

Australasian Institute of Dangerous Goods Consultants Conference 2008

*Dangerous Goods in Pharmaceutical
Manufacturing*

Case Study – Herbal Medicines

Presentation Outline

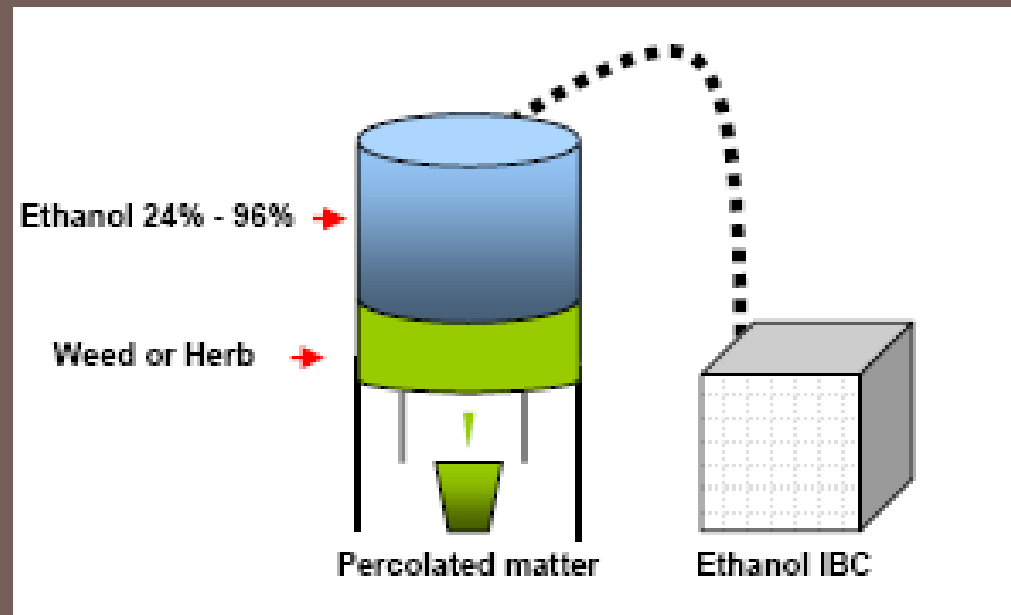
Session Objective: Provide an insight into the actions taken by a pharmaceutical company following a major review involving the QLD Dangerous Goods Regulators and associated Government Departments – the lessons learned.

- Introduction to the company and the initial site investigation.
- The main dangerous goods issues addressed on site.
- Differing regulatory requirements.
- The end result 2 years on and the future.

Plant Operation Summary

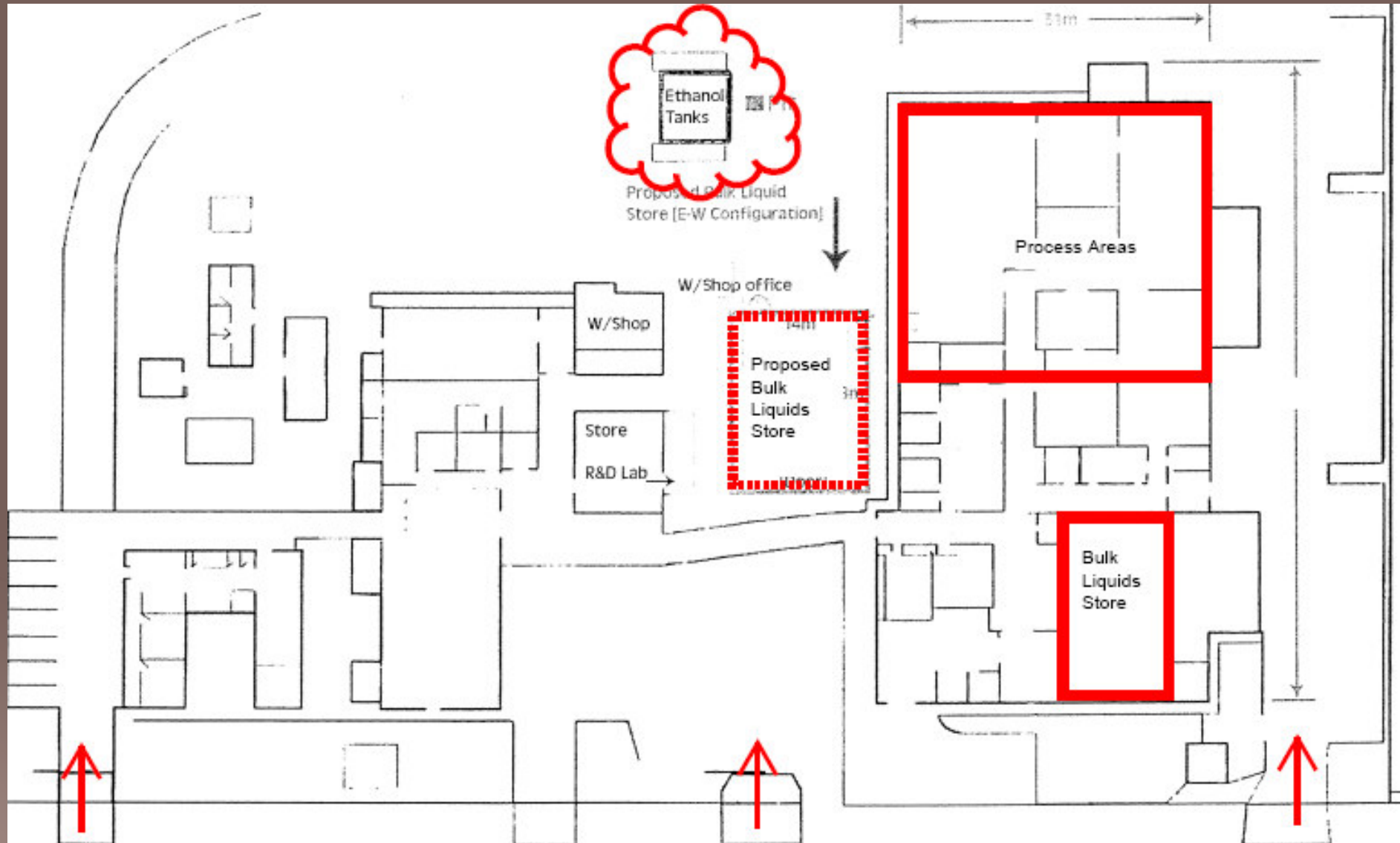
- One of the largest alternative medicine companies in Australia with facilities in Sydney, Ballina, Toowoomba Warwick and Brisbane.
- Main production plant based in Warwick, QLD.
- The main function of the plant is to extract plant oils from herbs and weeds using ethanol in the cold percolation process.

