RISK MANAGEMENT

مدیریت ریسک و مدیریت بحران

- The holder of a manufacturing authorisation must manufacture medicinal products so as to ensure that they are fit for their intended use,
- comply with the requirements of the **Marketing Authorisation (MA)**
- and do not place patients at risk due to inadequate **safety, quality or efficacy.**
- **دارنده مجوز تولید باید محصولات دارویی خود را به صورتی تولید کند که برای هدف تعیین شده مناسب بوده وبا الزامات مجوزهای بازاریابی مطابقت داشته باشد به نحوی که بیمار را بخاطر ایمنی، کیفیت و یا اثربخشی در معرض رسیک قرار ندهد.**
- The attainment of this quality objective is **the responsibility of senior management** and requires the participation and commitment by staff in many different departments and at all levels within the company, by the company's suppliers and by the distributors.
- Senior management has the ultimate responsibility to ensure an effective PQS is in place.
- رسیدن به این هدف کیفی از مسیولیتهای مدیر ارشد بوده و نیازمند شرکت و تعهد کارکنان در یخشهای مختلف در تمام سطوح در کارخانه توسط تامین کننده ها وتوزیع کننده ها می باشد.

  مسولیت نهایی برای اطمینان از برقرار بودن یک سیستم کیفیت دارویی موثر به عهده مدیر ازشد می باشد.

- To achieve the quality objective reliably there must be a **comprehensively designed** and **correctly implemented**:
- **system of Quality Assurance (QA)** incorporating
- **Good Manufacturing Practice (GMP),** and
- **Quality Control (QC)** and
- **Quality Risk Management (QRM).**
- It should be fully documented and its effectiveness monitored.

- برای رسیدن به یک هدف کیفی قابل اعتماد، باید موارد مذکور بطور جامع طراحی شده و به طور صحیح اجرا شود:

- Risk management principles are effectively utilized in many areas of business and government including finance, insurance, occupational safety, public health, pharmacovigilance, and by agencies regulating these industries.
- The importance of quality systems has been recognized in the pharmaceutical industry and it is becoming evident that quality risk management **is a valuable component of an effective quality system.**

- **اصول RM بطور موثری در بسیاری از زمینه های بیزینس و دولتی شامل: امور مالی، بیمه، ایمنی شغلی، بهداشت عمومی، نظارت دارویی وهمچنین توسط سازمان های رگولاتوری این صنایع بکار برده می شود.**
- **اهمیت سیستمهای کیفیت در صنایع دارویی کاملا شناخته شده است و این شاهد و مدرکی است که نشان می دهد QRM یکی از اجزا ارزشمند یک سیستم کیفیت موثر است.**

- It is commonly understood that risk is defined as :
- the combination of the probability of occurrence of harm and the severity of that harm. صدمه،آسیب
- **ترکیبی از احتمال وقوع یک آسیب و شدت آن می باشد**
- However, achieving a shared understanding of the application of risk management among diverse stakeholders is difficult because:
- each stakeholder might perceive different potential harms, place a different probability on each harm occurring and attribute different severities to each harm.
- رسیدن به یک درک مشترک در بکارگیری مدیریت ریسک در بین ذی نفعان مختلف سخت است چون:
- - هر یک از ذینفعان ممکن است آسیب های بالقوه متفاوتی را درک کنند، یا احتمالات مختلفی را برای وقوع هر آسیب بدهند، همچنین شدتهای مختلفی را به آنها اختصاص دهد.

- In relation to pharmaceuticals, although there are a variety of stakeholders, including patients and medical practitioners as well as government and industry, the protection of the patient by managing the risk to quality should be considered of prime importance.
- -تمام ذی نفعان اعم از بیماران، پزشکان در کنار دولت و صنعت باید هدفشان از مدیریت ریسک محافظت از بیمار در وهله اول باشد.

- The manufacturing and use of a drug (medicinal) product, including its components, necessarily entail some degree of risk.

- An effective quality risk management approach can further ensure the high quality of the drug (medicinal) product to the patient by providing a proactive means **to identify and control potential quality issues** during development and manufacturing.
- یک رویکرد مدیریت ریسک کیفیت موثر می‌تواند با ارائه ابزاری فعال برای شناسایی و کنترل مسائل بالقوه کیفیت در طول توسعه و ساخت، کیفیت بالای محصول دارویی (دارویی) را برای بیمار تضمین کند.

