

ERGONOMIC RISK ASSESSMENTS WITHIN A PHARMACEUTICAL COMPANY

Kipping, J-A

SHE Technical Support, Global Operations, AstraZeneca AB, SE-151 85 Sweden
E.mail: jan-anders.kipping@astrazeneca.com

This paper describes an attempt to integrate ergonomic risk assessments at different stages in the ordinary risk assessment process in a pharmaceutical company to improve ergonomics in new and changed assets. Two ergonomics checklists are used to support the risk assessors making the risk assessments. Early in a project a checklist for primary risk assessment to identify ergonomic hazards is used. Decisions are then made on how these hazards are to be managed in the design process. A second checklist is used for detailed ergonomic risk assessment at a later stage in the project process. Identified remaining risks are then assessed and managed according to a RAG (red-amber-green) scheme.

Keywords: ergonomic risk assessment, ergonomic checklist

1. Introduction

Investments in production facilities and equipment within the pharmaceutical industry often have a long lifetime. Great changes in production design are not common, compared to e.g. the car industry where new models are often introduced and small changes in the manufacturing process are made monthly or weekly. The registration process for medicines makes some changes in processes and equipment almost impossible at a reasonable cost. Thus it is important that the design of processes and equipment is right from the beginning. There are examples of equipment that has been in use for more than 40 years and if the design is not right from the beginning, one might have to live with it for a very long time. This is in particular true about faulty ergonomic design. There is often no personal protective equipment that can easily correct the deficiencies in design and protect the worker.

AstraZeneca is an international pharmaceutical company with research, development, manufacturing and sales in many countries. The biggest production sites are situated in Great Britain and Sweden.

2. Project process for capital projects

The project process life cycle for capital projects within the company has seven phases; business analysis, initiate, basic design, detail design, construction, commissioning and closure (see figure 2).

During the first four phases cost estimations are made which are then discussed during the decision-making process whether to continue the project process or not. The more the project advances the more exact the cost estimation will be and thus it will be harder

to get acceptance for large changes in the budget. Likewise it is harder and harder to get acceptance for costly changes in the project to overcome bad ergonomics.

It is essential that ergonomics requirements are identified as early as possible during the lifetime of a project and incorporated in the cost analysis to make this more exact. It is also essential to identify ergonomics requirements as early as possible to be able to choose the technical solution that has the best possibility to achieve good results. If a bad choice is made it is likely that at a later stage it will be impossible or very expensive to change the chosen technique. The only possible way to improve ergonomics at that stage might be expensive corrective actions. Unfortunately the reality is such in our company, as well as in most other companies, that the later in the project lifetime, the lower the likelihood of acceptance of cost increases.

3. SHE (safety, health and environment) risk management system

Within AstraZeneca a SHE risk management system is used where risk assessments are performed and documented at different stages in the project management process. The assembled documentation is called the “Basis of SHE”. (This concept is presented in more detail in a separate presentation by another author, Peter Svensson.)

The Risk Management Model

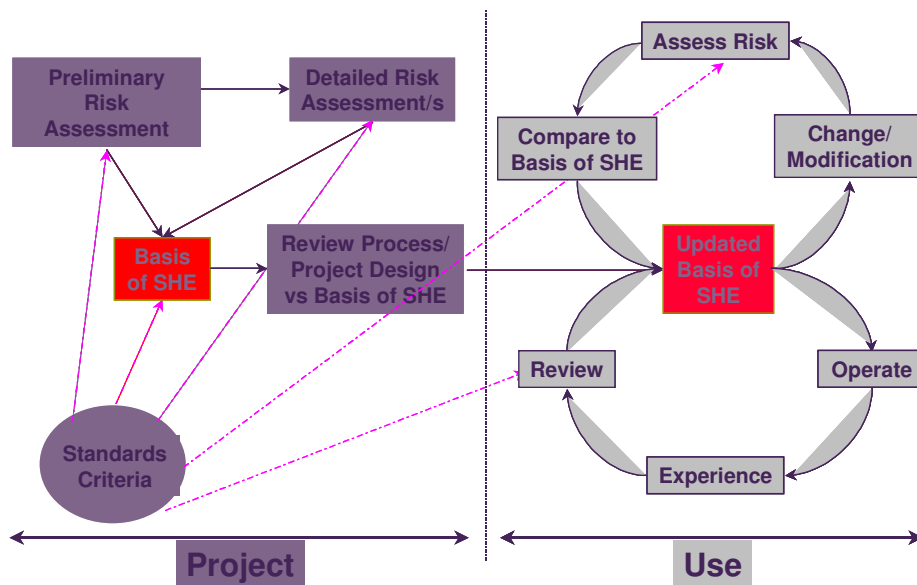


Figure 1.

