



Global Harmonization Task Force

Working Towards Harmonization in Medical Device Regulation

Training Seminar on Risk Management

Audit Strategy and Auditing Risk Management Requirements

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Audit Strategy and Auditing Risk Management Requirements

F.F.M.

- 1. Origin of terms – current definitions**
- 2. Objectives of an audit**
- 3. Regulatory auditing strategy**



Audit, auditing [*audire*] to hear, to perceive, to listen

Today: Systematic, independent and documented **process** for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled (ISO 19011:2002)

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



Strategy

[στρατος] army and [αγειν] to command. Goes back to Alcibiades, Pericles and Themisteclos, the best known *strategos* ruling Athens in the 5th century B.C.

Today:

Long term plan of action designed to achieve a particular goal. Applied originally to the military, today to many different fields.

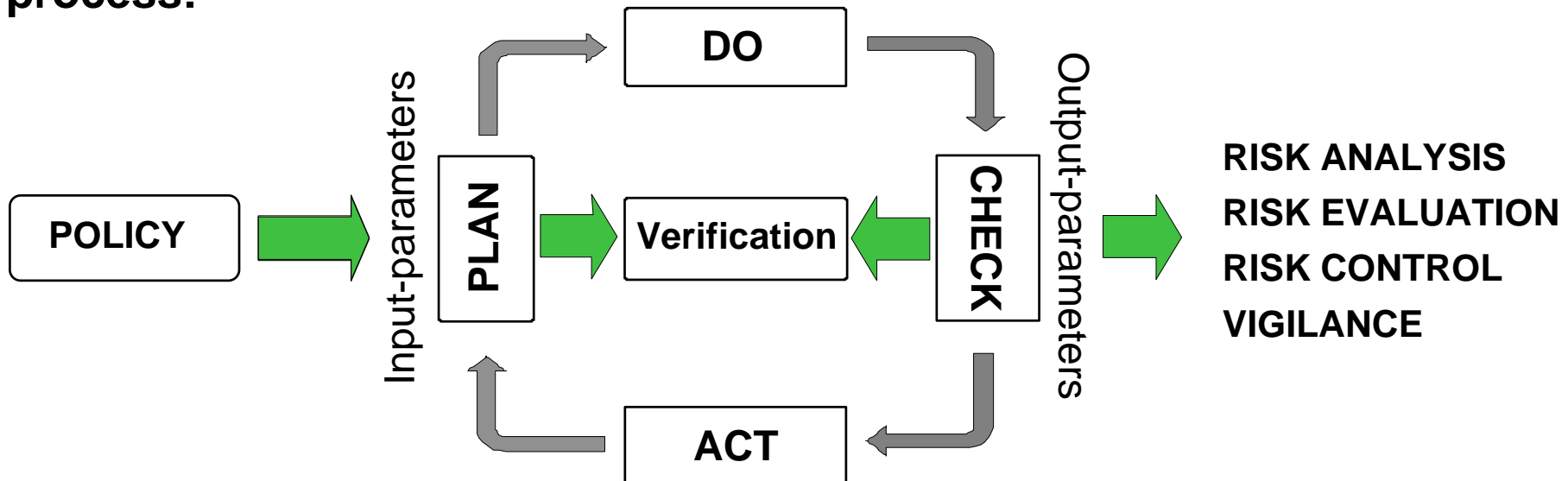


Risk Management

Systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risk (from ISO 14971:2000)

„... applicable to all stages of the life cycle of a medical device.“

Applicable standards such as ISO 14971 define Risk Management as a process:



**Q: Is the process appropriately defined? Are responsibilities assigned?
 Are the procedures implemented and assigned?
 Is the process effective in achieving the required results?**



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Strategic objectives are to evaluate

- a) depth of implementation (risk or crisis management?)
and**
 - b) effectiveness (are requirements met with?)**
- of the risk management system.**



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Regulatory audit

Audit of a quality management system to determine conformity with a quality management standard and the relevant **regulatory requirements** (GHTF SG4/N30R14)