- Additionally, use of quality risk management can:
- **improve the decision making** if a quality problem arises.
- Effective quality risk management can:
- تسهیل در تصمیم گیری های بهتر و آگاهانه تربوجود آورد
- می تواند به قانون گذاران، اطمینان بیشتری از توانایی شرکت برای مقابله با خطرات احتمالی بدهد و
- می تواند بر میزان و سطح نظارت مستقیم، تأثیر مفیدی داشته باشد.

- The purpose is to offer a systematic approach to quality risk management as a foundation or resource document.
- هدف در اینجا ارائه یک رویکرد سیستماتیک به مدیریت ریسک کیفیت به عنوان یک پایه یا سند منبع است.
- استفاده مناسب از مدیریت ریسک کیفیت می‌تواند الزام صنعت را برای پیروی از الزامات نظارتی تسهیل کند، اما آن‌ها را از بین نمی‌برد.
- جایگزین ارتباطات مناسب بین صنعت و تنظیم کننده ها هم نمی شود.
- This guideline **provides principles and examples of tools for quality risk management** that can be **applied to different aspects of pharmaceutical quality.**
- در اینجا اصول و نمونه هایی از ابزارها را برای مدیریت ریسک کیفیت ارائه داده می شود که می تواند در جنبه های مختلف کیفیت دارویی اعمال شود.
- These aspects include development, manufacturing, distribution, and the inspection and submission/review processes throughout the lifecycle of drug substances, drug (medicinal) products, biological and biotechnological products (including the use of raw materials, solvents, excipients, packaging and labeling materials in drug (medicinal) products, biological and biotechnological products).

PRINCIPLES OF QUALITY RISK MANAGEMENT :

Two primary principles of quality risk management are:

a) The evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient; and

b) The level of effort, formality and documentation of the quality risk management process should be commensurate with the level of risk.

- ارزیابی ریسک کیفیت باید بر اساس دانش علمی باشد و در نهایت با محافظت از بیمار مرتبط باشد. و
- سطح تلاش، رسمیت و مستندسازی فرآیند مدیریت ریسک کیفیت باید متناسب با سطح ریسک باشد.

GENERAL QUALITY RISK MANAGEMENT PROCESS:

Quality risk management is **a systematic process for the assessment, control, communication and review of risks** to the quality of the drug (medicinal) product across the product lifecycle.

مدیریت ریسک کیفیت فرآیندی سیستماتیک برای ارزیابی، کنترل، ارتباط و بررسی خطرات مربوط به کیفیت محصول دارویی (دارویی) در طول چرخه عمر محصول است.

