


# ***Implementing Standards Across International Borders***


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# Objectives

- Creating voluntary global standards
  - Performing assessments in a foreign country
  - Preparing for assessments by a foreign inspection team
  - Complying with voluntary and mandatory standards
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# Creating Global Standards

- Standards writing committee
  - International representation
  - Collegial associations
  - Voluntary participation
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# Challenges

- Timing of teleconference calls
  - Conduct of meeting
  - Coming to consensus
  - Scientific evidence vs professional bias
  - Local regulatory laws
  - Standards vs guidance
  - Maintaining time frame
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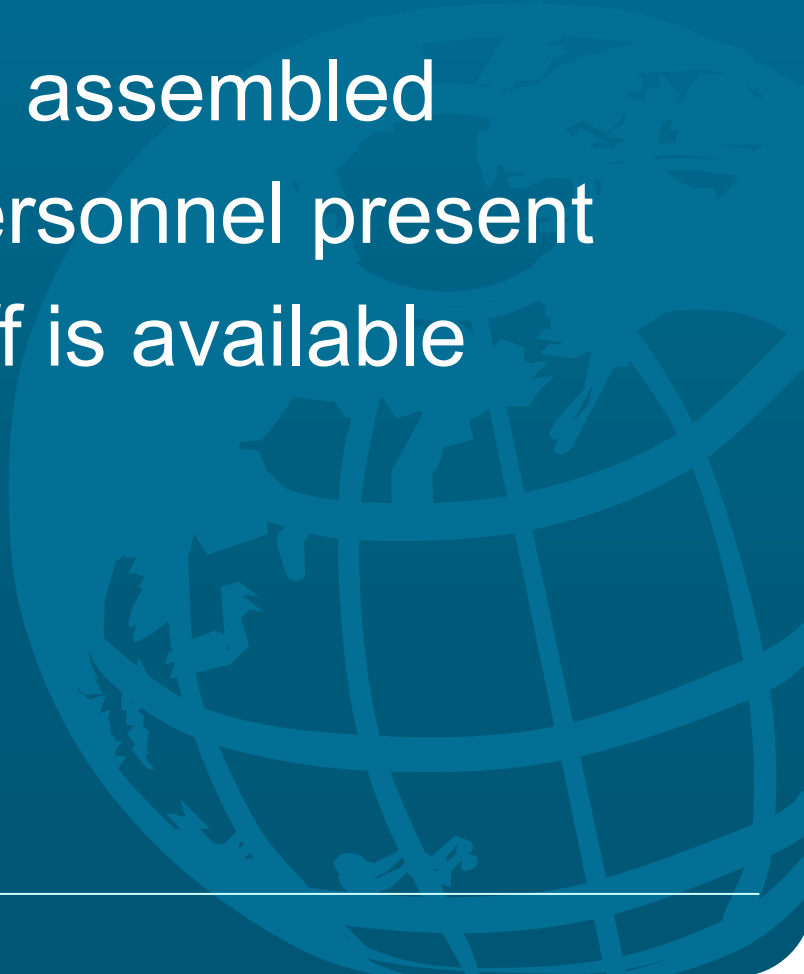
# Performing Assessments in a Foreign Country

- Assemble international team
- Assign team leader, additional inspectors and trainees
- Have relevant documents translated
- Thoroughly review material before hand
- Access to translator on-site

# Challenges

- Language barrier
  - Cultural and professional differences between countries
  - Unfamiliar methodologies
  - Unfamiliar local regulatory laws
  - Consistency of inspections
  - Assuring thorough inspection in allotted time
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# Preparing for Assessments by a Foreign Inspection Team

- Know the standards
  - Have all documents assembled
  - Have all relevant personnel present
  - Ensure that QA staff is available
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# Challenges

