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DESIGN AND SUPPLY OF 3000 LITRE FULLY AUTOMATIC AUTOCLAVE FOR THE PHARMACEUTICAL INDUSTRY

GEORGE COUVARAS

DESIGN AND SUPPLY OF 3000 LITRE FULLY AUTOMATIC AUTOCLAVE FOR THE PHARMACEUTICAL INDUSTRY

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A project report submitted to the Faculty of Engineering, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Engineering.

Johannesburg, 1985

DECLARATION

I declare that this project report is my own, unaided work. It is being submitted for the Degree of Master of Science in Engineering in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination in any other University.

.....

17TH day of DECEMBER 1985

ABSTRACT

The purpose of this project report will be:

(i) To outline the undertaking of a relatively small and unique project in the South African pharmaceutical industry which involved:

- Specification and contracts.
- Prices and estimates.
- Project organisation.
- Conceptual design.
- Planning.
- Drawings.
- Procurement.
- Manufacture and assembly.
- Cost and project controls.
- Installation, commissioning and handover.

(ii) To compare the actual handling of each phase of the project to the current, accepted theory on project management.

The major conclusions that can be drawn from the comparison of the actual to the theoretical handling of this project are:

(i) It is essential in the initial stages of the project to accurately define the scope of the project and to correctly establish systems and design parameters.

(ii) The correct contract agreement should be drawn up between the client and contractor.

(iii) During the life of the project appropriate and effective planning and control systems are required to monitor and correct costs, performance, productivity, timing and quality.

(iv) Where required, the contractor should also offer an effective maintenance and after sales service.

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1 INTRODUCTION

1.1 Requirements

Adcock Ingram of the pharmaceutical industry required a unique autoclave for the sterilisation of certain of their products and equipment.

1.2 Solution

Due to the uniqueness and size of this autoclave, Adcock Ingram appointed Kemmek (Pty) Limited as project consultants responsible for the manufacture, supply, installation, commissioning and final handover of the autoclave. The author was appointed by Kemmek (Pty) Limited as the project manager for this project.

1.3 Aims of this Report

The aims of this report are to outline the way this relatively small project was handled in the local environment and to compare the handling of this project with current theories on project management.

2 SPECIFICATIONS AND CONTRACTS

2.1 Initial Specifications

The project was initially conceived and developed solely by the client, Adcock Ingram, for their particular production requirements. Before approaching any contractors, Adcock Ingram compiled a specification for an autoclave based on their past experience with smaller, standard autoclaves.

2.1.1 Requirements

The autoclave was required for:

(i) The terminal sterilisation of a range of parental products filled in glass containers or ampoules.

(ii) The sterilisation of equipment such as receptor vessels, filter housings and machine parts which are used in the manufacture of such parental products.

2.1.2 Clients specification

According to the client, Adcock Ingram, the autoclave had to meet the following specifications:

(i) All contact parts had to be constructed of 316 L stainless steel.

(ii) An unusable chamber volume of 3000 litres was required.

(iii) The autoclave had to be horizontal so that it could be installed between two rooms.

(iv) The autoclave had to be fitted with doors at each end for the loading of dirty products from the one room and the unloading of the sterilised products in the other room.

(v) The autoclave's chamber and doors had to be suitable for a pressure of 276 Kpag and a vacuum of 5 Kpa abs.

(vi) The chamber of the autoclave had to be a cubical design for ease of loading and unloading trolleys packed with the items to be sterilised.

These trolleys were to be designed and supplied by the manufacturer of the autoclave.

(vii) As the autoclave was a pressure vessel it had to be constructed in accordance with the ASME VIII[1] code and in compliance with the rules pertaining to the design and construction of pressure vessels as prescribed in the Factories Act (Act 22 of 1941, as amended).

(viii) The operation of the autoclave had to be fully automatic so that a factory worker could easily operate the autoclave alone by:

- Loading the "dirty" items onto trolleys and then pushing the trolleys into the autoclave via the "dirty" end.

- Shutting the door and then selecting an appropriate programme for sterilisation.
  At this stage the items had to be automatically sterilised to an acceptable standard as laid down in SABS Specification 982[9].

- Unloading the sterilised items into the "clean" area via the "clean" side door.