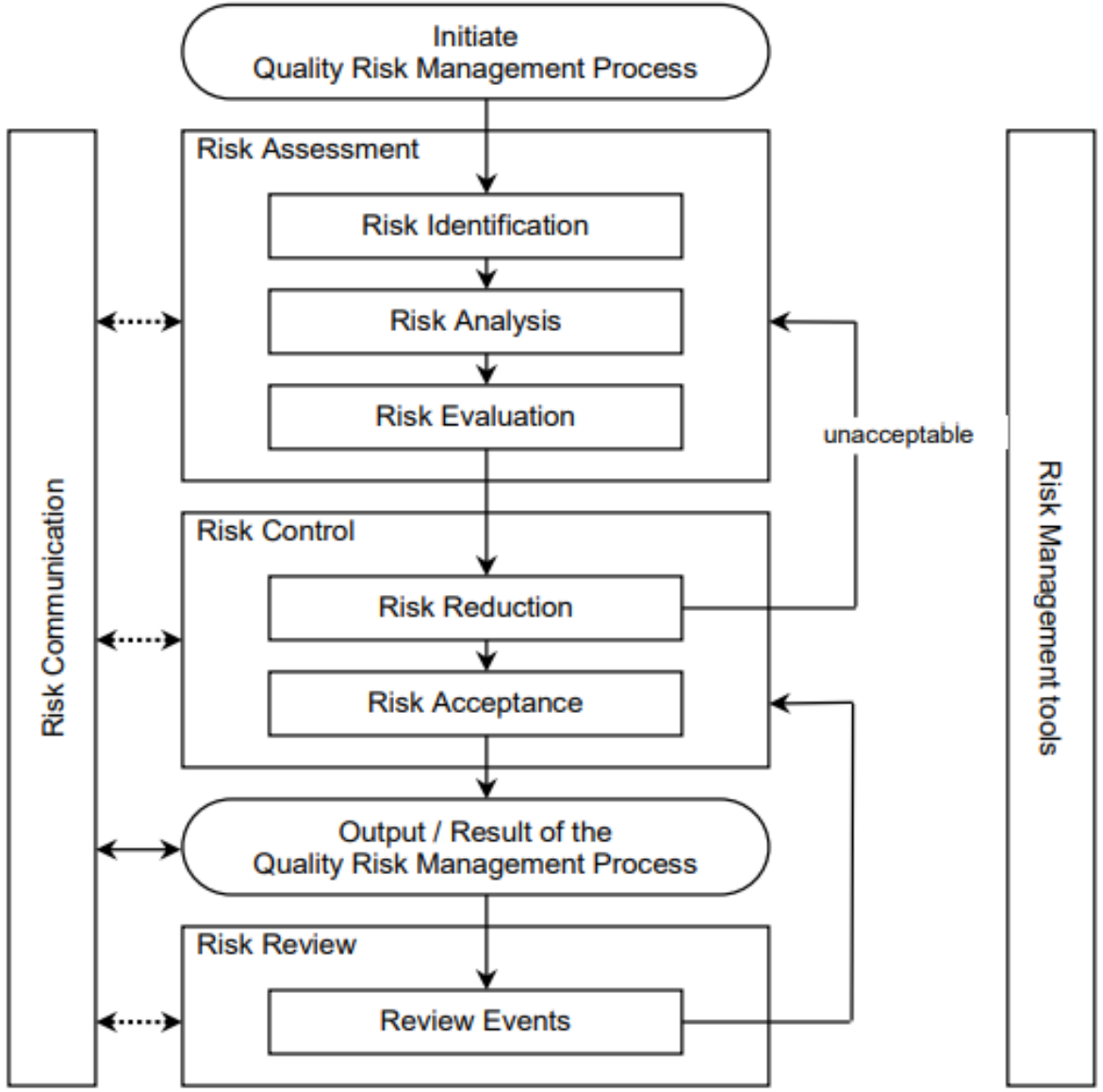
A model for quality risk management is outlined in the diagram (Figure 1). Other models could be used.

The emphasis on each component of the framework might differ from case to case but a robust process will incorporate consideration of all the elements at a level of detail that is commensurate with the specific risk.

تاکید بر هر یک از اجزای چارچوب ممکن است از موردی به مورد دیگر متفاوت باشد،(احتمال وقوع، تشخیص، شدت)

اما یک فرآیند قوی و مستحکم شامل در نظر گرفتن جزئیات تمام عناصر متناسب با آن ریسک خاص می باشد.

Figure 1: Overview of a typical quality risk management process



- Decision nodes are not shown in the diagram above because decisions can occur at any point in the process.
- These decisions might be to return to the previous step and seek further information, to adjust the risk models or even to terminate the risk management process based upon information that supports such a decision.
- این تصمیمات ممکن است بازگشت به مرحله قبل و جستجوی اطلاعات بیشتر، تنظیم مدل های ریسک یا حتی پایان دادن به فرآیند مدیریت ریسک بر اساس اطلاعاتی باشد که از چنین تصمیمی پشتیبانی می کند.
- Note: “unacceptable” in the flowchart does not only refer to statutory, legislative or regulatory requirements, but also to the need to revisit the risk assessment process.
- «غیرقابل قبول» در نمودارهم به الزامات قانونی یا نظارتی اشاره دارد و هم به بازبینی فرآیند ارزیابی ریسک

Responsibilities:

Quality risk management activities are usually, but not always, undertaken by **interdisciplinary teams**.تیم های بین رشته ای

When teams are formed, they should include experts from the appropriate areas (e.g. quality unit, business development, engineering, regulatory affairs, production operations, sales and marketing, legal, statistics and clinical) in addition to individuals who are knowledgeable about the quality risk management process

- **Decision makers should:**

a) take responsibility for coordinating quality risk management across various functions and departments of their organization; and

b) assure that a quality risk management process is defined, deployed and reviewed and that adequate resources are available.

c) مسئولیت هماهنگی مدیریت ریسک کیفیت را در میان بخش های مختلف سازمان خود بر عهده می گیرند. و

d) اطمینان حاصل شود که فرآیند مدیریت ریسک کیفیت تعریف، مستقر و بررسی شده است و منابع کافی در دسترس است.

