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Hazard Operability Analysis (HAZOP): A Quality Risk Management tool

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Abstract: Hazard and Operability Analysis (HAZOP) is a structured and organized technique for risk management. Advances in technology and trends to highly complex and integrated plant designs have informed people for methodical and supportable methods to recognize hazards of which the HAZOP study is generally recognized as the leading solution being able to cover standard and also compound technology. The hazard and operability study (HAZOP) is a creative technique for identifying hazards and operating problems in a process plant.

Keywords:HAZOP, Quality Risk Management, Hazard.

Introduction:

Risk management principles are effectually operated in several areas of industry and government including finance, insurance, work-related to safety, public health, pharmacovigilance, and by organizations regulating these industries. Even though there are some examples of the use of quality risk management (QRM) in the pharmaceutical industry. They are limited and do not embody the full contributions that risk management has to offer. In addition, the importance of quality systems has been recognized in the pharmaceutical industry, and it is becoming marked that quality risk management is a valuable component of an effective quality system.

These aspects include development, manufacturing, distribution, inspection, and submission/review processes throughout the lifecycle of drug substances, drug products, biological and biotechnological products (as well as the use of raw materials, solvents, excipients, packaging and labelling materials in drug products, biological and biotechnological products)¹.

Principles of QRM:

Two primary principles of quality risk management are:

- The evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient; and
- The level of effort, formality, and documentation of the quality risk management process should be commensurate with the level of risk.

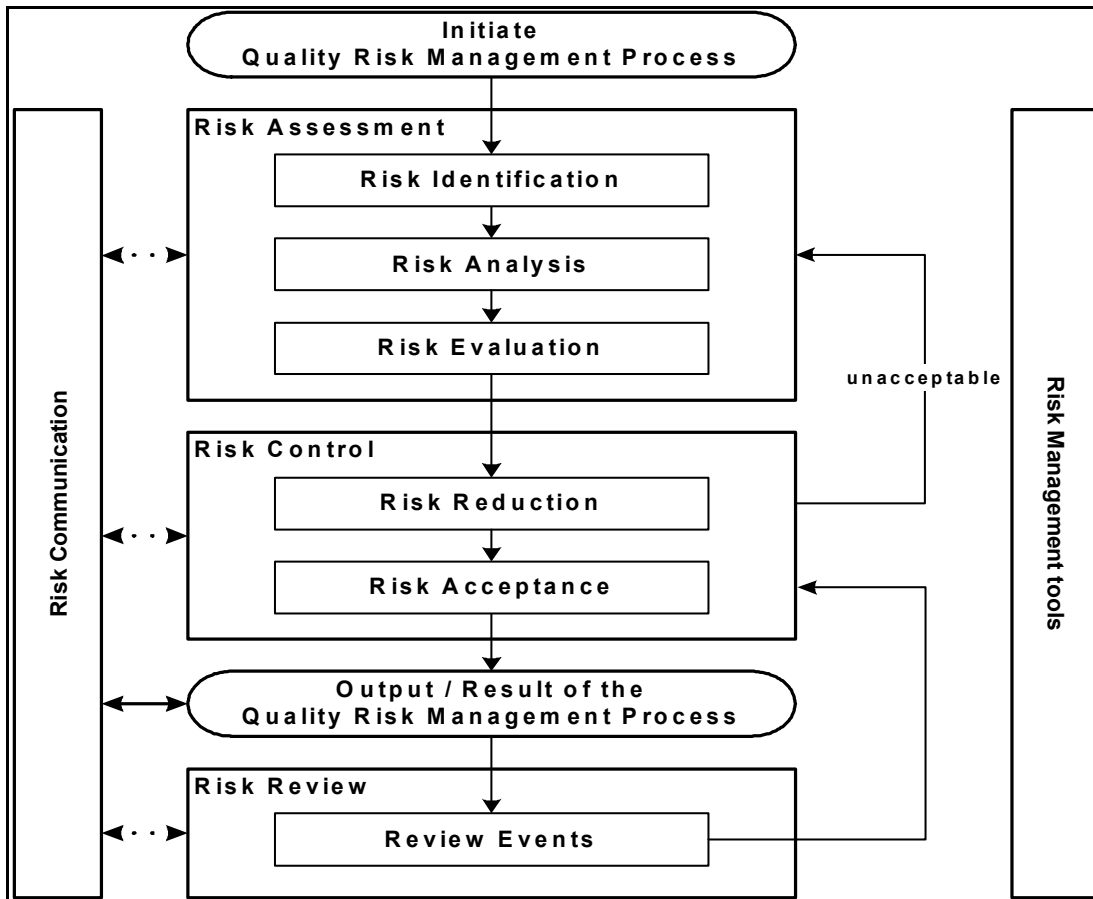


Figure 1: Overview of a typical quality risk management process¹Taken from: ICH Q9: Quality Risk Management. This figure is also available on the ICH website www.ich.org.

