



## Navigating International Regulatory Compliance Obstacles



# **Aseptico** Who We Are



- Established in 1975; headquartered in Woodinville, WA, USA
- Family-owned, privately held, US medical device manufacturer primarily serving the dental equipment space, including electric motors and portable field equipment
- ~100 Employees = SME (small to medium-sized enterprise); Multi-year STEP-Voucher recipient
- In addition to FDA, compliant with ISO 13485:2016, CE, and Health Canada regulatory requirements; Working on EU MDR
- Winner of 2016 President's E Award for Exports – the only Washington State company to do so!





# **Aseptico**® What We Do



*Advancing Global Business*

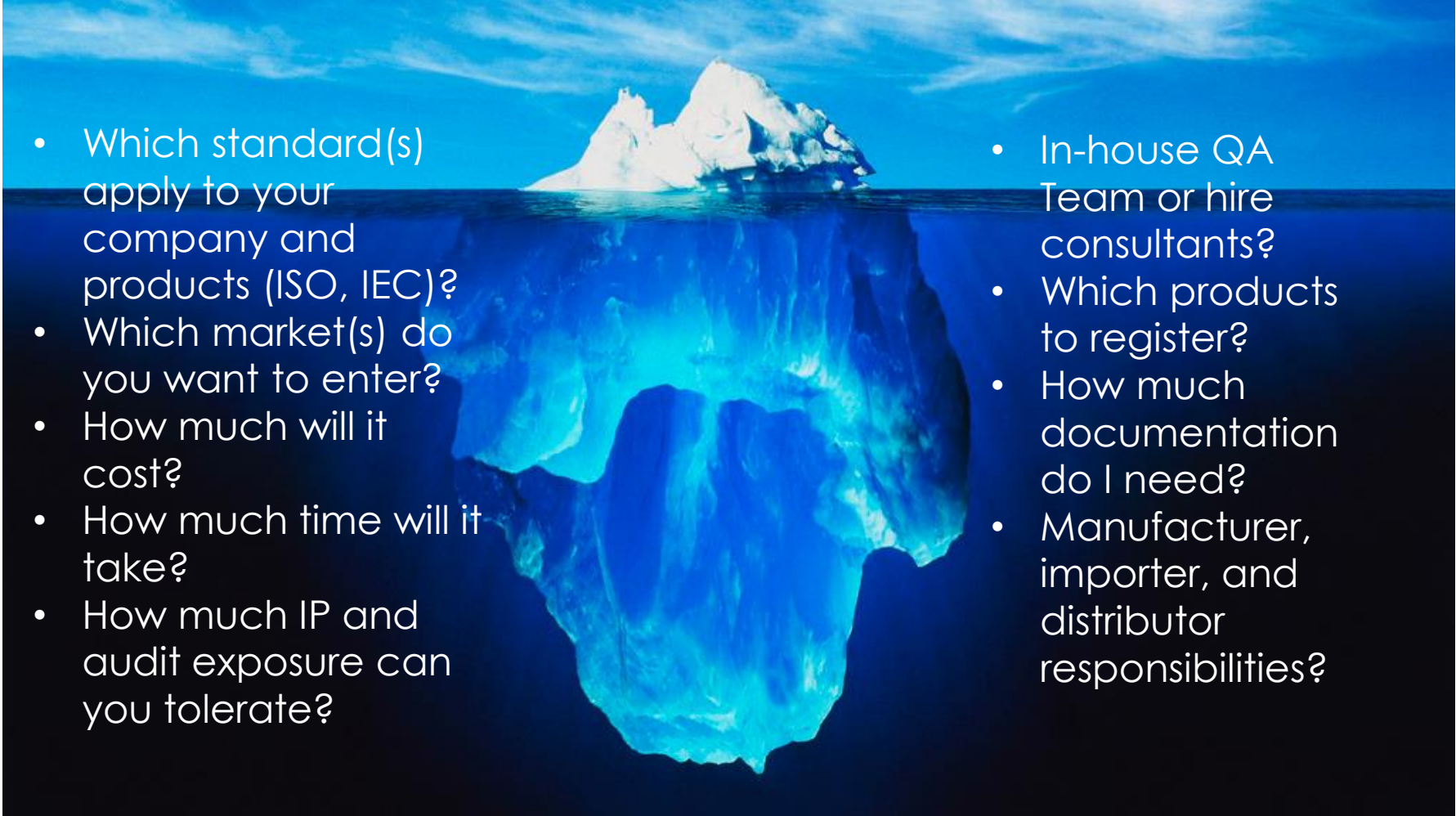
# Reasons for Regulatory Compliance



- Market participation
- Revenue generation
- Product safety
- Marketing

Without regulatory compliance, you can't play in the sandbox!

# Danger Ahead!

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- Which standard(s) apply to your company and products (ISO, IEC)?
  - Which market(s) do you want to enter?
  - How much will it cost?
  - How much time will it take?
  - How much IP and audit exposure can you tolerate?
  - In-house QA Team or hire consultants?
  - Which products to register?
  - How much documentation do I need?
  - Manufacturer, importer, and distributor responsibilities?



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# All Hands on Deck



- Ensure there is full management buy in
- Develop a regulatory compliance strategic plan
- Be prepared to surrender markets or delegate to strategic partners
- Consider selectively withholding products
- Apply for STEP Grants!
- Be patient

# Helpful Resources



**U.S. Chamber of Commerce**



# 2021 National Small Business Exporter Summit



**Thank You...**  
**Please share your questions**

