RASCHKA

NEWSLETTER

November 2015

Risk Analysis

When doing Risk Analysis (RA) in chemical and pharmaceutical industries, the main purpose is to make processes and production facilities safe, minimize risk in all aspects protecting people and environment. The goal of risk assessment is to reduce risks to an acceptable or tolerable level.

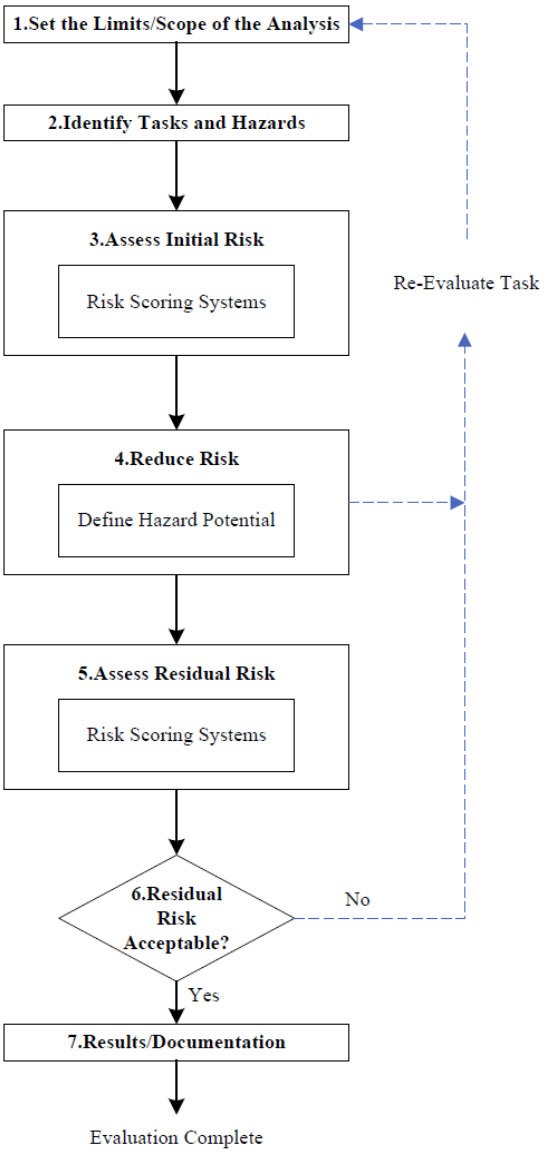
Risk analysis can serve a variety of purposes. It can, for instance, help decision makers and other interested parties to:

- Determine environmental and health concerns with a variety of substances, reaction products, off gas, waste, etc
- Compare new and existing technologies or determine the effectiveness of different control and mitigation techniques designed to reduce risk
- Select location (sites) for potential hazardous facilities
- Set management priorities, such as which of several activities should be considered first for regulators or corrective action

There are many forces influencing safety through different design stages, such as **cost, competition, quality, productivity, legal requirements, desire to capture knowledge and the safety awareness of the engineers**. In general there is considerable support that safety needs to be addressed during the design process rather than as a retrofit activity, and risk assessment pushes safety into the design process. Usually, an engineer's ability to integrate safety into the design process is limited by the training and education he or she has received. Within Raschka Engineering, the team has gained a vast amount of experience from a large number of projects which were successfully analyzed with regards to risks with the participation of various disciplines (process, instrumentation, equipment etc.) together with the plant operations team enabling familiarization with methodology and interaction within a cross functional setup.