(ix) The sterilisation operation had to be completed within two hours.

2.2 Awarding of Contract.

2.2.1 Prices

Based on the specification described above, Adcock Ingram approached several contract companies for a fixed price for the design and supply of such an autoclave.

As such an autoclave had never previously been fabricated in South Africa, only two contractors were prepared to submit quotations.

The one company was a Johannesburg based manufacturer of small autoclaves for sterilisation of laboratory equipment and other small items. They submitted a fixed price within four weeks of enquiry.

The other company, Kemmek (Pty) Limited, a group of consultant chemical engineers, was also prepared to submit a quotation. They had in the past, together with a sub-contractor, Albert Moore of Cape Town, been responsible for the supply of several large, locally made sterilizers in South Africa. Most of these autoclaves are in operation in the Johannesburg Hospital.

As such an autoclave had never been previously fabricated and tested, Kemmek submitted a price based on a cost plus for the development, design and specification with a fixed price to follow once the project had been more clearly defined.

Adcock Ingram however rejected such a quotation. As Kemmek were confident that they could handle the project, they decided to then submit a fixed price quotation. This was based on a specification drawn up by themselves detailing every item and the scope of work they were to supply.

Although this was costly and time consuming, it safeguarded both the client and the contractor, Kemmek, as both parties were then aware of the scope of supply.

Based on this revised fixed price, Kemmek were then awarded the contract and the author was then appointed as project manager.

2.2.2 Types of contracts

According to Harrison[6] there are theoretically four forms of contracts that can be drawn up between clients and contractors.

(i) Fixed price contract

In this type of contract, a contractor agrees to supply a well defined and fixed requirement, based on definitive specifications and drawings.

This type of contract is used where:

- There is little likelihood of significant changes to the design.
- The cost inputs remain stable.
- The project design is fully specified.
- There is no new technology involved.

Advantages of this type of contract are:

- The client is aware of the major part of the final cost of the project early on in the project.

- The client can select the most lucrative contract from all the competitive bids.

- The contractor is motivated to finish on schedule.

- The contractor has a high concern for cost control. If costs are managed properly and the work carried out efficiently, the contractor can achieve a higher profit than with any other type of contract.

Disadvantages of this type of contract are:

- Work on the project can only begin once all aspects have been fully specified and the contract awarded.

- Preparation of fixed price bids are costly to the contractor.

- If the contractor goes bankrupt during the life of the project, there are messy litigation problems.

- There is not the same direct client, contractor involvement as with other contracts. This can result in the contractor using inferior, cheaper quality materials to trim his costs.

- The contractor can make a loss if he underestimates or has trouble with the project.

- Every time the client requests a major change, the fixed price has to be adjusted and generally the project finishing time is adversely affected.

(ii) Cost plus contract

In this type of contract the contractor is reimbursed on the basis of all direct costs incurred plus a percentage of these costs to cover the contractor's overheads and profit.

Here the contractor is limited to a small margin of profit, but he has no risk of making a loss. This contract is appropriate for a project with new technology where considerable research and development is initially required.

Advantages of this type of contract are:

- The contractor can begin work on the project immediately while the specifications are being finalised.

- The client and contractor develop the project together. Corrective changes can be effected at the right time during the life of the project instead of at its end. The client is also involved with the selection of materials and is thus ensured of the most suitable quality.

- If the client is dissatisfied with the performance of the contractor, he can discharge the contractor with relatively little legal involvement. This however is generally done only in extreme cases of inefficiency as it is costly to appoint and familiarise another contractor with a project which has already begun.

- The contractor is ins[illegible]gainst expensive design changes by the client.

Disadvantages of this type of projects are:

- The contractor does not have the financial motivation to complete the project on time. This type of abuse is generally avoided as contractors have to maintain a good reputation to ensure the chance of being awarded future contracts.

- The client is not certain of the economic viability of the project as he is unaware of its final cost. If the client however exercises good controls, he can accurately forecast a final figure.

(iii) Cost plus and then fixed type of contract

With this type of contract the contractor is on a cost plus basis at the start of the project until all aspects of the project have been clearly defined. Thereafter a fixed price is set based on the specifications drawn up by the client and contractor.

