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Design and supply of 3000 litre fully automatic autoclave for the pharmaceutical industry

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8.4 Preparation of Order

Each order was carefully drawn up in favour of the supplier.

Apart from the general description of the items to be purchased, where applicable, the following clauses with their respective descriptions were included in the orders:

- Quality of the finish.
- Design pressures.
- Materials of construction.
- Safety requirements.
- Commissioning instructions.
- Delivery details.
- Insurance cover.
- Packaging instructions.
- Maintenance requirements.
- Inspection details.
- Manuals required.
- Spares required.
- Paint specifications.
- Payment terms.
- Guarantees.
- Penalty clause. On all critical items, as an incentive to avoid late deliveries, a penalty of 1% per week of total order was imposed for late delivery to a maximum of 10%.

8.5 Inspection

Before any items were delivered to site, they were thoroughly inspected by the contractor at the suppliers' works.

8.6 Comparison to Theory on Procurement

According to Harrison[6], firms supplying material and equipment are no different to other sub-contractors working on the project and are an essential part to the overall project organisation.

The procurement function on a project includes:

- The procuring of equipment and materials.
- A complete follow up of all items ordered to ensure they are in accordance with relevant specifications.
- A regular check on all orders to ensure that they are progressing on schedule and that they will be delivered on time.

This procurement function is usually handled by a separate buying department in close coordination with the project manager. With this project however, due to its relatively small size and budget, this function was handled directly by the project engineer with the assistance of one buyer who was mainly responsible for the administrative work.

The procurement function can be divided into four sub functions:

- Project liaison.
- Buying.
- Inspection.
- Progressing and expediting.

9.6.1 Project liaison

According to Kerzner[7], during this stage of the procurement function, the persons or departments in charge of buying should ensure that:

(i) Commodity lead times are accurately ascertained so that future requirements can be identified and incorporated in the overall project plan, and that engineering drawings and specifications can be revised in sufficient time.

With this particular project, the main concern in the overall plan was to establish the type of autoclave required and the lead times associated with its design and manufacture. The other services such as the instrumentation, electrics, pumps and piping were locally available and thus, although also vital to the overall project plan, did not constitute a major obstacle in the project completion time. Thus, once it was decided to design and manufacture the autoclave locally, all specifications and delivery times of secondary materials and equipment were planned around the manufacture of the autoclave.

(ii) An updated register of potential suppliers of equipment is maintained. It is essential to always seek out new sources of supply, processes and techniques which may enable the project to be completed more profitably and quickly.

With this project, wherever possible, three suppliers of similar equipment were always approached for information and quotations so as to ensure optimum equipment selection.

(iii) The suitability of potential suppliers is assessed. In the interests of the project, it is essential to continually examine both existing and potential sources of supply to ensure that:

- They are technically competent.
- They have adequate facilities and capacity to carry out the necessary requirements.
- They have sufficient inspection and quality control procedures to ensure products of an acceptable standard.
- They are financially sound.

Where necessary, potential suppliers should be visited by the project engineer with the aim of assessing the suppliers' reliabilities and capabilities to handle the work.

(iv) Accurate commodity prices are obtained to ensure that correct information is used in the preparation of orders.

With this project, as indicated above in Section 3.1, the contractor ensured that most prices which were obtained were not subject to escalation for twelve months. Where a supplier insisted on an escalation clause, that particular price was then based on escalation calculated according to SEIFSA[10].

Where imported equipment is required, the commodity prices should regularly be updated in accordance with the relevant rate of exchange until such time as the order is placed and the price can be fixed.

(v) The suppliers' commercial conditions, such as payment terms, are suitable.

(vi) The technical specifications, requisitions and enquiries for all materials and equipment are accurately itemised and prepared.

Where an item is of a unique design, nature and specification, as with the autoclave in this project, the client and contractor should participate fully in the compiling of the enquiry.

8.6.2 Buying

This stage of procurement involves the obtaining of bids from suppliers and the subsequent placing of orders.

There are basically four types of purchases involved:

(i) Equipment which is designed by the supplier, as in this case the heat exchanger used on the cooling cycle of the autoclave.