Risk management tools

A variety of tools can be used for the purposes of QRM, either alone or in combination. It is important to note that no single tool or combination of tools is applicable to every situation in which a QRM procedure is used. Examples of tools are listed in regulatory guidance^{2, 3} neither list is exhaustive. The important criterion for acceptability is that the tool or tools are used effectively to support the key attributes of a good risk assessment.

The Product Quality Research Institute (PQRI) Manufacturing Technology Committee (MTC) has produced a summary⁴ of common RM principles and best practices, several working tools to foster consistency in the use of ICH Q9⁵ in day-to-day RM decision-making, and a series of examples of RM applications currently in use by major pharmaceutical firms. They have also produced very helpful risk tool training modules for risk ranking and filtering, failure modes effects analysis (FMEA) ^(5, 6, 7), hazard operability analysis (HAZOP)⁸ and HACCP⁽⁹⁾.

Hazard operability analysis (HAZOP) a QRM tool

Definition of Hazard & Operability

Hazard

Any operation that could possibly cause a release of toxic, flammable or explosive chemicals or any action that could result in injury to personnel.

Operability

Any operation inside the design envelope that would cause a shutdown that could possibly lead to a violation of environmental, health or safety regulations or negatively impact profitability.

Origin of HAZOP study

- HAZOP were initially 'invented' by ICI in the United Kingdom and first appeared in the literature in the early 1970s.
- HAZOP started to be more widely used within the chemical process industry after the Flixborough disaster in 1974 that killed 28 people and injured scores of others
- The system was then adopted by the petroleum industry, which has a similar potential for major disasters.
- This was then followed by the food and water industries, where the hazard potential is as great, but of a different nature, the concerns being more to do with contamination rather than explosions or chemical releases.
- International Standard IEC61882 (HAZOP Studies Application Guide 2001)

HAZOP is an abbreviation for **HAZ**ard and **OP**erability analysis. The term 'HAZOP' originated in ICI and Skelton, B, (1997) defined it as a formal, systematic, critical, rigorous examination to the process and manufacturing intentions of new and existing facilities to assess the hazard potential of mal-operation or mal-function of individual items of equipment and the consequential effects. Wells, G, (1996), HAZOP is formal, systematic examination of a processing plant in order to identify hazards, failures and operability problems, and assess the consequences from such mal-operation.

HAZOP will generate a list of identified problems, usually with some suggestions for improvement of the system. It will improve safety, reliability and quality by making people more aware of potential problems. It also will help to sort out gaps and discrepancies in procedures and force plant personnel to get their instructions up to date.

Basic philosophy of HAZOP:

If a process operates within its intended design philosophy then undesired hazardous events should not occur. The objective of a HAZOP is mainly to identify how process deviations can be prevented or mitigated to minimize process hazards. Basic Ideas of HAZOP are to stimulate the imagination of a review team, including designers and operators, in a systematic way so that they can identify potential hazards in a design and to let the mind go free in a controlled fashion in order to consider all the possible ways that Process and operational failures can occur. Outcomes of HAZOP to recommend necessary changes to a system to meet company risk guidelines, and to recommend procedures or changes for eliminating or reducing the probability of operating deviations.

HAZOP used as an application at the correct stage in a project means that problems are identified and can be rectified during detailed design. It will provide a considerable amount of useful material for inclusion in the plant operating instructions. HAZOP components are Team, Procedure and Guide words.

Principles of HAZOP

A study is a detailed hazard and operability problem identification process, carried out by a team. HAZOP deals with the identification of potential deviations from the design intent, examination of their possible causes and assessment of their consequences.

Key features of HAZOP examination include the following.

