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Product Development and Quality Management Consulting and Training

FDA's New Emphasis on Purchasing Controls – What Plastics Component Suppliers to the Medical Device Industry Need to Know about Process Validation and Material Controls

SPE – Eastern New England Section & Medical Plastics Division

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Dr. Vinny Sastri
President, WINOVIA® LLC
www.winovia.com
+1 518-436-8110
VSastri@winovia.com

AGENDA

- Introduction
- Quality Management Systems - Chronology
- Supplier Controls
- Production Controls
- Process Validation
- Conclusion

FDA QUALITY SYSTEMS REGULATION - CHRONOLOGY

Jul 18, 1978 – FDA issued **current Good Manufacturing Practices** (cGMP) for **medical devices**

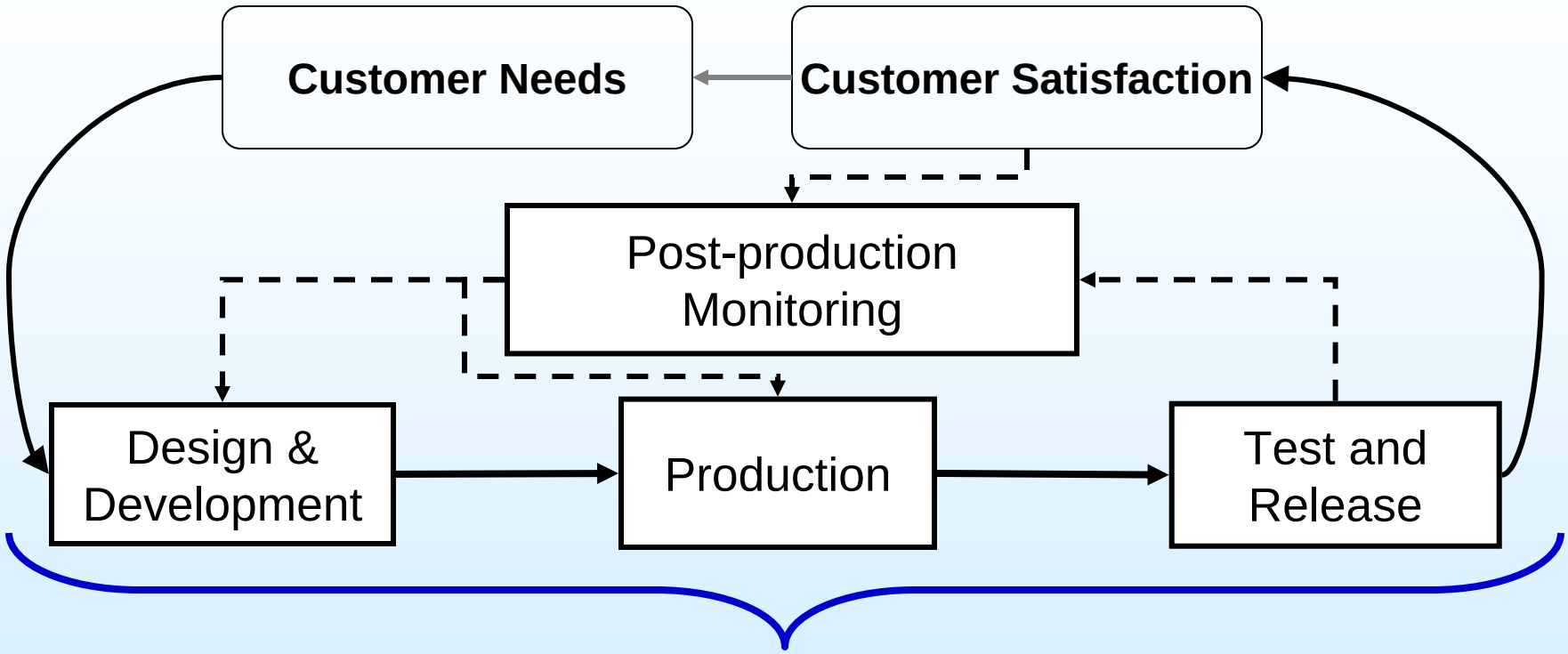
1978 to 1990 – FDA finds significant number of recalls due to ineffective or faulty **designs**

Nov. 28, 1990 – Safe Medical Device Act enacted. Provided FDA with the authority to add pre-production **design controls**

June 1, 1997 – New regulation becomes effective. Title changed from Current Good manufacturing Practices to "21 CFR Parts 820 **Quality Systems** Regulations".