(ii) Equipment which is designed by both the client and the supplier, as in this case the autoclave itself and the holding tanks.

(iii) Materials which are standard with regard to the suppliers' stocks, as in this case the piping, pumps, instruments and electrics.

(iv) Services such as in this case sub-contractors to supply, install and commission the computer system required for the autoclave's programmes.

The functions then involved in buying, and generally adhered to with this project, are:

(i) To determine suitable suppliers of material or equipment, not yet established in the earlier stages of the project.

(ii) To formulate and issue formal purchase enquiries.

(iii) To then commercially evaluate offers received from potential suppliers.

(iv) To compare offers received against the allocated budget allowances. In addition the project manager or buyer responsible should ensure that the funds and authorisation for that particular expenditure are available. Where the offers exceed the allowances, it is then necessary to obtain either a modification to the project requirements or an authorisation to overspend.

(v) To prepare suitable purchase orders in favour of the selected supplier embodying requirements with respect to:

- Quality.
- Design.
- Inspection.
- Documents and certificates required.
- Delivery or completion dates.
- Supporting services required.
- Contractual commitments.
- Payment terms and other commercial aspects.

(vi) To then issue the formal order with the selected supplier and to ensure that the supplier is in full agreement with the terms of the order and that he is aware of his contractual commitments and responsibilities. It is at this stage that any alterations to the orders should be made if any justifiable discrepancies arise.

(vii) To ensure, that where necessary, the supplier can execute work on sites removed from his normal place of business.

(viii) To resolve delays involving the manufacture and delivery of suppliers' equipment.

(ix) To determine and negotiate where necessary appropriate rates of pay and material costs to be paid for any additional work that may be requested and subsequently authorised.

(x) To impose the fiscal commercial conditions of the order on defaulting suppliers. These conditions could be penalties for late deliveries or damages claimed in respect of faults and deficiencies in guaranteed equipment or performances.

8.6.3 Inspection

This involves the physical inspection of equipment and materials to ensure that they comply with the purchase orders, relevant specifications and statutory regulations. The frequency of these inspections is dependent on the sophistication of the equipment being supplied.

With this project three major inspections were carried out at the sub-contractor's works during the manufacture and assembly of the autoclave. These inspections were carried out in conjunction with the client and were conducted at the manufacture stage, assembly stage and performance testing stage of the autoclave.

On the other hand, with relatively simple orders, such as the manufacture of the holding tanks, one inspection generally sufficed. This inspection was always carried out just before the equipment was to be delivered to site as only minor alterations were usually required.

At this stage, should the need arise for any major design alterations which might affect the outcome of the project, the project engineer should ensure that the proper authorisation is obtained and that the client is always kept fully informed.

8.6.4 Progressing and expediting

This function involves the continuous review of the performance of suppliers and sub-contractors. It involves the reporting of the status of all orders, from order placement to delivery. It also involves the exerting of pressures, where necessary, to ensure the maintenance of planned performance.

The functions of progressing and expediting are:

(i) To determine whether any purchase order should be subjected to routine progressing. This decision is normally dependent on the complexity, value and importance of the order and on the supplier's past delivery record.

As stated above, with this project, the only orders which required routine progressing were those orders for the autoclave and its computer system.

(ii) To obtain formal delivery commitments from the suppliers.

(iii) To obtain, where required, details of the suppliers' manufacturing plans and to monitor the progress of the work during manufacture as with this project where the manufacture of the autoclave was closely monitored.

(iv) To monitor suppliers during the life of the order and to eliminate or minimise, in conjunction with the suppliers, any disruptions or delays to their commitments.

(v) To conduct final, detailed, quality control inspections on equipment and materials to ensure that they comply with the specifications as laid out in the purchase orders. Depending on the item involved, it may be necessary for the client to be present at such final inspections.

(vi) To issue delivery instructions to supplier ·nce orders are completed to everyone's satisfaction.

(vii) To regularly advise interested parties as to the status of orders and to ensure that where necessary prompt remedial action is taken.

(viii) To ensure that goods are delivered in good condition to site and to ensure that any site operations, that are required from the suppliers, are conducted according to the contractual requirements.

