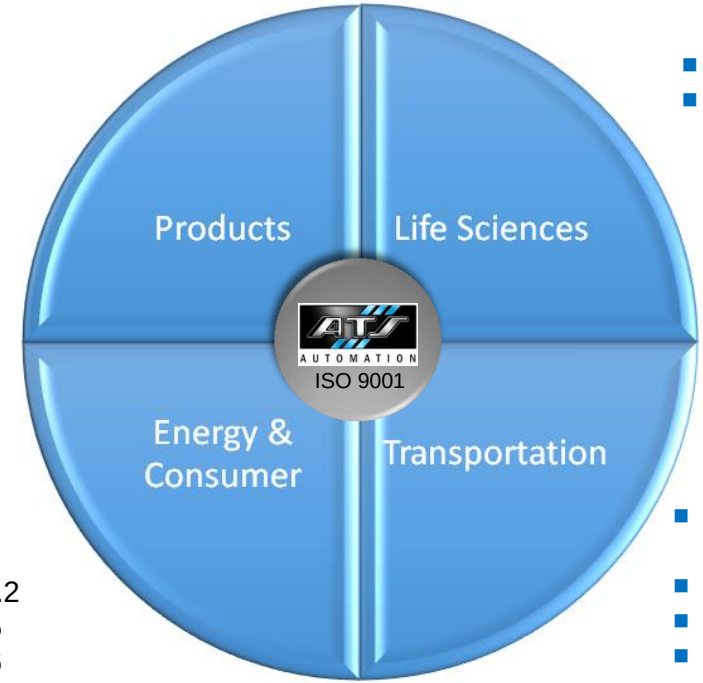
Global Quality System Overview

Agenda

ATS Certifications	**Company**
ISO Registration	**Governance**
Risk Management	**Mitigation**
Supplier Quality	**Performance**
Inspection	**Verification**
Quality Assurance : Gate Review	**Compliance**

ATS Certifications by Industry



- ISO 13485
- GMP

- ISO 13485
- GMP

- CWB 47.1
- CSA B51
- CSA z299.2
- CSA N285
- CSA N286
- C of A - PEO

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

Global 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

ISO 13485

NON-APPLICABLE ITEMS, ISO 13485:2016(E)

The following sections of the ISO 13485:2016 standard are not applicable to the scope of registration:

- Clause 4.2.3……..Medical Device File
- Clause 6.4.2……..Contamination Control (sterile medical device requirement only)
- Clause 7.3.10……Design and Development Files
- Clause 7.5.2……..Cleanliness of Product
- Clause 7.5.3……..Installation activities
- Clause 7.5.4……..Servicing Activities
- Clause 7.5.5……..Particular Requirements for Sterile Medical Devices
- Clause 7.5.7……..Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems
- Clause 7.5.9.2…...Particular Requirements for Implantable Medical Devices
- Clause 7.5.11……Preservation of Product
- Clause 8.2.6……..Monitoring & Measurement of Product (implantable device requirement only)

- **Justification for exclusion of specified sections**: ATS is not a medical device manufacturer and only provides equipment/tooling to this industry. ATS does not have any customer or regulatory obligations to support cleanliness of product, installation, requirements to support particular requirements for sterile medical devices or for the validation of processes for sterilization/sterile and implantable medical devices thus clauses 4.2.3, 6.4.2, 7.3.10, 7.5.2, 7.5.3, 7.5.4, 7.5.5, 7.5.7, 7.5.9.2 and 8.2.6 (implantable devices requirement only) 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

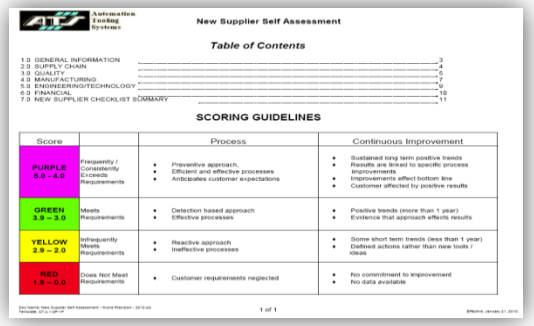
Global Quality Systems at ATS

- **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)
  - Global Gate Review
  - Global Acceptance Testing

Global 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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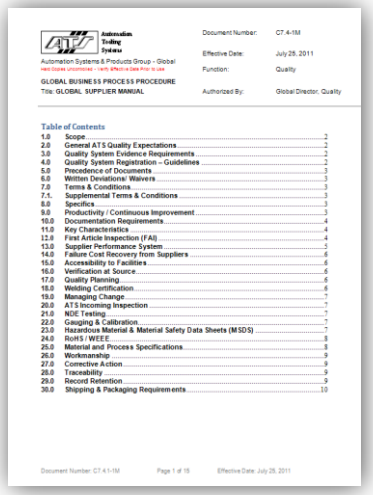
SCORING GUIDELINES

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 effect 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.



