



Club Founder
Dr. Mahmoud Bahgat



International Factories Club

**DESIGN &
DESIGN QUALIFICATION**

Online zoom

10 pm EGY-10 pm KSA-11 pm UAE



Dr. Ahmed Raafat
**Plant Manager
& Pharma Consultant**

SAT. 26TH JULY 2025



Co-Founder & Host:
Dr. Ahmed Rafat





Dr. Ahmed Mohamed Raafat

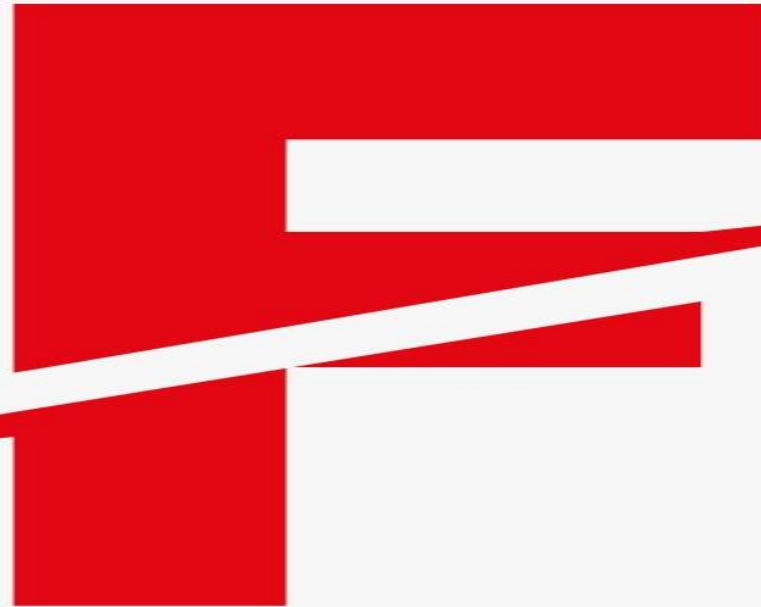
Education:

- B.Sc. of Pharmacy, Faculty of Pharmacy, Alex. University, Good, May 2000.
- M.B.A. from AASTM, GPA = 3.6, Jan. 2005.
- Operation Management Diploma, Knowledge Institute, Jan. 2010.

Experience:

- 02/2018 – Now: Plant Manager & Pharma Technical Design Consultant
- 04/2016 – 02/2018: Project Manager SAJA Pharmaceutical
- 09/2009 – 03/2016: Production Manager ADWIA Pharmaceuticals

