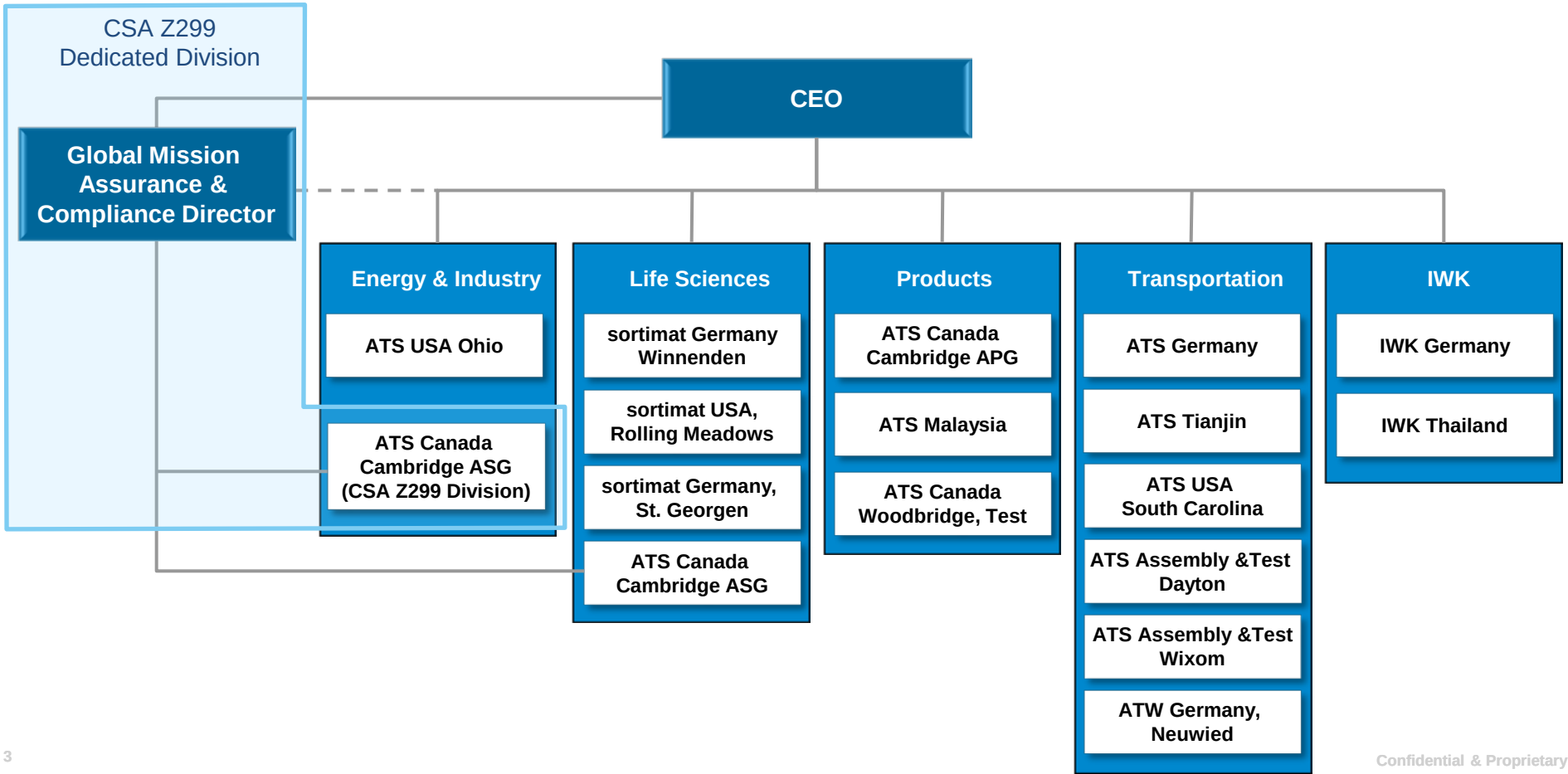
Quality System Overview

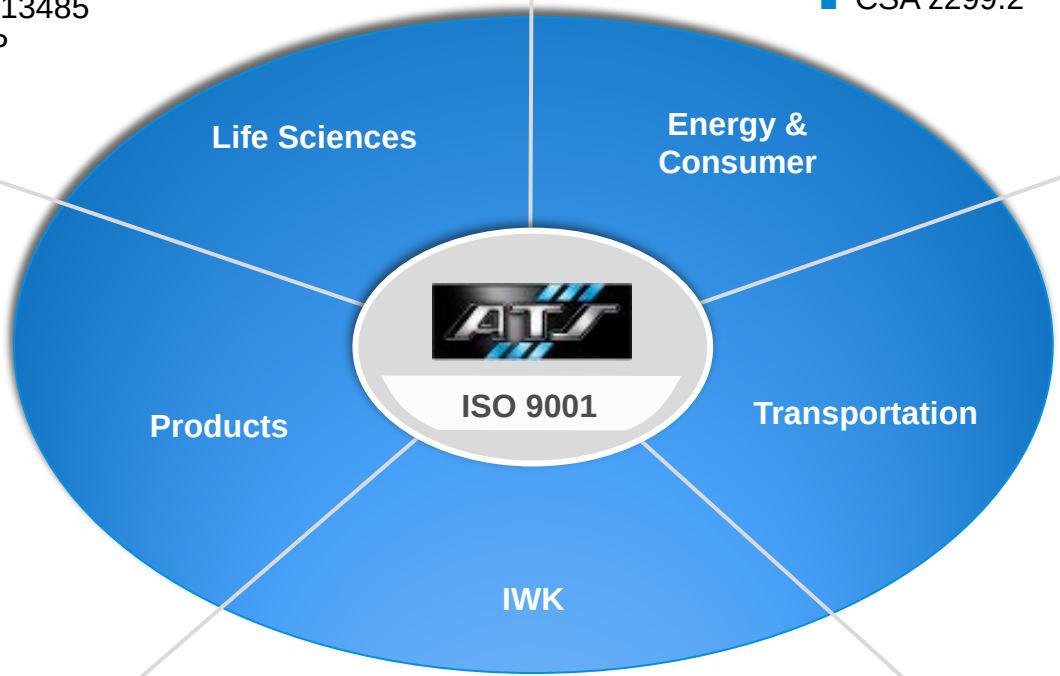
Agenda

ISO Registration & Corporate Requirements	**Governance**
Risk Management	**Mitigation**
Supplier Quality	**Performance**
Inspection	**Verification**
Quality Assurance : Project QE	**Compliance**

ATS Organizational Quality Structure



ATS Organizational Quality Structure



- ISO 13485
- GMP

- CWB 47.1
- CSA B51
- CSA z299.2

- CSA N285
- CSA N286
- C of A – PEO

- ISO 13485
- GMP

- VDA & ISO 14001 (Neuwied)
- NQA
- 10 CFR 20
- 10 CFR 50

- ISO 9001

Quality Systems at ATS

- Third party quality system registration with global appointment (BSI)
  - On line QMS System accessible globally
- Standardized common quality processes in Canada, US, Asia & Europe
- Continual Improvement
  - Common QMS structure
  - Corporate Quality Assessments
  - Global Metrics

BSI Management Systems

NON-APPLICABLE ITEMS, ISO 13485:2003(E)

The following sections of the ISO 13485:2003 standard are not applicable to the scope of registration:

- 7.5.1.2.1 (a) and (b)…….Cleanliness of product and contamination control
- 7.5.1.2.2…….Installation activities
- 7.5.1.3 / 7.5.2.2 ……Particular requirements for sterile medical devices
- 7.5.3.2.2 / 8.2.4.2……..Particular requirements for active implantable medical devices and implantable medical devices

- **Justification for exclusion of specified sections**: ATS is a supplier to the medical device industry and is not a medical device manufacturer. ATS does not have any customer or regulatory obligations to support contamination control, installation, service activities, requirements to support particular requirements for sterile medical devices or for the validation of particular requirements for active implantable medical devices and implantable medical devices therefore, clauses 7.5.1.2.1, 7.5.1.2.2, 7.5.1.3 / 7.5.2.2, 7.5.3.2.2, 8.2.4.2 under the ISO 13485 standard are not applicable.

Risk Management

ATS has established risk management throughout the project life cycle.