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GLOBAL BUSINESS PROCESS PROCEDURE

Title: GLOBAL SUPPLIER MANUAL

Document Number: C7.4-1M

Effective Date: July 25, 2011

Function: Quality

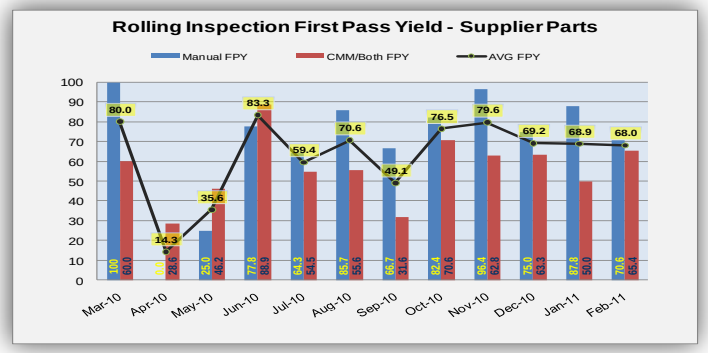
Authorized By: Global Director, Quality

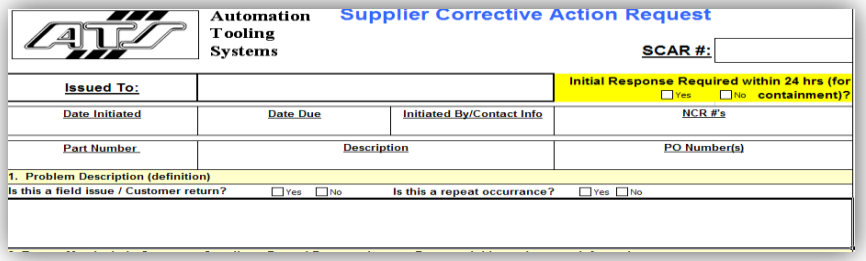
Table of Contents

Document Number: C7.4-1M Page 1 of 15 Effective Date: July 25, 2011

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




Automation Tooling Systems

Supplier Corrective Action Request

SCAR #:

Issued To:		Initial Response Required within 24 hrs (for containment)? ☐ Yes ☐ No
Date Initiated	Date Due	Initiated By/Contact Info	NCR #'s
Part Number	Description	PO Number(s)

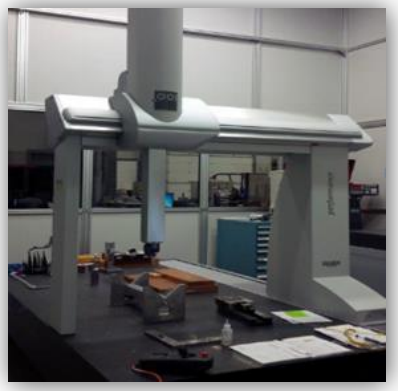
1. Problem Description (definition)

Is this a field issue / Customer return? ☐ Yes ☐ No Is this a repeat occurrance? ☐ Yes ☐ No

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
  - Quarantine

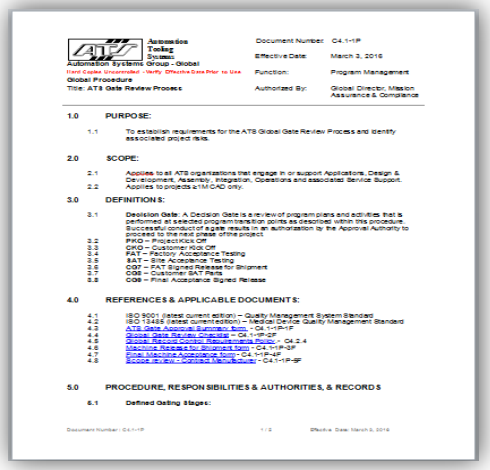
Note: Inspections functions may vary per division.



Global Gate Review

- **Decision Gate:** A Decision Gate is a review of program plans and activities that is performed at selected program transition points. Successful conduct of a gate results in an authorization by the Approval Authority to proceed to the next phase of the project.

