# "*Auditing ISO 9001 Clause 8.3, Design and Development of Products and Services*"

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# Objectives

Focus on issues found in Design and Development Processes during Quality Management System (QMS) Internal Audits

Identify effective tools and techniques that enhance the effectiveness of a Design and Development Process

# Agenda

- Quick Tutorial on Auditing in ISO 9001:2015
- ISO 9001:2015 has introduced “Risk”. What is it all about?
- ISO 9001:2015 Clause 8.3
  - Issues identified during audits
  - Positive features of effective processes
- What do we see in other industry standards
  - ISO 9100:2016 Aerospace
  - IATF 16949:2016 Automotive
  - ISO 13485:2016 Medical Devices
- Conclusions
- Questions

# Acknowledgements


- Angelo Scangas - QSG CEO/President for Medical Device Inputs
- Laura Halleck - QSG Sr Consultant for Automotive Inputs
- Derek Churchill - QSG Sr Consultant for Automotive Inputs

# Definition – Process Audit

"Internal auditing is an independent, objective assurance activity designed to add value and improve an organization's operations. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of processes"

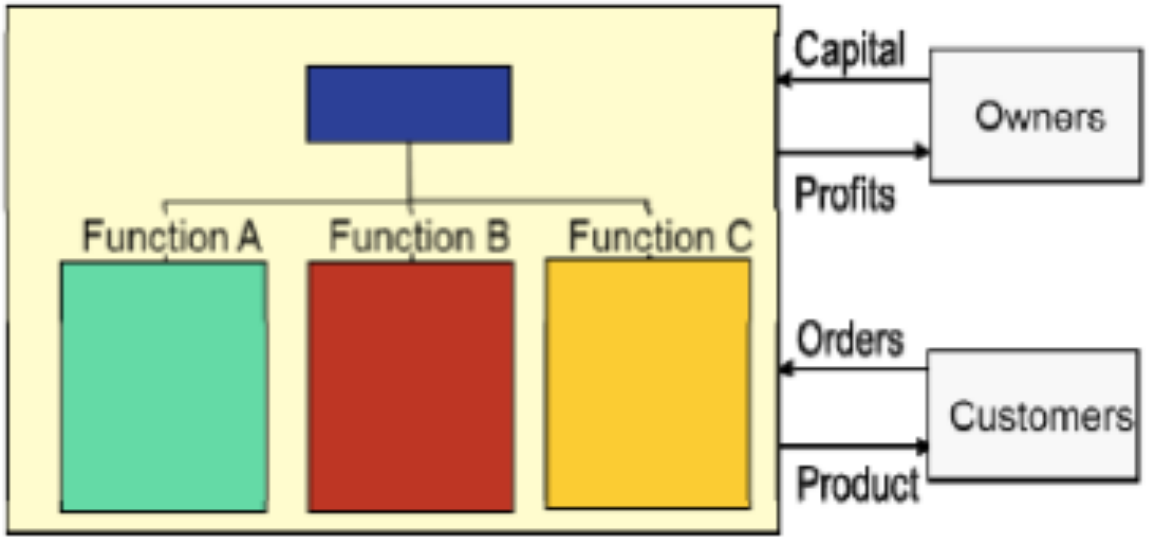
# Audit Key Concepts

- Audits review “Processes” not “People” in a *Quality Management System*
- Audits need to assess whether a process is “Effective” in addition to being compliant to procedures as well as statuary/regulatory requirements.
- Auditors need to be objective and focus on verifiable evidence

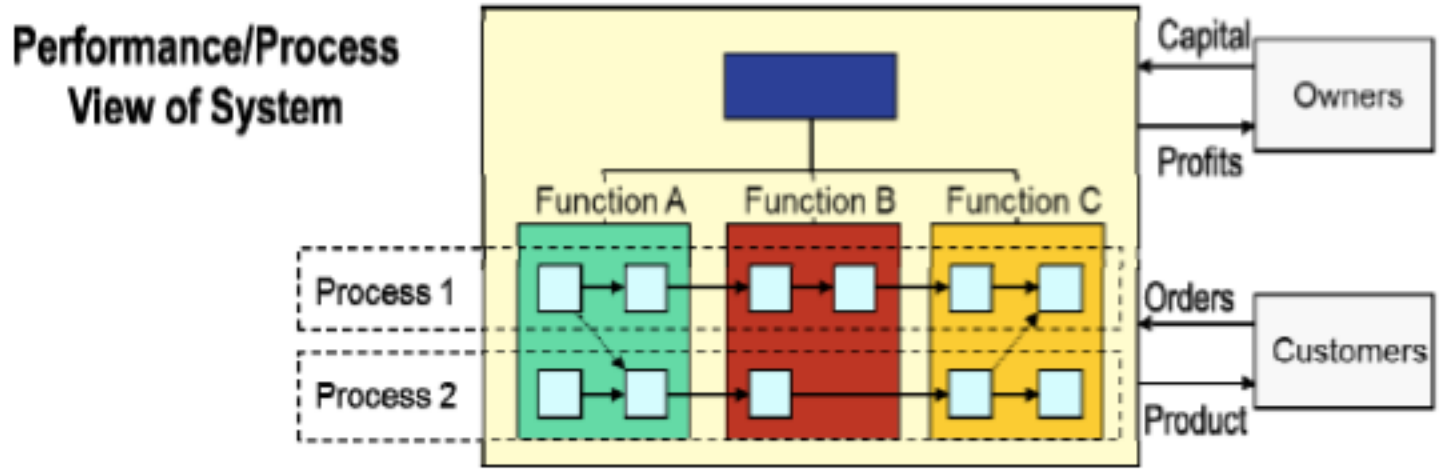
# What is a Quality Management System (QMS)?

An important aspect of a QMS is its process-oriented approach. Instead of looking at departments and individual processes, it requires an organization to look at how processes interact and integrate with each other.

**Traditional/Functional View of System**



# What is a Quality Management System?




**Bottom line**: A process audit is typically perpendicular to the organizational structure.

**Ex:** Design Function typically owns the Design Process but has to integrate other members in different functions to have a effective process

# ISO 9001:2015

- ISO 9001 is a standard that sets out the requirements for a quality management system.
- ISO 9001 is a *"Generic Standard"*.
- Generic means that the same standards can be applied:
  - to any organization, large or small, whatever its product or service,
  - in any sector of activity, and
  - whether it is a business enterprise, a public administration, or a government department.