- Proposal & Project Management Phase
  - Concept Technical Risk Assessment
  - Regulatory
  - URS
  - Defined Responsibilities
  - Risk Register
- Concept & Design Phase
  - Concept Technical Risk Assessment
  - Failure Mode Effect & Analysis
  - Safety Risk Assessment
  - Proof of Principle (POP)
  - Industry accepted standards and codes
- Procurement Phase
  - Supplier approvals
  - Supplier audits
  - Incoming inspection
  - Supplier performance monitoring
  - Defined procedures for identifying and isolating non-conforming product.
- Build & Integration Phase
  - Manufacturing review process
  - Compliance
  - Project Risk Management Process
  - Build Safety Risk Assessment
  - Project Risk Register
- Close Phase
  - Functional testing is completed in 3 phases
    - Internal Pre FAT
    - Factory Acceptance Testing
    - Site Acceptance Testing
- GMP Equipment Qualification Phase (as required by contract)
  - Installation Qualification (IQ)
  - Operational Qualification (OQ)
  - Traceability Matrix

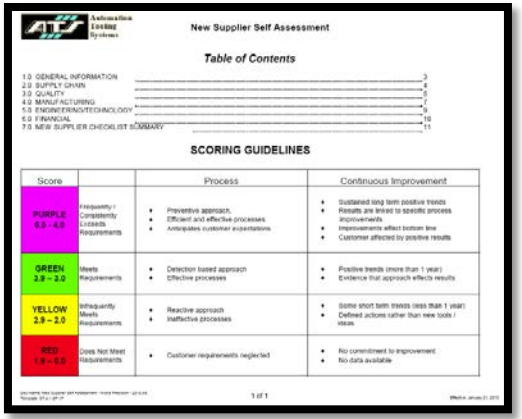
Quality Systems at ATS

- **Supplier Development**
  - Global Approval Process
  - Global Supplier Manual
  - Global Supplier Assessment Process
  - Global Key Supplier Scorecards

- **Quality Systems**
  - Global Business and Quality Management Systems
    - Microsoft Impact Award recipient for best business solution
  - Global metrics with common KPI’s submitted monthly
  - Global Quality procedures adopted to support one company approach
  - Global Process Deviation tool
  - Standard Supplier Corrective Action Management tool
  - Global Calibration software tool (Procal)
  - Global ISO Compliance audits (completed by Global Quality Director)

Supplier Quality & Development

- **Each supplier is approved thru the Evaluation process.**
  - See procedure for details C7.4.1-2P
  - Assessments are done by supplier self evaluation
  - Documentation reviewed
  - Audit performed (onsite or phone)
  - Approved and uploaded to Global Supplier Management Site


New Supplier Self Assessment

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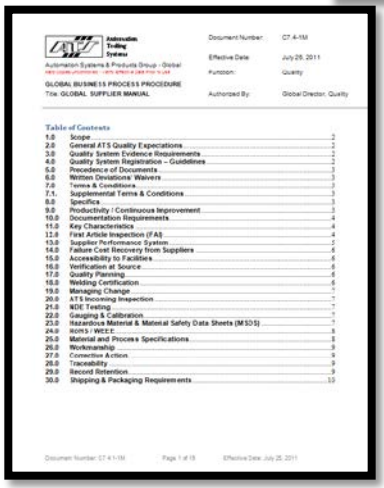
SCORING GUIDELINES

Score		Process	Continuous Improvement
PURPLE 5.0 – 4.0	Frequently / Consistently Exceeds Requirements	• Preventive approach, • Efficient and effective processes • Anticipates customer expectations	• Sustained long term positive trends • Results are linked to specific process improvements • Improvements affect bottom line • Customer affected by positive results
GREEN 3.9 – 3.0	Meets Requirements	• Detection based approach • Effective processes	• Positive trends (more than 1 year) • Evidence that approach effects results
YELLOW 2.9 – 2.0	Infrequently Meets Requirements	• Reactive approach • Ineffective processes	• Some short term trends (less than 1 year) • Defined actions rather than new tools / ideas
RED 1.9 – 0.0	Does Not Meet Requirements	• Customer requirements neglected	• No commitment to improvement • No data available

1 of 1

- **Global Supplier Manual**
  - See procedure for details C7.4-1M
  - Sections addressing (but not limited to)
    - T&C's
    - Documentation requirements.
    - Supplier performance system
    - Workmanship
    - Corrective action
    - Traceability
    - Etc.