Initiating a Quality Risk Management Process:

Quality risk management should include systematic processes designed to coordinate, facilitate and improve science-based decision making with respect to risk.

مدیریت ریسک کیفیت باید شامل فرآیندهای سیستماتیکی باشد که برای هماهنگی، تسهیل و بهبود تصمیم گیری مبتنی بر علم باتوجه خاص به ریسک طراحی شده اند.

Possible steps used to initiate and plan a quality risk management process might include the following: مراحل محتمل برای شروع و برنامه ریزی یک پروسه مدیریت ریسک کیفیت

a) Define the problem and/or risk question, including pertinent assumptions identifying the potential for risk مشکل و/یا سوال ریسک را تعریف کنید، از جمله مفروضات مربوطه که پتانسیل خطر را شناسایی می کند (شناخت و تعریف ریسک)

b) Assemble background information and/ or data on the potential hazard, harm or human health impact relevant to the risk assessment (جمع آوری اطلاعات و ریشه یابی علل)

c) Identify a leader and necessary resources (مشخص کردن مسوول و منابع لازم)

d) Specify a timeline, deliverables and appropriate level of decision making for the risk management process مشخص کردن تایم لاین و تعیین سطح مناسب و قابل اجرا برای تصمیم گیری در پروسه مدیریت ریسک)

Risk Assessment

Risk assessment consists of **the identification of hazard**s and **the analysis** and **evaluation of risks** associated with exposure to those hazards.

Quality risk assessments begin with a **well-defined problem description or risk question. .تشریح خوب مشکل یا سؤال ریسک**

هنگامی که ریسک مورد نظر به خوبی تعریف شده باشد، ابزار مدیریت ریسک مناسب و انواع اطلاعات مورد نیاز برای پرداختن به سوال ریسک به راحتی قابل شناسایی خواهد بود. .

As an aid to clearly defining the risk(s) for risk assessment purposes, three fundamental questions are often helpful:

1. What might go wrong?
2. What is the likelihood (probability) it will go wrong?
3. What are the consequences (severity)?

4. چه چیزی ممکن است اشتباه شود؟
5. میزان (احتمال) خرابی آن چقدر است؟
6. عواقب آن (شدت) چیست؟

- **Risk identification:**

is a systematic use of information to identify hazards referring to the risk question or problem description.

استفاده سیستماتیک از اطلاعات برای شناسایی خطرات مربوط به سوال خطر یا شرح مشکل است

Information can **include historical data, theoretical analysis, informed opinions**, and the **concerns of stakeholders**.

Risk identification addresses the **“What might go wrong?”** question,

including **identifying the possible consequences**.

This provides the basis for further steps in the quality risk management process.

این زمینه را برای مراحل بعدی در فرآیند مدیریت ریسک کیفیت فراهم می کند

- **Risk analysis:**
- is the estimation of the risk associated with the identified hazards.
- It is the qualitative or quantitative process of linking the likelihood of **occurrence** and **severity** of harms.
- In some risk management tools, the ability to detect the harm (**detectability)** also factors in the estimation of risk.

- تخمین ریسک مرتبط با خطرات شناسایی شده است.
- یک پروسه کیفی یا کمی هست که بین احتمال وقوع و شدت آسیب ارتباط برقرار می کند.
- در برخی از ابزارهای مدیریت ریسک، توانایی تشخیص آسیب (قابلیت کشف و تشخیص) نیز در برآورد ریسک نقش دارد.

- **Risk evaluation:**
- compares the identified and analyzed risk against given risk criteria.
- Risk evaluations consider the strength of evidence for all three of the fundamental questions.
  - ریسک شناسایی شده و تحلیل شده را با معیارهای ریسک معین مقایسه می کند.
  - ارزیابی ریسک قدرت شواهد را برای هر سه سوال اساسی در نظر می گیرد.