- The examination is a creative process. The examination proceeds by systematically using a series of guide words to identify potential deviations from the design intent.
- The examination is carried out under the guidance of a leader who ensures comprehensive coverage of the system under study.
- The examination relies on experienced specialists from various disciplines.
- The examination should be carried out in a climate of positive thinking and frank discussion.
- Solutions to identified problems are not a primary objective but are recorded for consideration by those responsible for the design.

When a HAZOP should be held

- During various stages of plant design
 - At the beginning of the project as a 'safety and environmental specification'.
 - Towards the end of process definition, when the Process Flow sheets are available as a Safety and Environmental Review.
 - When P&IDs are at 'Approved for Design' stage (Final design HAZOP).
- During construction site inspections ensure that recommendations arising from the HAZOP or other safety and environmental reviews are being implemented.
- A pre-commissioning study reviews plant procedures and perform a conventional safety audit.
- Once operational, an audit of plant and procedures at regular interval ensures ongoing safety awareness.

HAZOP study of existing plant

- Can be done at any time.
- Mainly used to improve operating procedures or when modifying plant.
- Sometimes used to identify possible improvements in plants where accident or incident rate is abnormally high.
- Can be used in conjunction with plant safety audits.
- Needs exceptional care to fully define the scope and aims of the study.
- Despite detailed operation knowledge, much of the original design intent is often unknown.

Strength of HAZOP

- HAZOP is a systematic, reasonably comprehensive and flexible.
- It is suitable mainly for team use whereby it is possible to incorporate the general experience available.
- It gives good identification of cause and excellent identification of critical deviations.
- The use of guide words is effective and the whole group is able to participate.
- HAZOP is an excellent well-proven method for studying large plant in a specific manner.
- HAZOP identifies virtually all significant deviations on the plant all major accidents should be identified but not necessarily their causes.

Weakness of HAZOP

- HAZOP is very time consuming and can be laborious with a tendency for boredom for analysts.
- It tends to generate many failure events with insignificant consequences and generate many failure events which have the same consequences.
- It takes little account of the probabilities of events or consequences, although quantitative assessments are sometime added. The group generally let their collective experiences decide whether deviations are meaningful.
- HAZOP is poor where multiple-combination events can have severe effects.
- When identifying consequences, it tends to ignore contributions that can be made by operator interventions.

HAZOP Usage¹⁰

HAZOP is best suited for evaluating hazards in facilities, equipment, and processes and is capable of evaluating systems from various viewpoints.

Design

- Evaluating system design capability to meet user specifications and safety principles.
- Identifying faults in systems.

Physical and operational environments

- Evaluating environment to certify system is appropriately situated, supported, serviced, controlled, etc.

Operational and procedural controls

- Evaluating engineered controls (ex: computerization), sequences of operations, procedural controls (ex: human interactions) etc.
- Evaluating different operational modes – start-up, standby, normal operation, steady & unsteady states, normal shutdown, emergency shutdown, etc.

Advantages¹⁰

- Helpful when confronting hazards that are difficult to quantify,
 - Hazards rooted in human performance and behaviors.
 - Hazards that are hard to spot, examine, isolate, tally, predict, etc.
 - Methodology doesn't force you to explicitly rate or measure deviation probability of occurrence, severity of impact, or ability to detect.
- Built-in brainstorming methodology.
- Systematic & comprehensive methodology.
- More simple and intuitive than other commonly used risk management tools.

Disadvantages¹⁰

- No means to assess hazards involving interactions between different parts of a system or process.
- No risk ranking or prioritization capability
 - Teams may optionally build-in such capability as required.
- No means to assess effectiveness of existing or proposed controls (safeguards)
 - May need to interface HAZOP with other risk management tools (ex: HACCP) for this purpose.

HAZOP Methodology¹⁰

The HAZOP analysis process is executed in four phases as illustrated below:

Definition

- Define scope and objectives
- Define responsibilities
- Select Team

Preparation

- Plan the study
- Collect data
- Agree style of recording
- Estimate the time
- Arrange a schedule

Examination

- Divide the system into parts
- Select a part and define design intent
- Identify deviation by using guide words on each element
- Identify consequences and causes
- Identify whether a significant problem exists
- Identify protection, detection, and indicating mechanisms
- Identify possible remedial/mitigating measures (optional)
- Agree actions
- Repeat for each element and then each part.

