ADVANCED COMPLIANCE AND PERFORMANCE

Client: Italian

Industrial Sector: Chemical/Pharmaceutical

Revenue: 1 - 1,3 MLD EUR

For over 50 years the Company has been developing, producing and marketing reagent kits for laboratory diagnostics throughout the world.

- **Numbers:**
- 8 sites around the world
- 20,700 assets
- 45,000 spare parts
- 24 months of project development, currently in continuous support



Solutions used:

- HxGN EAM platform in SaaS Hexagon
- Infor OS
- Interconnection between HxGN EAM and SAP

Systems intergrations:

- **HxGN EAM**
- SAP (ERP system)
- LIMS (Lab. Information Management System)

Client's Objectives and Challenges:

- Comprehensive management CFR21-PART 11 compliant multi-site pharmaceutical processes
- Interconnect label printers for CFR21-PART 11 compliant asset tagging containing QR codes, maintenance data, expiration dates and many other fields
- Complete management of calibration modules:
 - Calibration in direct comparison (EAM standard module)
 - Two more advanced modules for initial uncertainty determination and metrological confirmation tools

Achieved results:

- Optimize processes asset management, calibration and other processes - with greater accuracy and efficiency
- Complete traceability of maintenance activities via Audit Trail and certified **Electronic Signature**
- 99.5% of maintenance and calibration activities are scheduled
- **Identification** and **direct management** of multi-site-process-machine line KPIs



HxGN EAM helped us achieve a centralized and complete management process of maintenance and calibration, validation and activities in compliance with legal obligations.

CERTIFIED ISO 9001 & ISO 27001









CERTIFIED PARTNER





SUPPORTING MEMBER





make IT smart!