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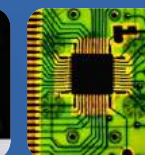
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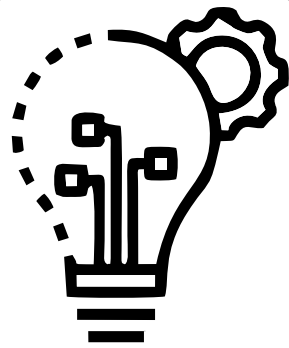
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V 1.28

**TECHNICAL COMPLIANCE, SUPPLY CHAIN & GLOBAL TRADE
MAKING BUSINESS AND SOFTLANDING WITH CONFIDENCE**





Process engineering

- Assessment of current degree technical/regulatory compliance.
- Assets and risk management.
- Capacity development: Design, Update & Upgrade of process & technologies (re-engineering).
- Vocational reconversion.
- Process & facilities certification.
- Government licenses/permits.
- Trademark and IP registration.



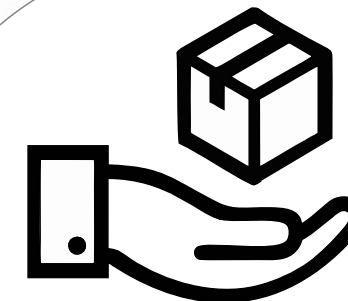
Sourcing

- Continuous assessment of suppliers and contractors (including 2nd-party audit).
- Suppliers development.
- Integration among suppliers.
- Optimization of inventories.
- Vocational reconversion.
- Competences development.
- Socio-economic development.



Manufacturing/Production

- Continuous maintenance of the requirements framework and assessment of compliance.
- Delegated control: (a) quality, HSE, and safety; (b) deviations, defects, nonconforming process & products; (c) waste, rework, complaints and returns.
- Delegated manufacturing.
- Capacity/process optimization.



Logistics

- Fulfillment of warehousing and transportation requirements.
- Active support in international commerce activities, including warehousing, transportation (intermodal), and customs.
- Assurance of the integrated security in the supply chain.



Softlanding Improving Time to Market T2M

- Business structures creation.
- Analysis of business scenarios and demand eco-systems.
- Tax and pricing strategies.
- Market development:
 - Analysis of entry barriers.
 - Business channels (sales, distribution, care/service).
 - Registration as a supplier.
 - Partners development.

Extra: Food/Bev/Med-Dev safety

Food Safety (FDA/FSMA 7-CFR Title 21)
★ ISO 22000 series / FSSC 22000
Organic Foods (ISO 19657 - CFR)