ارزیابی ریسک

- ممیزی داخلی
- پروژه کنترل تغییرات
- ارزیابی صلاحیت تجهیزات
- ایجاد بهبود استراتژیک

- In doing an effective risk assessment, **the robustness of the data set** is important because it **determines the quality of the output**.
- Revealing assumptions and reasonable sources of uncertainty will enhance confidence in this output and/or help identify its limitations.
- در نظر گرفتن فرضیات و منابع معقول در رابطه با عدم قطعیت داده ها و اطلاعات، اعتماد به این خروجی را افزایش می دهد و/یا به شناسایی محدودیت های آن کمک می کند.
- Uncertainty is due to combination of incomplete knowledge about a process and its expected or unexpected variability.
- دانش ناقص در مورد یک فرآیند و تغییرات مورد انتظار یا غیرمنتظره آن.
- Typical sources of uncertainty include gaps in knowledge gaps in pharmaceutical science and process understanding, sources of harm (e.g., failure modes of a process, sources of variability), and probability of detection of problems.

- The output of a risk assessment is either a quantitative estimate of risk or a qualitative description of a range of risk.
- When risk is expressed quantitatively, a numerical probability is used. Alternatively, risk can be expressed using qualitative descriptors, such as "**high", "medium", or "low**",
- which should be defined in as much detail as possible.

ماتریس ریسک ترکیبی از

-شدت خطر

-احتمال وقوع خطر

-احتمال تشخیص (قابلیت تشخیص)

Risk matrix

Severity X Probability X Detectability = Risk assessment (Score)

Severity (consequence) of failures

L-Low

یک اثر منفی کوچک انتظار می رود، انتظار نمی رود آسیب اثرات طولانی مدت داشته باشد

M-Medium

شدت منفی متوسط مورد انتظار است، می توان انتظار داشت که اثر اثرات کوتاه تا متوسط (منفی) داشته باشد

H-High

اثر منفی بسیار قابل‌توجه مورد انتظار است، می‌توان انتظار داشت که این اثر پیامدهای بلندمدت قابل‌توجهی و پیامدهای کوتاه‌مدت فاجعه‌بار بالقوه داشته باشد

Probability of Failure

حذف یا کنترل علل بالقوه شکست‌ها تنها راه کاهش سطح ریسک با تغییرات هدفمند در فرآیند اس
ت

L-Low

هر۶ ماه یکبار اتفاق می‌افتد

M-Medium

سالی یکبار اتفاق می افتد

H-High

کمتراز یک‌بار در سال اتفاق می‌افتد

- Sometimes a **"risk score"** is used to further define descriptors in risk ranking.
- In quantitative risk assessments, a risk estimate provides the likelihood of a specific consequence, given a set of risk-generating circumstances.
- Thus, quantitative risk estimation is useful for one particular consequence at a time.
- ارزیابی کمی ریسک، برآورد ریس کبه ما این توانایی رو می دهد تا بتوانیم احتمال یک پیامد خاص را با توجه به مجموعه ای از شرایط مولد ریسک مشخص کنیم.
- بنابراین، برآورد کمی ریسک برای یک پیامد خاص در یک زمان، مفید است.
- Alternatively, some risk management tools use a relative risk measure to combine multiple levels of severity and probability into an overall estimate of relative risk.
- The intermediate steps within a scoring process can sometimes employ quantitative risk estimation.
- و در مقابل بعضی از ابزارهای مدیریت ریسک از یک معیار ریسک نسبی برای ترکیب سطوح چندگانه شدت و احتمال در یک برآورد کلی از ریسک نسبی استفاده می کنند.
- گام‌های میانی در فرآیند امتیازدهی گاهی اوقات می‌توانند از تخمین کمی ریسک استفاده کنند

- **Risk Control:**
- Risk control includes decision making **to reduce** and/or **accept** risks.
- The purpose of risk control is to reduce the risk to an acceptable level.

- The amount of effort used for risk control should be proportional to the significance of the risk. مطابقت و متناسب بودن تلاش و اهمیت ریسک

- Decision makers might use different processes, including benefit-cost analysis, for understanding the optimal level of risk control.
  - آنالیز نفع و هزینه

- Risk control might focus on the following questions:

a) Is the risk above an acceptable level? ریسک بالاتر از سطح قابل قبول است

b) What can be done to reduce or eliminate risks?

c) What is the appropriate balance among benefits, risks and resources?

d) Are new risks introduced as a result of the identified risks being controlled?