# Planning the Quality Management System

# ISO 9001:2015 Risk & Opportunities

When planning for the quality management system, the organization shall consider the issues referred to in 4.1(Context of the Organization) and the requirements referred to in 4.2 (Interested Parties) and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);

b) prevent, or reduce, undesired effects;

c) achieve continual improvement.

# ISO 9001:2015 Risk & Opportunities

The organization shall plan:

a) actions to address these risks and opportunities;

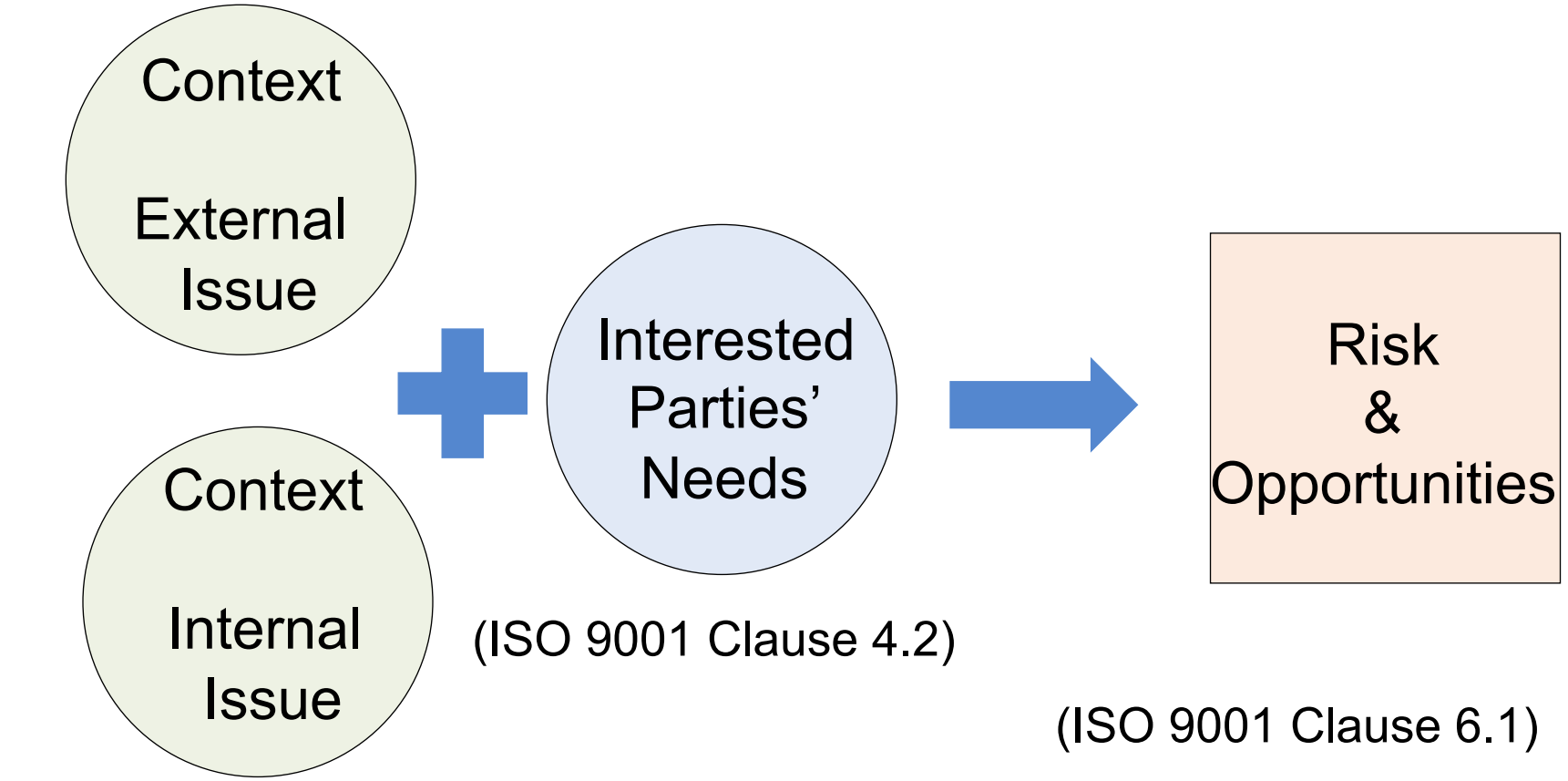
b) how to:

1) integrate and implement the actions into its quality management system processes (see 4.4);

2) evaluate the effectiveness of these actions.

*Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.*

# Quality System Planning



# Quality System Planning(cont.)

Risk
&
Opportunities

(ISO 9001 Clause 6.1)

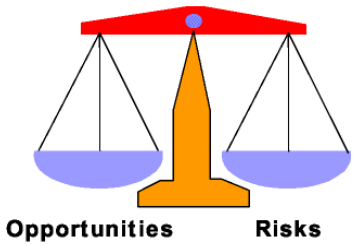
**Plan:** Determine Action Plans to address Risks and Opportunities (Clause 6.1.2)

**Do:** Integrate and implement actions into its quality management system processes (Clause 4.4)

**Check:** Evaluate effectiveness of actions taken (Clause 9.3)

**Act:** Learn from results and reassess Context and Interested Parties (Clause 10.3)

# What is “Risk-Based Thinking”?




- Risk-based thinking is something we all do automatically and often sub-consciously
- The concept of risk has always been implicit in ISO 9001 – the 2015 revision makes it more explicit and builds it into the whole management system
- Risk-based thinking is already part of the *process approach*
- Risk-based thinking makes *preventive action* part of the routine

- *Risk is often thought of only in the negative sense. Risk-based thinking can also help to identify opportunities. This can be considered to be the positive side of risk*

# ISO 9001:2015 Risk & Opportunities

ISO 9001:2015 is a list of requirements

But

Does not prescribe how to do anything

Including Risk & Opportunities

But

Most Clients rely on

Risk Matrices and Risk Registers

# What is Risk? (*)

Risk is the possibility of events or activities impeding the achievement of an organization's strategic and operational objectives.

