SG3 Guidance Documents

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Guidance On Quality Systems For The Design And Manufacture Of Medical Devices

- Consensus is growing among industry and regulatory authorities that a suitable quality system should incorporate the principles of ISO 9001 plus additional healthcare-related requirements specific to medical devices.
- These additional health-care related requirements are embodied in the European standard EN 46001 and in the Quality System Regulations of the USA, Japan and Canada.

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Guidance On Quality Systems For The Design And Manufacture Of Medical Devices (cont.)

- This document provides guidance on the implementation of quality systems for medical devices, based on ISO 9001 (1994 version) and is organised according to the clause numbering of ISO 9001.

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Guidance On Quality Systems For The Design And Manufacture Of Medical Devices (cont.)

- applicable to the design, development, production, installation and servicing of medical devices
- describes concepts/methods to be considered for establishing and maintaining quality systems
- it is recognised that there may be alternative ways that are better suited to a particular device/manufacturer

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Design Control Guidance for Medical Device Manufacturers

- This guidance document is in the need of revision
- SG3 Members assigned sections to review and update. Must decide on total rewrite or simple update
- However, fundamental principles remain valid …. see following slides

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Design Control Guidance for Medical Device Manufacturers

- Design Controls are a component of a comprehensive Quality System that covers the life of a device. The assurance process is a total systems approach extending from the development of device requirements through design, production (including changes), distribution, use, maintenance, and, eventually, obsolescence.

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Design Control Guidance for Medical Device Manufacturers (cont.)

- Intended to assist manufacturers in understanding the quality system requirements concerning design controls
- Documented design control policies and procedures provide improved visibility of the design process
- Applies to the design of medical devices and the associated manufacturing processes

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Design Control Guidance for Medical Device Manufacturers (cont.)

- **Examples of topics for which procedures may be appropriate:**

- Risk management
- Device reliability
- Device durability
- Device maintainability
- Device serviceability
- Human factors engineering
- Software engineering
- Use of standards
- Compliance with regulatory requirements
- Document Controls
- Etc

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Process Validation Guidance

- This process validation guidance is intended to assist manufacturers in understanding quality system requirements concerning process validation.
- In general, the validation of a process is the planned mechanism or system used by a manufacturer to obtain, record, and interpret data with the goal to demonstrate that the output of the process is within expected parameters.

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Process Validation Guidance (cont.)

- **Process validation:**
  - The purpose of process validation is to establish by objective evidence that a process **consistently** produces a result or product meeting its predetermined requirements.

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Process Validation Guidance (cont.)

- **This activity may be considered to fall into three phases:**

1) Installation Qualification (IQ)
2) Operational Qualification (OQ)
3) Performance Qualification (PQ)

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Process Validation Guidance (cont.)

Installation Qualification (IQ):

- establishing by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturer's approved specification and that the recommendations of the supplier of the equipment are suitably considered.

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Process Validation Guidance (cont.)

Operational Qualification (OQ):

- establishing by objective evidence process control limits and action levels which result in product that meets all predetermined requirements.

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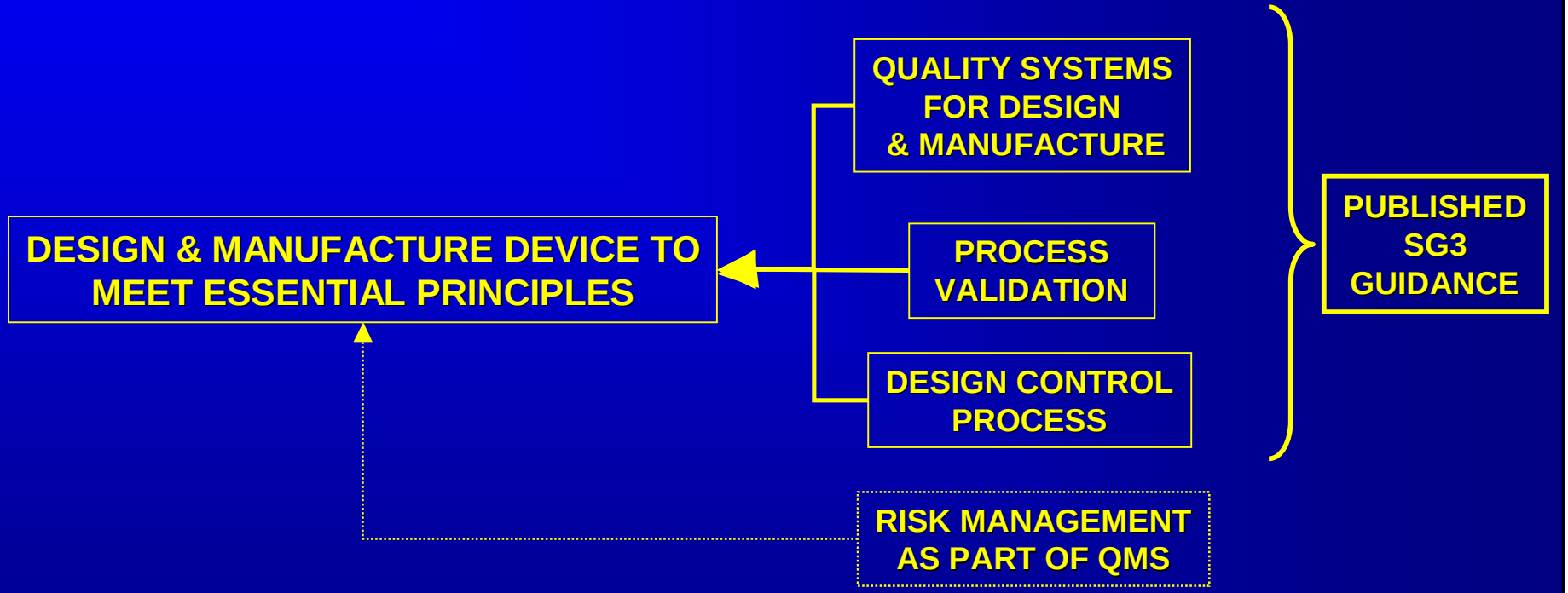
Process Validation Guidance (cont.)

Performance Qualification (PQ):

- establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements.

Summary


QUALITY SYSTEMS FOR DESIGN & MANUFACTURE
PROCESS VALIDATION
DESIGN CONTROL PROCESS
PUBLISHED SG3 GUIDANCE
DESIGN & MANUFACTURE DEVICE TO MEET ESSENTIAL PRINCIPLES
RISK MANAGEMENT AS PART OF QMS

For further information, please visit www.ghtf.org

Thank you on behalf of the GHTF and Study Group 3 for your time and attention.

Questions?