Strategic objectives are to evaluate

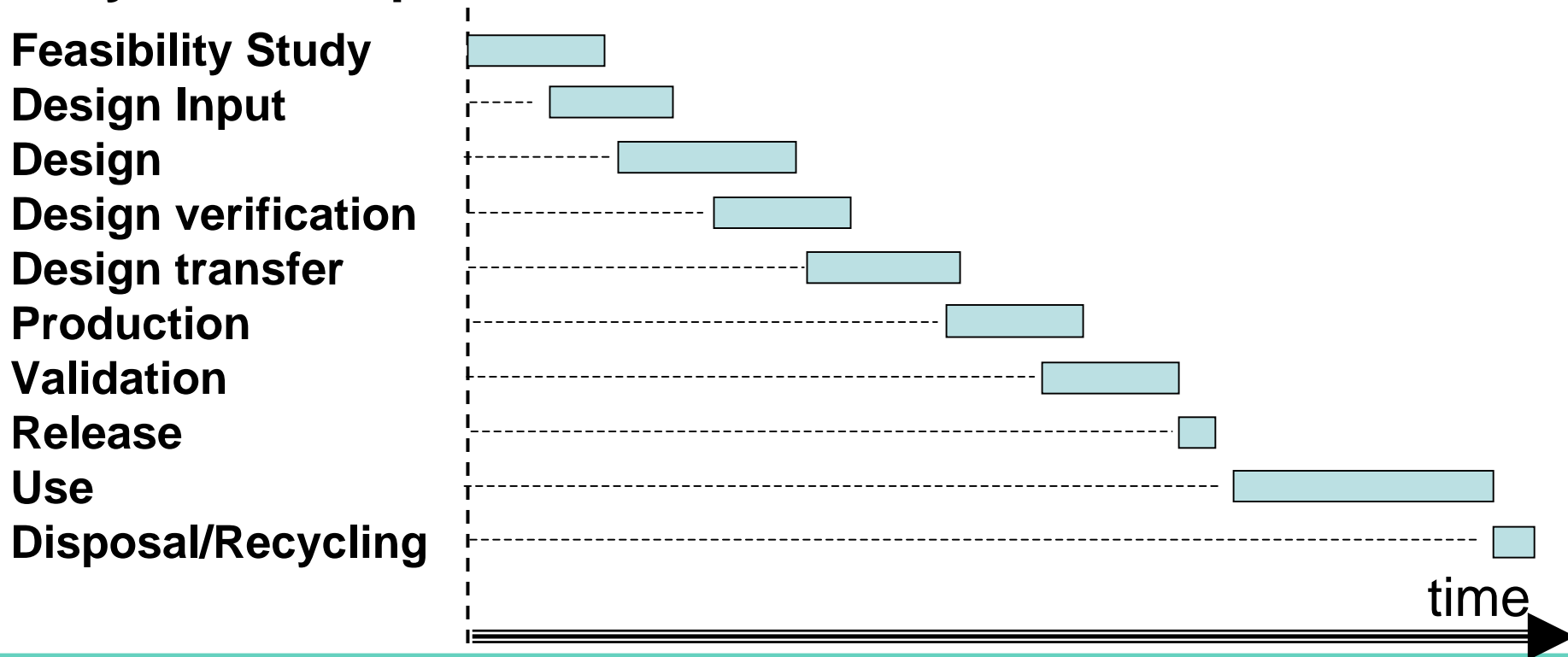
a) depth of implementation (risk or crisis management?)