(*) Bob Deysher's preferred definition

# Risk Definitions

Risk can be defined by two (2) parameters

- Severity
  - This is the *Seriousness* of the harm
- Probability
  - This is the *Probability* that the harm will occur

# Risk in Industry Specific Clients

| Industry | Standard | Risk Definition | Source |
|---|---|---|---|
| Generic | ISO 9001:2015 | Effect of uncertainty on objectives | ISO 31000:2018 |
| Aerospace | AS9100:2016 | An undesirable situation that has both the likelihood of occurring and a potentially negative consequences | IAQG Risk Management Guidance Material |
| Automotive | IATF 16949:2016 | Same as Generic | |
| Medical Device | ISO 13485:2016 | Combination of the probability of occurrence of harm and the severity of that harm | ISO 14971:2019<br>ISO 24971:2020 |

# Risk Assessment - Quantitative

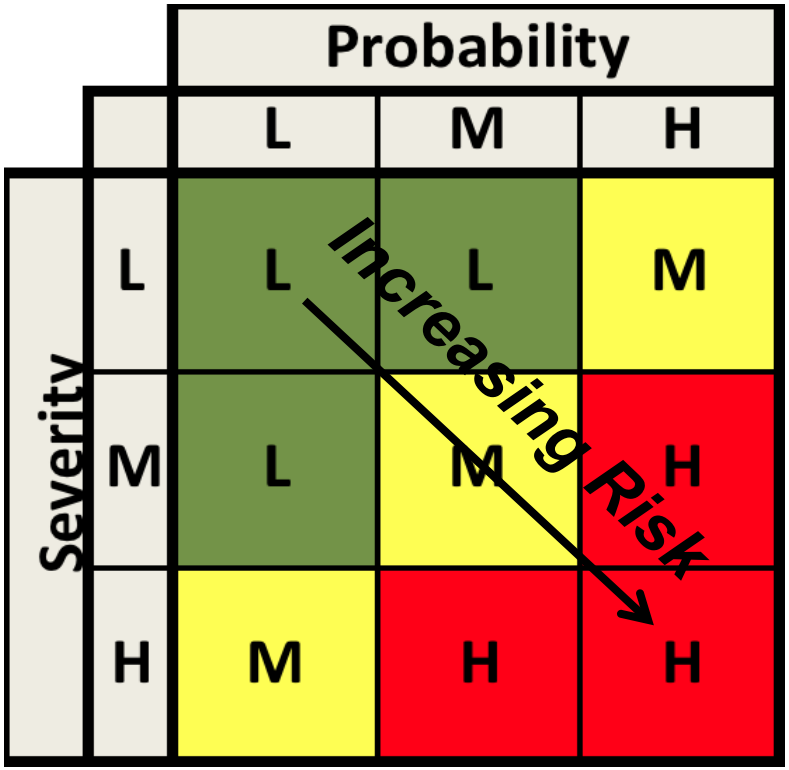
**RISK OUTCOME**

- Low
- Moderate
- Significant
- High

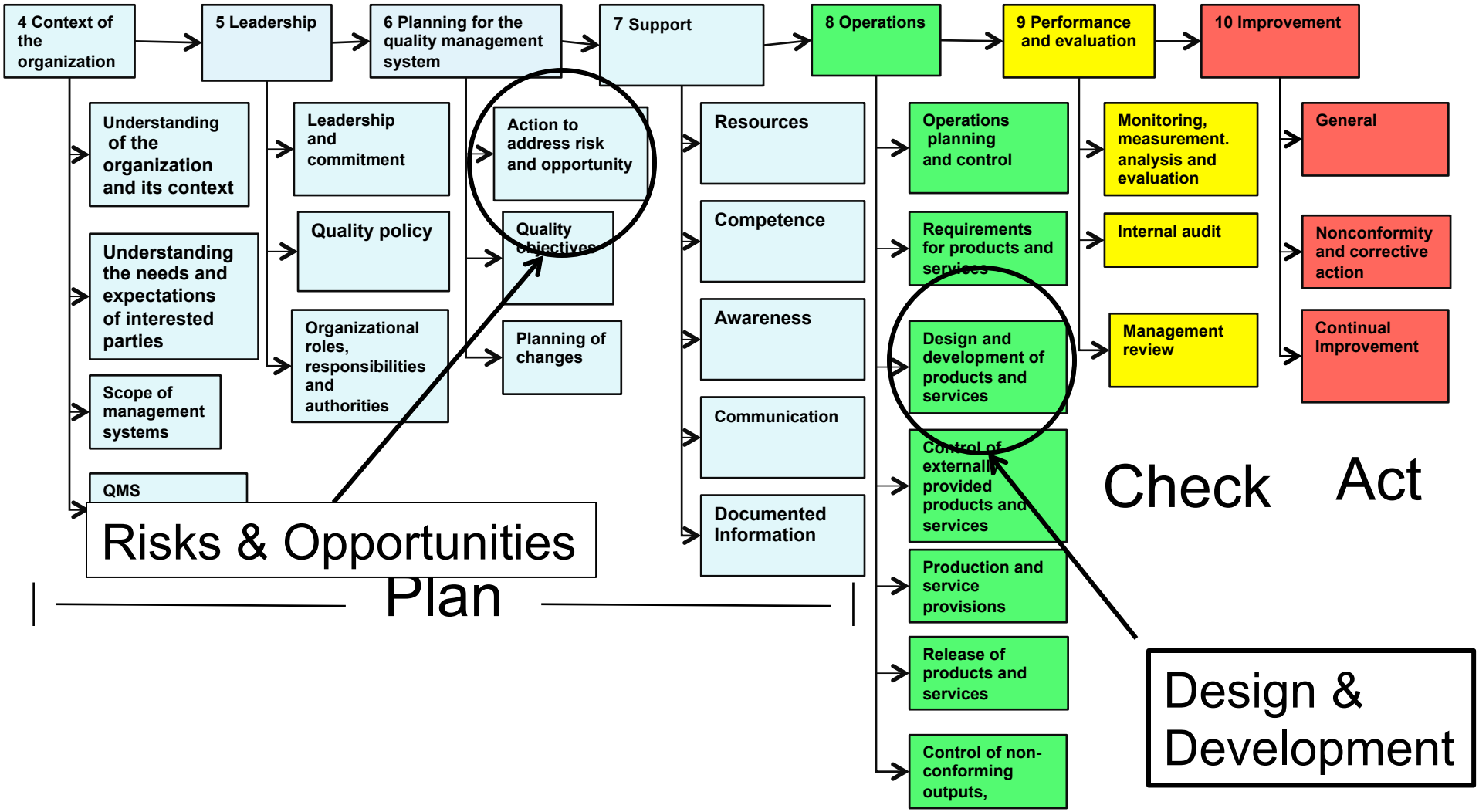
| Likelihood | Consequence | | | | |
|---|---|---|---|---|---|
| | Insignificant 1 | Minor 2 | Moderate 3 | Major 4 | Catastrophic 5 |
| Almost Certain 5 | 5 | 10 | 15 | 20 | 25 |
| Likely 4 | 4 | 8 | 12 | 16 | 20 |
| Possible 3 | 3 | 6 | 9 | 12 | 15 |
| Unlikely 2 | 2 | 4 | 6 | 8 | 10 |
| Rare 1 | 1 | 2 | 3 | 4 | 5 |

