Remarks on Auditing, Regulatory Auditing and Regulatory Auditing Strategy

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Remarks on Auditing, Regulatory Auditing and Regulatory Auditing Strategy

1. Origin of terms - definitions of today
2. Objectives of an audit
3. Regulatory auditing strategy
4. Proposal to GHTF Steering Committee

1. Origin of terms - definitions

Audit, auditing

Origin	audire (latin)	to hear, to perceive (e.g. what is going on during an audit) to listen (e.g. to answers of questions of the auditor)

Definitions

Audit	Systematic, independent and documented **process** for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled (ISO 9000:2000)
Audit	A management tool for monitoring and verifying the effective implementation of an organization's policy for quality ... (ISO/CD. 3 19011:2002)

1. Origin of terms - definitions

Regulatory requirements

Any part of a law, ordinance, decree or other regulation which applies to quality systems of medical device manufacturers (GHTF SG4 (99)28)

Regulatory audit

Audit of the auditee's quality system to determine compliance with the relevant **regulatory requirements** (GHTF SG4 (99)28)

1. Origin of terms - definitions

Process

Origin procedere (latin) to proceed, to go on - a series of actions which produce a change or development

Definitions

Process Set of interrelated or interacting activities which transforms **inputs** into **outputs** (ISO 9000:2000)

- Is the process identified and appropriately defined?
- Are responsibilities assigned?
- Are the procedures implemented and assigned?
- Is the process effective in achieving the required results?

1. Origin of terms - definitions

Strategy

Origin

strategos (greek) stratos army
agos commander-in-chief

356 B.C. Aeneas manual for the „strategos“

Definitions

Strategy is a general plan or set of plans to achieve something, especially over a long period
(Collins Cobuild English Dictionary)

Strategy is the logic that gives direction to the activities of the organisation. Strategy is articulated by top management in plans that are implemented at lower levels and updated over time
(Barnett - Stanford University)

1. Origin of terms - definitions

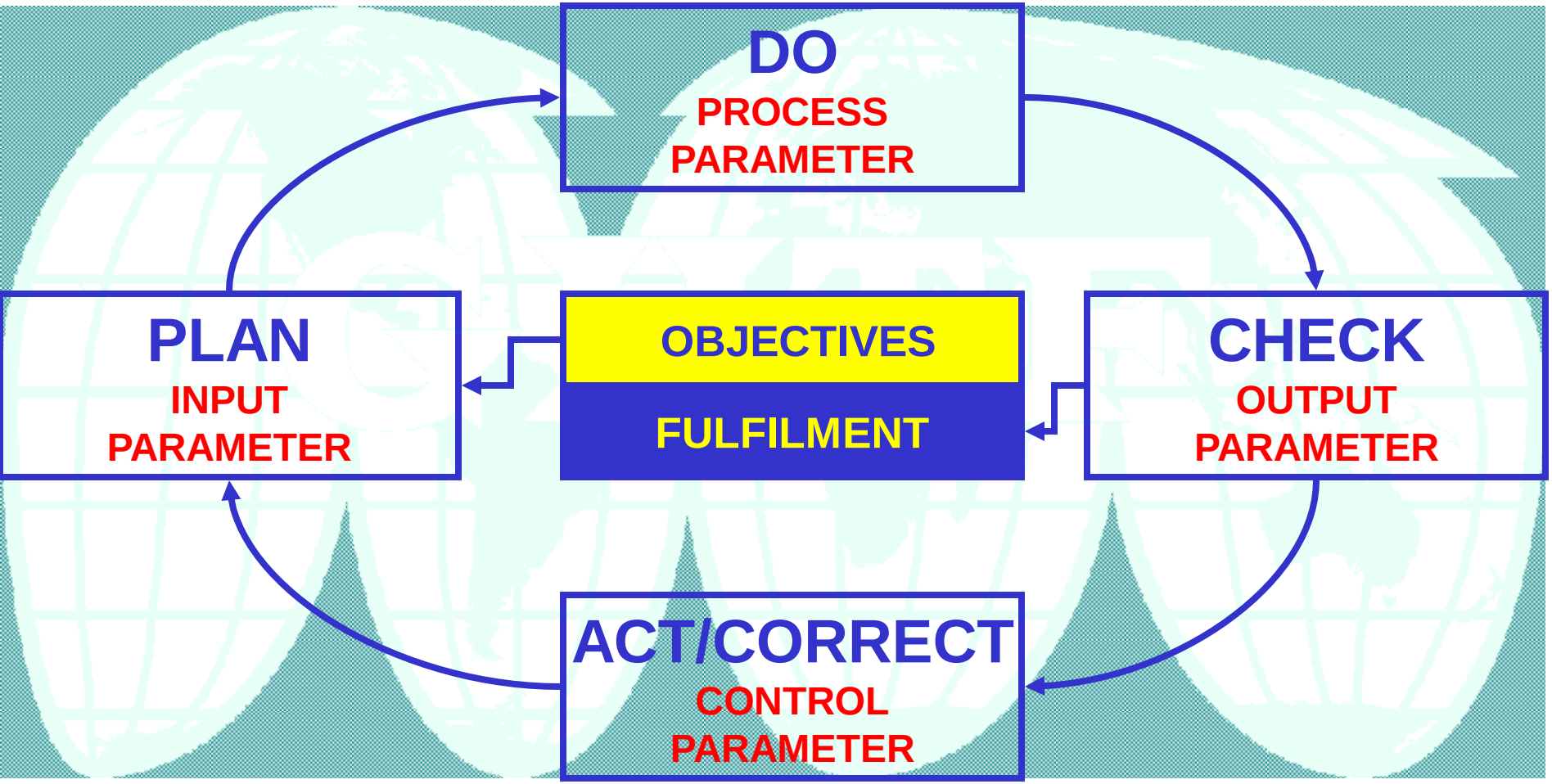
Regulatory auditing strategy, effectiveness of quality systems

