

# Conformity Assessment

Supporting Transatlantic Trade  
Standards and Conformance for Business and Regulators

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- ❖ **What** is conformity assessment? It is the demonstration that a product (process, system, person or body) meets requirements.
- ❖ **Why** conformity assessment? To have a reasonable level of confidence that a product meets market or regulatory requirements.
- ❖ Conformity assessment may take several forms -- testing, certification (of products or management systems), inspection and accreditation.
- ❖ These activities may be used by themselves or in various combinations.
- ❖ **Who** carries out these activities? The supplier, the buyer, an independent third party and/or government.

- Each conformity assessment activity has its advantages and disadvantages. Each has its place and its applications.
- The risks associated with non-compliance should guide the rigor and independence of the conformity assessment scheme.
- How much risk are stakeholders willing to accept?
- How much confidence do stakeholders need?
- What resources are available?
- Penalties associated with non-compliance (market and regulatory) and timely mechanisms that effectively remove non-compliant products (recall systems) should be taken into consideration.

- ✓What about competence? What about confidence in the independence, impartiality, technical know how and management processes of organizations that carry out conformity assessment?
- ✓Accreditation (of laboratories and conformity assessment bodies) is used when it makes sense for a third party to determine if an organization meets certain criteria.
- ✓Accreditation determines if the organization has staff with appropriate knowledge, if they understand the technical requirements and have the right equipment, if the conflicts of interest exist and are appropriately managed, if the operation is managed adequately, if there is a complaint and appeals process, etc.

In the United States,

- ❖ Supplier's declaration – formal and informal – is extensively used.
- ❖ In some sectors private sector programs preceded government regulation and are sufficiently effective that government intervention is avoided.
- ❖ There is a great diversity of approaches to conformity assessment, both by the government and the private sector.
- ❖ There is reliance on private sector standards and conformity assessment programs (per the National Technology Transfer and Advancement Act and OMB Circular A119).



# Thank you for your attention

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