- **Risk reduction**
- focuses on processes for mitigation or avoidance of quality risk when it exceeds a specified (acceptable) level.کاهش یا جلوگیری از وقوع
- Risk reduction might include actions taken to mitigate the severity and probability of harm. کاهش شدت و یا کاهش احتمال خطر
- Processes that improve the detectability of hazards and quality risks might also be used as part of a risk control strategy. فرآیندهایی که تشخیص خطرات و ریسک های کیفی را بهبود می بخشد، ممکن است به عنوان بخشی از استراتژی کنترل ریسک نیز استفاده شوند
- The implementation of risk reduction measures can introduce new risks into the system or increase the significance of other existing risks.
- Hence, it might be appropriate to revisit the risk assessment to identify and evaluate any possible change in risk after implementing a risk reduction process.

- **Risk acceptance:**
- is a decision to accept risk.
- Risk acceptance can be a formal decision to accept the residual risk or it can be a passive decision in which residual risks are not specified.
- For some types of harms, even the best quality risk management practices might not entirely eliminate risk.
- In these circumstances, it might be agreed that an appropriate quality risk management strategy has been applied and that quality risk is reduced to a specified (acceptable) level.
- This (specified) acceptable level will depend on many parameters and should be decided on a case-by-case basis.

- **Risk Communication:**
- Risk communication is the sharing of information about **risk and risk management between the decision makers and others**.
- Parties can communicate at any stage of the risk management process (see Fig. 1: dashed arrows).
- The output/result of the quality risk management process should be appropriately communicated and documented (see Fig. 1: solid arrows).
- Communications might include those among interested parties; e.g., regulators and industry, industry and the patient, within a company, industry or regulatory authority, etc.
- The included information might relate to the existence, nature, form, probability, severity, acceptability, control, treatment, detectability or other aspects of risks to quality.
- Communication need not be carried out for each and every risk acceptance. Between the industry and regulatory authorities, communication concerning quality risk management decisions might be effected through existing channels as specified in regulations and guidances.

- **Risk Review**
- Risk management should be an ongoing part of the quality management process. A mechanism to review or monitor events should be implemented.
- The output/results of the risk management process should be reviewed to take into account new knowledge and experience.
- Once a quality risk management process has been initiated, that process should continue to be utilized for events that might impact the original quality risk management decision, whether these events are planned (e.g. results of product review, inspections, audits, change control) or unplanned (e.g. root cause from failure investigations, recall).
- The frequency of any review should be based upon the level of risk. Risk review might include reconsideration of risk acceptance decisions