Definitions

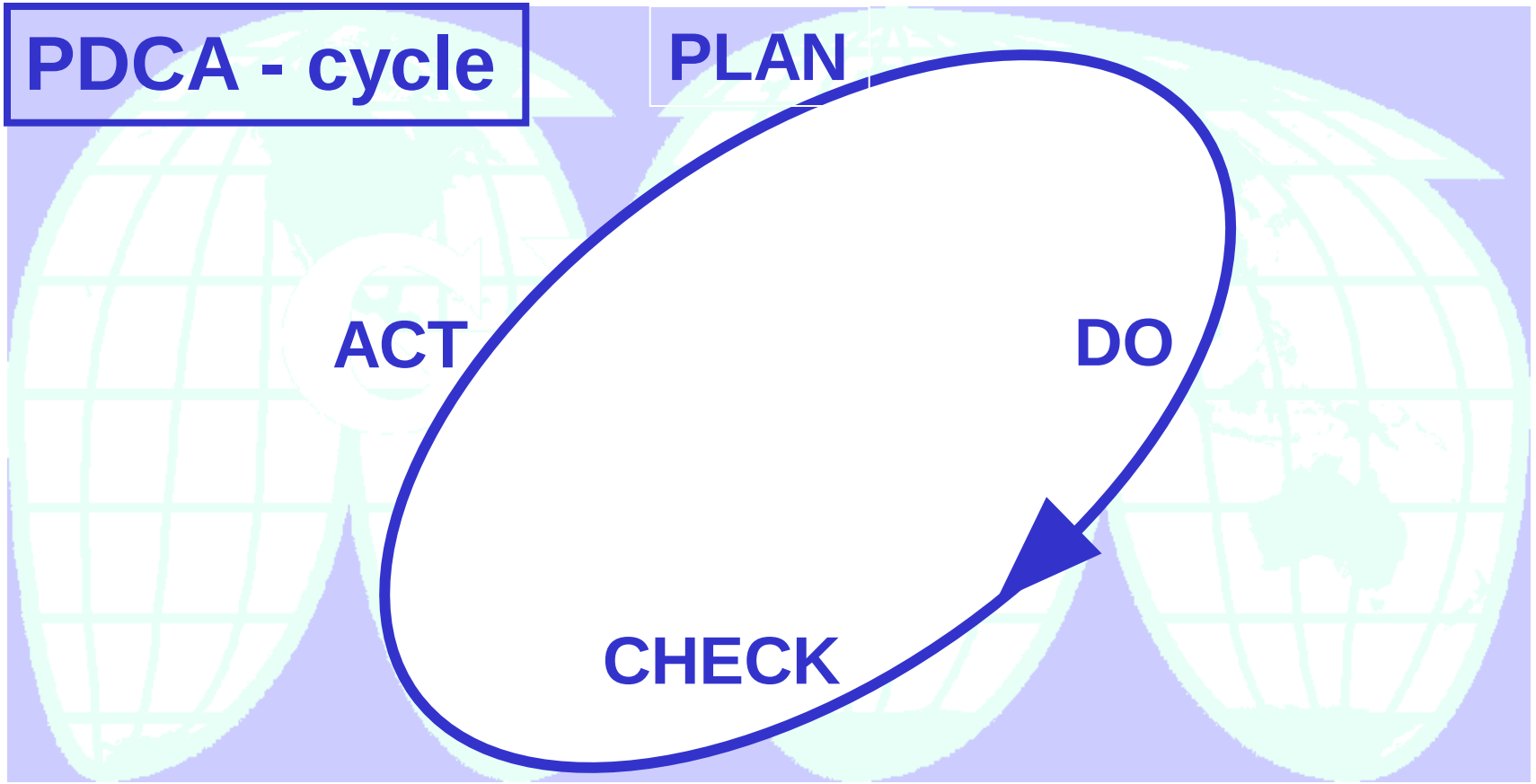
Regulatory auditing strategy is the process how to audit the effectiveness of quality systems including the fulfillment of regulatory requirements of medical device manufacturers

