



**GWENT GROUP**  
ADVANCED MATERIAL SYSTEMS

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# The Gwent Group of Companies

Quality Assurance Presentation

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# 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.



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# 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



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# Qualifications



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# 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



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# 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



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# PRODUCT REALISATION OVERVIEW

THE PROCEDURES FOR CONTROLLING THIS ARE VERY STRICTLY MAINTAINED.

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

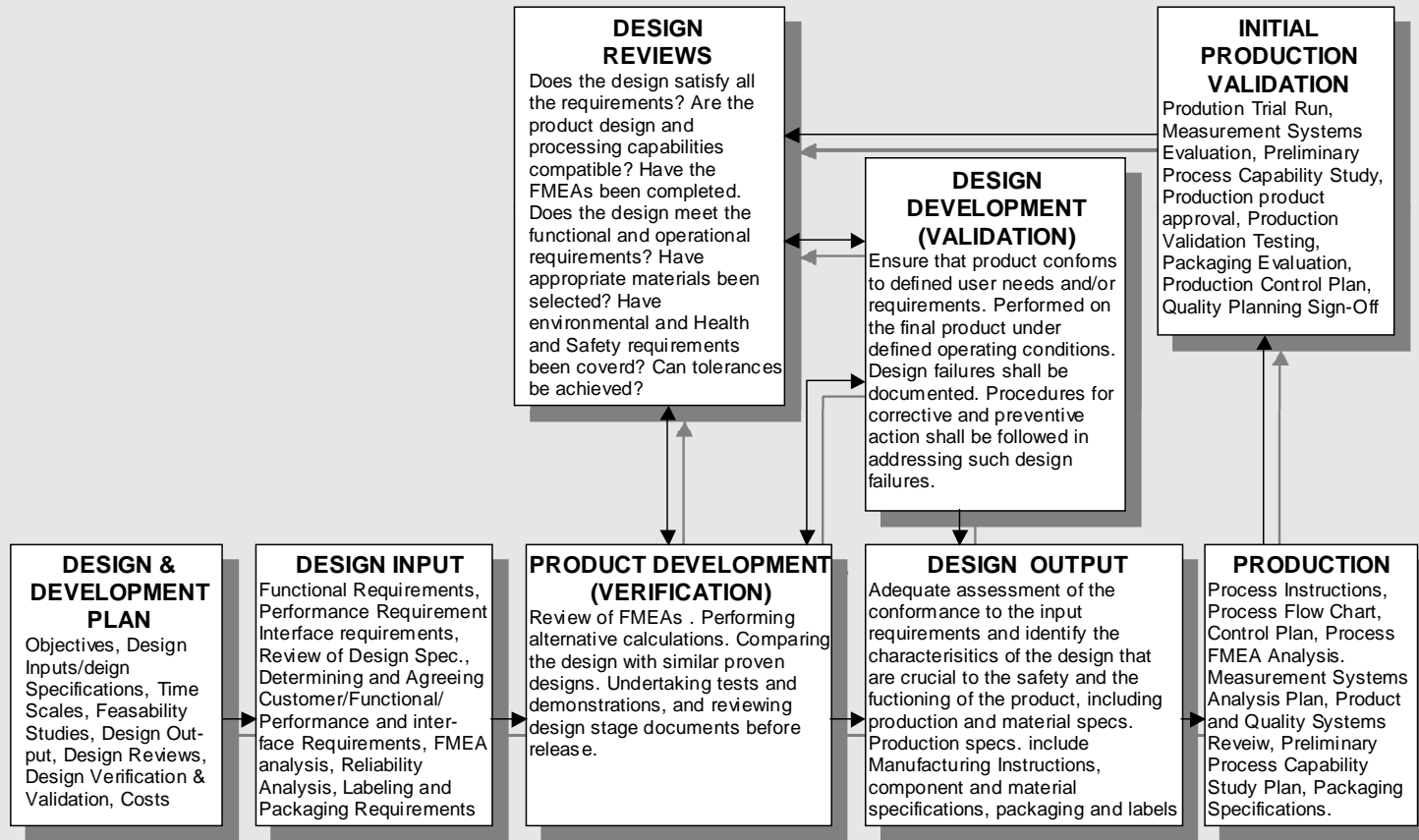
THEY DIFFER IN DETAIL AND APPLICATION DEPENDANT ON WHETHER THE CUSTOMER IS SUBSCRIBING TO ISO9001, ISO 13485 OR ISO/TS 16949

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



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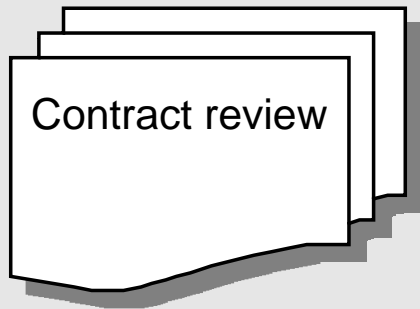
# DESIGN AND PRODUCTION CONTROL





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# PRODUCT REALISATION



## **DESIGN & DEVELOPMENT PLAN**

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



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# 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



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# 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.



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# 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



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# 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



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# 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

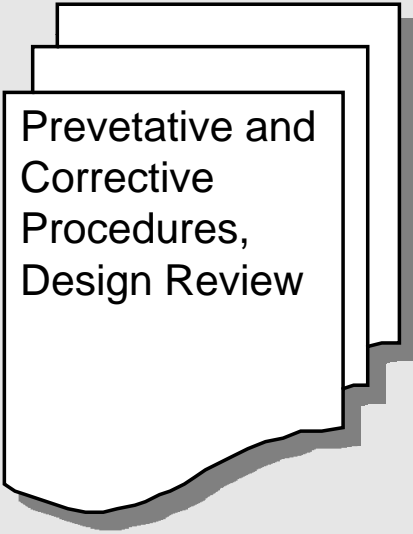


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# PRODUCT REALISATION

## **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



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# 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.



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