International



Factories *Club*

Sharpen your skills



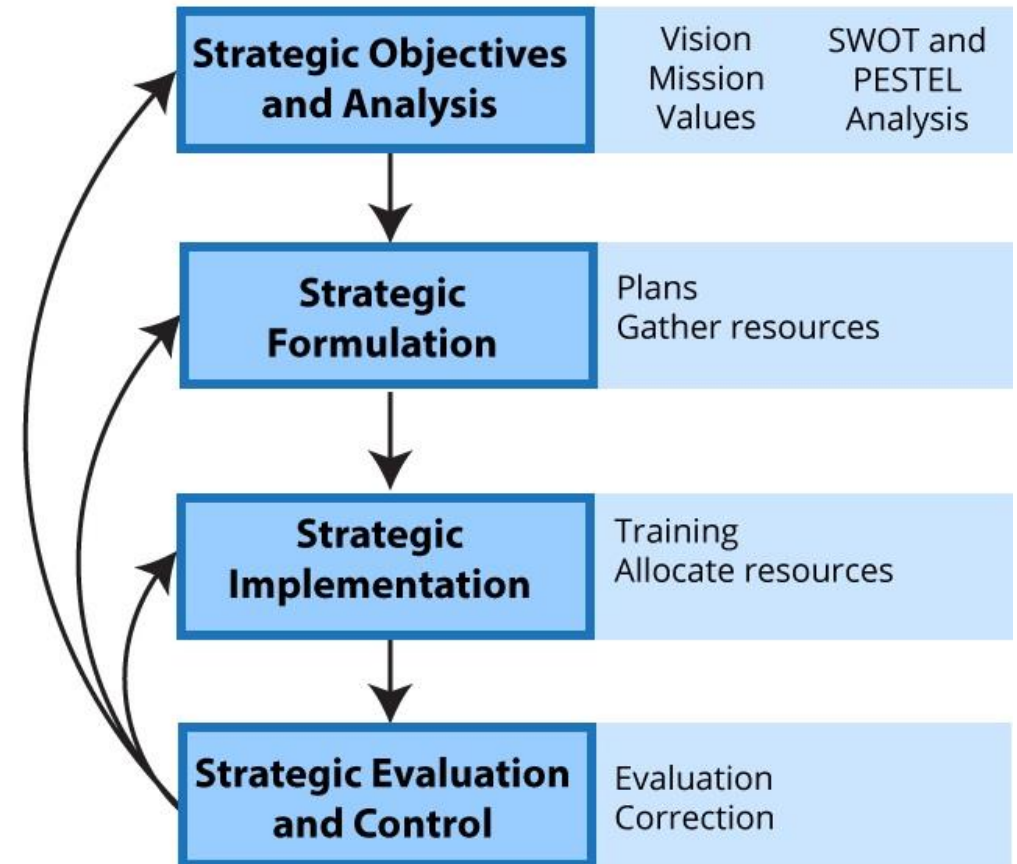
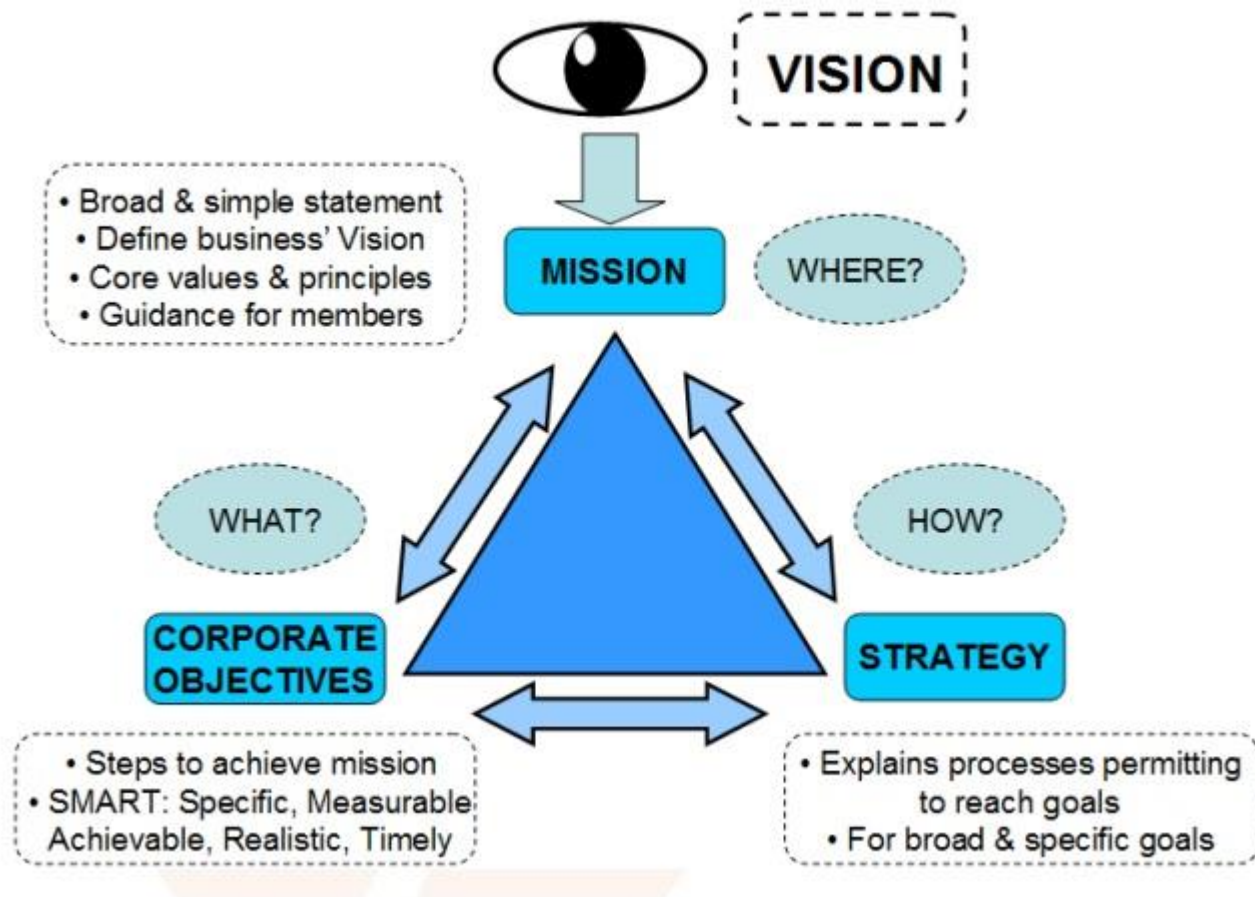
DESIGN & DESIGN QUALIFICATION

By: Dr. Ahmed Mohamed Raafat

CORPORATE STRATEGY

- Strategies at this level are more conceptual and futuristic than the other levels.
- It defines the organization's overall direction and the high-level ideas of how to move towards it.
- These represent the long-term aspirations of a company, outlining the desired future state.





Types of Design:

Type

01.

Facility Design

02.

Equipment Design

03.

System Design

04.

Software D





How the
customer
explained it.