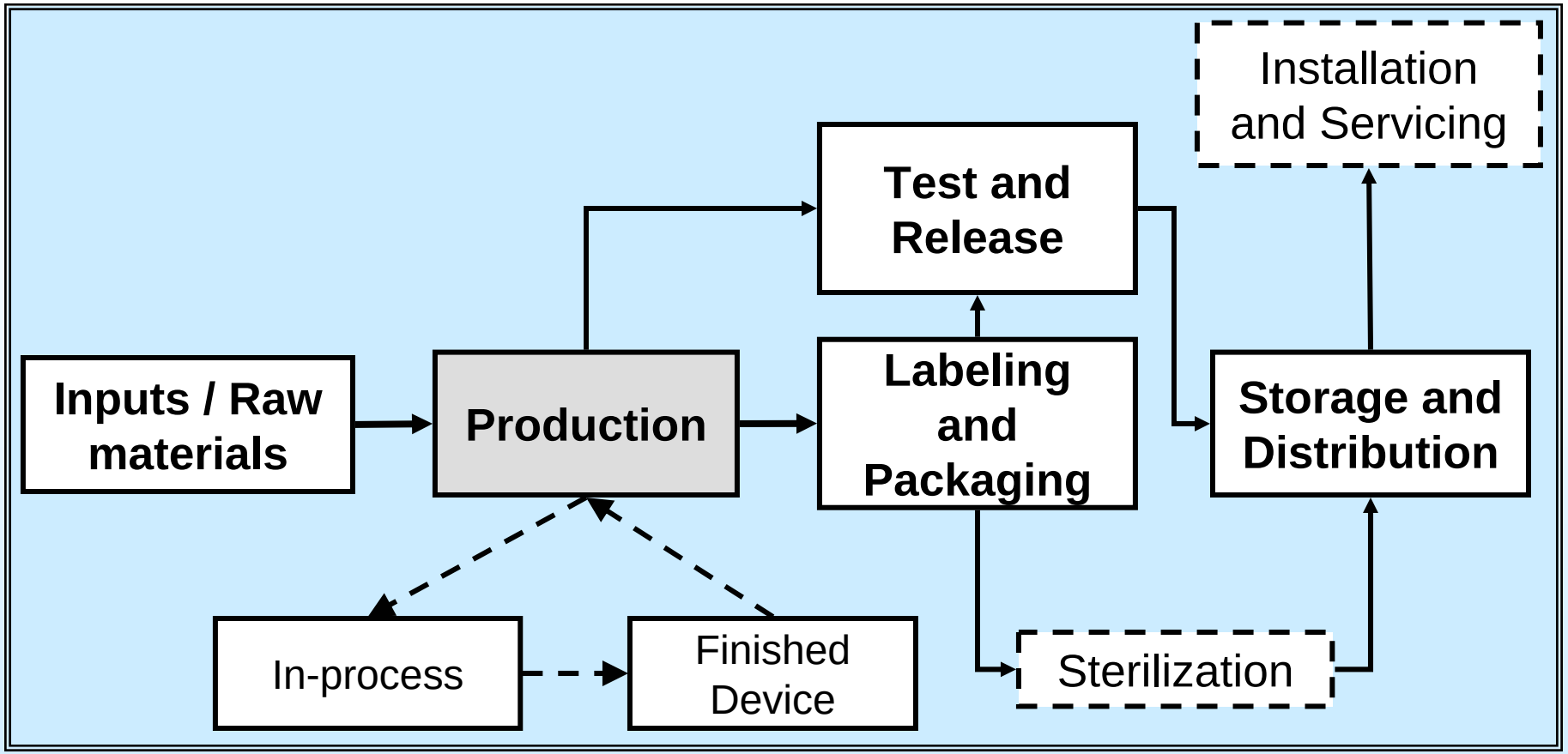
September 2004 – Emphasis on **risk management** (ISO 14971)