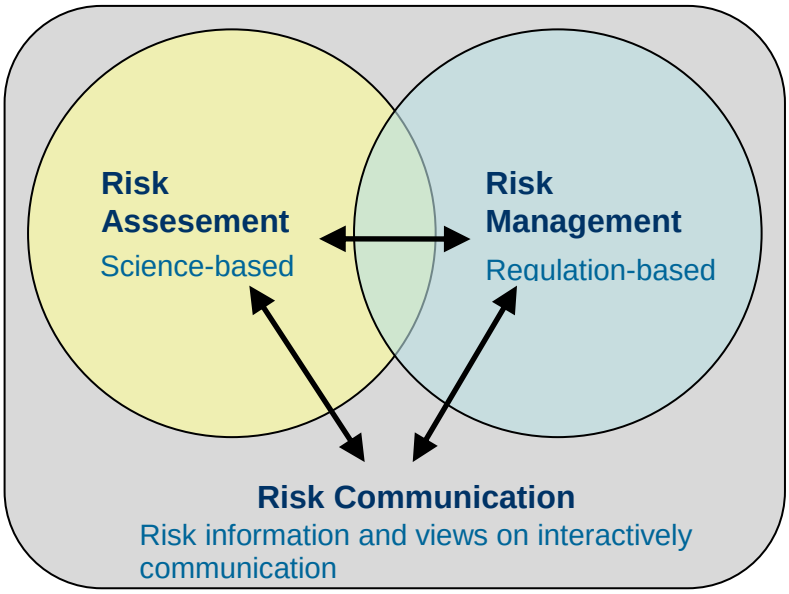
Different methods are available for risk analysis; some are more suitable than others for certain industries or processes. However, most important people performing risk analysis must be **familiar and well trained** using the chosen method. In addition it is important that a **positive and open atmosphere** is created where everybody from different disciplines is comfortable and the contribution is being made in a friendly environment.

A general risk assessment process describes the seven basic steps in completing a risk assessment. One step in particular, identifying hazards, is critical because if hazards are omitted the associated risks will remain unknown.



Fundamental of Risk Analysis

Risk Analysis is a science-based, structured approach in accordance with an open and transparent process. All risk analysis can be referred to the following elements:



Common Methods of Risk Analysis

Hazard and operability study (HAZOP) is a structured and systematic examination of a planned or existing process or operation in order to identify and evaluate problems that may represent risks to personnel or equipment, or prevent efficient operation. The HAZOP methodology, which is a qualitative technique, asks for systems or processes to be sub divided into discrete steps. With analyzing parameters like flow, temperature, pressure, level, concentration, volume, etc. which is further analyzed using deviation guiding words such as high, low, reverse, etc., followed by possible reasons for the anticipated deviations. The quality of this analysis is only as good as the team and it is of high importance to assemble a multi-disciplinary group which is familiar with the process and methodology of a HAZOP study.

Failure modes and effects analysis (FMEA) is a procedure in product development and operations management for analysis of potential failure modes within a system for classification by the severity and likelihood of failures. A successful FMEA activity helps a team to identify potential failure modes based on past experience with similar products or processes, enabling the team to design those failures out of the system with the minimum of effort and resource expenditure, thereby reducing development time and costs. It is widely used in manufacturing industries in various phases of the product life cycle and is now increasingly finding use in the service industry. Failure modes are any errors or defects in a process, design, or item, especially those that affect the customer, and can be potential or actual. Effects analysis refers to studying the consequences of those failures.

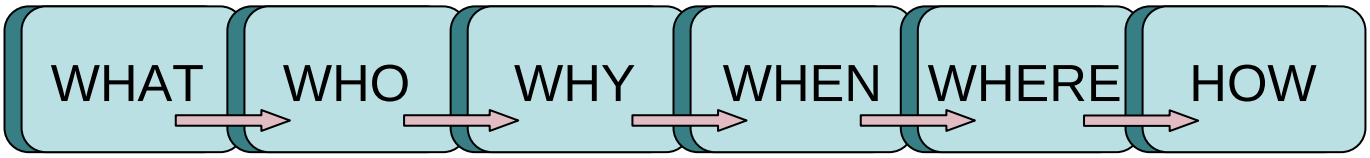
Checklist Analysis is a systematic evaluation against pre-established criteria in the form of one or more checklists. A systematic approach built on the historical knowledge included in checklist questions, used for high-level or detailed analysis, including root cause analysis and applicable to any activity or system including equipment issues and human factor issues. Generally performed by an individual trained to understand the checklist questions, sometimes performed by a small group not necessarily risk analysis experts. Analysis is mainly based on interviews, documentation reviews and field inspections generating qualitative lists of conformance and nonconformance with recommendations for corrective actions.