How the Project
Manager
Understood it.



How the
Engineer
Designed it.



How the
Technician
Built it.



How the
Customer really
wanted it.

COMPANY SIZE



**SMALL
BUSINESS**



**MEDIUM
BUSINESS**



**LARGE
BUSINESS**



ENTERPRISE

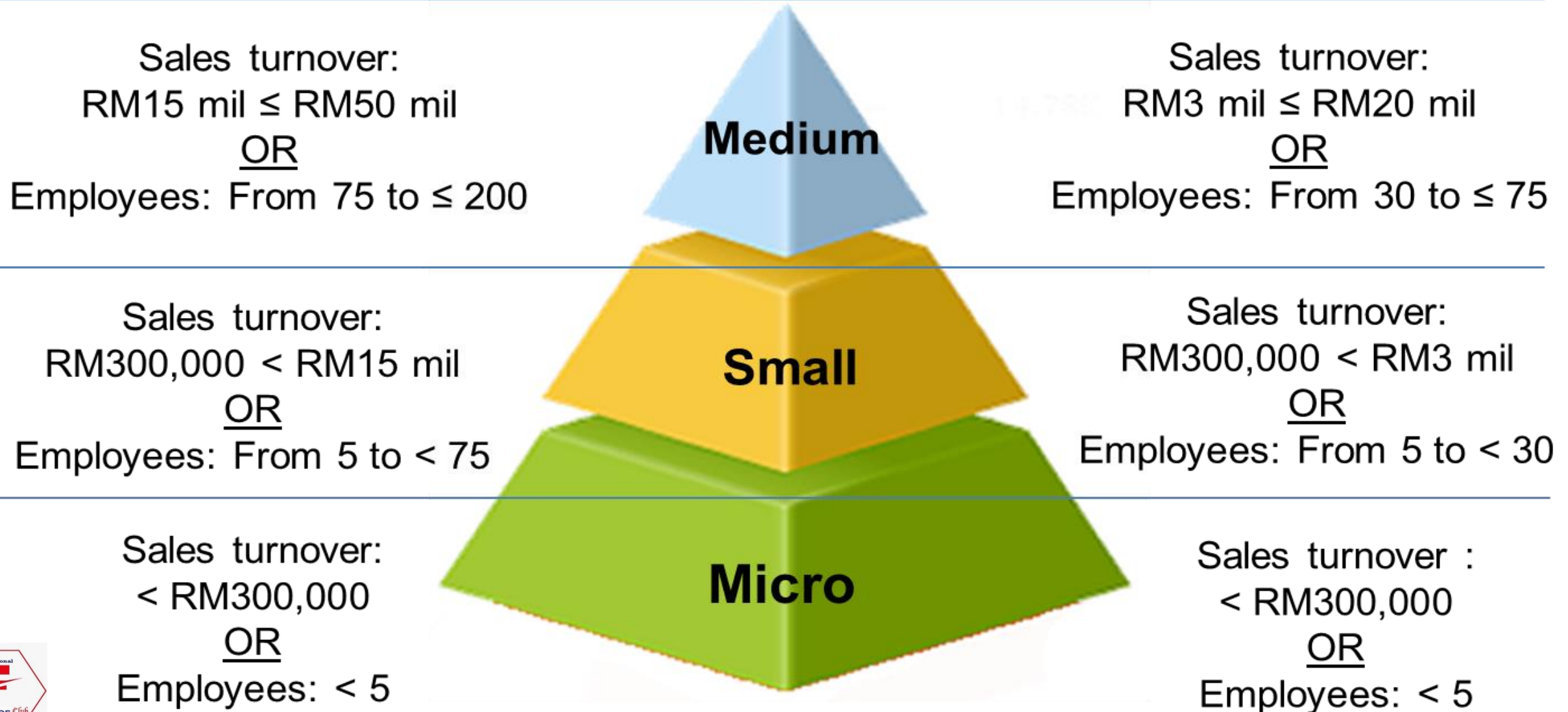


**GLOBAL
CORPORATION**



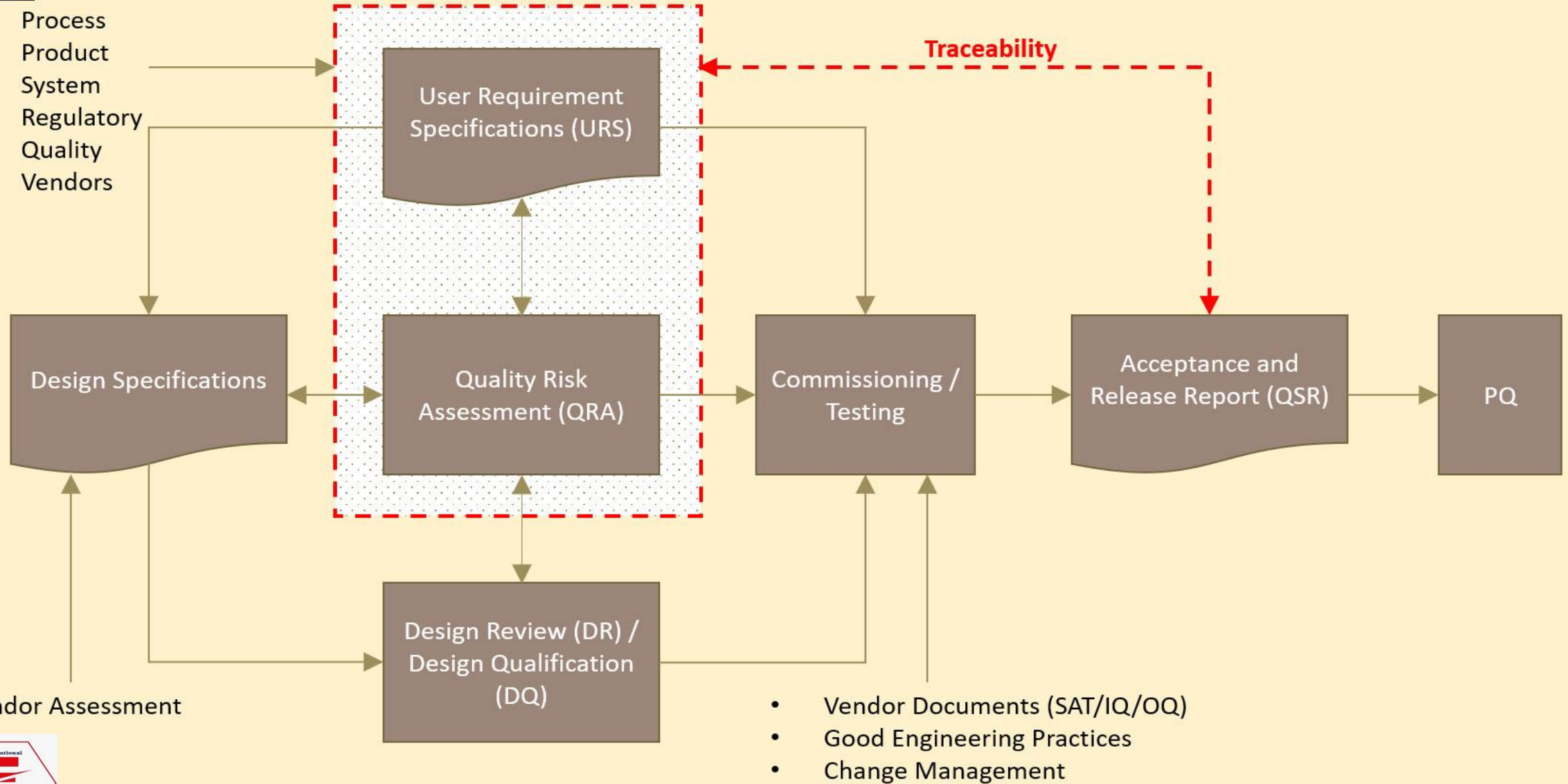
Manufacturing

Services and Other Sectors



SME's

- Process
- Product
- System
- Regulatory
- Quality
- Vendors



User Requirements Specification (URS):

Purpose: Captures the user's needs and expectations for a system or product.

Focus: Defines what the system or product should do from the user's perspective.

Characteristics: Typically written in non-technical language, focusing on functionality and desired outcomes.

Design Specification:

Purpose:

Defines how the system or product will be designed and implemented to meet the user requirements.

Focus:

Details the how of the system, including technical specifications, design choices, and implementation details.

Characteristics:

Written in technical language, often including detailed specifications, diagrams, and technical drawings.