and

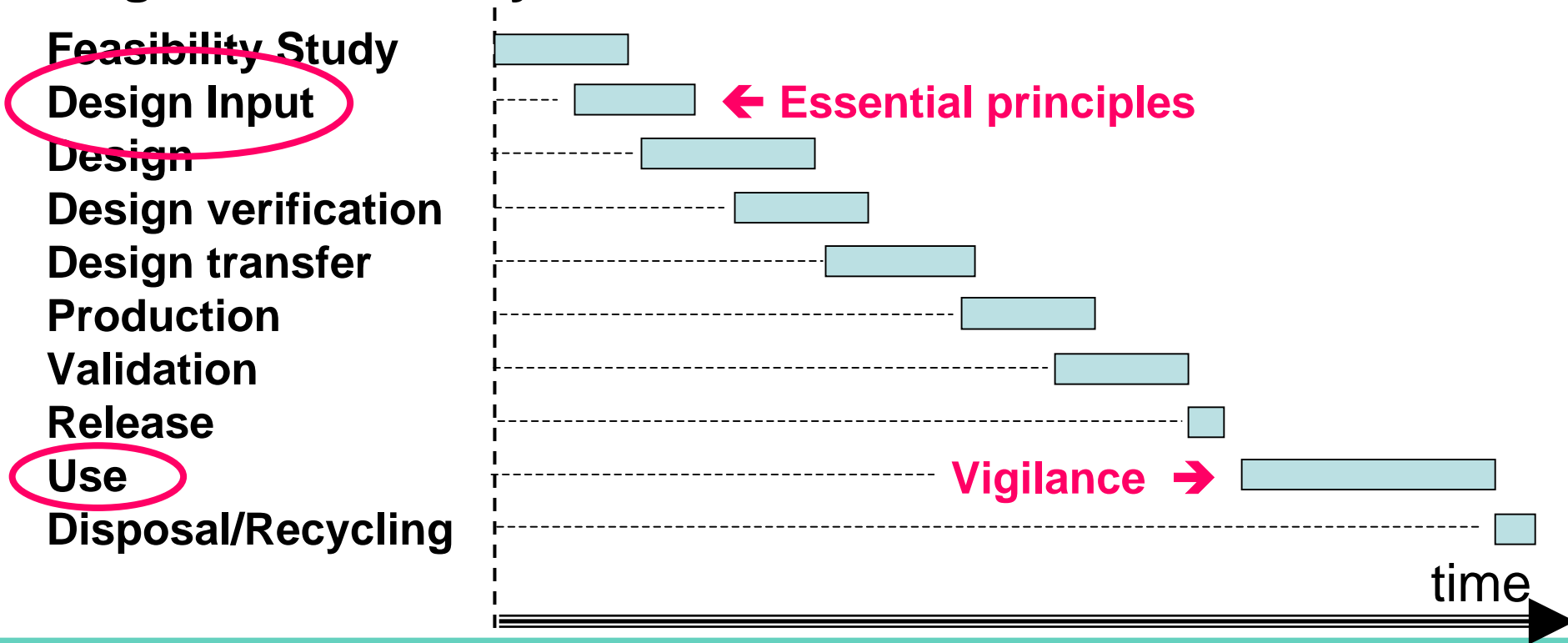
b) effectiveness (are requirements met with?)

of the risk management system.

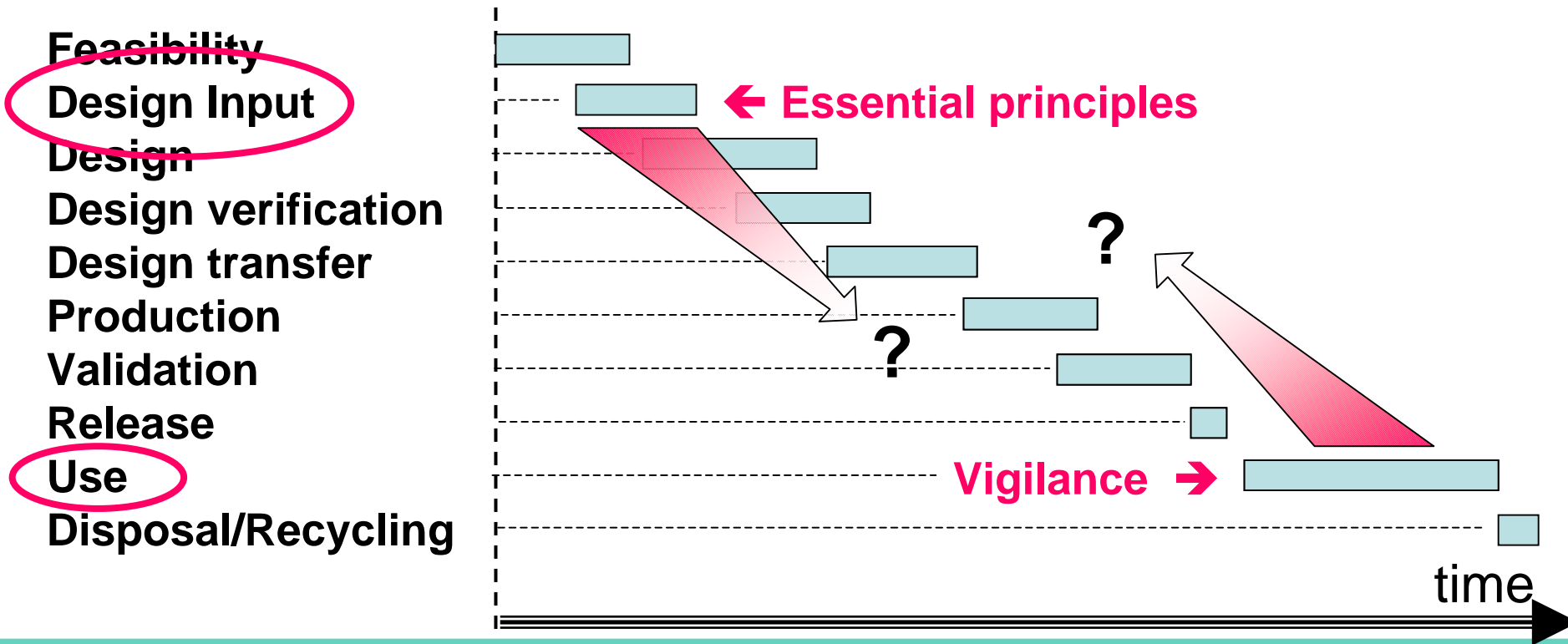
a) Evaluate depth of implementation – throughout the life cycle of the product



