The
Gwent Group of Companies

Quality Assurance Presentation
The Gwent Group of Companies

Suppliers to Major Multinational Companies in :-

The Automotive Industry.
The Fuel Cell Industry.
The Electro-ceramics Industry.
The Pharmaceutical Industry.
The Bio Science Industry.
The Electronic Display Industry.
and
General Electronics.
The GEM Quality Management System

Recognises the need of the market for quality and fitness of purpose of the companies' products.

The strategic decision was made on the adoption of a Quality Management system.

An internationally recognised standard
Qualifications

ISO 13485: SGS
ISO TS 16949: SGS
ISO 9001:2000: SGS
UKAS QUALITY MANAGEMENT 005
QUALITY STANDARDS

OVERVIEW

• ISO 9001:2000
• THE INTERNATIONAL QUALITY STANDARD

• ISO 13485:2003
• THE QUALITY STANDARD AS APPLIED TO MEDICAL DEVICES.

• BASED ON ISO 9001

• ISO 16949:2002
• REQUIREMENTS FOR APPLICATION OF ISO 9001 TO THE AUTOMOTIVE INDUSTRY
QUALITY SYSTEM OVERVIEW

• ONE QUALITY SYSTEM COVERING ALL THREE STANDARDS

• IT ADDRESSES EACH SECTION OF THE STANDARDS

  • Documentation and Records Control
    • Management Responsibility
    • Resource Management
    • Product Realization
  • Measurement, Analysis and Improvement
PRODUCT REALISATION

OVERVIEW

THE PROCEDURES FOR CONTROLLING THIS ARE VERY STRICTLY MAINTAINED.

PARTICULARLY FOR ESTABLISHING CUSTOMER REQUIREMENTS, QUALITY PLANNING, DESIGN CONTROL AND PRODUCTION CONTROL

THEY DIFFER IN DETAIL AND APPLICATION DEPENDANT ON WHETHER THE CUSTOMER IS SUBSCRIBING TO ISO9001, ISO 13485 OR ISO/TS 16949

1. Contract Review
2. Advanced Product Quality Planning
3. Design Projects
4. Production Control
DESIGN AND PRODUCTION
CONTROL

DESIGN REVIEWS
Does the design satisfy all the requirements? Are the product design and processing capabilities compatible? Have the FMEAs been completed. Does the design meet the functional and operational requirements? Have appropriate materials been selected? Have environmental and Health and Safety requirements been covered? Can tolerances be achieved?

DESIGN DEVELOPMENT (VALIDATION)
Ensure that product conforms to defined user needs and/or requirements. Performed on the final product under defined operating conditions. Design failures shall be documented. Procedures for corrective and preventive action shall be followed in addressing such design failures.

INITIAL PRODUCTION VALIDATION
Production Trial Run, Measurement Systems Evaluation, Preliminary Process Capability Study, Production product approval, Production Validation Testing, Packaging Evaluation, Production Control Plan, Quality Planning Sign-Off

DESIGN & DEVELOPMENT PLAN
Objectives, Design Inputs/design Specifications, Time Scales, Feasability Studies, Design Output, Design Reviews, Design Verification & Validation, Costs

DESIGN INPUT
Functional Requirements, Performance Requirement Interface requirements, Review of Design Spec., Determining and Agreeing Customer/Functional/ Performance and interface Requirements, FMEA analysis, Reliability Analysis, Labeling and Packaging Requirements

PRODUCT DEVELOPMENT (VERIFICATION)
Review of FMEAs. Performing alternative calculations. Comparing the design with similar proven designs. Undertaking tests and demonstrations, and reviewing design stage documents before release.

DESIGN OUTPUT
Adequate assessment of the conformance to the input requirements and identify the characteristics of the design that are crucial to the safety and the functioning of the product, including production and material specs. Production specs. include Manufacturing Instructions, component and material specifications, packaging and labels

PRODUCTION
PRODUCT REALISATION

DESIGN & DEVELOPMENT PLAN
Objectives, Design Inputs/design Specifications, Time Scales, Feasibility Studies, Design Output, Design Reviews, Design Verification & Validation, Costs

Contract review
PRODUCT REALISATION

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PFMEAs, Production Control Plan,
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PRODUCT REALISATION

PRODUCTION
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