What –If Analysis is a structured brainstorming method of determining what things can go wrong and judging the likelihood and consequences of those situations occurring. The answers to these questions form the basis for making judgments regarding the acceptability of those risks and determining a recommended course of action for those risks judged to be unacceptable. An experienced review team can effectively and productively discern major issues concerning a process or system. Lead by an energetic and focused facilitator, each member of the review team participates in assessing what can go wrong based on their past experiences and knowledge of similar situations.

Fault Tree Analysis (FTA) attempts to model and analyze failure processes of systems. FTA is basically composed of logic diagrams that display the state of the system and is constructed using graphical design techniques. FTA can be used as a valuable design tool, can identify potential accidents, and can eliminate costly design changes. It can also be used as a diagnostic tool, predicting the most likely system failure in a system breakdown. FTA is used in safety engineering and in all major fields of engineering.

The Core Content of Risk Analysis (5W1H)

We generally call RA's core content as 5W1H, which is what, who, why, when, where and how.



WHAT: objects of risk analysis
Scientific risk analysis is the basis of establishing project design plans. We must be clear about to which industry the object belongs to, which phase (like design, construction, commissioning, operation and maintenance) the object is. Analysis content should cover the aspects including process, safety and GMP analysis etc. For effective risk communication, a systematic method should be established, including background documents collection, necessary information gathering and risk notification preparation etc.
WHO: personnel involved in risk analysis
In general it includes end user, engineer, validation, process design, production, SHE and maintenance etc.
WHY: the reason for doing risk analysis
Risk analysis is a preventive measure rather than a corrective measure. Reduce the risk by identifying the design defect and operation hazards via RA and controlling risk to an acceptable level. It shall bring quality, safety and reliability to project design, construction and operation at the same time.
WHEN: when is the right time to perform a risk analysis
Risk analysis is usually carried out at the beginning of the detail design (process to be analyzed must be defined and process information must be available) and is usually repeated after "as built" information are available prior to the start up of a system or plant.
WHERE: location of risk analysis
Find a good place of doing risk analysis to make sure all personnel involved can be present in one room (teleconference is not considered to be a good option for a thorough and effective team effort)
HOW: execution of risk analysis
The use of software to support RA shall be considered because of the fact that it can greatly improve efficiency and accuracy. Necessary data and information is collected and stored in the software system such as system structure and functional specification, operation and maintenance information, working environment condition, lowest working requirement and production quality data. Factors such as potential deviations, probability of occurrence, causes and the capability to control process parameters need to be discussed and recorded in a fully traceable system.

Risk Mapping

The process of "risk mapping" will help to visualize risk exposure and is usually a starting point for assessment and prioritizing of organizational or technical actions.

Truly understanding the risks that are present depends on the commitment of a team of professionals from a variety of the company's functions. This team must define the scope of the analysis, identify the risks, rate them for likelihood and consequences, establish a risk-tolerance boundary and then plot the risks to determine their priority.