(ix) To ensure that once an order is satisfactorily executed, final payment is promptly effected. In most items, a certain percentage of the total cost is retained for a certain period after delivery, usually three months as with this project. This retention is a safeguard to ensure against any unforeseen faults in quality or operation. If such faults do arise, the suppliers should be notified immediately to avoid the expiry of the retention period.

The following chapters include a description of how this progressing and expediting was carried out on the project in this report.

9 MANUFACTURE, ASSEMBLY AND TESTING OF AUTOCLAVE

9.1 Manufacture

The chamber, jacket and doors of the autoclave were constructed at the works of the sub-contractor, Albert Moore.

As the autoclave is a pressure vessel, it was constructed in accordance with the ASME VIII code[1] and under the supervision of an independent inspection authority.

The relevant inspection certificates and those certifying the quality of the stainless steel were then submitted to the client.

At the end of this stage of manufacture, the client and contractor carried out a detailed inspection of the work.

9.2 Assembly

The autoclave was assembled on a framework. All piping, instruments, pumps, vacuum pumps, minicomputer and printer were assembled on this framework as per the contractor's design.

Thus, the autoclave could easily be commissioned at the assembly point before despatch.

Also, the autoclave could be transported as one unit to the Adcock Ingram site where only the connections to the various services and holding tanks had to be completed.

During this assembly stage, another detailed inspection was carried out by the client and contractor.

9.3 Performance Tests

Before the autoclave was despatched to the client, the client and contractor carried out extensive performance tests. These tests lasted six days.

During these performance tests, samples of ampoules and receptor vessels supplied by the client were put through the sterilising cycles to ensure that they were sterilised to an acceptable standard as laid down in SABS Specification 982. The following major problems arose and were rectified:

(i) The autoclave has eight strategically placed thermocouples and once the chamber has reached the sterilising temperature, these eight thermocouples were required to register a temperature variance of no more than one degree centrigrade. During the tests, temperature variances of up to five degrees centigrade were registered. The reason for this was found to be that the one door gasket was not sealing completely. The gasket was consequently replaced and the tests were then repeated with satisfactory results.

(ii) After the sterilising cycle is completed, the chamber is cooled down to forty degrees centigrade using cooling water in the jacket. This step was designed to be completed within thirty minutes, but during the tests it was taking up to 90 minutes. After re-checking the cooling system, it was found that the pump supplying the cooling water was cavitating. The suction lines to the pump were redesigned and replaced. The rate of cooling consequently reduced to within the acceptable limit of thirty minutes.

(iii) Other minor problems such as aligning the pipework around the autoclave, properly securing the instruments to the framework and attaching clear and concise operating instructions on the face of the autoclave, were rectified.

Once the performance tests were completed to everyone's satisfaction, the autoclave was despatched to the client's site.

With every project this period of testing is crucial and should be used to overcome all unforeseen problems which might arise during the project's life. With this project it was found that the time finally spent on such tests was approximately one percent of the project life. This time, however, is dependent on the size and nature of the project. It is therefore the project engineer's responsibility to initially assess the complexity of the project and to allocate the appropriate testing period.

With every project this period of testing is crucial and should be used to overcome all unforeseen problems which might arise during the project's life. With this project it was found that the time finally spent on such tests was approximately one percent of the project life. This time, however, is dependent on the size and nature of the project. It is therefore the project engineer's responsibility to initially assess the complexity of the project and to allocate the appropriate testing period.

10 COST AND PROJECT CONTROLS

According to Kerzner[7], control systems are generally implemented for two reasons:

(i) To monitor efficiency, progress and cost.

(ii) To assist the project manager in maintaining an effective grasp on the project.

It is essential that the controls that are implemented are relevant and effective and not weak and too late.

10.1 Budget

At the quotation stage of the project the contractor drew up a budget itemising every activity and equipment as he understood the project. With each activity an expected cost was associated. The total of all these costs, plus the contractor's profit and contingency included, was the budget price for the project.

After the conceptual design stage and final approval by the client this budget, with its associated activities and costs was updated. From time to time, during the life of the project, this budget was again adjusted four times to meet new requirements by the client or to include items which were essential to the project and which were initially overlooked. On completion of the project, the actual cost of the work performed was 15% higher than the initial budgeted cost for the work scheduled.

