



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

The Gwent Group of Companies

Quality Assurance Presentation



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

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.



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

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



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

Qualifications



005



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

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



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

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



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

PRODUCT REALISATION OVERVIEW

THE PROCEDURES FOR CONTROLLING THIS ARE VERY STRICTLY MAINTAINED.

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

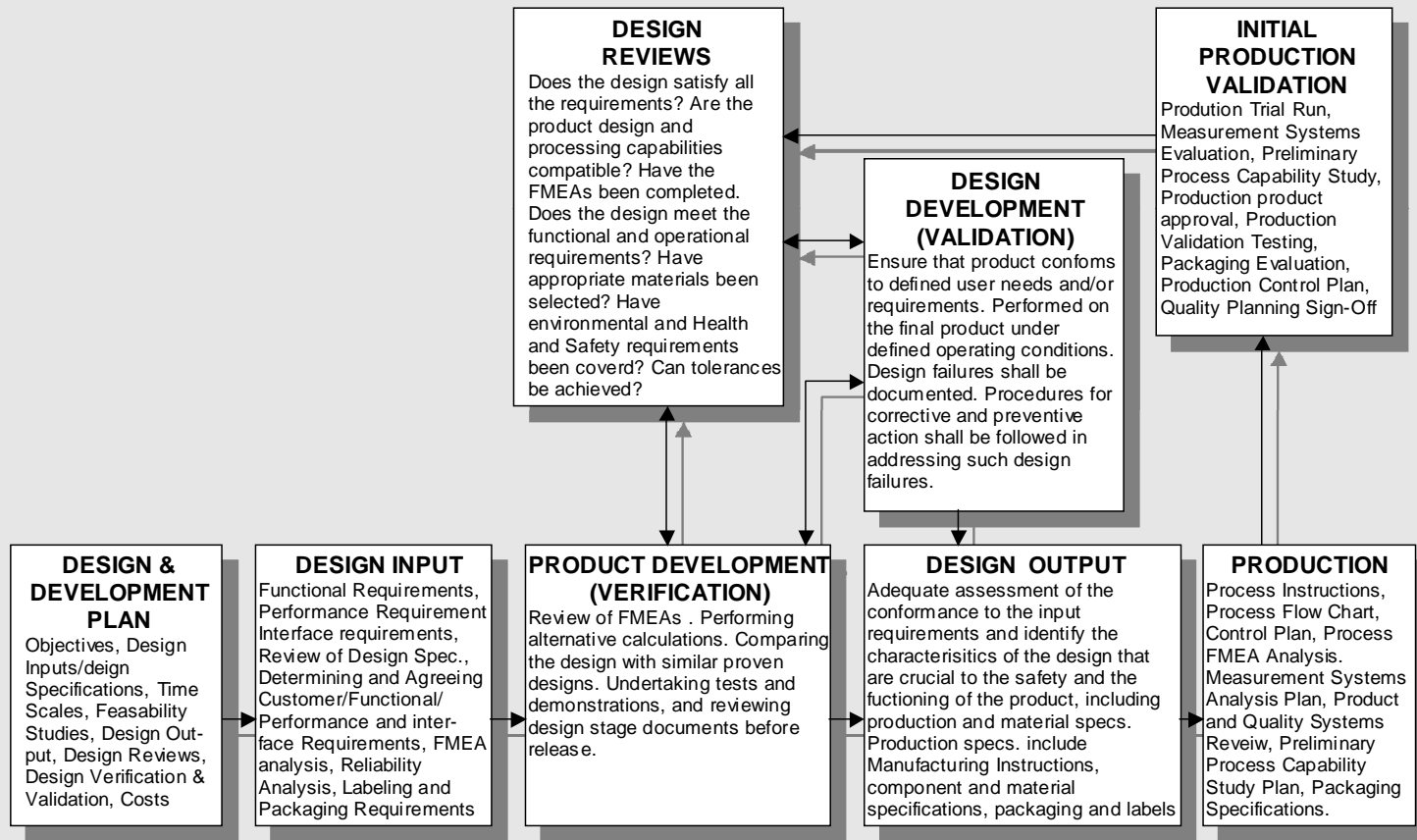
THEY DIFFER IN DETAIL AND APPLICATION DEPENDANT ON WHETHER THE CUSTOMER IS SUBSCRIBING TO ISO9001, ISO 13485 OR ISO/TS 16949