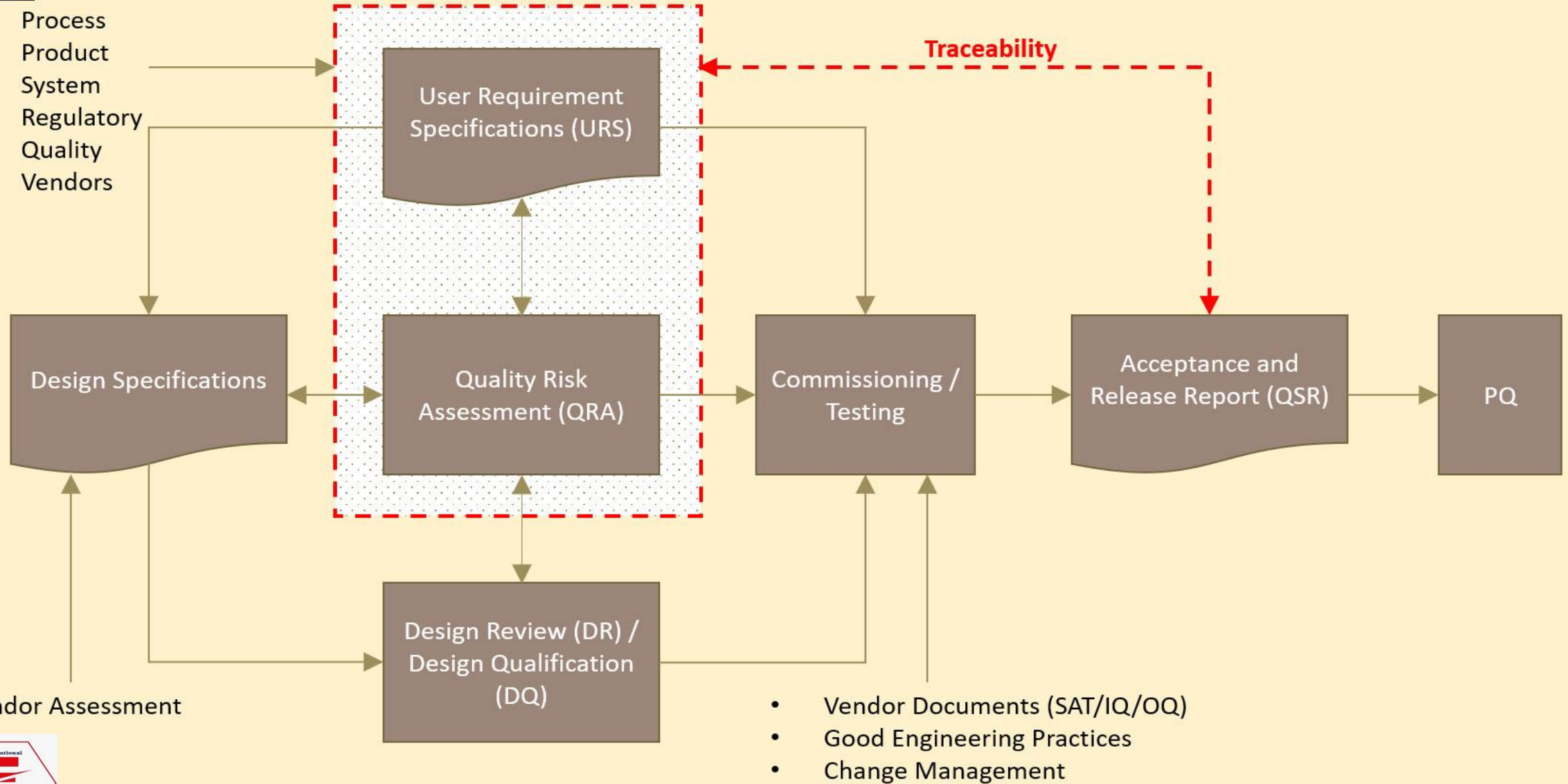
Relationship URS & DS:

URS is the "what" and the Design Specification is the "how".+

- They are distinct but interconnected documents crucial for successful system or product development.
- The URS provides the foundation for the Design Specification.
- The Design Specification is derived from and aims to satisfy the requirements outlined in the URS.
- The Design Specification may include multiple documents, such as Functional Specifications, Interface Specifications, and Performance Specifications, to address different aspects of the system.

SME's

- Process
- Product
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Quantitative Risk Assessment (QRA):

QRA is a systematic process for identifying, analyzing, and evaluating potential risks associated with a project's design. It involves:

Hazard Identification: Identifying potential hazards and hazardous scenarios.

Frequency Analysis: Estimating the likelihood of each hazard occurring.

Consequence Analysis: Assessing the potential consequences of each hazard, including impact on people, environment, and assets.

Risk Quantification: Calculating the overall risk by combining frequency and consequence.

Risk Mitigation: Developing and implementing risk reduction measures to reduce the likelihood or consequences of hazards.

Relationship between DS and QRA:

The DS provides the framework for the project, while the QRA helps ensure the design is safe and reliable.

QRA findings can inform design choices, leading to adjustments in the DS to mitigate identified risks.