Increasing Risk

# Risk Assessment - Qualitative



# ISO 9001:2015 Structure



# ISO 9001:2015 Cause 8.3

8.3 Design and development of products and services

- 8.3.1 General
- 8.3.2 Design and development planning
- 8.3.3 Design and development inputs
- 8.3.4 Design and development controls
- 8.3.5 Design and development outputs
- 8.3.6 Design and development changes

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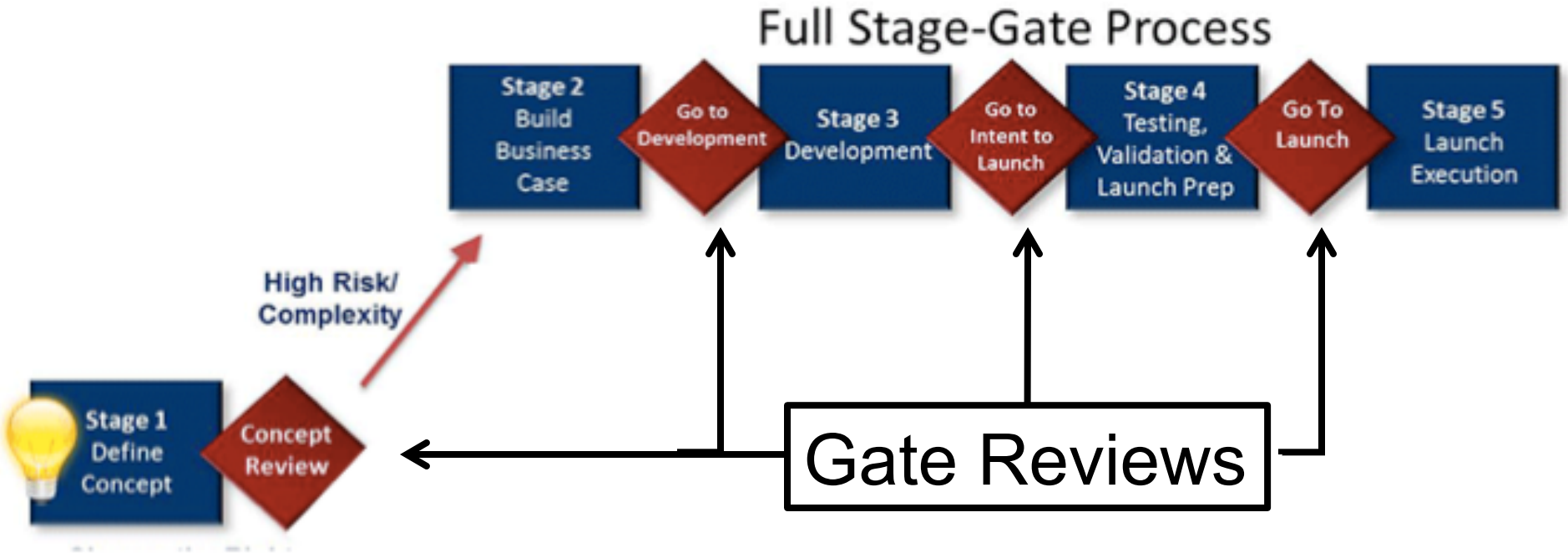
# 8.3.2 Design and development planning

In determining the stages and controls for design and development, the organization shall consider:

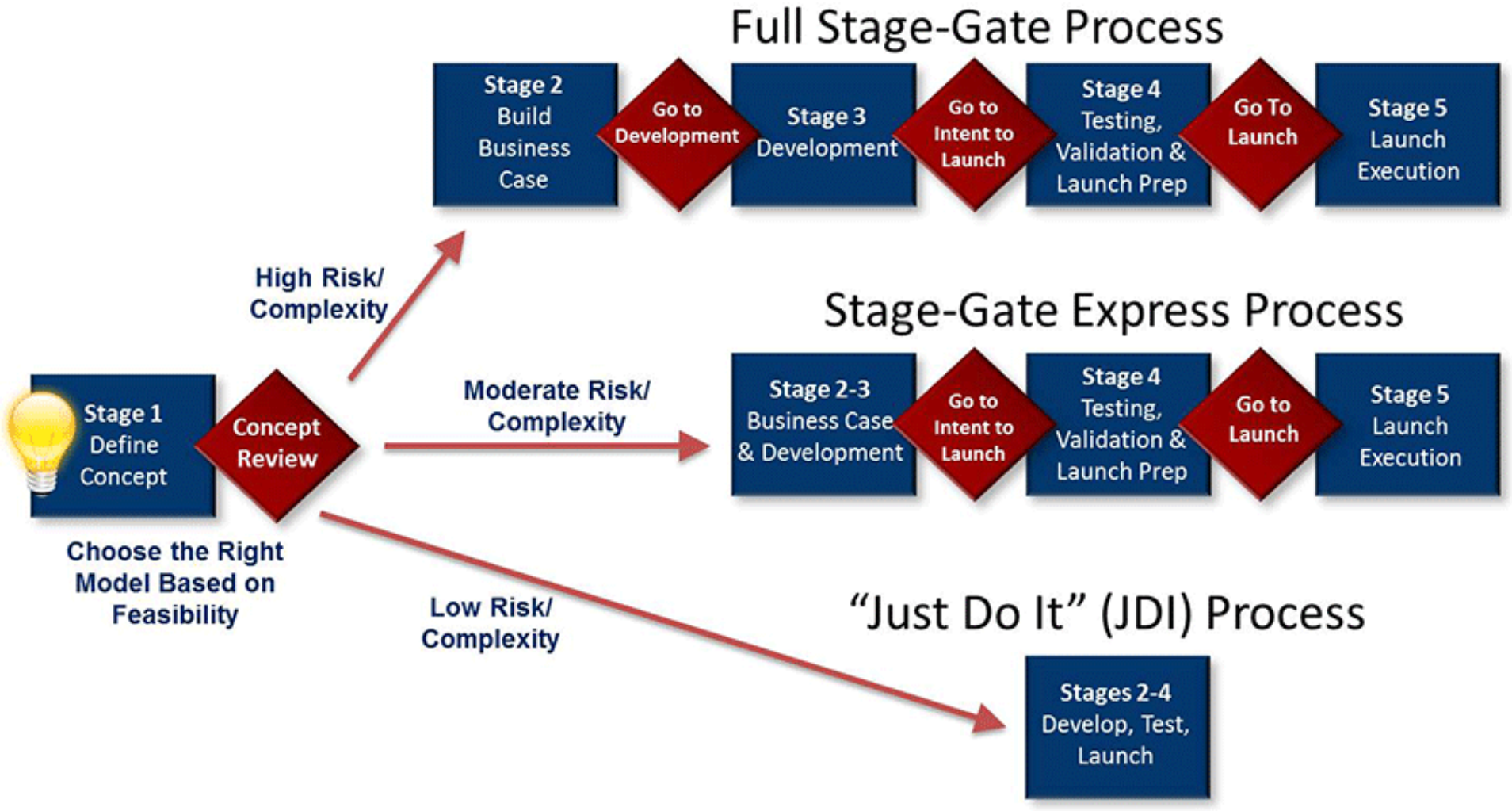
> *b) the required process stages, including applicable design and development reviews;*

Audit Findings:

- Stage Gate Procedure does not match Client Process
- Stage Gate Reviews have missing required approvals
- One size fits all design and development programs


Full Stage-Gate Process
Stage 1
Define
Concept
Concept
Review
High Risk/
Complexity
Stage 2
Build
Business
Case
Go to
Development
Stage 3
Development
Go to
Intent to
Launch
Stage 4
Testing,
Validation &
Launch Prep
Go To
Launch
Stage 5
Launch
Execution
Gate Reviews

# ISO 9001:2015 allows for Multiple Stage Gate Flows



# 8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;

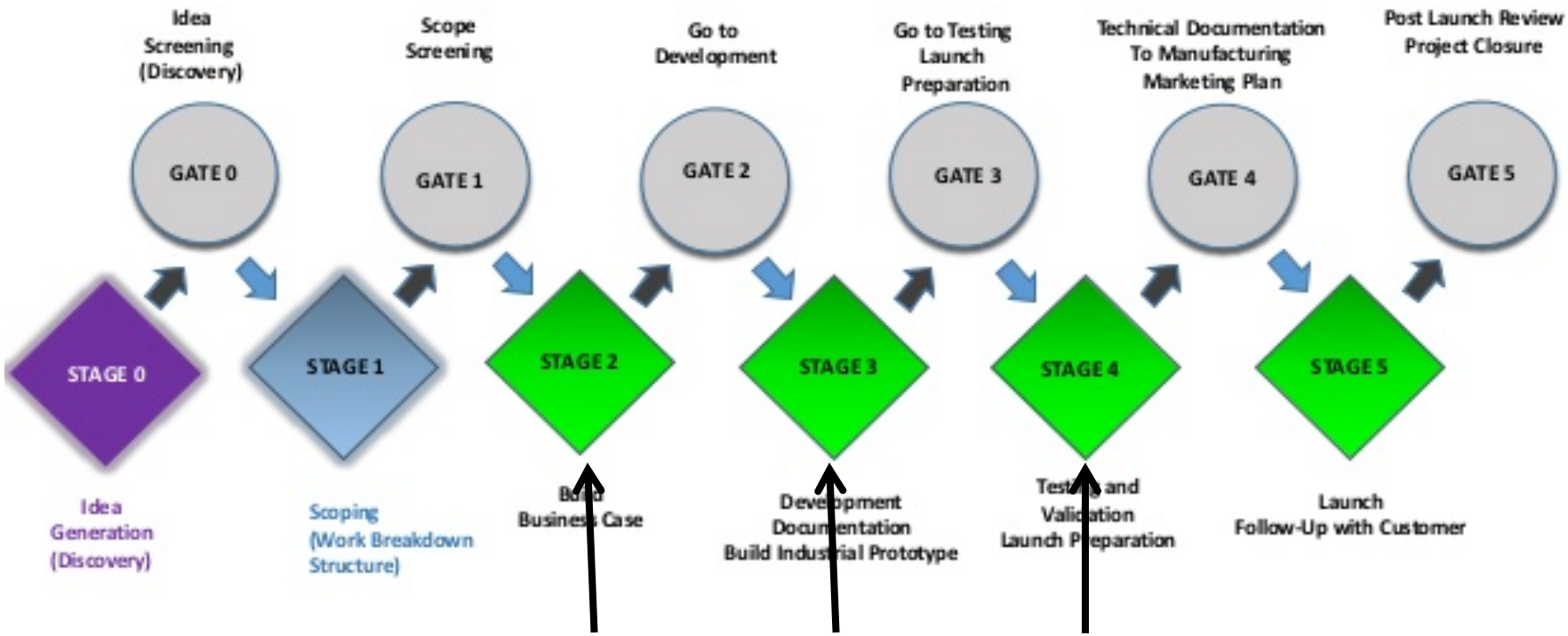
f) documented information of these activities is retained.