Effectiveness of quality systems is given if the quality objectives are reached and the implemented quality system works as a control circuit according to the Deming PDCA-cycle (plan, do, check, act). Management is responsible for the effectiveness of a quality system

Deming - PDCA - Cycle



Process input: Objectives



Process output: Fulfilment

2. Objectives of a regulatory audit

The regulatory audit must be conceived in such a way that

- the effectiveness of the quality system including the fulfilment of regulatory requirements is measured in a systematic and independent manner within a reasonably short time
- the audit is process-oriented and risk-based: focus on key areas of the manufacturer's quality system
- the audit is transparent to the auditee
- the audit result is independent of the auditor - a necessity for harmonisation and mutual recognition of audit results

3. Regulatory auditing strategy (1)

The auditing strategy is based on the audit objectives and consists of the following steps:

- The quality system is subdivided in quality subsystems: “management controls”, “process management” and “CAPA”
- The “process management” subsystem can be composed of further subsystems, e.g.: “design controls”, “production and process controls”, “material controls”, “records, documents, change controls”
- The audit starts with an off-site preinspection of records from the manufacturer

3. Regulatory auditing strategy (2)

The auditing strategy is based on the audit objectives and consists of the following steps:

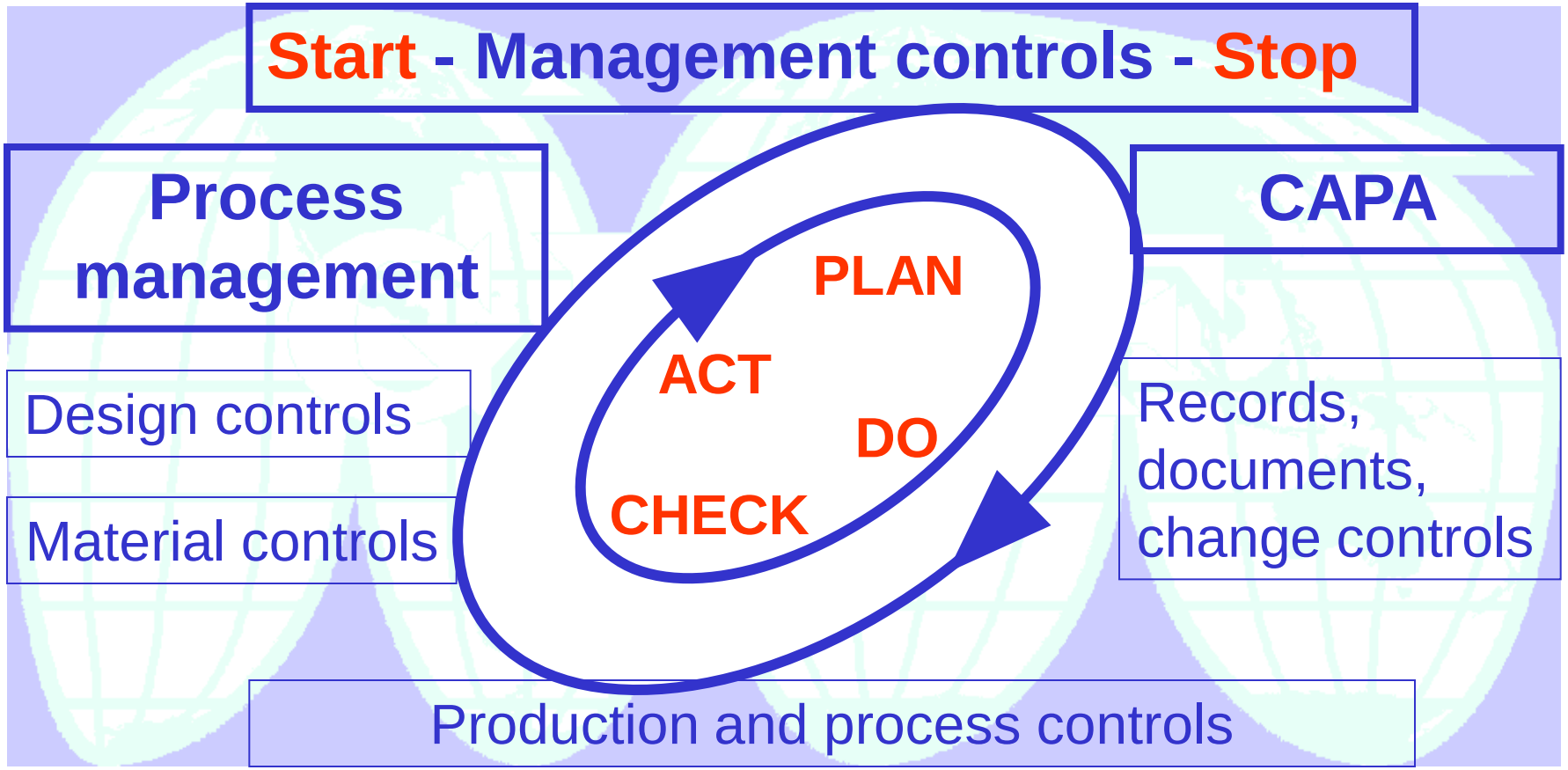
- The on-site audit starts with a review of the manufacturer's "management controls": review of top systemwide procedures and policies. For more information the auditor follows the "top down" approach
- According to the PDCA-concept the auditor is not only looking for "plan" and "do" procedures in each subsystem but also for the "check" and "act" procedures - the "corrective and preventive actions :CAPA"

3. Regulatory auditing strategy (3)

The auditing strategy is based on the audit objectives and consists of the following steps:

- The PDCA-concept is not only applied in each subsystem but in the whole quality system
- The use of sampling tables allow the auditor to document the non-existence or the existence of compliance problems through statistically valid sampling

Regulatory Audit of the Quality System



3. Regulatory auditing strategy (3)

Conclusion

Uniform approach which is independent of the

- auditor
- auditing organisation
- regulatory system

Benefits

- Systematic and transparent audit process - both for the regulatory sides and the manufacturer
- Reductions in audit time and audit costs

4. Proposal to GHTF Steering Committee

The objectives oriented top-down approach following the PDCA - cycle should be used for auditing the GHTF work in the Study Groups and also in the Steering Committee