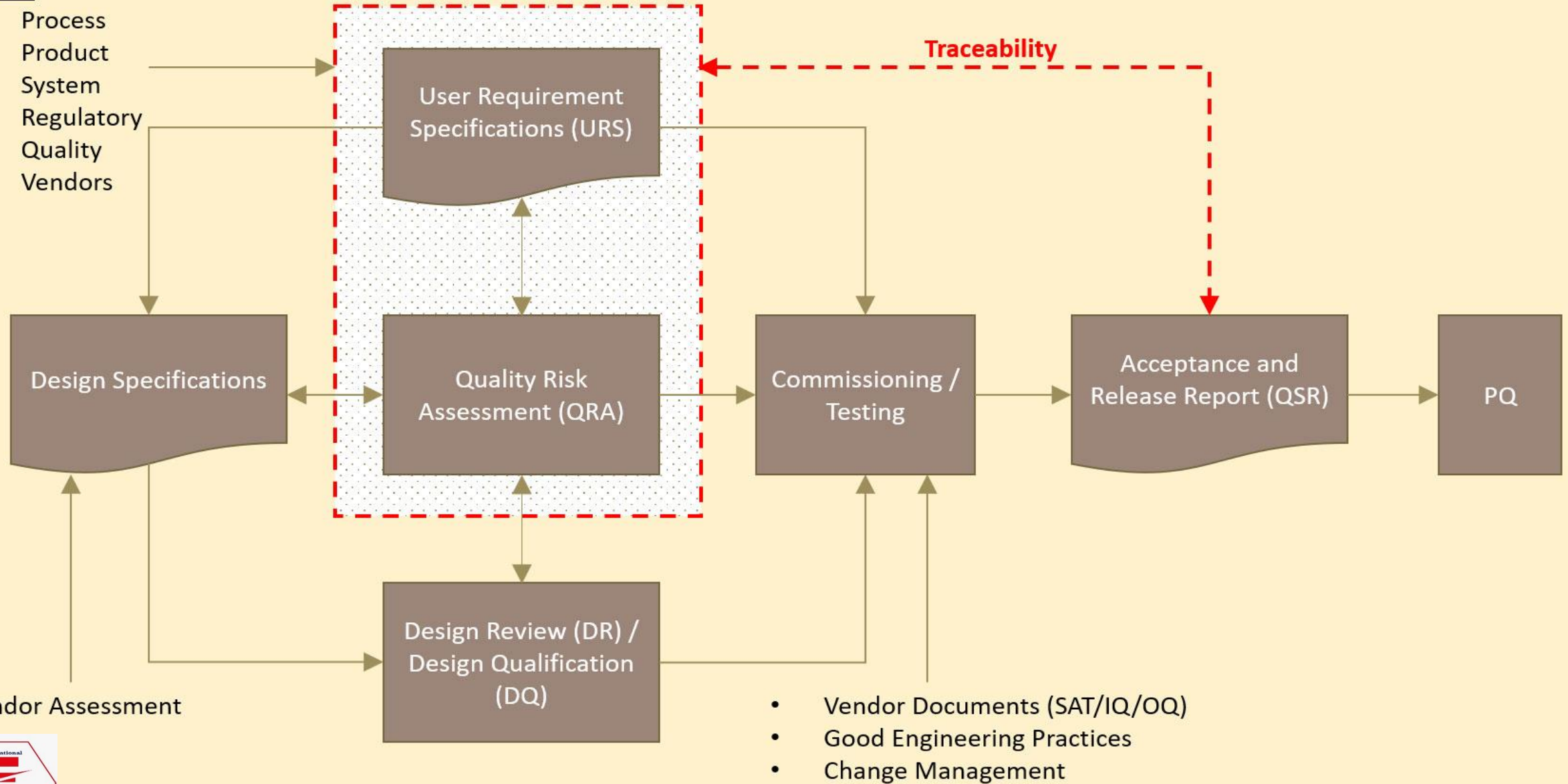
Early QRA during the design phase can help prevent costly redesigns and delays later in the project.

The QRA process often relies on data and information provided in the DS.

Well-defined DS and a thorough QRA are crucial for ensuring a successful and safe project.

SME's

- Process
- Product
- System
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Design Review:

Definition:

A design review is a formal process of evaluating a design against its specifications and requirements.

Purpose:

It aims to identify potential problems, assess the design's suitability and effectiveness, and ensure it meets the project's objectives.

Process:

Design reviews often involve presentations, discussions, and feedback from stakeholders, including designers, developers, and users.

Importance:

Design reviews help prevent costly errors, improve the quality of the design, and ensure that the final product is fit for purpose.

Relationship between DS and DR:

- The design specification provides the criteria against which the design is reviewed.
- The design review ensures that the design meets the requirements outlined in the design specification.
- Design reviews can lead to updates in the design specification as new information or issues are identified.

When Design Reviews are executed?

Early Stages:

After Defining User Needs & Design Input Requirements:

This ensures the design is grounded in user needs and technical specifications.

After Defining Design Outputs:

Reviews at this stage confirm the design meets defined requirements before moving to verification.

Preliminary Design Review (PDR):

A PDR is conducted when the system concept is initially baselined, and before detailed design can proceed. It often happens during the Technology Maturation & Risk Reduction phase.

When Design Reviews are executed?

Mid-Stages:

Prior to Design Verification:

This review ensures the design is ready for testing and validation.