# 8.3.4 Design and development controls

Audit Findings:

- Clients do not appreciate difference between verification, validation and design reviews.
- Validation plans do not comprehend manufacturing capability and evaluate too few samples
- Actions taken from resulting failures
  - Failure analysis not capable of getting to root cause
  - Decisions to move on do not adequately evaluate risk/ benefit issues
- Incomplete FMEA's

# Stage Process Model Diagram



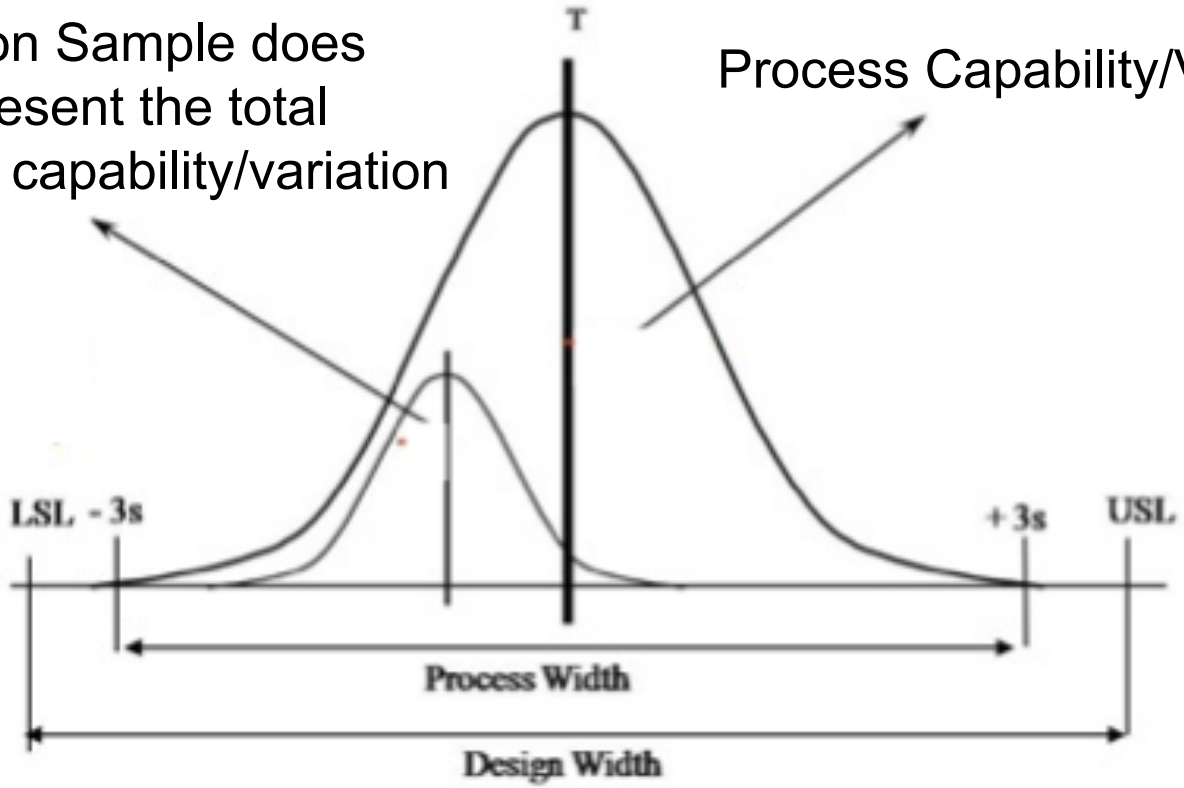

Stage Review Verification Validation

Risk Analysis DFMEA PFMEA/CP

*Risk Analysis & FMEA's are living documents*

# Validation Considerations/Risks

Risk –
Validation Sample does not represent the total process capability/variation



# FMEA Form

| # | Process Function (Step) | Potential Failure Modes (process defects) | Potential Effect(s) of Failure | SEV | Class | Potential Cause(s) of Failure | OCC | Current Process Controls | DET | RPN | Recommend Actions | Responsible Person & Target Date | Taken Actions | SEV | OCC | DET | RPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | | | | | |
| 5 | | | | | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | | | | | |
| 7 | | | | | | | | | | | | | | | | | |
| 8 | | | | | | | | | | | | | | | | | |
| 9 | | | | | | | | | | | | | | | | | |
| 10 | | | | | | | | | | | | | | | | | |
| 11 | | | | | | | | | | | | | | | | | |
| 12 | | | | | | | | | | | | | | | | | |
| 13 | | | | | | | | | | | | | | | | | |
| 14 | | | | | | | | | | | | | | | | | |
| 15 | | | | | | | | | | | | | | | | | |

Identify completed actions taken for reducing the occurrence or improving the detection

