Case Study on the manufacture of a key ingredient for a COVID-19 vaccine

Carolyn Nicholls
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RISK & HAZARD MANAGEMENT

Introduction

- A project with significant challenges; to deliver a key ingredient for a COVID-19 vaccination in the height of the pandemic with immense time pressure and limitations presented by COVID-19 measures.
- Inherent safety is the starting point for any good design.
- Importance of the **right people**, using the **right processes** at the **right time,** for successful risk understanding and management.
- Rethinking of the traditional (rigid) approaches to hazard studies.

An interesting example of a project with significant challenges; to deliver a key ingredient for a COVID-19 vaccination in the height of the pandemic with immense time pressure and limitations presented by COVID-19 measures.

The available timeframe highlighted the importance of inherent safety as the starting point for any good design and provided the opportunity to focus on innovative and pragmatic solutions for process safety.

The company typically uses the traditional 6 stage hazard study approach from its heritage. Traditional approaches were challenged and tailored for modern application, for instance hazard studies were carried out remotely to comply with restrictions.

Careful thought and adaptation made for a more pragmatic, more useful, and successful approach. Process safety reviews were used as check points, and to provide breathing space and assurance to the designers. A competent and agile team made this possible, with independent input.

This case study will discuss the importance of the **right people**, using the **right processes** at the **right time,** for successful risk understanding and management.

The case study will highlight the key process safety decisions in the design, and the approach to the risk understanding and management.

Pressure forces people to think differently and challenge the norms. This is a great example of where those pressures have revealed efficiencies and techniques that will be shared and adopted into future projects.

Project Brief

- In Aug 20 told to drop everything and design a full scale plant to supply excipient to a major vaccine manufacturer
- Given a team of three process engineers overnight and told to start designing

Project Background

Highly sensitive, so not able to say much about the project.

The purpose of the plant is to deliver a key ingredient for a COVID-19 vaccination.

Plant was completely new, not a redesign of similar plants elsewhere which was a challenge. Starting from a nearly blank sheet.

The pressures are obvious - urgent need to deliver the COVID vaccine.

Project Timeline

Project initiated	Initial design	Detailed design	Installation	Commissioning	Steady State Production
• 11th August 2020	• First sketch 14th August 2020 • Quotes for vessels within 2 weeks • Purchases within 3 weeks		• January 2021	• 2 weeks of commissioning activities • Solvent ready March 2021	• Operator training 6 weeks • May 2021

A 2 year project, condensed to 8 months

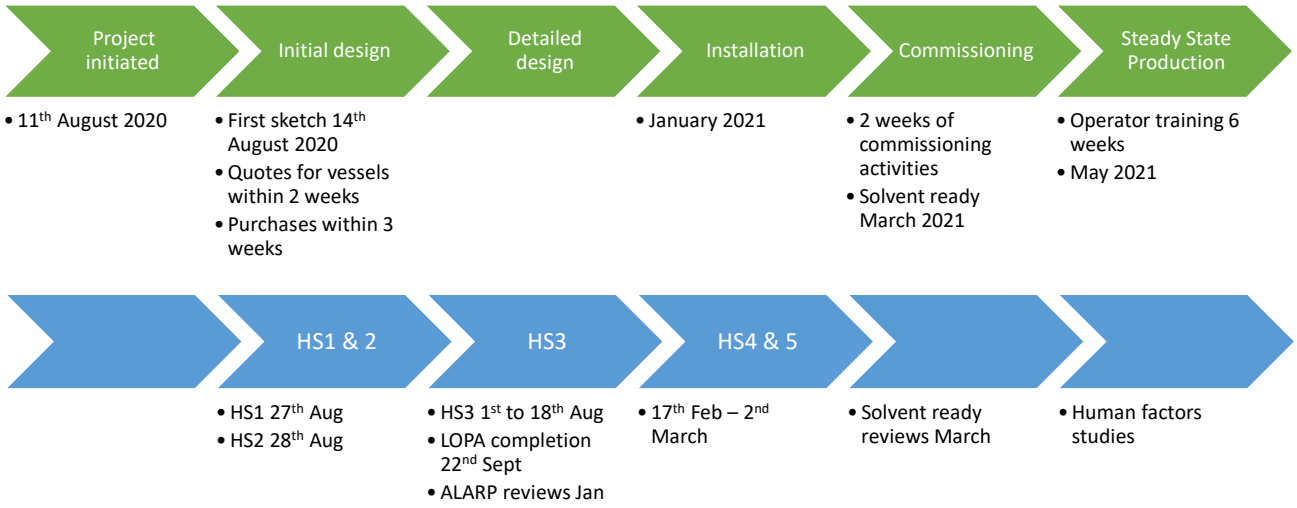
Pilot plant to full scale production. A two year project delivered in 8 months.

Design Decisions

- Kept design in house, working to teams strengths
- Design with equipment ratings above maximum of any input pressures
- Single source suppliers, no long tender process
- Automate for safety, reliability and improved repeatability of quality
- Avoided need for SIL rated systems
- Considered hazardous area zones very early on, to allow equipment specifications
- Full 3D model produced early on
- Pipe sections welded offsite and brought on to site, accepting some modifications may be needed

The available timeframe highlighted the importance of inherent safety as the starting point for any good design and provided the opportunity to focus on innovative and pragmatic solutions for process safety.

6 stage hazard studies



This company normally adopts the traditional 6 staged hazard study approach, developed by ICI.