- A checklist is completed throughout all gates providing a health indicator score.
- Corporate monitoring is completed on a monthly frequency.



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Global Procedure

Title: ATS Gate Review Process

Document Number: C4.1-1P
Effective Date: March 2, 2016
Function: Program Management
Authorized By: Global Director, Mission Assurance & Compliance

1.0 PURPOSE:

1.1 To establish requirements for the ATS Global Gate Review Process and identify associated project risks.

2.0 SCOPE:

2.1 Applies to all ATS organizations that engage in or support Applications, Design & Development, Assembly, Integration, Operations and associated Service Support.
2.2 Applies to projects ≥1M CAD only.

3.0 DEFINITIONS:

3.1 **Decision Gate:** A Decision Gate is a review of program plans and activities that is performed at selected program transition points as described within this procedure. Successful conduct of a gate results in an authorization by the Approval Authority to proceed to the next phase of the project.
3.2 PKO – Project Kick Off
3.3 CKO – Customer Kick Off
3.4 FAT – Factory Acceptance Testing
3.5 SAT – Site Acceptance Testing
3.6 CQT – FAT Signed Release for Shipment
3.7 CQS – Customer SAT Parts
3.8 CQS – Final Acceptance Signed Release

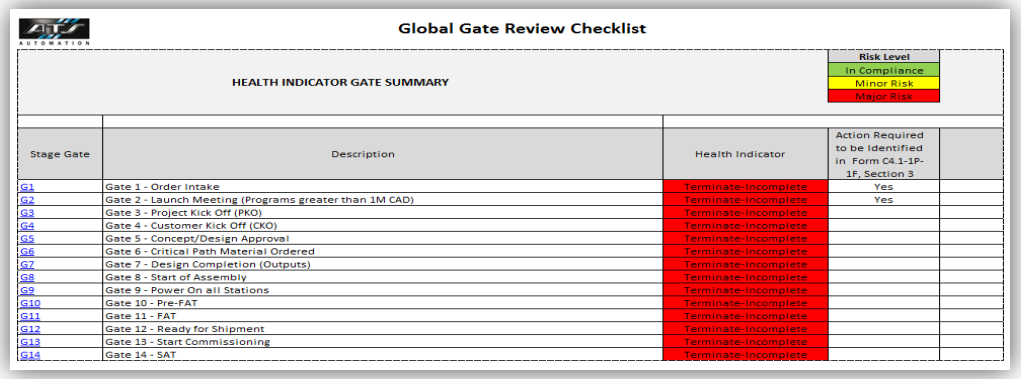
4.0 REFERENCES & APPLICABLE DOCUMENTS:

4.1 ISO 9001 (latest current edition) – Quality Management System Standard
4.2 ISO 13485 (latest current edition) – Medical Device Quality Management Standard
4.3 ATS Gate Approval Summary form – C4.1-1P-1F
4.4 Global Gate Review Checklist – C4.1-1P-2F
4.5 Global Record Control Requirements Policy – C4.2.4
4.6 Machine Release for Shipment form – C4.1-1P-3F
4.7 Final Machine Acceptance form – C4.1-1P-4F
4.8 Scope review - Contract Manufacturer – C4.1-1P-5F