10.2 Variance Analysis

The cost of each activity in the budget was divided over the life of the project dependent on how and when the money was to be spent.

Every two weeks the amount spent on each activity was compared with the budgeted cost for that period. This simple comparison was however no indication of whether the work was effectively performed for the money spent and consequently corrective measures were not always carried out at the right time.

Fortunately, as this project was fairly small and simple, it was easy to maintain an effective control over costs.

Kerzner[7] states that with this type of analysis there is a tendency to collect and summarise costs by function or type equipment on a project e.g. pumps, piping, instruments, etc. This is a useful form of summary for overall control but should only be a secondary form of analysis.

Variance analysis of cost should be integrated with variance analysis of progress, through some measure of progress.

Although, this project was effectively controlled with the simple comparison methods described about, ideally the following variance analysis should have been carried out on each activity for each time period and cumulative time:

- Scheduled start versus actual start.
- Scheduled finish versus actual finish.
- Scheduled time for activity versus actual time for activity.
- Budgeted cost versus actual cost.
- Budgeted manhours versus actual manhours.
- Scheduled quantity versus actual quantity.
- Budgeted unit cost versus actual unit cost.

However for large projects, this simple variance analysis does not assist the project manager to have a forward looking control system. This can be done by using modern methods of project control as described below.

10.3 Modern Methods of Project Control

Modern methods of organising project control systems are based on:

- Defining control centres.
- Performance analysis and forecasting.

10.3.1 Control centres

There are three basic control centres for costs and performance.

(i) [illegible]

These are discrete tasks or activities as defined on a bar chart or an arrow diagram. Here analysis is based on budget versus actual variance measurements.

(ii) Overheads

Overheads are costs which are not direct to any activity and thus cannot be accurately allocated to the work packages. These costs are divided amongst the work packages based on the presumed benefit the work packages receive from these indirect costs. Analysis of these costs is based on an expenditure rate over time.

(iii) Cost accounts

This is an aggregation of the work packages into separate sections of the project. From these separate sections, full performance analysis, forecasting of final costs and completion dates are then obtained.

10.3.2 Performance analysis and forecast of the final cost

This method of analysis uses three basic terms:

- BCWS is the budgeted cost of work scheduled.
- BCWP is the budgeted cost of work performed.
- ACWP is the actual cost of work performed.

These three elements are then used to evaluate the following:

(i)	Cost variance	= BCWP - ACWP
(ii)	Scheduled variance in cost terms	= BCWP - BCWS
(iii)	Cost performance index (CPI)	= BCWP/ACWP
(iv)	Schedule performance index in monetary terms (SPI)	= BCWP/BCWS
(v)	Estimate to complete the project (ETC) (where BAC = budget at completion)	= (BAC - BCWP)/CPI
(vi)	Estimate at completion or the forecast cost (EAC)	= ACWP + ETC

Thus on large projects these items can be computerised and issued periodically in the form of a performance report. From analysis of such a report, the project manager can then keep a good control on the project.

10.4 Additional Factors in Project Control

As a supplementary to the cost and project control systems outlined above, the following additional factors, which had a direct influence on the efficiency of this project, were given attention:

10.4.1 Project reports and meetings

Internally, in his own company, the contractor drew up project reports twice a month outlining the status of the project. The purposes of these reports were to:

- Communicate information on progress and problems.

- Ensure that proper control analysis and actions were carried out.

- Report any design problems.

- Highlight the results of variance and performance analysis in terms of time, money and manpower.

- To show present status of the project plan.

- Report any significant events and changes to estimates and budget.

- Identify problems and the steps taken to overcome them.

Based on the abovementioned internal report, a similar report was then drawn up for the client. These reports were then discussed every two weeks at meetings held with the client. The main purposes of these reports and meetings with the client were to:

- Keep the client informed on the status of the project.

- Effect any changes required either by the client or the contractor and thus to avoid any unnecessary major costly alterations at the end of the project.

- Identify problems and indicate steps taken to overcome them.

- Maintain a tight control on the project.

These reports in general contained the following:

- Summary page.
- Progress report.
- Back up data.

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