Risks

ISO 31000
NIST RMF

Business Associates

Anti-Money Laundering/
Counter-Terrorism
FATF - FinCEN / OFAC

Supply chain and process security

Supply Chain Security - ISO 28000/1 ★

Info-security, Cybersecurity & Traceability

ISO 27001 ★
ISO 27017/18 ★
ISO 27032
NIST SP.800

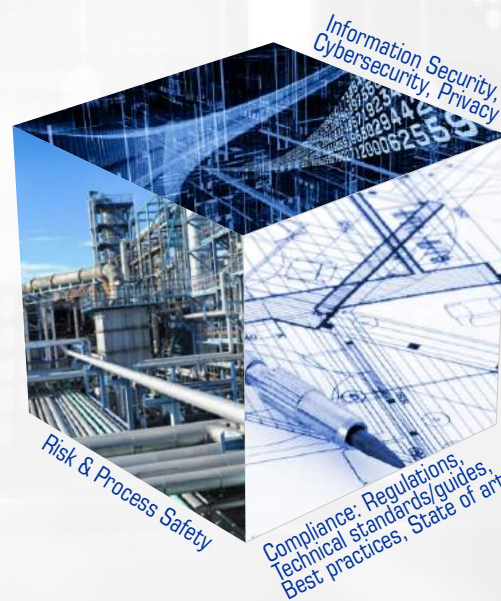
Transportation Security

+ Sanitary/Phitosanitary risk
ISPM / FDA-USDA / FAO-IPPC

Physical security

- Access
- Facilites

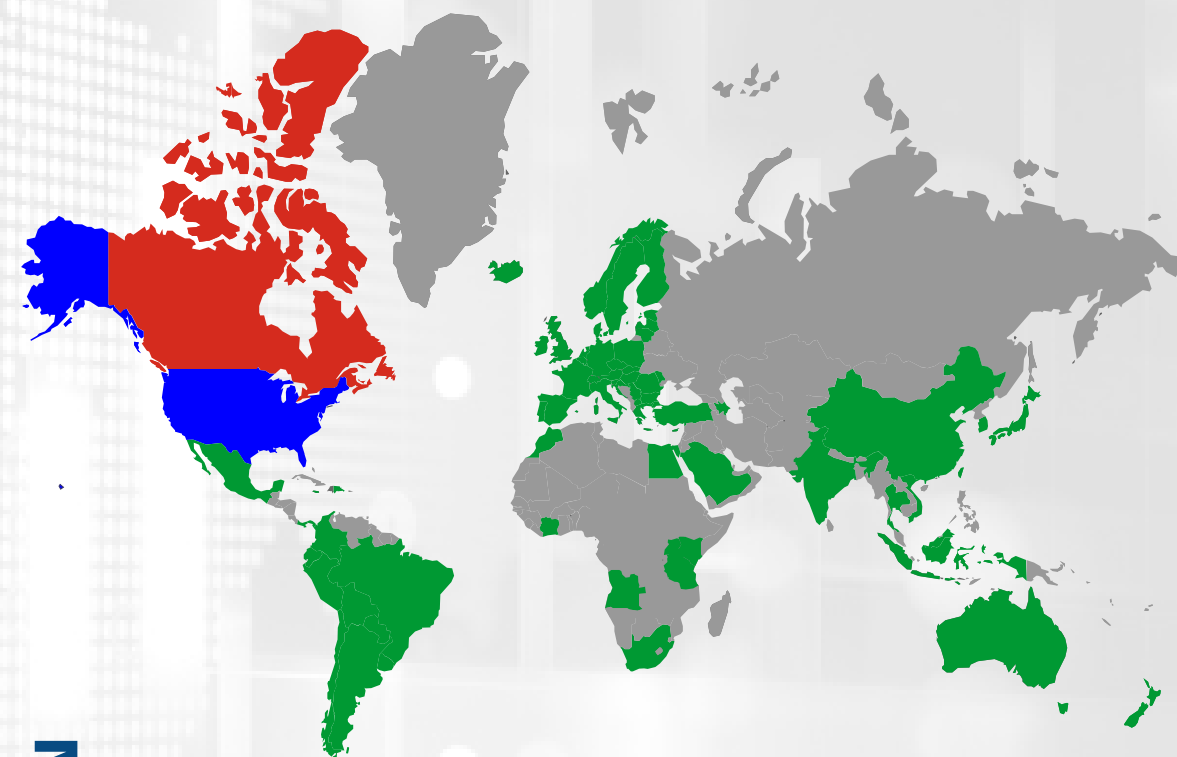
People security + training



★ Management systems with a star can be certified.

INTELLIGENT SUPPLY CHAIN AND TECHNICAL COMPLIANCE

* Achieving the maximum degree of compliance and conformity to do business local & globally with confidence, quality & safety



GLOBAL SUPPLY CHAIN Programs supported

- CTPAT (US) - Customs Trade Partnership Against Terrorism
US Customs and Border Protection (CBP) / SCS initiative.
+ Maritime Transportation Security Act (MTSA) on IMO/ISPS
- AEO/OEA (EU/WCO) - Authorized Economic Operators (AEOC/AEOS)
European Union & World Customs Organization SCS program.
CTPAT ↔ AEO/OEA Mutual Recognition Agreements
- PIP (Canada) - Partners in Protection
SCS program of the Canada Border Services Agency.
- SAFE Framework (Global)
World Customs Organization (WCO) Trade Security program.
International Ship and Port Facility Security Code (ISPS Code)
- International Maritime Organization (IMO)