Regulatory risk management requirements focus on two stages of the life cycle:



How do they interface? Are they 'synchronized'?





Essential principles contains in section „Design and manufacturing requirements“ 31 requirements addressing technical risks;

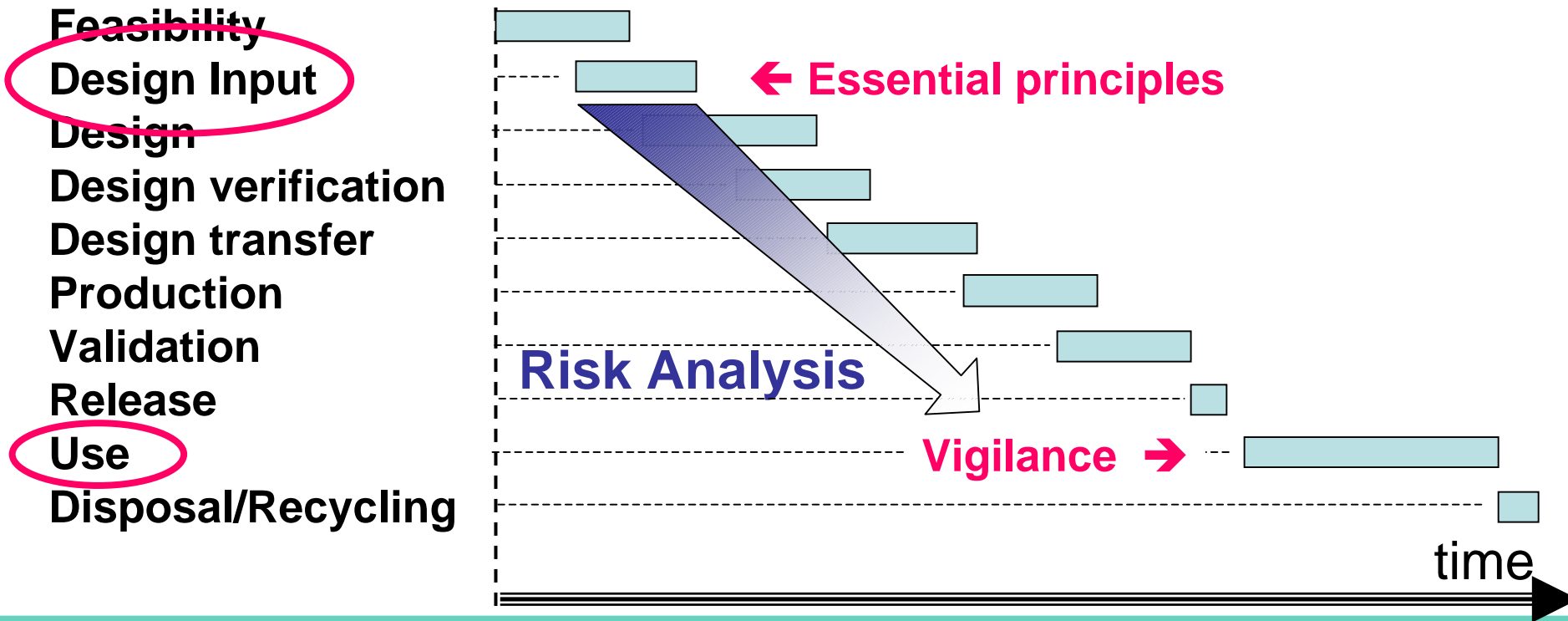
17 specify „to eliminate or minimize risks as far as practicable“

9 specify constructive solutions / safety measures

5 state in general terms „... to ensure patient safety“!