Redo RPN calculation assuming new actions are taken to assess effectiveness

# 8.3.6 Design and development changes

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

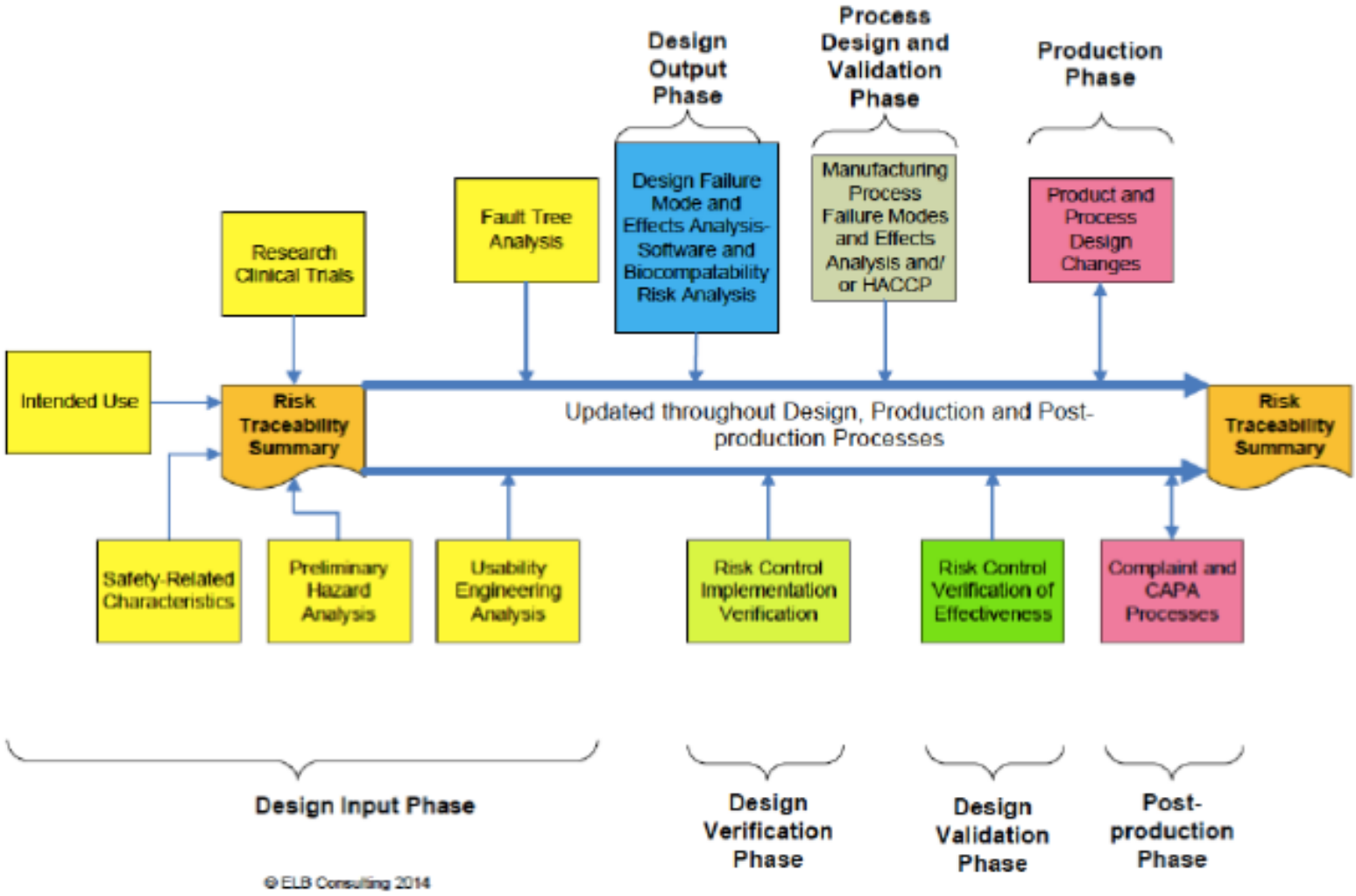
Audit Finding:

- Test Plan not based on “Risk”
- Inadequate design review, verification, validation – Subsequent manufacturing/customer problems
- Disposition of existing inventory

# Industry Specific Issues

- Medical Devices
  - Same as ISO 9001:2015 certified companies
  - Validation including Field Testing (Effectiveness/Safety)
  - “State of the Art” changes modifying product/safety risk
  - Risk Analysis as a Design/Development Process Input
- Aerospace
  - Same as ISO 9001:2015 certified companies
  - External Information/Contract Input to Design
    - International Traffic in Arms Regulations (ITAR)
    - Defense Priorities and Allocation System Program (DPAS)
  - Counterfeit Part (Supplier Management)
  - Critical, Key Characteristics, Special Requirement gaps
- Automotive
  - Fewer/different issues in Design
  - Advanced Product Quality Planning (APQP)

# Typical Use of Risk Management Tools – Medical Products(*)




(*)"Medical Device RISK MANAGEMENT; Compliance with ISO 14971:2019". Edwin Bills, 6/4/2020

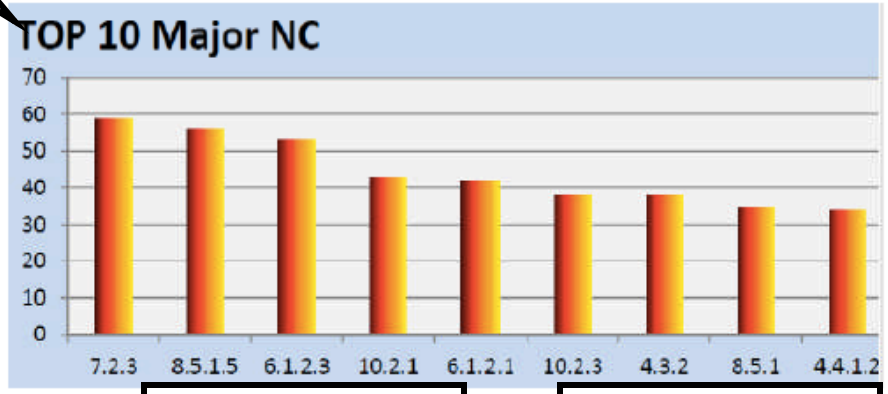
# ark Thinking
# Lesson Learned & Stats

No Major Design NC's

**IATF Stakeholder Conference**
13 September 2017
Oberursel, Germany
Rüdiger Funke (BMW Group)

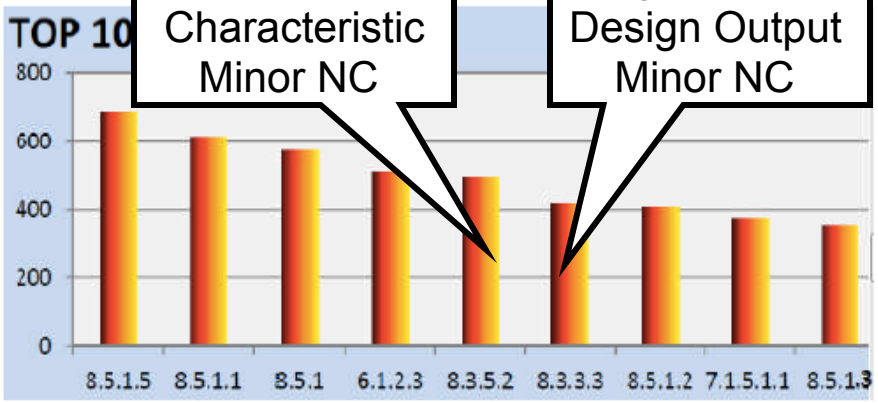
**Basis for the calculation:**

| | | |
|---|---|---|
| **Audits with nonconformity data assigned** | | 3,172 |
| Audits with no nonconformities raised | | 56 |
| **Number of nonconformities raised** | | 16,916 |
| No. of Major Nonconformities raised | | 1,447 |
| No. of Minor Nonconformities raised | | 15469 |
| **Number of nonconformities per audit** | | 5.33 |
| **Ratio** | Major nonconformities / ∑ nonconformities | **8.55%** |
| Ratio | Audits with no nonconformities raised [0.0] / Audits with nonconformity data assigned | 1.77% |
| Audits containing NCs 100% resolved | | 14 |
| Audits containing only NCs 100% resolved | | 1 |
| No. of Nonconformities 100% resolved | | 49 |
| Ratio | ∑ Audits containing NCs 100 resolved / ∑ Audits "acceptable, failed & terminated" | 1.16% |