Automation Tooling Systems

Automation Systems & Products Group - Global

GLOBAL BUSINESS PROCESS PROCEDURE

Title: GLOBAL SUPPLIER MANUAL

Document Number: C7.4-1M
Effective Date: July 29, 2011
Function: Quality
Authorized By: Global Director, Quality

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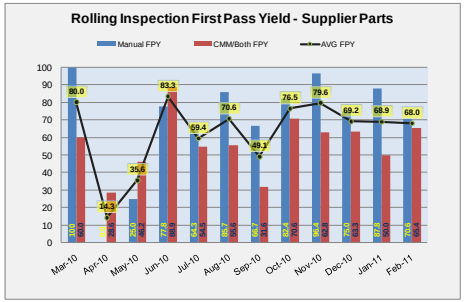
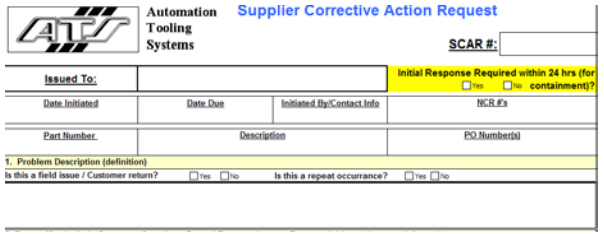
Supplier Quality & Development

- **Supplier Development and Monitoring**
  - **Monthly MRB meetings**
    - Supplier Quality and Supply chain review the supplier results monthly
    - Items covered each meeting:
      - Review Open issues on MRB Action Items list
      - OTD
      - NCR's
      - Inspection FPY
      - Top Worst offenders
      - Reduce NCRs on top 50% of Occurrences from FY10
      - Top Best suppliers
      - LAR
      - PPM
      - SCAR activity
      - Review of Poor Performing Suppliers
      - Issue actions and update MRB Action item Plan



  - **Supplier Corrective Actions**
    - Follow the 8D principle.
    - Suppliers are required to respond within 10 days.
    - Closure to the SCAR is required within 30 days.



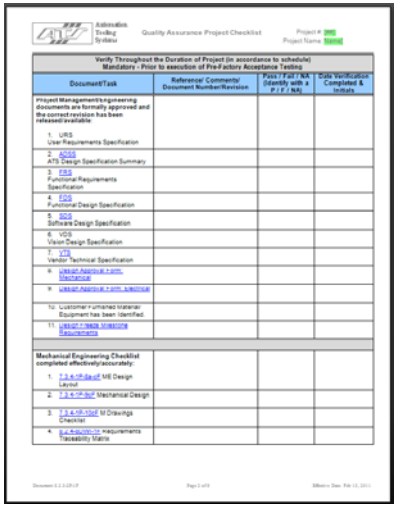
Quality Inspection

- Quality Control:
  - Receiving Inspection
  - CMM measurement capability
  - Key characteristic feature control
  - Product Audit approach
  - External Calibration (ISO 17025)
  - Supplier Source Inspection
  - Non conformance Management (online global DB implementation in process)
  - Quarantine

Quality Assurance

Quality Assurance

- QMS - ISO 9001 & ISO 13485 Audits, CSA N285, CSA Z299.1, CSA B51
- Six Sigma Black Belt on site
- RAB Lead Auditor on site
  (Qualified to 14001, 18001 13485, AS9100 & 9001)
- Real time root cause & corrective action teams
- Statistical capability
- Quality Contract Reviews
- Project Quality Engineering
- Project compliance



Quality Assurance Project Checklist

Verify Throughout the Duration of Project (in accordance to schedule) Mandatory - Prior to execution of Pre-Factory Acceptance Testing			
Document/Task	Reference/ Comments/ Document Number/Revision	Pass / Fail / NA (Identify with a P / F / NA)	Date Verification Completed & Initials
Project Management's engineering documents are formally approved and the correct revision has been released/available:			
1. URS User Requirements Specification			
2. ADSS ATS Design Specification Summary			
3. FRS Functional Requirements Specification			
4. FDS Functional Design Specification			
5. SDS Software Design Specification			
6. VDS Vision Design Specification			
7. VTS Vendor Technical Specification			
8. [illegible]			
9. [illegible]			
10. Customer-furnished Material/ Equipment has been identified.			
11. [illegible]			
Mechanical Engineering Checklist completed effectively/accurately:			
1. [illegible] Mill Design Layout			
2. [illegible] Mechanical Design			
3. [illegible] Drawings Checklist			
4. [illegible] Requirements Traceability Matrix			

AUTOMATION