**Raw Herb → Extract →
Liquid and / or → Tablet**



Plant Operation Summary Cont....

- The plant has five main areas where flammable liquids are stored and / or in process, these include:
 - ❑ Bulk ethanol storage (approx 40m³ externally).
 - ❑ Bulk liquids store (approx 25m³ internally in IBC's).
 - ❑ Percolation packing rooms (herb / weed preparation)
 - ❑ Percolation rooms (processing areas).
 - ❑ Bottling and distribution.



Before project commencement

- As required by QLD Dangerous Goods Regulations the organisation had always applied for their annual Flammable & Combustible Liquids License with little knowledge of their obligations as a “Large Dangerous Goods Location”. The license was always issued each year by the local Council with no questions asked.
- Beginning 2006 – The facility was subject to a random inspection by QLD Workplace Health & Safety resulting in the identification of significant safety concerns. The scale of works that would need to be done was significant and could have resulted in total or partial shutdown of the facility. Directives were issued
- Management agreed that there was a certain amount of naivety with regard to the everyday use of ethanol on the site – the processes used were those employed by the whole herbal medicine industry **“this is how things had always been done”**.

Stakeholders

Who was involved:

- Client (employees, site management & Board of Directors)
- QLD Workplace Health & Safety
- QLD CHEM Services
- QLD Office of Electrical Safety
- Southern Downs Regional Council
- External Consultants

Main DG Issues

- Ethanol in IBC's stored in an area attached to the process building and offices – with no fire separation.
- Ethanol decanted into open vats with hoses and buckets as part of normal operation.
- Bulk ethanol tanks located in close proximity to the site boundary.
- All process areas where ethanol was regularly decanted contained sources of ignition including electrical switchgear, motors, lighting, computers, use of forklifts internally, insect zappers etc.
- Whilst the building had recently had a significant mechanical ventilation upgrade for TGA purposed this ventilation contained sources of ignition and provided a link for hazardous zones within one work space to extend into another.
- Hazardous areas not identified.
- Safe operating procedures did not have an emphasis on the hazards associated with the storage and handling of flammable liquids whilst this was the main function of the facility.

Some Frustrations...

- Why had these issues not previously been identified by the Council (during the annual license review) and other specialist contractors and consultant that had been working on the site. Would insurance be valid? And could the site operate without a license.
- Lack of practical understanding of the intent of the QLD Dangerous Goods Regulations and guidance standards resulted in unrealistic and financially unattainable objectives being set for corrective actions.

Some examples:

- Replacement of a newly installed 700K mechanical air handling system – installed to TGA requirements.
- Replacement of all electrical wiring and equipment within all working areas.
- Construction of an alternative bulk liquids store.
- Relocation of external bulk ethanol tanks.
- Immediate cessation of electric forklift use.
- Installation of in room bunding.

Some Frustrations Cont...

- Dangerous goods legislation is not always complementary with other regulatory requirements which are fundamental for operating within the pharmaceutical industry – TGA air handling / clean room requirements.
- Very limited written commitment from the Council stating what solutions would be acceptable in order for the site to obtain a new license.
- Initially strict compliance with AS 1940: 2004 moved to a performance based approach quiet slowly.
- Finding contractors to carry out the work has been extremely difficult, in particular the selection and installation of new motors and associated wiring.

Approach Taken

- Immediate hazard identification and risk assessment.
- All possible operational changes that could reduce site risk were introduced immediately.
- Results of risk assessment presented to board in order to determine the financial investment required.
- Whilst time frames to action the Directives issued were significantly exceeded, the client regularly communicated progress on site and provided monthly action plans to the Regulators.
- Physical works have started to be carried out in order of priority.
- Some works have required significant capital investment and are still in planning phase – bulk liquids store.
- Scheduling as much physical construction work as possible during the shutdown maintenance period.
- Programmed replacement of electrical equipment and associated wiring.

Where are we now?

- Ethanol detection system installed but still to be commissioned.
- Flameproof forklifts on site.
- Removal of all excess electrical equipment and replacement of essential equipment with a flameproof type – ongoing. Change to pneumatic pumps where possible.
- Blocking of drainage that was linking work areas together – spills could carry over into another work area.
- Reduction in onsite storage within the bulk liquids store.
- Currently tendering for the construction of the external bulk liquids store – to be completed by December 08.
- Labelling of all packages and vats in process.
- Overall site placarding reviewed.
- Fire Brigade review.

Thank you for your attention

Any Questions?