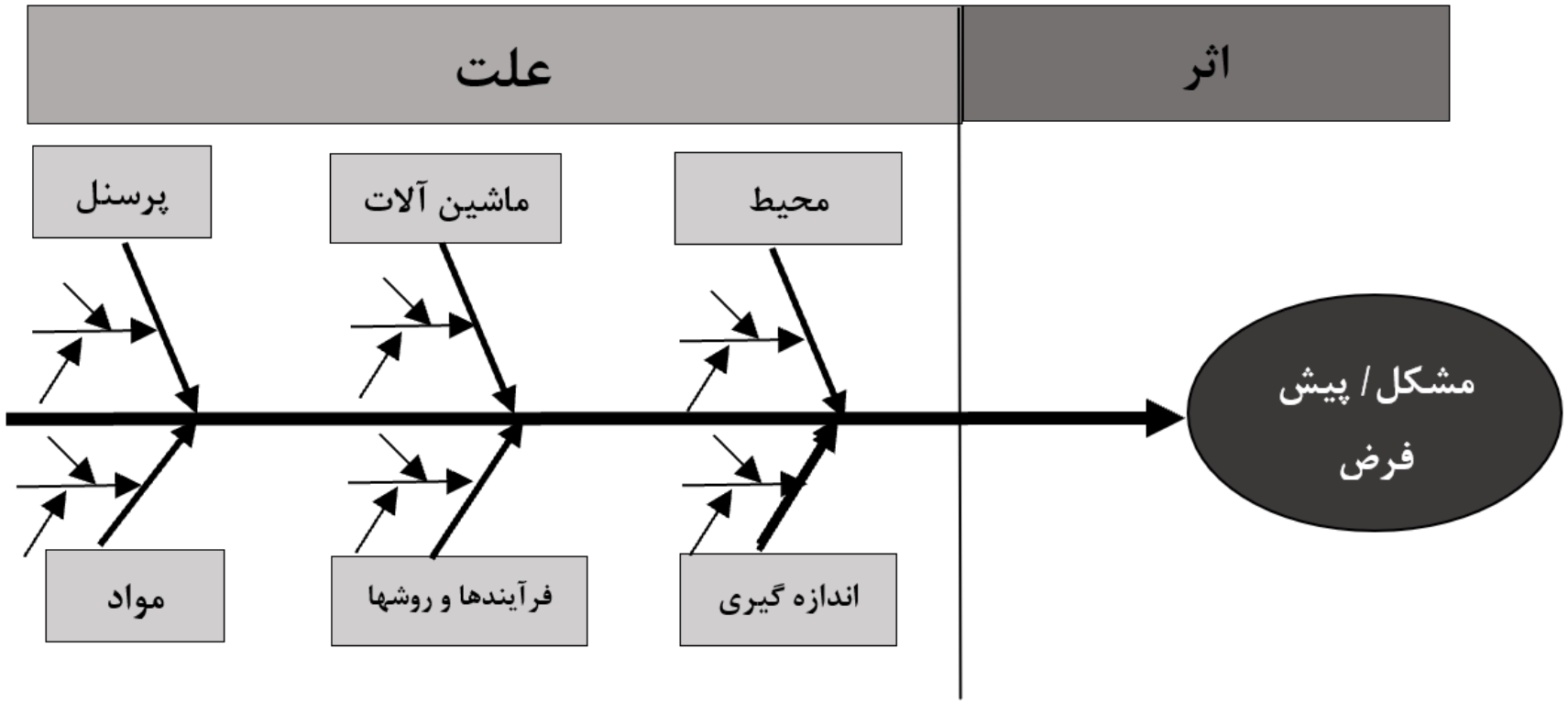
- **RISK MANAGEMENT METHODOLOGY**
- Quality risk management supports a scientific and practical approach to decision making.
- It provides documented, transparent and reproducible methods to accomplish steps of the quality risk management process based on current knowledge about assessing the probability, severity and sometimes detectability of the risk.
- QRM از رویکرد عملی و علمی برای تصمیم گیری پشتیبانی می کند.
- روشهای مستند ، شفاف و تجدیدپذیر فراهم می کند تا مراحل فرآیند مدیریت ریسک کیفیت را بر اساس اطلاعات به روز در مورد ارزیابی احتمال، شدت و گاهی قابلیت تشخیص ریسک به اجرا درآورد.

- Traditionally, risks to quality have been assessed and managed in a variety of informal ways (empirical and/ or internal procedures) based on, for example, compilation of observations, trends and other information.
- Such approaches continue to provide useful information that might support topics such as handling of complaints, quality defects, deviations and allocation of resources.
- Additionally, the pharmaceutical industry and regulators can assess and manage risk using recognized risk management tools and/ or internal procedures (e.g., standard operating procedures).

- به طور سنتی، ریسک‌های کیفیت به روش‌های غیررسمی مختلفی (روش‌های تجربی و/یا داخلی) بر اساس، برای مثال، گردآوری مشاهدات، روندها و سایر اطلاعات، ارزیابی و مدیریت می‌شوند.
- چنین رویکردهایی همچنان اطلاعات مفیدی را ارائه می‌کنند که ممکن است موضوعاتی مانند رسیدگی به شکایات، نقص‌های کیفی، انحرافات و تخصیص منابع را پشتیبانی کند.
- علاوه بر این، صنعت داروسازی وقانون گذارها می‌توانند ریسک را با استفاده از ابزارهای شناخته‌شده مدیریت ریسک و/یا رویه‌های داخلی (مانند رویه‌های عملیاتی استاندارد) ارزیابی و مدیریت کنند.