1. Contract Review
2. Advanced Product Quality Planning
3. Design Projects
4. Production Control



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

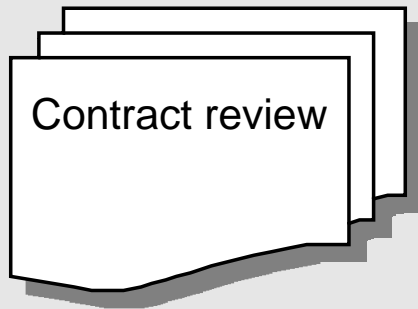
DESIGN AND PRODUCTION CONTROL





GWENT GROUP
ADVANCED MATERIAL SYSTEMS

PRODUCT REALISATION



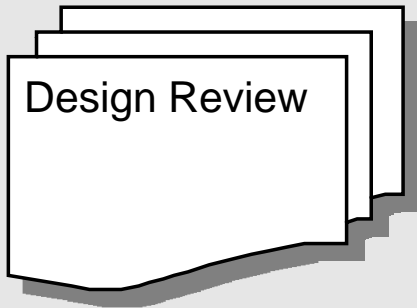
DESIGN & DEVELOPMENT PLAN

Objectives, Design
Inputs/design Specifications,
Time Scales, Feasibility
Studies, Design Out- put,
Design Reviews, Design
Verification & Validation,
Costs



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

PRODUCT REALISATION



DESIGN INPUT

Functional Requirements,
Performance Requirement
Interface requirements,
Review of Design Spec.,
Determining and Agreeing
Customer/Functional/
Performance and inter- face
Requirements, FMEA
analysis, Reliability Analysis,
Labelling and Packaging
Requirements



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

PRODUCT REALISATION



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.



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

PRODUCT REALISATION

DESIGN REVIEWS

Does the design satisfy all the requirements? Are the product design and processing capabilities compatible? Have the FMEAs been completed.

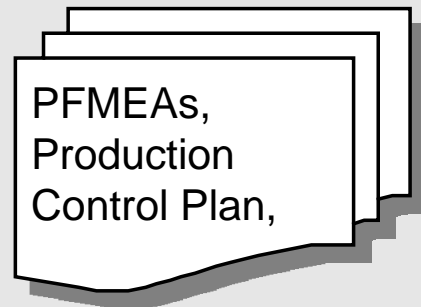
Does the design meet the functional and operational requirements? Have appropriate materials been selected? Have environmental and Health and Safety requirements been covered? Can tolerances be achieved?

DFMEAs, Lab.
Books,
Capability
Studies



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

PRODUCT REALISATION



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



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

PRODUCT REALISATION

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

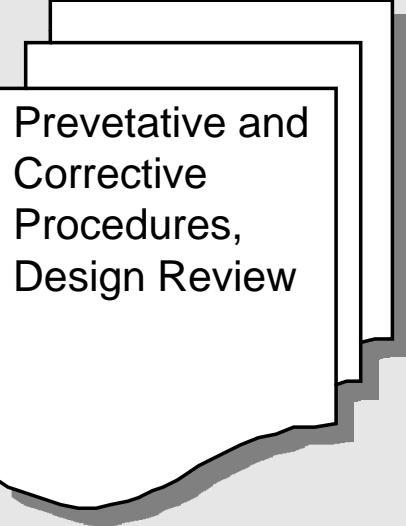


GWENT GROUP
ADVANCED MATERIAL SYSTEMS

PRODUCT REALISATION

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.



Prevetative and
Corrective
Procedures,
Design Review



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

PRODUCT REALISATION

PRODUCTION

Process Instructions,
Process Flow Chart,
Control Plan, Process
FMEA Analysis.

Measurement Systems
Analysis Plan, Product
and Quality Systems
Review, Preliminary
Process Capability Study
Plan, Packaging
Specifications.



GWENT GROUP
ADVANCED MATERIAL SYSTEMS

Les. Embury
Managing Director
The Gwent Group,
Monmouth House,
Mamhilad Park,
Pontypool NP4 0HZ.
United Kingdom.

sales@gwent.org

<http://www.gwent.org>

Tel: +44 (0)1495 750505

Fax: +44 (0) 1495 752121