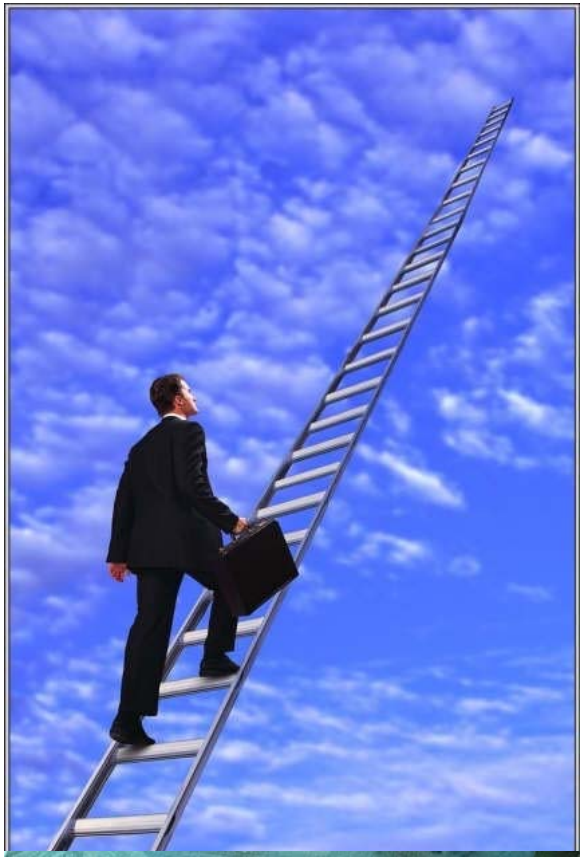


Safety Management: An integrating Tool in the Pharmaceutical Quality Management System

Dr. R. KARUPPASAMY M.Com.,MBA.,M.Phil.,Ph.D.,PLME(IIM-A)

Director, Management Studies, SNS College of Technology, Coimbatore.

Secretary-LEAD Researchers Forum,

rkrangoli@gmail.com

98421-54884


www.China-wallpaper.com

Market leaders in terms of sales

The top 15 pharmaceutical companies by sales are:

Rank	Company	Sales ($M)	Based/Headquartered in
1	Pfizer	43,363	United States
2	GlaxoSmithKline	36,506	United Kingdom
3	Novartis	36,506	Switzerland
4	Sanofi-Aventis	35,642	France
5	AstraZeneca	32,516	United Kingdom
6	Hoffmann–La Roche	30,336	Switzerland
7	Johnson & Johnson	29,425	United States
8	Merck & Co.	26,191	United States
9	Abbott	19,466	United States
10	Eli Lilly and Company	19,140	United States
11	Amgen	15,794	United States
12	Wyeth	15,682	United States
13	Teva	15,274	Israel
14	Bayer	15,660	Germany
15	Takeda	13,819	Japan

GROWTH TRENDS

- Growing need of medicines and medical treatments
  - Introduction of new drugs
  - Techno – friendly surgeries
  - 360000 major operations/day
- Increase in Bulk drug manufactures & Pharmaceutical companies
  - 1800 companies/annum

OPPORTUNITIC AREAS

- Introduction of combination Therapy
  - Cost effective combinations

    (African Market: Cipla)
  - Molecular Remodeling
  - Research & Development

    Indian Companies 6 % to 7 %/ pfizer 20 %
  - Medical tourism / cross border surgeries
  - Inter – disciplinary approach

    Nano with pharma and Bio – tech with pharma

INDIA – CASE STUDY

- Increasing Diseases profile
  - Life style disorders
  - Food habits
  - Occupational diseases
- Chronic Diseases
  - Cardiovascular Diseases (LDL/HDL)/ Asthma / Diabetic etc.,
- Bio medical equipment Imports (Rs.20,000 cr)
- Indigenious Technology
  - Ranbaxy, Cipla, Alkem
  - Pfizer

SAFETY & QUALITY IN Pharmaceutical Industry

- Quality plays a major role
- Each Drug has to achieve its standard (USFDA)
  - Ex: Ciprofloxacin – Bulk purity & content uniformity
- Most of the medicines are first tested with animals
- Manufacturing System
- Disclosure of contra – indication, patient compliance etc

SAFETY ISSUES

- No. of accidents are increasing
- Manufacturing System / Equipments
- Human Risks
- Quality of Raw Drugs / Open market
- Lack of R & D
- Lack of continuous research on existing drugs (Azithromycin /Roxithromycin/ clarithromycin)

SAFETY ISSUES

- Clinical Trials
  - Non – disclosure of negative aspects
- Combination Therapy – negative
- Chemical reactions – Hidden
  - Metallic taste / nausea
  - Mono therapy- Ranitidine, Omeprazole, Lanzaprozole, Pantaprozole
  - Pylokit, Omikit, H – Pylorikit
- Complications – Osteoporosis(BMD) / Finpecia

IP PROTECTION & SAFETY

- Us Pharma companies are No. 1 in IP protection
- 15 % to 22 % of their Revenue are used for R & D
- Research – Documentation patent life
- India had only process patent up to 2002, product patent was introduced only after 2002.
- Absence of world wide common IP Law allows duplication.
- WIPO – Mailbox system