- **Tools**
- Below is a non-exhaustive list of some of these tools بخشی از لیست ابزارها می باشد
- Basic risk management facilitation methods (Fish bone, flowcharts, check sheets etc.) متدهای بهبود مدیریت ریسک پایه
- Failure Mode Effects Analysis (FMEA)
- Failure Mode, Effects and Criticality Analysis (FMECA)
- Fault Tree Analysis (FTA)
- Hazard Analysis and Critical Control Points (HACCP)
- Hazard Operability Analysis (HAZOP)
- Preliminary Hazard Analysis (PHA)
- Risk ranking and filtering
- Supporting statistical tools

Root cause


علت
اثر
پرسنل
ماشین آلات
محیط
مشکل/ پیش فرض
مواد
فرآیندها و روشها
اندازه گیری

- It might be appropriate to adapt these tools for use in specific areas pertaining to drug substance and drug (medicinal) product quality. Quality risk management methods and the supporting statistical tools can be used in combination (e.g. Probabilistic Risk Assessment). Combined use provides flexibility that can facilitate the application of quality risk management principles.
- The degree of rigor and formality of quality risk management should reflect available knowledge and be commensurate with the complexity and/ or criticality of the issue to be addressed.

- INTEGRATION OF QUALITY RISK MANAGEMENT INTO INDUSTRY AND REGULATORY OPERATIONS
- Quality risk management is a process that supports science-based and practical decisions when integrated into quality systems (see Annex II).
- As outlined in the introduction, appropriate use of quality risk management does not obviate industry's obligation to comply with regulatory requirements.
- However, effective quality risk management can facilitate better and more informed decisions, can provide regulators with greater assurance of a company's ability to deal with potential risks, and might affect the extent and level of direct regulatory oversight. In addition, quality risk management can facilitate better use of resources by all parties.

- Training of both industry and regulatory personnel in quality risk management processes provides for greater understanding of decision-making processes and builds confidence in quality risk management outcomes.
- Quality risk management should be integrated into existing operations and documented appropriately. Annex II provides examples of situations in which the use of the quality risk management process might provide information that could then be used in a variety of pharmaceutical operations.
- These examples are provided for illustrative purposes only and should not be considered a definitive or exhaustive list. These examples are not intended to create any new expectations beyond the requirements laid out in the current regulations.

- DEFINITIONS
- Decision maker(s) – Person(s) with the competence and authority to make appropriate and timely quality risk management decisions
- Detectability - the ability to discover or determine the existence, presence, or fact of a hazard
- Harm – damage to health, including the damage that can occur from loss of product quality or availability
- Hazard - the potential source of harm (ISO/IEC Guide 51)
- Product Lifecycle – all phases in the life of the product from the initial development through marketing until the product's discontinuation
- Quality – the degree to which a set of inherent properties of a product, system or process fulfils requirements (see ICH Q6a definition specifically for "quality" of drug substance and drug (medicinal) products.)
- Quality risk management – a systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product lifecycle
- Quality system – the sum of all aspects of a system that implements quality policy and ensures that quality objectives are met

- Requirements – the explicit or implicit needs or expectations of the patients or their surrogates (e.g. health care professionals, regulators and legislators). In this document, “requirements” refers not only to statutory, legislative, or regulatory requirements, but also to such needs and expectations.
- Risk – the combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51)
- Risk acceptance – the decision to accept risk (ISO Guide 73)
- Risk analysis – the estimation of the risk associated with the identified hazards
- Risk assessment – a systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.

- Risk communication – the sharing of information about risk and risk management between the decision maker and other stakeholders
- Risk control – actions implementing risk management decisions (ISO Guide 73)
- Risk evaluation – the comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk
- Risk identification – the systematic use of information to identify potential sources of harm (hazards) referring to the risk question or problem description
- Risk management – the systematic application of quality management policies, procedures, and practices to the tasks of assessing, controlling, communicating and reviewing risk

- Risk reduction – actions taken to lessen the probability of occurrence of harm and the severity of that harm
- Risk review – review or monitoring of output/results of the risk management process considering (if appropriate) new knowledge and experience about the risk
- Severity – a measure of the possible consequences of a hazard Stakeholder – any individual, group or organization that can affect, be affected by, or perceive itself to be affected by a risk.
- Decision makers might also be stakeholders. For the purposes of this guideline, the primary stakeholders are the patient, healthcare professional, regulatory authority, and industry
- Trend – a statistical term referring to the direction or rate of change of a variable(s)