November 2008 – **Supplier / Purchasing Controls**

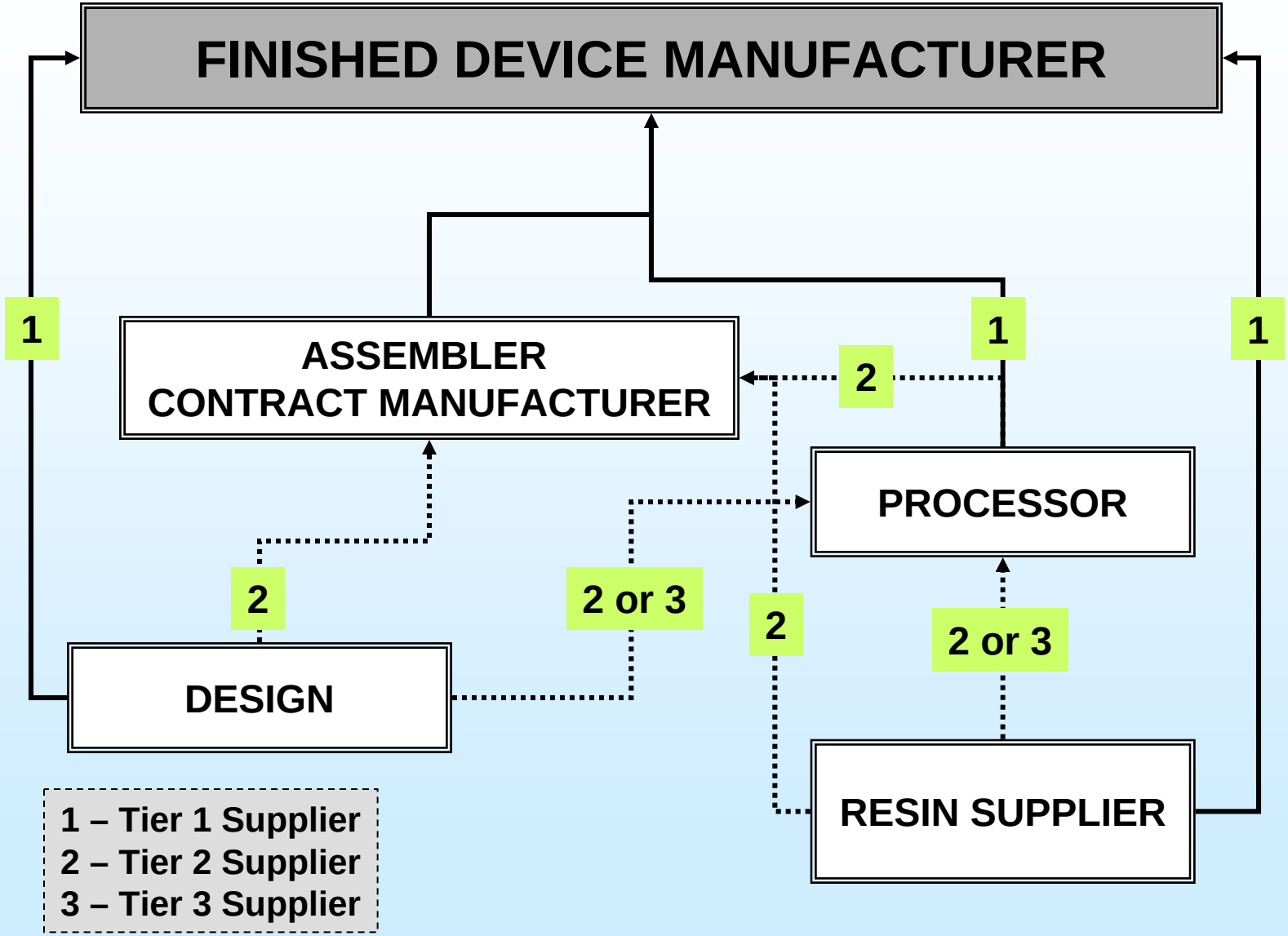


Quality Systems – A Total Systems Approach