After Design Verification and Prior to Design Validation:

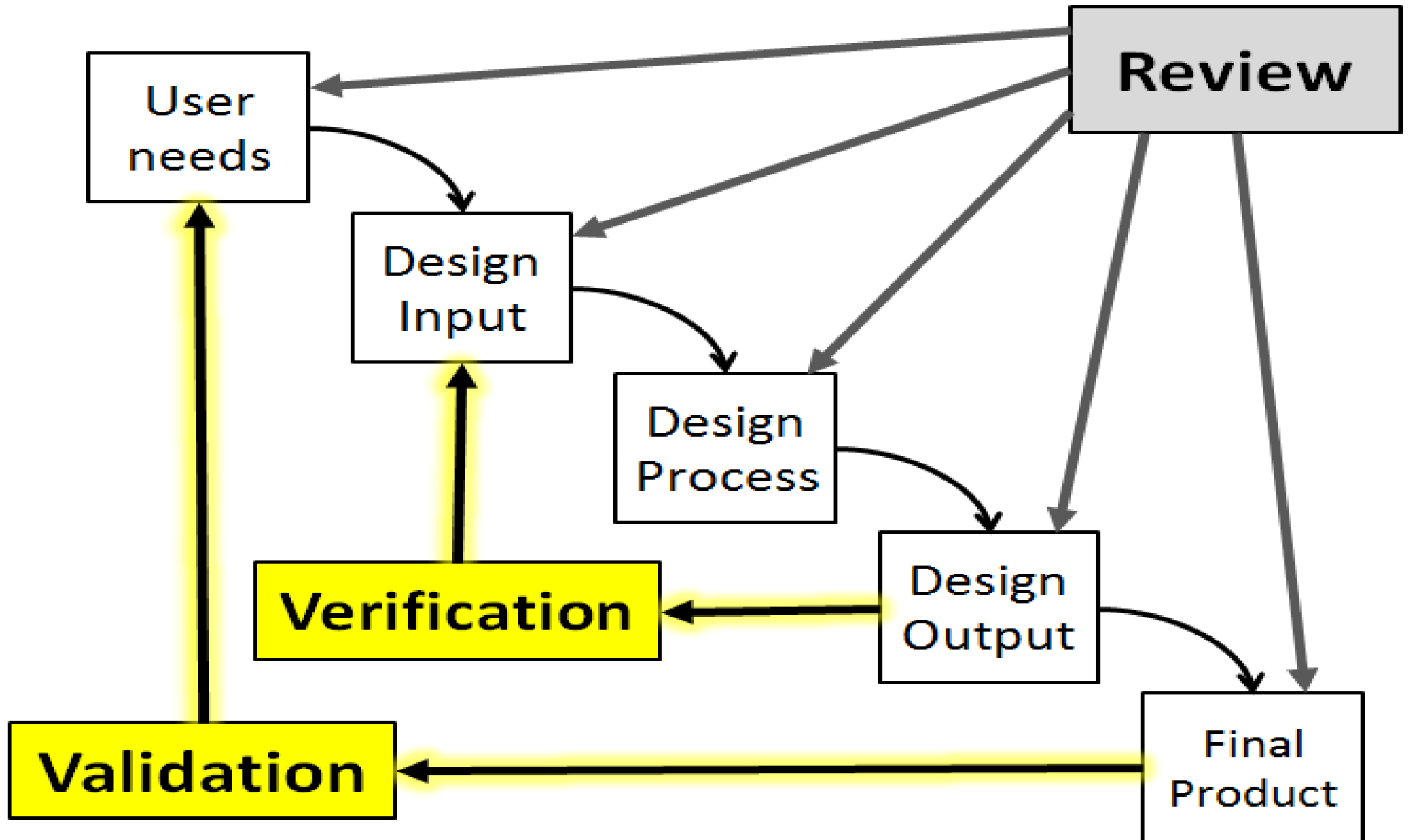
This review checks the results of verification and ensures readiness for validation.

Relation between Design Verification & Design Validation:

- Design verification and design validation are distinct but related processes in product development in regulated industries.
- **Verification** ensures that the design output meets the design input requirements.
- **Validation** ensures the final product meets user needs and intended uses.

Verification asks, "Did we build the product right?"

Validation asks, "Did we build the right product?"



When Design Reviews are executed?

Late Stages:

When Ready for Design Transfer:

This ensures the design is ready for implementation.

Technical Design Review (TDR):

Often conducted at various phases, including final validation, to ensure development stays on track.

Usability Review:

This is performed when a prototype is ready, but before the final design is approved, to assess ease of use.

Design Qualification (DQ):

- **Purpose:** DQ is a documented verification that the design, once implemented, will meet the intended use and quality standards.
- **Focus:** Demonstrates that the design, when built, will fulfill user requirements and quality standards.
- **Key Activities:** Verifying that the design meets all specified requirements, including GMP and regulatory standards, and that potential risks have been adequately addressed.
- **Output:** DQ report, which serves as documented evidence that the design is suitable for its intended purpose.