FOOD (AND BEVERAGES) SAFETY

- **ISO 22000 / FSSC** - Food Safety Management Systems;★
- ISO 17025 metrology/measurement practices;
- The **FDA** Food Safety Modernization Act (FSMA);
- Organic farming & production (FDA/**USDA**-AMS);
- Sanitary/Phitosanitary risk (USDA / FAO-IPPC);
- Other frameworks: - Food Service Packaging Institute (FPI)/loP/PPM;
- The Safe Quality Food Institute (SQFI) (FMI);
- The BRCGS Global Food Safety Standard;
- International Featured Standards (IFS);
- The Global Food Safety Initiative (GFSI).



Farming > Manufacturing/Processing > Packaging > Conservation > Storage > Transportation

LIQUOR, ALCOHOL (INDUSTRIAL/FUEL), AND TOBACCO

- **ISO 22000 / FSSC** - Food Safety Management Systems;★
- ISO 17025 metrology/measurement practices;
- The **FDA** Food Safety Modernization Act (FSMA);
- Alcohol and Tobacco Bureau (TTB) regulated industries;
- The Craft Beverage Modernization Act;
- (TTB) Certificate of Label Approval/Exemption (COLA);
- Other frameworks: - Food Service Packaging Institute (FPI)/loP/PPM;
- The Safe Quality Food Institute (SQFI) (FMI);
- The BRCGS Global Food Safety Standard;
- International Featured Standards (IFS);
- The Global Food Safety Initiative (GFSI).



Fabrication > Packaging > Storage > Transportation

MEDICAL DEVICES (AND SUPPLIES) AND PHARMA

- **ISO 13485** - Quality Management Systems (QMS) for Medical Devices;★
- ISO 14971 / ISO 24971 / Serie ISO 1642 / Serie IEC 62366 / ISO 31000 Risk Management Systems (RMS) for Medical Devices;
- Serie ISO 10993 / ISO 21726 - Evaluation of Medical Devices;
- Serie ISO 80002 / IEC 62304 - Medical Device Software (QMS);
- Serie ISO 11607 - The FPI/loP/PPM packaging guidelines.
- USA: - FDA Center for Medical Devices & Radiological Health (CDRH);
- The FDA Food Safety Modernization Act (FSMA) Title 21;
- Europe: - (EU) Medical Devices Directive (MDD)
- (EU) Medical Device Regulation (MDR);
- (EU) The In Vitro Diagnostic Medical Devices Regulation (IVDR);
- ETSI (ERM Group) Serie 300 (EMC) - Radio Equipment Directive (RED).



Fabrication > Packaging > Storage > Transportation

INDUSTRY AND ADVANCED MANUFACTURING

- **ISO 9001** - Quality Management Systems (QMS) + Specific product QMS;★
- Globally Harmonized System of Classification and Labeling of Chemicals (GHS);
- USA: - EPA The Toxic Substances Control Act (TSCA) / The Pollution Prevention Act (PPA);
- DoT Pipeline and Hazardous Materials Safety Administration (for transportation);
- USDA Movement of used vehicles, machinery and equipment (VME);
- Europe: - Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- Global: - HAZCOM / OSHA Hazard Communication Standard (HCS) & NIOSH;
- EU/US specific industry technical/safety specifications;
- IFC & NFPA Fire prevention;



PROFESSIONAL SERVICES

- **ISO 9001** - Quality Management Systems (QMS);★
- Software: - (SQUARE) ISO 25000, ISO 25010, Serie ISO 8000 ★
- IT, Systems, Software Quality Requirements/Evaluation;
- Finance: - Serie ISO 9564, Serie ISO 11568, ISO/TC 68/SC 2
- Healthcare: - ISO 21091 / 13940 / 17975, Serie ISO 81000, HIPAA
- Marketing: - ISO 20252 - Marketing services
- Sustainability: - ISO 20121 and ISO series 311XX / 219XX