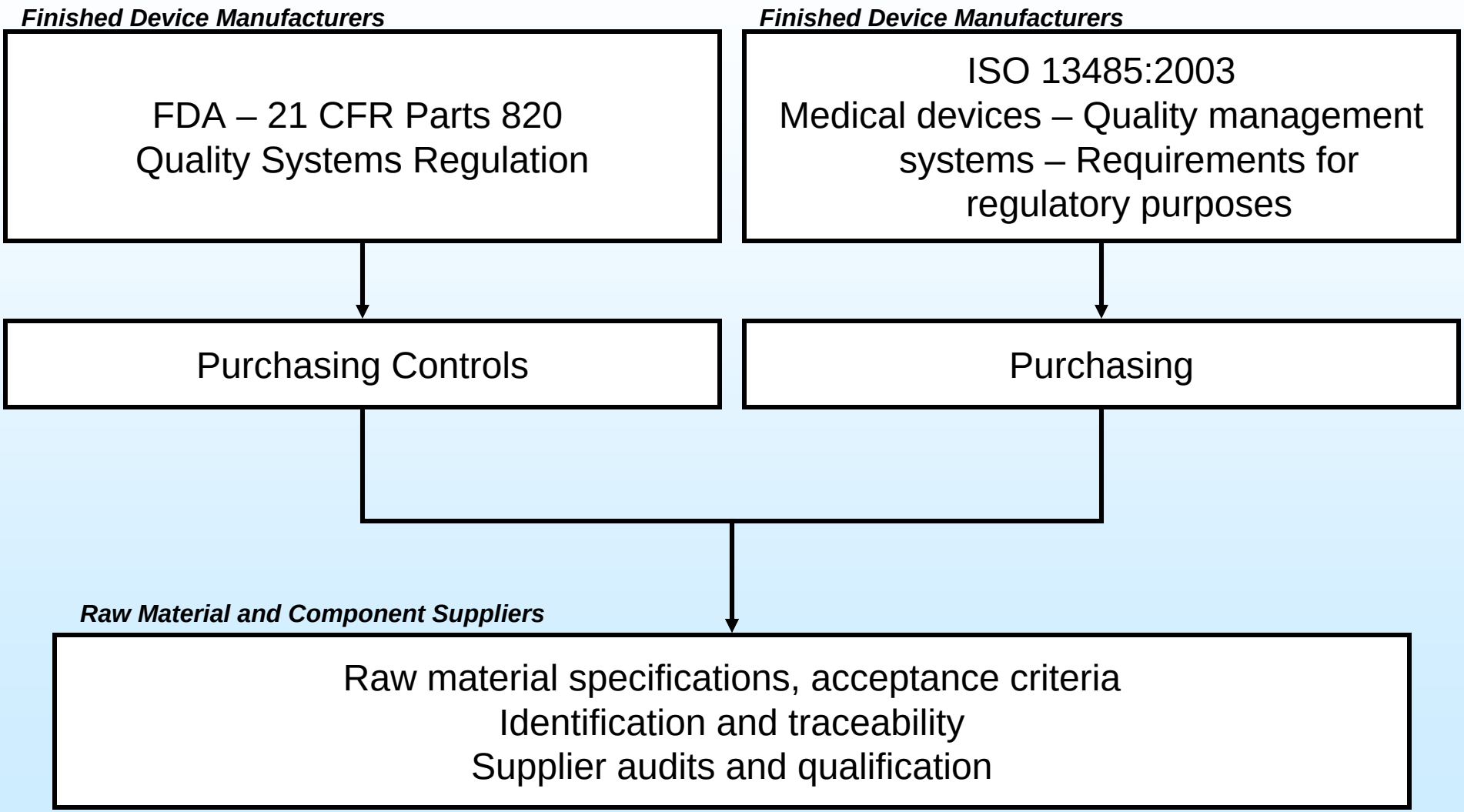
QUALITY BY DESIGN



From in-coming raw materials to storage and distribution and if applicable – installation and servicing