What is Design Qualification (DQ) and how does it relate to Design Review (DR)?

The introductory paragraph to Design Review and Design Qualification in Section 5 of the [ISPE Baseline Guide Volume 5: Commissioning and Qualification Second Edition](#), summarizes concisely the relationship between Design Review and Design Qualification as follows:

“DR and DQ are not intended to be separate activities, but rather separate documentation in which DQ is focused on Critical Aspects (CAs)/Critical Design Elements (CDEs) and involves the Quality Unit as an approver. There should be minimal duplication of work. The final report from DR is a key input into the DQ process.”

Relationship Between DR and DQ:

- DR is an input to the DQ process.
- The final report from the design review can be used as a key input for the DQ process, ensuring that the design meets all requirements.
- DR identifies potential issues early in the design phase, allowing for corrections before they become costly problems during implementation or qualification.
- DQ confirms that the design, as finalized after DR, is suitable for its intended use.

DR helps ensure the design is correct, while DQ confirms that the correct design is being built.



Types of Design Qualification:



Type

Description

01.

Facility Design Qualification

Ensures facility layout, walls, HVAC zones, and flow patterns meet GMP

02.

Equipment Design Qualification

Confirms machinery is designed per functional and cleaning requirements

03.

System Design Qualification

Validates design of utility systems (WFI, HVAC, compressed air, etc.)

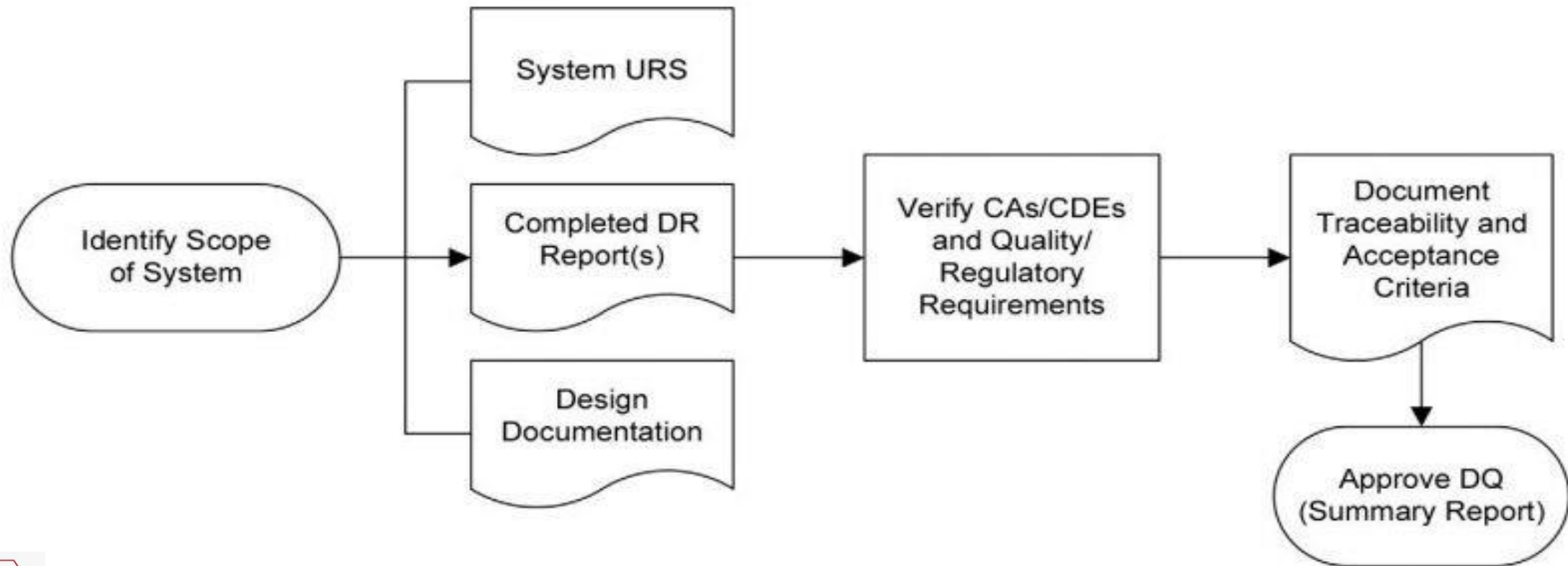
04.

Software DQ

Verifies design logic and specifications



Design Qualification Process



CONCLUSION

- Design Qualification is a vital step in ensuring the suitability and compliance of designs in the industry.
- By following a systematic approach to Design Review and Design Qualification, organization can identify and address potential issues early on, mitigating risks and ensuring quality and safety.

CONCLUSION

- The active involvement of stakeholders are crucial for a successful Design Qualification process.
- By adhering to Good **X** Practices and incorporating a science and risk-based approaches, organization can enhance the effectiveness and efficiency of validation efforts.

Thank
you