Documentation and follow-up

- Record the examination

- Sign off the documentation
- Produce the report of the study
- Follow up that actions are implemented
- Re-study any parts of system if necessary
- Produce final output report

Definition Phase

The Definition Phase typically begins with preliminary identification of risk assessment team members. HAZOP is intended to be a cross-functional team effort, and relies on specialists (SMEs) from various disciplines with appropriate skills and experience who display intuition and good judgment. SMEs should be carefully chosen to include those with a broad and current knowledge of system deviations. HAZOP should always be carried out in a climate of positive thinking and frank discussion.

During the Definition Phase, the risk assessment team must identify the assessment scope carefully in order to focus effort. This includes defining study boundaries and key interfaces as well as key assumptions that the assessment will be performed under.

Preparation Phase

The Preparation Phase typically includes the following activities:

- Identifying and locating supporting data and information.
- Identification of the audience and users of the study outputs.
- Project management preparations (ex: scheduling meetings, transcribing proceedings, etc.).
- Consensus on template format for recording study outputs.
- Consensus on HAZOP guide words to be used during the study

HAZOP guide words are key supporting elements in the execution of a HAZOP analysis. According to IEC Standard 61882:

The identification of deviations from the design intent is achieved by a questioning process using predetermined "guide words". The role of the guide word is to stimulate imaginative thinking, to focus the study and elicit ideas and discussion.

Examination Phase

The Examination Phase begins with identification of all elements (parts or steps) of the system or process to be examined. For example:

- Physical systems may be broken down into smaller parts as necessary
- Processes may be broken down into discrete steps or phases
- Similar parts or steps may be grouped together to facilitate assessment

The HAZOP guide words are then applied to each of the elements. In this fashion a thorough search for deviations is carried out in a systematic manner. It must be noted that not all combinations of guide words and elements are expected to yield sensible or credible deviation possibilities. As a general rule, all reasonable use and misuse conditions which are expected by the user should be identified and subsequently challenged to determine if they are "credible" and whether they should be assessed any further. There is no need to explicitly document the instances when combinations of elements and guide words do not yield any credible deviations.

Documentation & Follow-up Phase

The documentation of HAZOP analyses is often facilitated by utilizing a template recording form as detailed in IEC Standard 61882. Risk assessment teams may modify the template as necessary based on factors such as:

- Regulatory requirements

- Need for more explicit risk rating or prioritization (ex: rating deviation probabilities, severities, and/or detection)
- Company documentation policies
- Needs for traceability or audit readiness
- Other factors

Relevant Guide Words¹⁰

A set of guide words is chosen as relevant to the operation to be studied and then systematically applied to all parts of that operation. This may entail application of the guide words to each process line within a P&ID, or by following each stage of an operation from start to finish. Appendix 1 shows examples of guide words and variations on them.

The choice of suitable guide words will strongly influence the success of the HAZOP in detecting design faults and operability problems.

Examples of Lists of Guide Words for use in HAZOPs¹⁰

Guidewords	Guide Word Meaning
NO OR NOT	Complete negation of the design intent
MORE	Quantitative increase
LESS	Quantitative decrease
AS WELL AS	Qualitative modification/increase
PART OF	Qualitative modification/decrease
REVERSE	Logical opposite of the design intent
OTHER THAN	Complete substitution
EARLY	Relative to the clock time
LATE	Relative to the clock time
BEFORE	Relating to order or sequence
AFTER	Relating to order or sequence

HAZOP WORKSHEET							
AREA:							
UNIT:							
DRAWINGS:							
DESIGN INTENT:							
SI No	GUIDE WORD	DEVIATION	CAUSES	CONSEQUENCES	SAFEGAURDS	RECOMRNDATIONS	ACTION BY

Figure 2: HAZOP worksheet¹²

Standards and guidelines

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Conclusion

HAZOP is the preferable method for risk management in the pharmaceutical industry as HAZOP analysis include higher consistency, better quality, increased safety and its contribution towards cost saving includes decreased expansion time and reduced waste and non-value added procedures. The HAZOP process is based on the principle that a team approach to hazard analysis will identify more problems than when individuals working separately combine results. The HAZOP team is made up of individuals with varying backgrounds and expertise.

The expertise is brought together during HAZOP sessions and through a collective brainstorming effort that stimulates creativity and new ideas, a thorough review of the process under consideration is made.

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