Compliance is demonstrated through Risk Analysis!

The Risk Analysis is a link between Essential Principles and Vigilance:

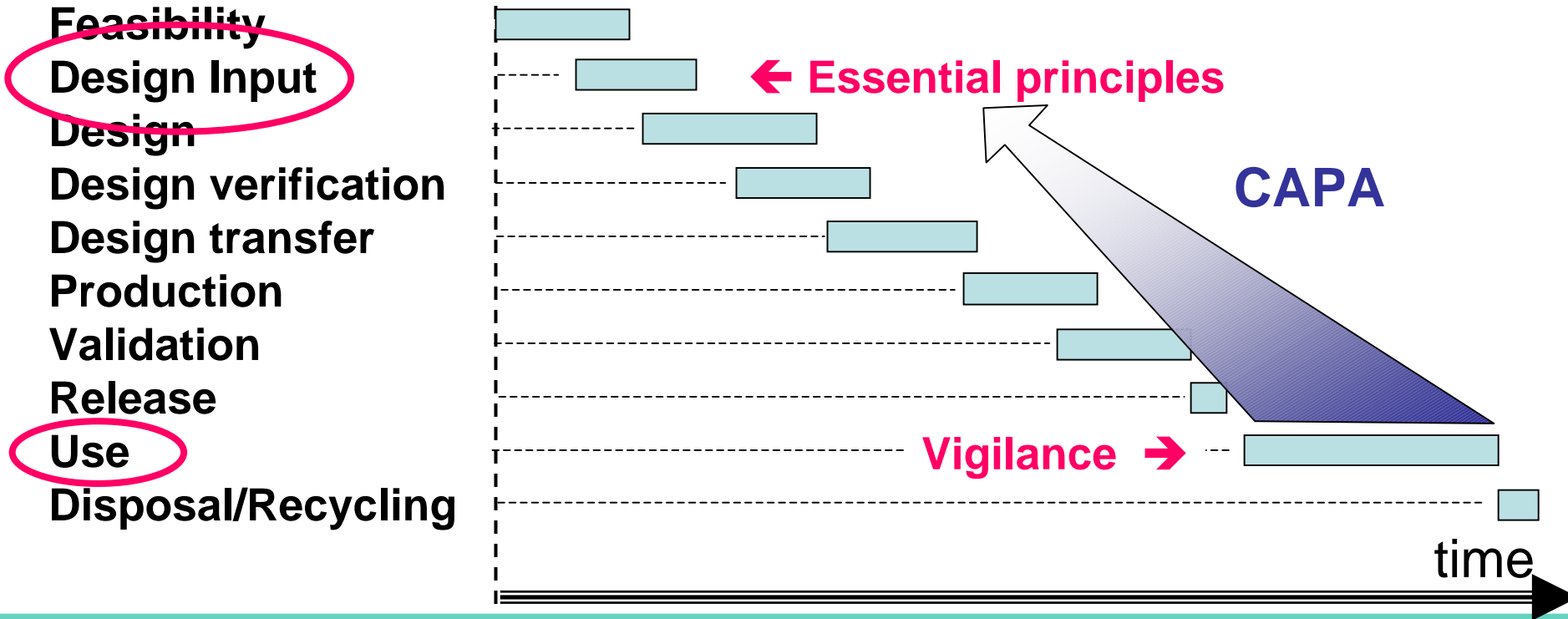




Vigilance obligates the manufacturer to „... institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary **corrective actions**, taking account of the nature and **risks in relation to the product**.

A CAPA-system must be risk based!

Recall and reporting form part of a risk based CAPA-system!



