High Tech Design Safety, Inc.

Managing requirements for product development at the concept and product requirements stage;
Then on to Approval
Vision and Purpose

- To develop products through a process that maximizes return on investment and quality, while minimizing time-to-market, design reiteration, length and depth of testing.
To provide confidence through Early selection and identification of global certification requirements followed on with practical implementation and evaluation of equipment to global standards
Early Design Requirements

- Product Purpose
- Market Segments
- Performance
- Cost
Areas of Focus

- Equipment and Products
  - Electrical Panels, Controls, Systems
  - Consumer
  - Semiconductor
  - Flat Panel Display
  - Industrial equipment
  - Medical
  - Solar
  - Green Energy
  - Gas Delivery

- Standards and Protocols
  - CE
  - ATEX
  - IECEx
  - UL
  - CSA
  - NFPA
  - SEMI S2
  - NEBS
  - EMC/EMI
  - ROHS
  - China
Conformity Paths

Design Phase
- Product Requirements
- Hazards Risk Analysis
- Standards Identification
- Design Guides
- Design Review
- Prototype Safety
- Alpha and Beta System Review

Conformity Assessment
- Markets
- Standards
  - Harmonization
- Documentation Package
- Test Plan
- Evaluation and Test
- Exit Briefings
- Conformance Reviews
- Conformity Paths
- Technical Construction File
- Final Product Report
- Conformity Certificates
Regulatory and certification

Which Markets
- USA
- Canada
- South America Central America Mexico
- European Union
  - United Kingdom
- Rest of The World
  - Japan
  - China
  - Russia
  - South America
Do I really need certification at this point

- Low Voltage
- Low hazard
- Low Risk
  - Business decisions?
Customers Decide

- Government
  - National Labs
- Jurisdictions
- Hospitals
- Hotels

Examples
Risk, Liability, and the Market

- What is the risk
- What could be lost
- What is the liability
- Initial Risk Assessment
Must Be Certified

- Medical equipment
- Line voltage and above
- Pressure vessels
- Explosion protection
- Safety Devices
- Life safety equipment
So now what...

- Scope
- Standards
- Components
- Testing

- Required design features
Example From Audience

- Your Product
Example Explosion Prevention
NAEx, IECEX, and ATEX

- Scoping includes;
  - Determining the Countries of use gives use the approvals scheme needed
    - USA and Canada   NAEx
    - EU   ATEX
    - Rest of World   IECEX
  - The required Hazardous Locations Approval Levels
    - Zone 0
    - Zone 1
    - Zone 2
    - Class 1 Div. 1
    - Class 1 Div. 2
NAEx North American Approvals including UL and CSA
  ◦ Requires Normal ordinary Locations UL CSA Approval as well.
ATEX European Approvals for Surface and Mining
IECEX Global Approval from IECEx for Surface and Mining
MSHA Approval from USA Mine Safety
Request and Scope 
Equipment to be Approved

1. Protection Techniques available
2. Parts and Suitability
3. Power inlets
4. Glands and cabling

Additionally Approval of:
1. Installation Instructions
2. Manuals
3. Markings
4. Technical Construction File
Additional Requirements

- Quality System Approvals both Designer and Contract Mfg.
  1. Quality Systems Conformance, Depth, and Activity
  2. On Site and Off Site Construction and Manufacturing
- With Follow up Services for Quarterly inspection
- And change notice consulting and review and submission
Then you Need

- Efficient Path to conformity
  - Through knowledgeable and practical people
  - That know technology
  - Understand design
  - And can apply the standards

- Minimizing time and costs while achieving conformity is key.
Missed Steps

- Expectations of Labs
- Lack of documentation
- Shipping without clearance to market
- No driver manager for process
Next Steps

- Complete Quote for Project
- PO for HTDS
- Review Existing Designs /Requirements
- Build Technical Construction File
- Evaluation and Testing
- Quality System Approval
- Marking
- Follow up Auditing
Estimated Costs and Needs

- **Phase 1**
  - Scope, plan project, collect data, system details, review TCF, develop markings, and scopes for testing, initialize labs, and complete phase 1
  - $TBD
  - Time Line 1–2 Months

- **Phase 2**
  - Test Equipment, complete conformity reports, build out inspections files, complete iteration on design changes and documentation changes.
  - $TBD plus fees
  - Time Line 2–4 Months

- **Phase 3 (If Required, This is atypical)**
  - Submit to MSHA for USA Mining approvals
  - $TBD plus fees
  - Time Line 1–2 Months

$TBD Total Estimated Costs
CE Marking

- CE Process

- Directives
  - Machinery Directive,
  - Low Voltage Directive
  - EMC / EMI Directive

- Pressure Equipment Directive
  - Standards
  - Technical Construction File
  - Evaluation and Testing
Machinery Directive

- Safety for mechanical systems
  - Guarding
  - Failure modes
  - Support
  - Lighting
  - Gases
  - Exhaust

- Required Tests
  - Function and Failure Modes
  - Guarding
Low Voltage Directives

- Electrical Safety for Industrial Equipment
- Prevention of Shock
- Fire

- Required Tests
  - The maximum temperature of any external or internal surface
  - Grounding
  - High Pot
  - Voltages
  - Function and Failure Modes of Controls
EMC / EMI Directives

- Ensure interference does not cause a hazard operation
- Ensure system does not generate significant interference to other systems
- Required Tests
  - Minimize through engineering review and design
  - Full testing (other labs recommend) $45,000
  - Savings $45,000 and 2–3 months
Pressure Equipment Directive

- Ensure system is safe under working and possible maximum pressures
- Ensure capability to relieve and lock out pressure
- Determine exposure from an explosion
- Welds, materials, fittings, ratings, listings, and details for file.
- Cryo Standards
Thank You.

Presenter
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Our Clients

And many more...
Clients

- Dell / M3 Design
- Applied Materials
- Tokyo Electron
- IBM
- Samsung
- Texas Instruments
- Accent Optical
- Accretech USA
- Caterpillar
- Halliburton
- National Oilwell Varco
- AMD
- SEMATECH
- Ideal Power
- ATMI
- Praxair
- FOC
- Aviza
- Intota
- LifeStream
- Concurrent
- Emerson
- Xtreme Power
- Global Foundries
- Nanometrics
- Accent
- Metrosol
- N–Line
- PolyFlow
- Tresark
- XsunX
- Bilco
- WaveFront Sciences
- Atonometrics
- Intotoa
- Turck
- PTI
- NEMKO
- Novellus
- Fulcrum
- Cymer
- Slicing Tech
- CAE Online
- Concurrent
- FAS Tech
- NEXX Systems
- Intota
- Ceres
- VUV
- PR Labs
- Varian
- Precision Flow
- Venable
- Bio–RAD
- Thermal
- Motion Computing
- Choc Alive
- ColdBox
- Fireboy
- AMAT (Solar)
- And many others
Why chose HTDS?

- We were founded to solve the equipment manufacturers needs
- We prevent the test lab problem
- Our goal is to get the product to conformity
- We select the proper standards and minimize testing while maximizing product options
- Saving 4–6 months of time line
Contact Information

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