	Economic environmental/social consequences				
Likelihood	Negligible	Low	Medium	High	Extremely high
Extremely high	H	H	E	E	E
High	M	H	H	E	E
Medium	L	M	H	E	E
Low	L	L	M	H	E
Negligible	L	L	M	H	H

	Code	Explanation
Rating risk level	(E)	Extreme risk-detailed action plan required
	(H)	High risk-needs senior management attention
	(M)	Moderate risk - specify management responsibility
	(L)	Low risk - managed by routine procedures

Common methods available in Raschka Engineering – HAZOP

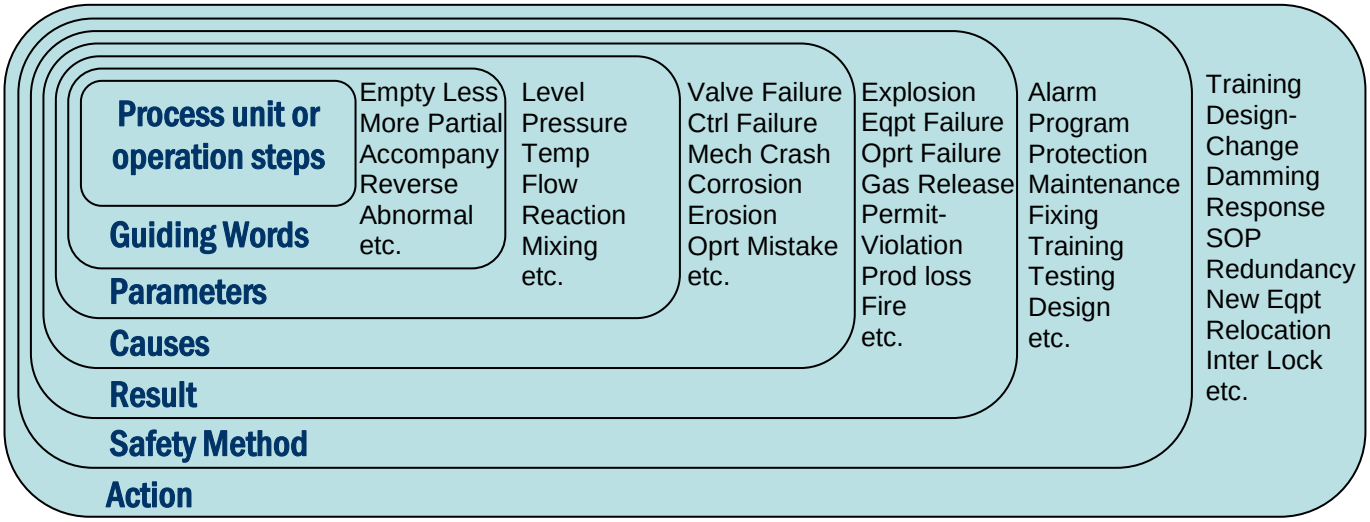
Raschka Engineering often use HAZOP method to perform Risk Analysis, in combination with the software RAMS (Risk Analysis Management System)

HAZOP Analysis

The essential of Raschka Engineering's HAZOP analysis is a systematic framework of process analysis, the main steps are:

- Divide system and facilities into different analysis units –Technical Nodes Definition
- Define normal working specification of each unit, like parameters in the right range –Key parameters definition
- Define abnormal working specification –deviation definition
- Analyze deviation with brainstorm –Discussion and Analysis

