# CAPABILITIES STATEMENT

**GlobalNEP, LLC is a consulting services provider in the Life Sciences industries (Pharmaceutical, Biotech and Medical Devices)**
**Duns Number: 081251815**

**ASTM International Organizational Member (E55 Committee) #2059689**

## PAST PERFORMANCE / Relevant Projects

- Parenteral Facilities Instrumentation & Controls
- **Data Integrity** Remediation Project
- **Quality Risk Management** Global projects and Training
- **Remediation** Project – Consent Decree (Facilities, Utilities and Equipment)
- Electronic Batch Record Implementation
- Packaging Line Serialization – CSV Support
- Release by Exception Project (Fette Compression Machine and Bioreactor)
- **Risk–based** C&Q of Process Equipment and Utilities

## Accomplishments

- Selected to design entire **QRM Strategy** for new product introduction, shifting from single–API to multi–API facility. Internal Audits (J&J) and Quantic Audits with zero observations.
- Selected to define and lead the rollout for global MES implementation strategy. Client based in Canada / Platform: **Werum PAS–X**
- Third contract extension for **Managed Services** agreement (local support) at biotechnology firm / Pas–X and **OSI Soft's Pi** platforms.
- Partner of the Year – Award by Strategic Sourcing @ Johnson & Johnson

ASTM INTERNATIONAL MEMBER

**Key Differentiators:**

SMEs in ICH Q8/Q9/Q10
Reviewer and Approver of ASTM–E2500
ASTM E55 Organizational Member
16+ years of Experience in Regulated Industry
**Patient–Driven / Quality and Compliance oriented**

## Clients

AMGEN
Johnson & Johnson
Pfizer
teva
Mylan
Patheon part of Thermo Fisher Scientific
Bristol-Myers Squibb
ETHICON a Johnson & Johnson company
Baxter

## Technologies

Wonderware by Schneider Electric Authorized Distributor
CERTIFIED PARSEC
Rockwell Automation
THINMANAGER
vmware PARTNER PREMIER SOLUTION PROVIDER
OSIsoft. partner
OEEsystems Operational Excellence Solutions
NPN NUTANIX PARTNER NETWORK
OPTEL

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## GlobalNEP's Core Competencies are divided in three Business units:

### Software Development / Integration

- SCADA & PLC
- DB Administration
- MES
- Data Historian
- Desktop & Mobile Apps
- Data Analytics
- Business Intelligence
- Real-Time Prediction
- ERP

### Technical Workforce

- Engineers
- Scientists
- Technicians
- C&Q Specialists
- Validation Specialists
- Quality Consultants
- Lab. Technicians
- Project Managers
- Contract to Hire

### Managed Services (24/7 Help Desk)

- Help Desk
- Tech Support
- System Administration

### Software (SaaS)

- LIMS
- DMS / QMS
- ERP

QRM Software

### Regulatory Compliance

- **Risk-based Validation Services**
- **Quality Risk Management**
- CAPAs / Investigations
- Regulatory Affairs
- Validation: Process, Cleaning
- C&Q: Facilities / Utilities
- Remediation

### MES Design and Implementation

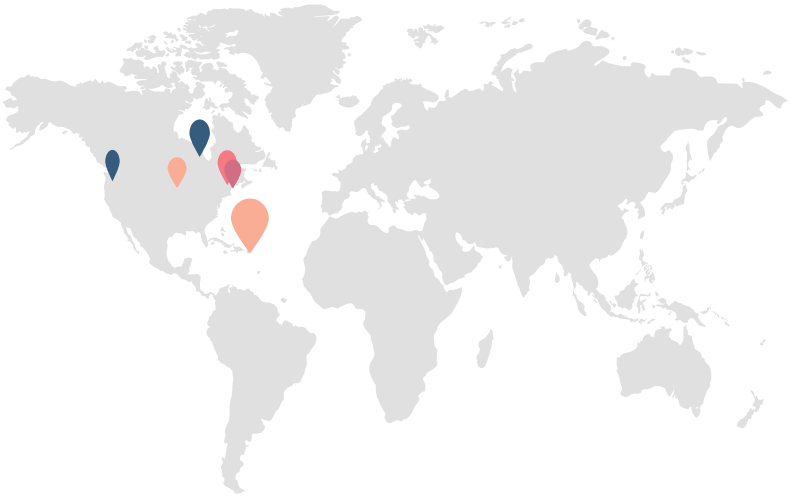
- Requirements Gathering
- Line Performance Analytics
- SPC
- Custom Reports
- Dashboards

**(787) 365-3296 / jon@globalnep.com**

**WWW.GLOBALNEP.COM**

## MISSION STATEMENT

**Use our solid Network of Experience Profesionals to Help manufacturing organizations optimize and improve product quality and efficiency of operations by implementing latest global practices, integrating Operational Technologies and Information Technologies.**



## GLOBAL PARTNERS:

Inteldot · CINCO · PSI · JCA · OPTEL · NUTANIX PARTNER NETWORK · THINMANAGER A Rockwell Automation Technology · OEEsystems Operational Excellence Solutions · OSIsoft · vmware