5.0 PROCEDURE, RESPONSIBILITIES & AUTHORITIES, & RECORDS

6.1 **Defined Gating Stages:**

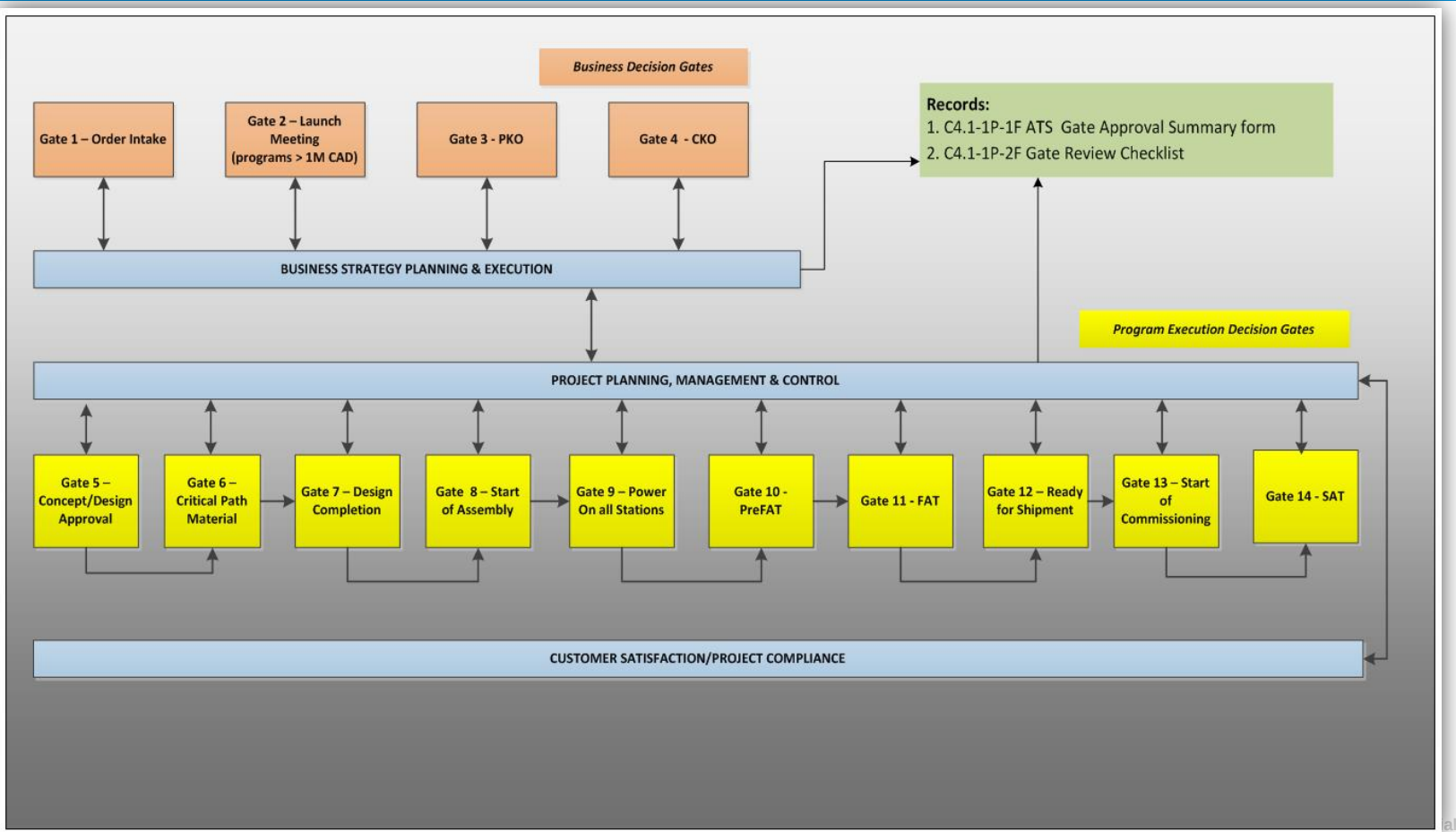
Document Number: C4.1-1P 1 / 3 Effective Date: March 2, 2016



Global Gate Review Checklist

HEALTH INDICATOR GATE SUMMARY			Risk Level: In Compliance / Minor Risk / Major Risk	
Stage Gate	Description	Health Indicator	Action Required to be Identified in Form C4.1-1P-1F, Section 3	
G1	Gate 1 - Order Intake	Terminate-Incomplete	Yes	
G2	Gate 2 - Launch Meeting (Programs greater than 1M CAD)	Terminate-Incomplete	Yes	
G3	Gate 3 - Project Kick Off (PKO)	Terminate-Incomplete		
G4	Gate 4 - Customer Kick Off (CKO)	Terminate-Incomplete		
G5	Gate 5 - Concept/Design Approval	Terminate-Incomplete		
G6	Gate 6 - Critical Path Material Ordered	Terminate-Incomplete		
G7	Gate 7 - Design Completion (Outputs)	Terminate-Incomplete		
G8	Gate 8 - Start of Assembly	Terminate-Incomplete		
G9	Gate 9 - Power On all Stations	Terminate-Incomplete		
G10	Gate 10 - Pre-FAT	Terminate-Incomplete		
G11	Gate 11 - FAT	Terminate-Incomplete		
G12	Gate 12 - Ready for Shipment	Terminate-Incomplete		
G13	Gate 13 - Start Commissioning	Terminate-Incomplete		
G14	Gate 14 - SAT	Terminate-Incomplete		

Global Gate Review



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