SAFETY IN THE PHARMACEUTICAL INDUSTRY

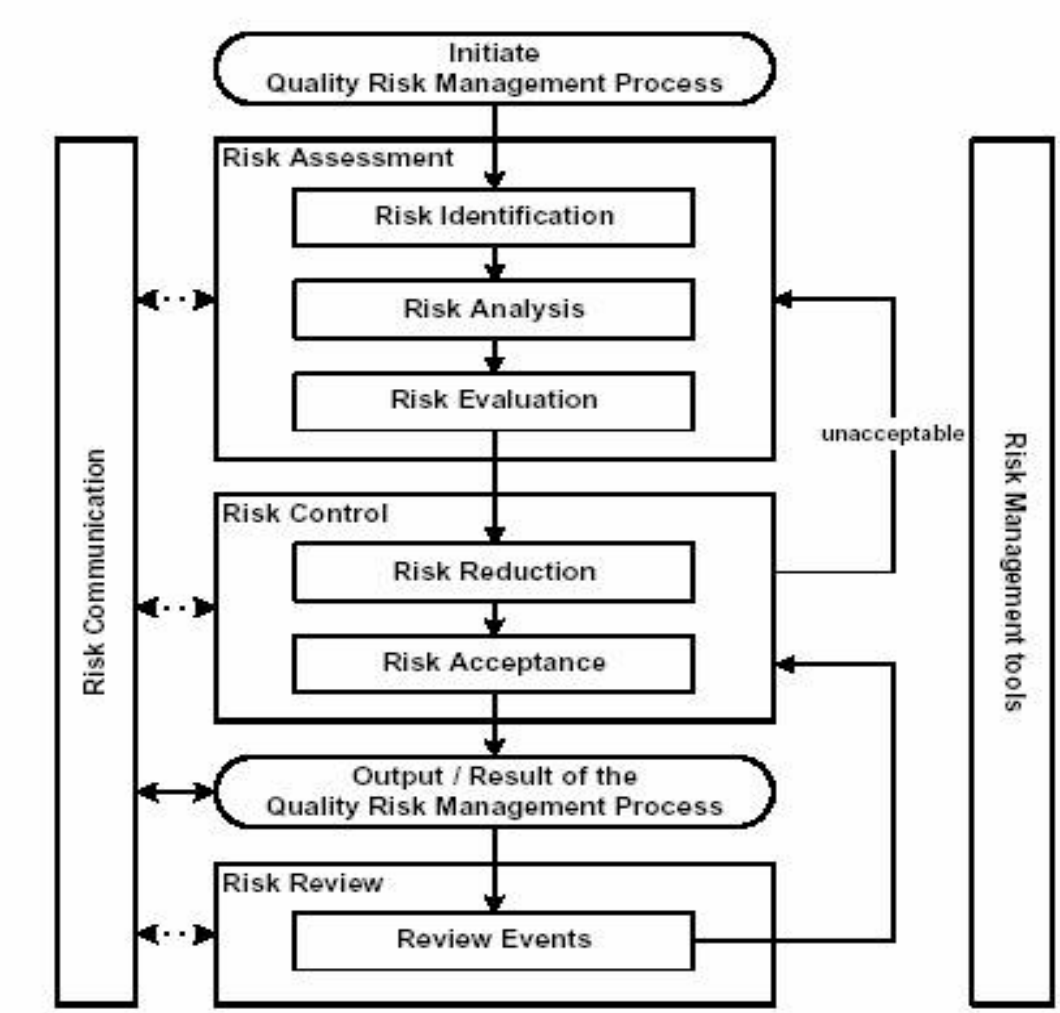
- Integrated building technology protects pharmaceutical and chemical processes
- The correct building technology will protect people, assets and the environment. This is paramount in the pharmaceutical industry, with its considerable security requirements. Critical processes require specific protective measures: integrated building technology solutions provide safety in the pharmaceutical industry.

EFFECTIVE QUALITY RISK MANAGEMENT

- Effective quality risk management facilitates better and more informed decisions and provide FDA regulators with greater assurance of a company's ability to deal with potential risk. Risk management principles are effectively utilized in many areas of business and development including finance, insurance, occupational safety, public health, pharmacovigilance and agencies regulating these industries. It can be applied to different aspect of pharmaceutical quality including development, Manufacturing, Distribution, Inspection, submission and review processes through the life cycle of drug substances, drug product, biological and biotechnological product (including use of raw material,solvent,exciepient,packaging and labeling.)

Model for quality risk management

Shown at http://www.sportbikes.dhs.org


Initiate
Quality Risk Management Process
Risk Assessment
Risk Identification
Risk Analysis
Risk Evaluation
unacceptable
Risk Control
Risk Reduction
Risk Acceptance
Output / Result of the
Quality Risk Management Process
Risk Review
Review Events
Risk Communication
Risk Management tools

CONCLUSION

- Risk assessment is identification of hazards and the analysis and evaluation of risk related to with exposure to those hazards. As an aid to clearly defining the risk for risk assessment few fundamental are often useful, such as
- what might go wrong?
- What is the probability and consequence of wrong occurrence?
- While doing effective risk assessment, the robustness of the data is important as it determines the quality of outcome.
- The risk assessment can be either quantitative or qualitative parameter.