The main principles here are that information is reviewed as the project develops. The design is challenged at appropriate intervals to ensure it doesn't progress too far without risks being addressed. It provides the environment for inherently safer design. It is a staged gate process that sits well against traditional project stages.

This project wasn't your traditional project. Standard staged gates were too linear. A truly agile project approach had to be adopted. This doesn't lend itself to the traditional stop and study routine of the 6 staged hazard studies.

Hazard Studies

Hazard Study Stage	Objectives	Key Notes for this project
Concept & Feasibility (HS1)	Understand the project and develop a plan of studies and other activities required to understand and manage the hazards.	• Inherent safety considerations. • Materials hazards and compatibility • Layout and location. • ALARP demonstration – clear list of relevant good practice. • Past incident data collated to inform later studies. • Solid foundation.
FEED HAZID (HS2)	Consequence led study to allow overall understanding of key hazards to be managed.	• Carried out on PFD and early P&IDs.

Rather than sticking to the typical checklists and formats, we went back to the original principles of what was intended by each of the staged studies.

This is a great opportunity to reflect on what was done, and pick out the learnings that we will carry forward. Hazard studies may never look the same again!

Hazard Studies

Hazard Study Stage	Objectives	Key Notes for this project
Detailed design HAZOP (HS3)	Systematic study of the design to understand potential deviations from design intent.	• LOPA normally done earlier to identify risk gaps • Initial LOPAs generated at HS2 and developed at HS3 • HS3 done early, some design aspects changed. Would normally want design to be frozen. • P&ID reviews of changes, adoption of recommendations made in initial HS3. • Full HS3 review on final design. • Action close out meetings weekly. • ALARP review done sequentially – every meeting asked – what could we do differently?

Hazard Studies

Hazard Study Stage	Objectives	Key Notes for this project
Pre Start Up Checks (HS4 & 5)	Confirmation that key safety features identified in earlier studies are installed as planned.	• Moved away from checklist approach. • Solvent ready reviews. • Reliance on other focused / targeted reviews and studies rather than duplicating.

- HS4/5 somewhat combined. Alternative approach taken – guidewords given to senior managers on site to review independently and then collated by RAS. Guidewords focused on key risk controls.
- HS5 – looked at what other studies already covering, to avoid duplicating efforts.

Pragmatic Approach

- Remote studies
- No time to stop at each stage gate
- Hazard study iterations
- Action close out
- HS4/5 interview and site tour format
- Solvent ready reviews
- Change risk assessments

Studies used to challenge and inform. There was no stopping, so had to keep things moving. Studies were 'live'.

Remote Studies

- Kept cameras on
- Ground rules
- Lots of ‘short’ sessions
- Full team engagement
- Strong leadership

Remote studies wasn’t something we had really done before. We had always avoided them in the past, thinking face to face were much more productive and valuable. This wasn’t an option here. Had to run remotely so as not to risk the on site personnel, couldn’t jeopardise the progress of the project.

The remote sessions were very successful. Some reasons why:

- Kept cameras on – could see if someone was itching to speak, or disagreed with something – not as easy as when in the room, but still got some of the body language.
- Ground rules – to make sure we got best use of all sessions, we couldn’t afford to waste any time
- Lots of ‘short’ sessions – remote sessions are more draining, so we had to be wary of this
- Full team engagement – everyone knew how important it was, so they committed time and resource fully
- Strong leadership – was important to be able to say, ok we aren’t quite ready, or that’s enough for today

Agile

- LOPAs, drafted after HS2, and then reviewed at HS3
- Risk quantification revisited at multiple points. ALARP built in at every stage, with a final review, using LOPAs to focus further efforts.
- Time was in diaries, re-purposed depending on availability, what information was ready
- Regular third party interjection – questioning / asking to be convinced
- Design changes - Regular review of changes, flag any that were considered critical, team re-study.
- Studies kept 'live' as actions closed out.
- Action close out by team, team decision on amount of evidence needed to close out. Significant items confirmed as adopted at HS4.

Wasn't a linear project timeline, had to keep agile.

Action Management

- Actions were closed as we were going. Very important to stay on top of as once plant went live it wasn't stopping.
- Regular meetings to ensure 'readiness'
- Included other studies on the path to getting ready to go live with the plant – PUWER, Human factors…

Dealing with Road Blocks

- Anything considered as a hold up risk – taken ‘offline’ and assessed if acceptable to proceed / temporary measures to allow progress
  - mystery heat generation
  - breakaway couplings causing offload issues
- Delay / stop if needed before allowing to continue or go live.

Solvent Ready

- Focused approach for HS4/5
- Collated list reviewed and high priority actions identified. These had to be done before solvent could enter the plant. This included electrical and DSEAR sign off.
- Daily meetings for updates on these actions.
- One week later, plant was ready for solvent.
- Solvent ready acceptance of bulk tanks, followed by rest of the plant sequentially

Commissioning

- Run on days with two engineers
- Commissioned in two weeks – expected to be four to six
- First batch the week after, released for use
- Operator support and training for six weeks after on 24/7 basis. Rolling day and night cover by two project engineers until all Operators capable of running plant by themselves

Steady State

- Continuing phone support 24/7 if required. Used a lot at first, now very little.
- Regular packing off and all material product used in a major vaccine throughout the world.

Ingredients for Success

Right People

- Engaged and focused team.
- Competent team with multidisciplinary composition.
- Independence for reviews.

Right Process

- Not letting go of the rigorous process.

Right Time

- Freeing time by going back to first principles and creating an agile approach.


RAS
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