FINISHED DEVICE MANUFACTURER
1
ASSEMBLER
CONTRACT MANUFACTURER
1
2
1
PROCESSOR
2
2 or 3
2
2 or 3
DESIGN
RESIN SUPPLIER
1 – Tier 1 Supplier
2 – Tier 2 Supplier
3 – Tier 3 Supplier

MATERIAL SUPPLIERS & THE QUALITY SYSTEMS REGULATIONS



PURCHASING CONTROLS

- Control over products or services obtained from suppliers
- Can extend to their subcontractors
- Regulatory bodies will inspect / audit manufacturers to confirm that they have objective evidence of control over their products and services from their suppliers

Quality Management System – Medical Devices – Guidance on control of products and services obtained from suppliers

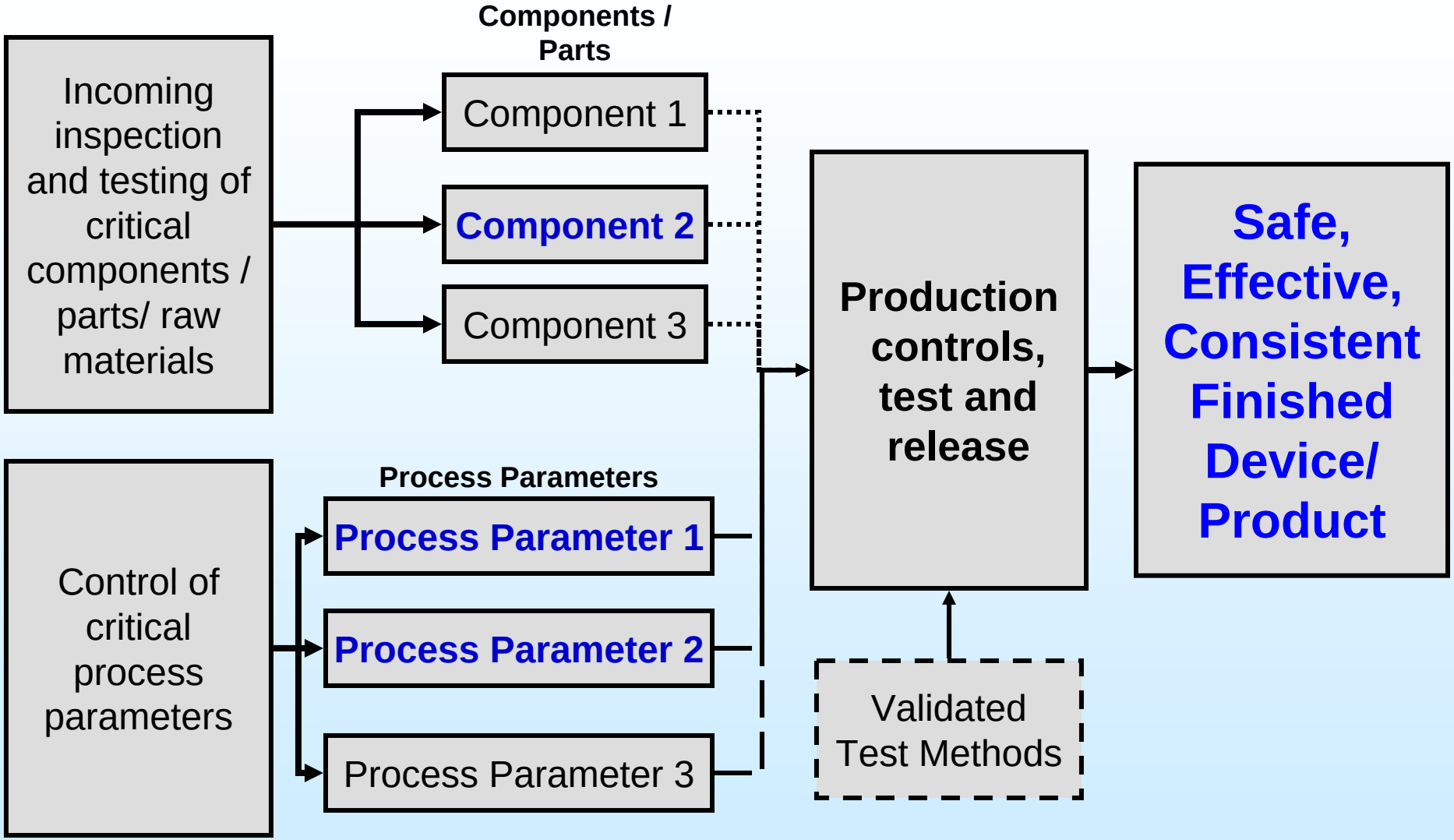
http://www.ghtf.org/documents/sg3/sg3final-N17.pdf