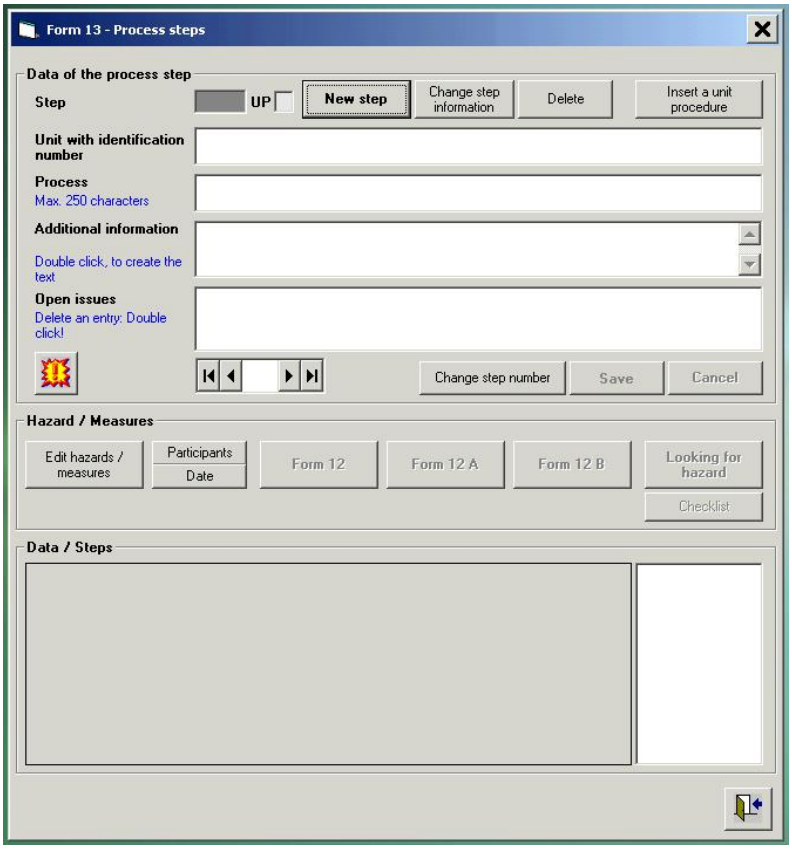
HAZOP is a systematic and structured procedure, quite effective on process and operation, including how is the operability, how is the risk, what accident may happen, is current safety level sufficient, do we need to increase safety level etc. The following chart shows the core content of HAZOP analysis:

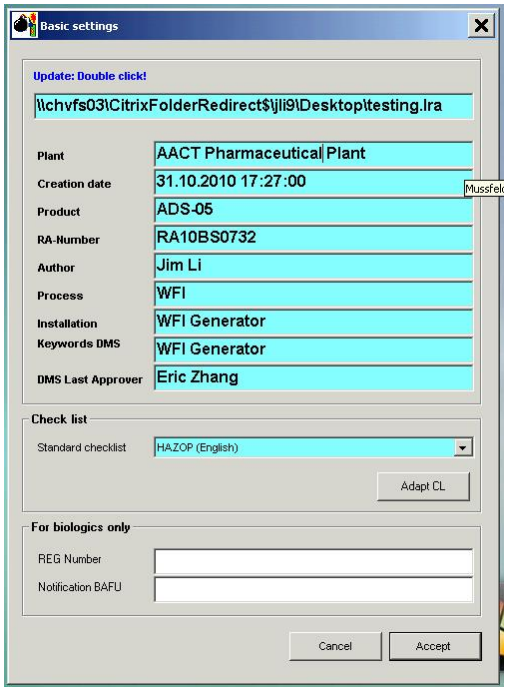


RAMS

RAMS (Risk Analysis Management System), is a professional software tool which can significantly simplify HAZOP analysis. A series of standard forms and documents have also been developed to make the application easier and to improve efficiency. For some RA object which needs special technical requirements like bio-pharmaceutical engineering, small pilot plant or utilities, standard documents and forms can also be found in RAMS.

