Process Hazard Review (PHR) for the pharmaceuticals industry

Ensuring compliance with Control of Major Accident Hazards (COMAH) regulations for a top tier site.

The Roche UK Ltd site in Dalry, Ayrshire, produces vitamin A, B1 and B5 as well as being the largest producer of vitamin C worldwide.

Due to the storage of toxic substances, including sodium cyanide and phosphorous oxy-chloride, it has been classified a ‘top tier’ establishment under the COMAH regulations.

This means that in addition to the Major Accident Prevention Policy (MAPP), required by the lower tiers, they need to prepare a Safety Report which must include:

- A policy on how to prevent and mitigate major accidents
- A management system for implementing that policy
- An effective method for identifying any major accidents that might occur
- Measures (such as safe plant and safe operating procedures) to prevent and mitigate major accidents
- Information on the safety precautions built into the plant and equipment when it was designed and constructed
- Details of measures (such as fire-fighting, relief systems and filters) to limit the consequences of any major accident that might occur
- Information about the emergency plan for the site, which is also used by the local authority in drawing up an off-site emergency plan

ABB was initially contacted to carry out consequence assessment modelling of a number of potential major accident hazards.

Once this initial report was completed, work began on risk identification for the PHR. This then formed the basis of the safety report to satisfy COMAH regulations.

At this stage Roche had approximately 10 months to complete a safety report to meet their deadline.
Solution
Using state-of-the-art computer modelling packages, ABB specialists assessed the extent and severity of the identified accident scenarios to determine whether they were classified as ‘major accidents’.

An ABB process safety specialist worked alongside Roche to develop a methodology for carrying out COMAH risk assessments. This had to demonstrate that a rigorous methodology had been followed and needed to be consistent with existing Roche procedures for process safety studies.

Having jointly developed a major accident risk analysis methodology a plant was selected for a pilot study led by ABB. This was a multi-stage batch pharmaceutical intermediate plant with 6 process steps including high-pressure hydrogenation. The Roche specialist was then able to roll out the methodology across the site to cover all the plants handling dangerous substances.

The key issue from a preliminary assessment of the safety report by the Health and Safety Executive (HSE) was the need for further demonstration that risks had been reduced to as low as reasonably practicable (ALARP). ABB provided consultancy support to identify and assess further improvement measures using a qualitative cost benefit analysis approach.

Benefits
- Maintaining their license to operate by meeting regulatory obligations through a successful COMAH submission
- Demonstration of a suitable and sufficient risk assessment process
- Tailoring of ABB’s standard PHR methodology to meet company guidance, avoiding potential conflict with the Swiss parent safety department
- Cost effective rollout across the site by local resources
- Effective ALARP demonstration allowed acceptance of safety report within the deadline set
- Full range of World Class support services from a single source