The advantage of this type of contract is that the project gets a quick start. The disadvantage of this type of contract is that it limits competitive tendering by contractors. The client does however have the opportunity of changing the contractor before the fixed price section of the work is awarded, although this does not generally occur.

(iv) Cost plus with bonus/penalty enhancement type of contract

With this type of contract, the client pays the total actual nett cost of the work. The contractor's profit is paid separately as a fee subject to upper and lower limits. Thus, based on his performance, the contractor's fee can either be boosted by a bonus or reduced by a penalty.

The amount of the fee is determined by comparing the actual cost of the project to the target cost as tendered by the contractor. This target cost is updated at regular intervals depending on any major specification changes that occur during the life of the project.

Incorporating this bonus/penalty into his fee, gives the contractor an incentive to avoid overspending.

Contractor's fee = 0,045 FTC + 1/3 (FTC - AC)

Where FTC = Final Target Cost

and AC = Actual Cost

This is however subject to the contractor's fee always being greater than or equal to 0,02 FTC.

This fee can also be modified to incorporate a time incentive so the contractor can be motivated to complete the project on time or earlier.

Contractor's fee = 0,034 FTC + 1/3 (FTC - AC)
+ (0,034 FTC)|{1 + 2 (TCT - ACT)}/ACT|

Where TCT = Target Completion Time
and ACT = Actual Completion Time

Again the contractor's fee is always greater than or equal to 0,02 FTC.

The main advantage of this type of contract is that there is always a close client/contractor working relationship.

The main disadvantage of this type of contract, is that no matter how bad the contractor's performance is, he is always assured of his minimum fee i.e. in the above case, 2% of the final target cost of the project.

2.2.3 Contract awarded in actual situation

In this case, the insistence by Adcock Ingram for a fixed price before the start of the project, was an error which affected the project throughout its life. At such an early stage of a project with new concepts, it was very difficult to accurately specify all the basic requirements.

As outlined above, it is essential to all concerned that before a fixed price contract can be drawn up, all interested parties should be totally familiar with the extent of their commitments in the project. Also, it is vital that the project be fully specified with only minor design changes being anticipated in the future.

In the actual case, in the early stages of the project both the client and contractor were not fully confident in the initial selection of the autoclave and its computer system. As described in Section 5.2 below, this resulted in a re-assessment of the basic specifications of the project. This in turn led to several costly design changes and time delays.

According to the theory as outlined in Section 2.2.2 above, this initial groundwork should however have been carried out on a cost plus basis with a fixed price contract only being drawn up once all the major design specifications had been finalised.

Understandably, Adcock Ingram was in favour of a fixed price contract from the start as they required to be aware of the extent of their financial commitment for budget purposes. They were also of the opinion that any other type of contract, based on a cost plus basis, would have been inflationary and might have been abused by the contractor.

In the actual case however, the most appropriate method of drawing up a contract, which would have best suited all concerned, would have been as follows:

(i) As this project was of a unique nature, with no past records on which any future design work could have been based, all the initial groundwork, feasibility studies and specifications should have been carried out by both the client, Adcock Ingram, and the contractor, Kemmek (Pty) Limited.

During this stage of the project the contractor should have been employed on a cost plus basis where all the hours he spent working on the project were reimbursable. The advantages of drawing up this type of contract at this stage in the project, would have been:

- The client would have been totally involved during this stage of the project.

- The client would have been in total control of the specifications and thus could have ensured the selection of the most appropriate materials and equipment.

- The contractor would not have been in jeopardy of losing any money and could thus have concentrated on laying the groundwork for accurately specifying and planning the project.

- The client would have been in control of the financial aspect of this stage of the project and would thus have avoided any cost abuses.

- This stage of the project would have been taken up to the point where the client together with the contractor would have specified all the major equipment, defined all the design parameters, selected all the vital materials and defined the aims of the project.

- The client would have by this time have had an accurate assessment of the final cost of the project.

(ii) Based on the specifications drawn up during the first stage of the project, the client should then have requested a fixed price quotation from the contractor for the completion of the project. If for any reason, the client was dissatisfied with the performance of the contractor during the first stage of the project, he could again have approached the marketplace for comparative bids from other contractors.

Author Couvaras George
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