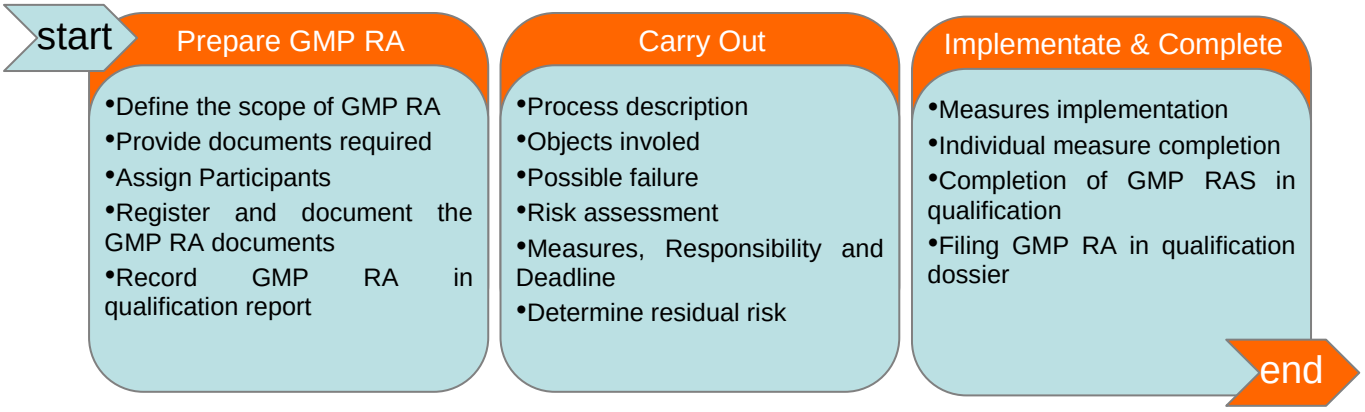
RAMS requires the user to fill in relevant information in the standard forms only (like attached Form 13, process steps) and the standard RA reports will be generated automatically.





Common methods available in Raschka Engineering - FEMA

FEMA is often used for GMP-related risk analysis, the specific process is shown as below:



Preparation of GMP RA

GMP RA team leader (or relevant qualified personnel) to organize RA preparation before setting up RA team. Depending on the size of the plant or the complexity of installed equipment to carry out the GMP RA at unit/system level, sub-plant level and plant level, also to list all the functional location. Then to prepare RA documents include validation plan (VP), user requirement specification (URS), functional specification (FS) and P&ID etc. Establish the RA team from different disciplines and document all the related files and records.

Carrying Out GMP RA

After completion of preparation, GMP RA team can be summoned to RA meeting by the leader. Record the process description in detail, divide process steps, list all the parameters, fill in FEMA Matrix with risk number, functional steps and relevant equipments, find out the possible failure and its cause, analyze the probability of occurrence (O), severity of impact on product (S) and probability of detection (D), each has 1 to 5 points. If risk priority number (RPN=O*S*D) is larger than 24, then it belongs to critical risk and need imperative measures and record down the content, category, responsible people and deadlines. After that the residual risk assessment would be carried on to finish GMP RA measures implementation form and document it.

Implementation and Completion of GMP RA

Measures established in the RA meeting to reduce GMP risk should be carried out by the relevant responsible personnel and completed within deadlines. Each measure should be recorded with the completion status and signature, and then filed. On completion of unit or system qualification report, check if all of the GMP RA measures have been completed in the meantime. The GMP RA completion report will finally be transferred into the 'Plant Qualification Report'.

In this context, Raschka Engineering's service could include:

- Moderate Risk Analysis
- Risk analysis consultancy
- Professional Risk Analysis Training
- Process Design Review
- Continuous improvement
- Process Optimization based on Risk Analysis

Please feel free to contact us in order to discuss your needs with our expert team, we would be very happy to share our experience in risk management.

An extensive service list is available on our website:
http://www.raschka-engineering.com

Raschka Engineering Ltd

Raschka Engineering Ltd. Liestal, Switzerland (previously known as Lonza Engineering) now reflects the superior and well known Raschka FBI technology in its name together with its wholly owned subsidiary Raschka Engineering & Consulting Co., Ltd, China provides customer oriented services with a professional, experienced and highly motivated engineering team. We have 20 years of successful project management experience in China which makes us a perfect partner for the chemical, pharmaceutical and biopharmaceutical industry. A board range of services with a project reference list underlining our capabilities is available upon request.

Raschka Engineering has successful managed multiple complex projects such as continuous operating plants for the production of food and feed additives as well as active pharmaceutical ingredient plants including waste gas and liquid waste treatment facilities.

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