Special Characteristic Minor NC

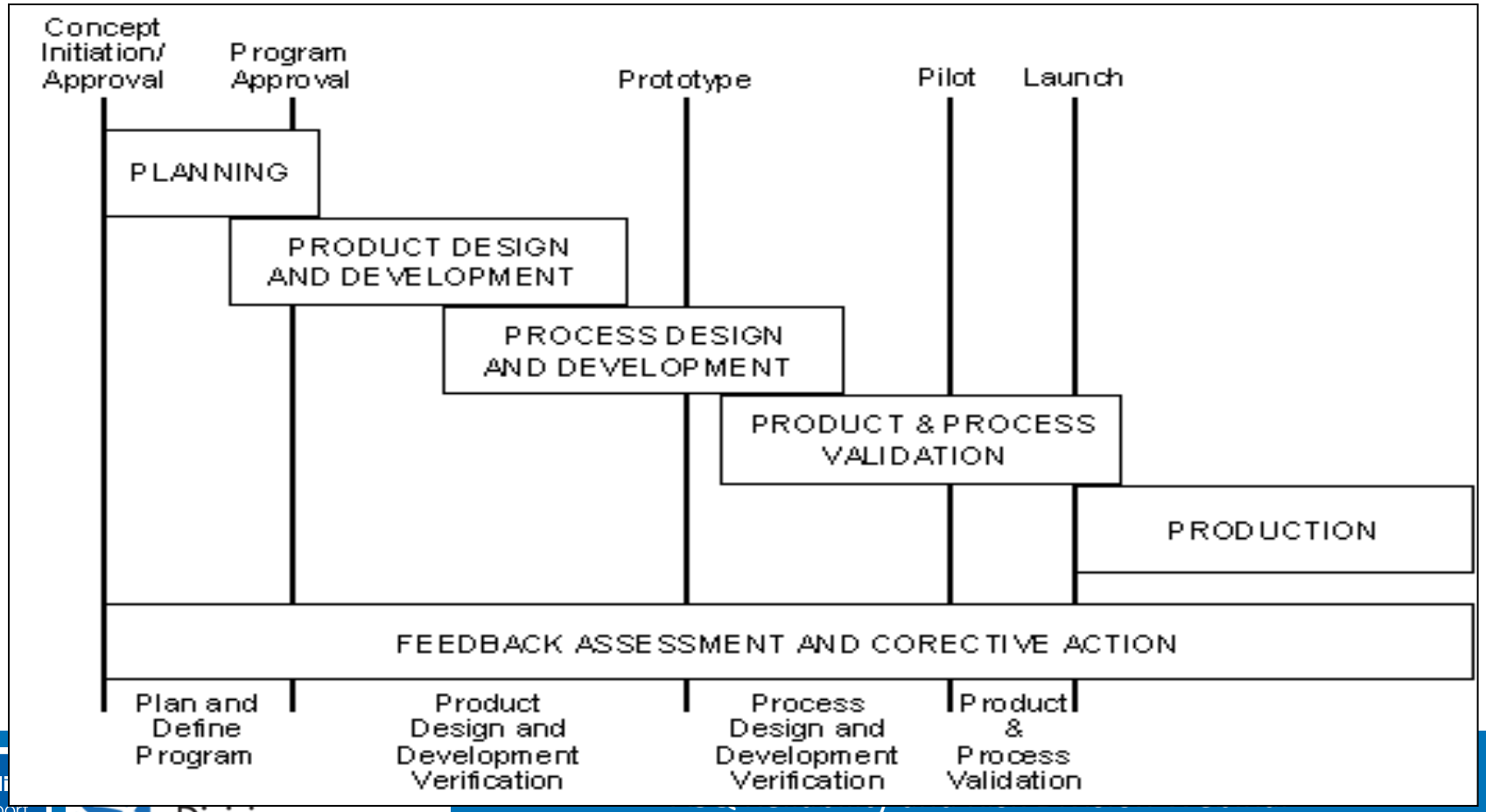
Mfg Process Design Output Minor NC




ASQ DNV-GL flex

# APQP – timing chart and phases - AIAG

The Advanced Product Quality Planning process consists of **four** phases and **five** major activities and has some 20+ supporting tools (e.g. DFMEA, PFMEA, CTQ, Special Characteristics, Control Plan, SPC) along with ongoing feedback assessment and corrective action.



# Conclusions

- Companies that tailor their design and development procedure (Stage Gate) to how they actually deliver a successful product have fewer audit issues

- Companies that measure the effectiveness of their design and development process have fewer audit issues

# A Question for You to Consider?

How do you know your
Design & Development Process
is effective?

How about measuring
Performance Against Schedule(PAS)?
Engineering Change Order/Pareto?

# Questions?

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# Bob Deysher - Senior Consultant Quality Support Group

Bob has over 40 years of manufacturing experience in the semiconductor industry working for Western Electric, Digital Equipment Corporation and Intel Corporation. In that time he has held senior management positions in industrial engineering, process engineering, product introduction, package assembly, manufacturing, quality, and reliability. He has also worked as a senior staff member and consulting engineer in quality and reliability in between senior managerial assignments

At the Quality Support Group, Bob's areas of training and consulting include ISO 9001 & AS9100, Toyota Production System (TPS) and Lean, Corrective Action and Problem Solving (8D), as well as Risk Based Thinking (RBT), ISO 31000, and ISO 14971.

Bob has a BS and MS from Lehigh University, Bethlehem, PA.

# A Little About Quality Support Group

Quality Support Group Inc. (QSG) is a leading international consulting and training firm delivering organizational continuous improvement. Headquartered in Boston, Massachusetts, QSG has been helping organizations reach their core objectives since 1993.

QSG offers on-site training, public workshops, consulting, grant writing and much more.

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