LEVEL OF SUPPLIER CONTROLS

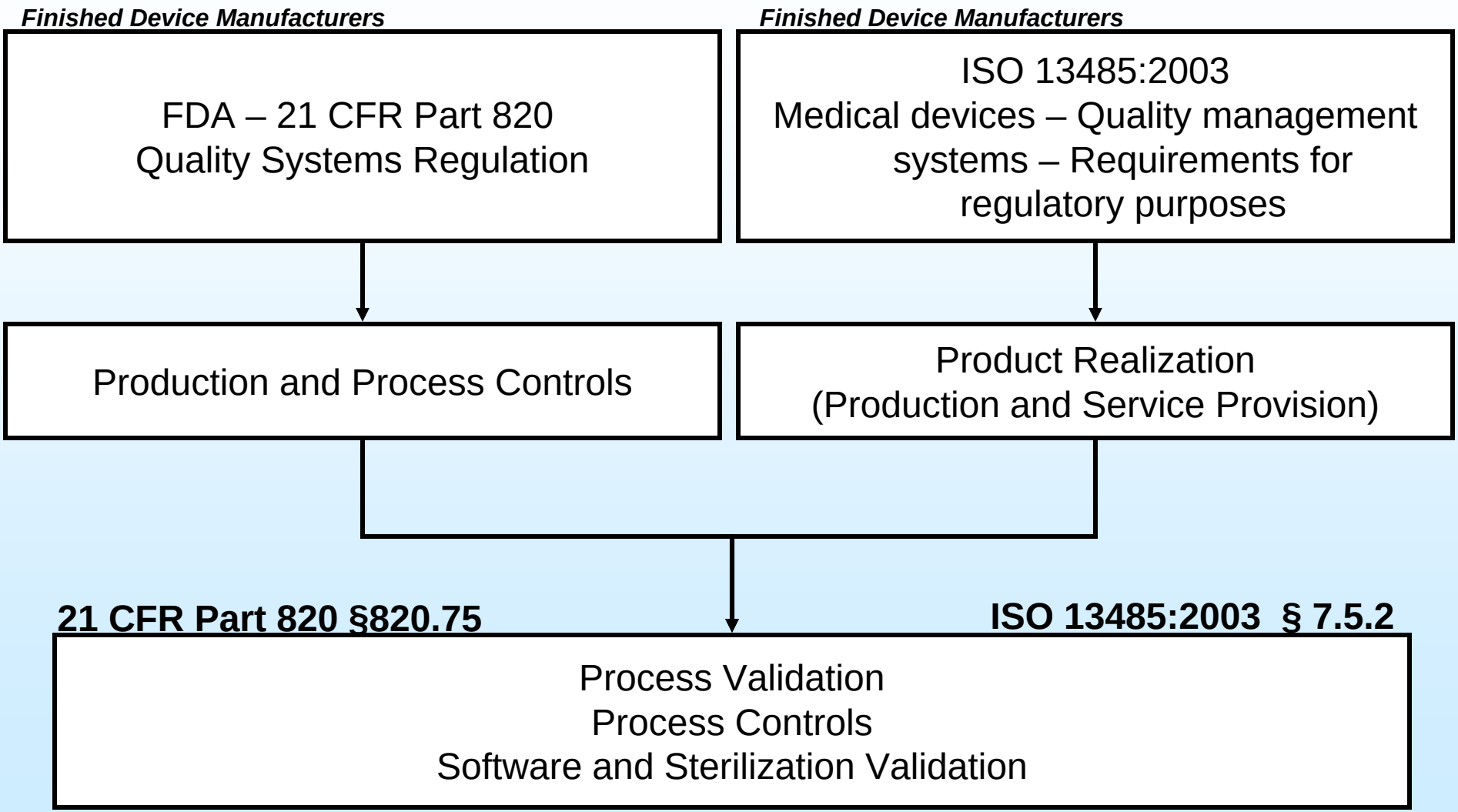
1. Custom built or off the shelf part
2. New or existing parts
3. Criticality of part
4. Complexity of part
5. Sole source or multiple sourced
6. Technical capabilities and requirements
7. Quality trends and issues
8. Communication and responsiveness
9. Problem solving capability