USA: CAPA/Recall classification considers „taking account of the nature and risks in relation to the product“ (21 CFR 7.3):

	Adverse health consequences	
	Temporary or medically, reversible health consequence	Serious adverse health consequence
Reasonable probability	Class II	Class I
Remote probability	Class II/III?	Class II
Not likely	Class III	Class III



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Q: Do recall risk parameters correspond with those used for verifying compliance with the Essential Principles?

	Adverse health consequences	
	Temporary or medically, reversible health consequence	Serious adverse health consequence
Reasonable probability	Class II	Class I
Remote probability	Class II/III?	Class II
Not likely	Class III	Class III

EU: Corrective Action / Recall → no regulatory requirements specifying when, how and why!

		<u>Incident or recall</u> caused by (possible) incident?	
		Yes	No
Serious?	Yes	Report!	–
	No	–	–

**Q: Have recall criteria been documented?
 Are they based on the results of the risk analysis?
 How are they used in the CAPA-system?**



Strategic objectives are to evaluate

a) depth of implementation (risk or crisis management?)

and

b) effectiveness (are requirements met with?)

of the risk management system.



b) Evaluate effectiveness of the risk management system.

b1) Completeness:

Q1: Have all sources of risk been adequately managed?

Have all sources of risk been adequately managed?

Feasibility Study

Design Input

Design → Hazard analysis ISO 14971?

Design verification → Essential principle 2 met with?

Design transfer → Critical design vs. process parameter / FMEA

Production → Manufacturing materials, purchased parts, ...

Validation → Device risk-benefit assessment / production processes

Release

Use → Previously unknown risks / FTA

Disposal/Recycling → Ecological regulations, cross-infection, ...

Q2: Have appropriate risk analysis methods been applied accordingly?

b) Evaluate effectiveness of the risk management system.

b2) Systematic and valid acceptability decisions:

Q3: How have risk acceptability criteria been defined?

- Validity of reference data?
- Appropriate risk modelling?
- Documented systematic procedure?

(Applies to benefits, i.e. MDD clinical evaluation as well!)



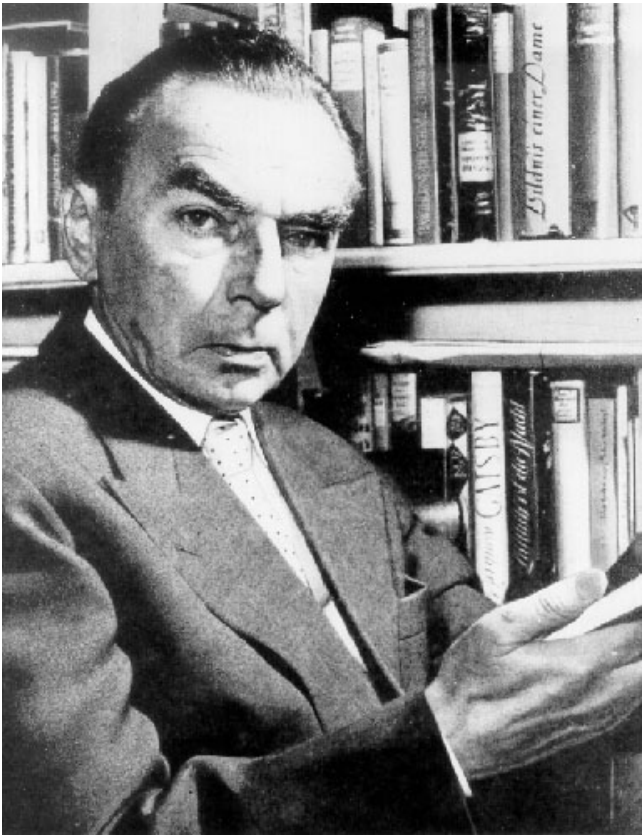
b) Evaluate effectiveness of the risk management system.

b3) Depth of understanding and commitment:

Q4: Is the concept of risk understood throughout the organization – degree of training?

b4) Transparency of documentation:

Q5: Is the risk management report identified in the STD?



"Schau prüfend deckwärts,
die Nähe des möglichen Schadens
liegt nicht in der Schärfe des Schwerts,
vielmehr in der Dicke des Fadens."

[Erich Kästner, Damokles Schwert]

"Perceive what is above your head,
not the sharpness of the sword
will rule the imminence of harm,
but rather the strength of the cord."

[Erich Kästner, Damokles' Sword]