we did was back in 2019. Working with Rx-360 enabled us to get buy-in from the industry on the audit we sponsored," said Chris Boytim, Supplier Quality Manager for NewAge Industries. As someone who has worked for NewAge Industries for nearly 25 years, Chris sees the value Rx-360 provides his organization. "Working with Rx-360 on audit findings and CAPA management is always a collaborative experience."

Mary Marcus is the General Manager for NewAge Industries and has worked for the company for 14 years. She has similar feelings about Rx-360. "Sponsoring audits through Rx-360 gives us the opportunity to form relationships with customers, to learn what their wants and needs are; they are highly valuable." She also noted that NewAge Industries' CEO, Ken Baker, feels the same way. "Ken sees the incredible benefits of our Rx-360 membership. He is a big advocate for Rx-360. The value is easily identifiable by suppliers."



auditsPLUS® Database for Members

Home

Audits

Resource Documents

Audit Requests

Licensing Requests



Pharma Leaders United in Safety



Joint Audit Program®

NEW AUDIT REQUEST INSTRU...

LICENSE REQUESTS INSTRUC...

SPONSORSHIP INSTRUCTIONS

- Secure, customized database with individual login
- Convenient access to Audit Document Packages for audits sponsored or licensed by the individual and their peers
- Members enjoy a customized KPI dashboard reflecting company-wide activity

Thank You!

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