1. Acceptance activities
2. Process validation
3. Corrective and preventive actions; root cause analysis
4. Traceability
5. Documentation, objective evidence
6. Change management
7. Records and document retention

ESSENTIAL COMPONENTS AND PROCESS PARAMETERS



PRODUCTION CONTROLS & THE QUALITY SYSTEMS REGULATIONS



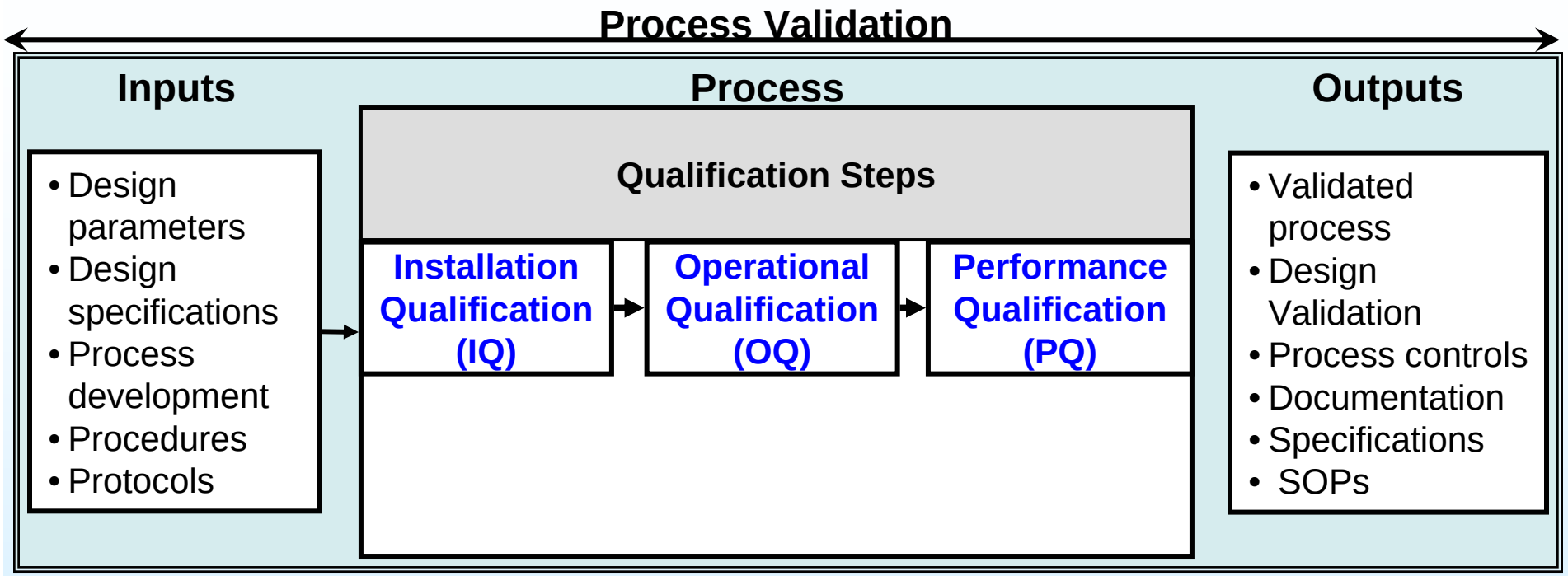
Verification

Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

Process Validation

Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.

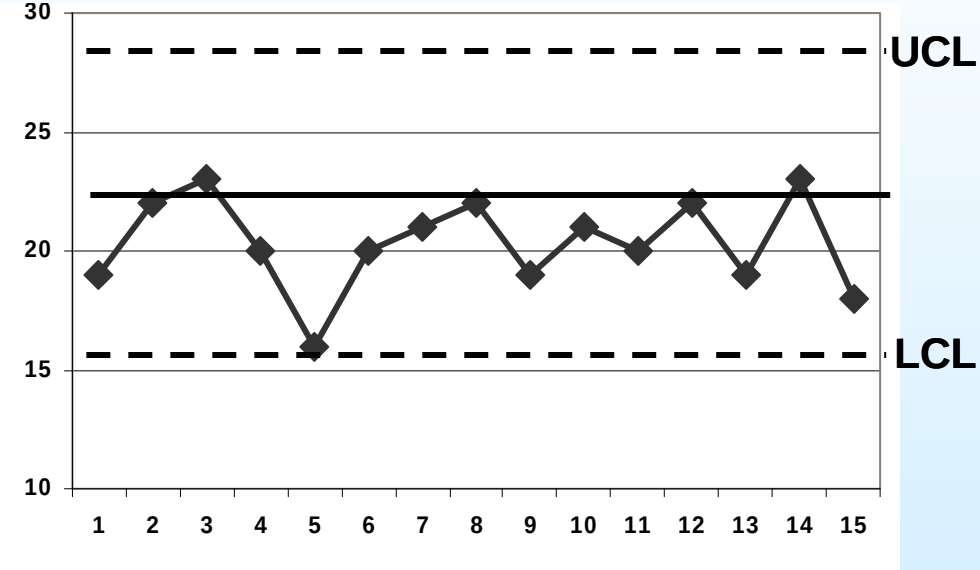
PROCESS VALIDATION FLOW



Installation Qualification (IQ)	Is the equipment installed and operating according to specifications?
Operational Qualification (OQ)	Is the process fully characterized and are critical process parameters / operating windows identified?
Performance Qualification (PQ)	Does the process, when run under nominal settings and under normal operating conditions, produce product that consistently meets specifications?

Process parameters and the corresponding in-process controls must be deduced from the knowledge based on objective evidence and data from development or historical data.

Quality by Design



SPC – Statistical Process Control

SQC – Statistical Quality Control

- Early involvement in the design process
- Understand criticality of material or part in the overall product (risk)
- Establish appropriate systems and process to meet customer requirements
- Identify and control critical product and process parameters

Thank You !

Questions?

WINOVIA® LLC is a consulting company that provides customized, sustainable solutions and strategies in new product development, quality management and high performance materials. (www.winovia.com)

WINOVIA® LLC provides consulting and training in:

- **FDA and ISO Quality Systems Regulations for Medical Devices**
- **Quality Systems Audits and Assessments**
- **Design Controls**
- **Production Controls and Process Validation**
- **Design for Six Sigma and New Product Development**
- **Six Sigma and Total Quality Management**
- **Technology Roadmaps**
- **Risk Management**
- **Corrective and Preventive Action**
- **Plastics and Materials Selection**