Early in the project process a preliminary risk assessment shall be performed where significant SHE hazards (SHE risk sources) are identified and philosophies and control measures to manage those hazards are established. The preliminary risk assessment should start as early as possible in the project process. The work needs to start during

the early part of the basic design phase, but ideally it should start during the initiate phase - the sooner the better.

RA in Project Life-Cycle

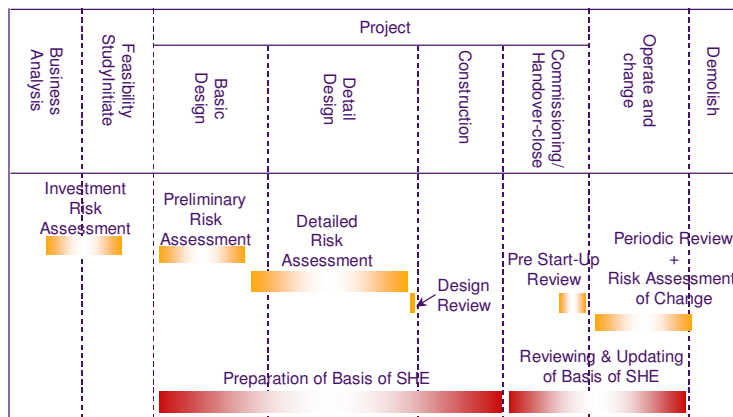


Figure 2.

Later during the project process a detailed SHE risk assessment shall be performed. The work normally starts towards the end of the basic design phase and continues into the detailed design phase. When the design phase is finished, and before the construction phase starts, there should be a review where the plans are checked to ensure that all risks have been identified and control measures have been incorporated to enable the risks to be managed properly.

After the construction phase and during the commissioning phase, there is a final review to ensure that the final product is identical to that which has been assessed and that no changes have been made during the construction phase that could give rise to increased levels of risk.

4. Ergonomic risk assessments

To support risk assessors certain tools have been developed to help them make better assessments of ergonomic risks.

During the basic design phase the project has not come that far. Normally no choice of process technique or equipment has been made. Different ideas and preliminary drawings are discussed and assessed. To support the preliminary risk assessment there is a preliminary ergonomics checklist to help identify possible ergonomic hazards early in the project. For those ergonomics hazards identified, philosophies and control measures should be developed to manage them in the same way as other hazards.

For example: Heavy lifting has been identified as a hazard.

The philosophy to manage that hazard could be: No manual lifts above 10 kg should be performed. A way to achieve this could be that lifting equipment is designed and available for all lifts above 10 kg. This is then to be taken into account during all the design phases and has to be followed up.

When the detailed risk assessment is performed the project has normally advanced further. Often there are detailed plans available. The choice of process technique has been made but the final suppliers might not have been decided upon and no equipment has been purchased.

Another checklist for detailed ergonomic risk assessments is now available to support the risk assessment process. The checklist is based upon the Swedish regulation, AFS 1998:1 with some influence from an In-House manual handling assessment procedure from AstraZeneca UK and detailed assessment criteria from “Ergonomitermometern”, Antonsson & Bjurvall 1999.

An assessment shall be made for each workstation for example on a production line. The red-amber-green scheme from AFS 1998:1 is used to facilitate the evaluation of the result of the assessment:

-Green, OK there should be no major ergonomic risks.

-Red, there are major ergonomic risks. Normally the design needs to be improved.

-Amber, a more detailed analysis needs to be performed. E.g. if work operator rotation is going to be used on the line an ergonomic assessment for the operator's exposure during a full shift should be performed. It is often wise and recommended to call for help from an experienced ergonomist for further assessments in these cases.

Information and support material concerning ergonomics, and tools for ergonomic risk assessments can be found and downloaded from an internal ergonomics website. The target group for the website is primarily managers, project managers and risk assessors but all employees have access and can use the material.

There are e-learning modules about ergonomics, specific checklist about work in the laboratory, work with fume cupboards, office and computer work etc. Here different ergonomic guidelines and best practices can also be found. All material is available in English, the official company language. Some parts are also available in Swedish and there are plans to translate some information to other languages. To ease the understanding of the information supplied, mainly for people who do not have English as their native language, many pictures and simple animations are used to improve the understanding and learning.

5. References

AFS 1998:1, Arbetsmiljöverkets författningssamling, Belastningsergonomi
Antonsson, A-B., Bjurvald, M. 1999. Ergonomitermometern. Prevent