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Improving Diagnostics Manufacturing

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Summary

This article benchmarks key operational figures in the healthcare diagnostics manufacturing business. Its manufacturing operations lie between pharmaceuticals and healthcare consumables. Pharmaceutical manufacture requires a highly regulated facility, with less emphasis on manufacturing cost. Healthcare consumables manufacture is less highly regulated, but cost pressure is intense. Lying between these two, diagnostics manufacture suffers from regulatory constraints and manufacturing cost pressures. Controlling cost in a regulated environment demands **excellent Operations in order to compete**.

This review is based on facilities in the UK and USA and reflects the issues faced by real companies in this field. It puts figures to what is the norm and highlights where opportunities for improvement lie. There are always many places that improvements could be made. However, improvement efforts absorb energy and resources and need to be focussed.

The mantra is "Improve the Vital Few", but first be sure what these are.

Source of Data

The figures are based on thirteen different product lines with a total manufacturing expenditure of $300M/year. Individual product lines may spend between $1M and $80M per year and include a product range from 1 to 50 with final pack SKUs many times that. Detail has been analysed using a consistent methodology.

Key Measures

Key measures are:

- Operating Expense
- Inventory
- Response Time

We assert that an improvement is only an improvement if ALL these measures get better, or, at least, none of them get worse. For example a proposal to reduce cost by adding inventory is not an improvement, whilst a reduction in Response Time for the same inventory and cost is.

Where one measure gets better and others get worse, you will need to do something else to compensate. A couple of suggestions are made in the Opportunities section at the end of this article.

Before suggesting any improvements, we will take a look at what these figures typically are.

Manufacturing Cost

This is top of the list, because it is what you spend most of your time worrying about!

You can study the management accounts to find out how much is spent on materials labour and overhead (MLO). This is the conventional view and will typically show 35% of expense on materials. Making sense of labour and overhead is confused by the cost centres and accounting assumptions used. Usually you can identify “direct” labour, but a closer look shows that this does not correspond fully to what you would see on the shop floor. For example, you see QC people doing valuable work, but the chances are that they are classified as “indirect” labour.

You need other views. One such is an Activity Based Costing (ABC) approach. Here costs are broken down according to what drives them up or down. Categories are typically

- Volume related: those that change in proportion to the volume made
- Batch related: those that change in proportion to the number of batches processed
- Product related: those that change with the product range
- Facility related: those that are the same whatever is made

In a highly regulated business, batch related issues are often very significant and this approach is particularly good at highlighting them. Further, many products use raw materials of biological origin which are inherently variable. This means that constant expert vigilance is needed for each product, often requiring highly qualified scientists to conduct investigations for the lifetime of the product and certainly long after the original development is complete. This effort is recorded as “Product related” cost.

Another view comes from a combination of approaches. If you combine MLO and ABC views you get a different understanding of what is really driving costs and hence where to look for the best opportunities.

Fig 1 compares typical figures from these alternative views.

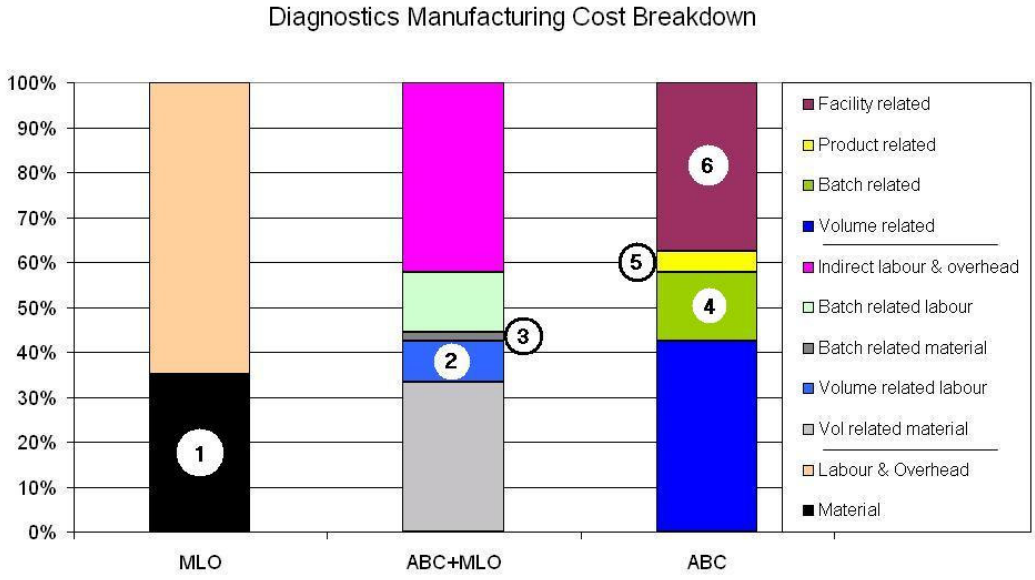

Fig 1

Important observations:

1. Material costs are 35% of the total
2. Only 9% is spent on people visibly processing material (e.g. putting solutions in bottles, assembling components and then packing them into boxes). This is Volume related labour.
3. 2% of expense (6% of material) is "wasted" on material consumed simply because of batch processes (e.g. bulk solutions left unused, for pump priming or as samples taken for QC). This is Batch related material expense.
4. 15% of expense is Batch related: batches twice as big would halve this.
5. 5% of expense is purely because of Product complexity.
6. 38% of expense is largely fixed. As well as rent and rates, this includes site management, HR, finance, most engineering, as well as industry specific costs such as Regulatory affairs and QA related costs. More detailed analysis shows that this proportion can be reduced if a manufacturing site shares more than one product line. Interestingly, this is not in proportion to the number of product lines. The figure is 31% for shared facilities and 44% for those with a single product line.
7. 6% of expense (20% of material) is wasted altogether.

Fig 2 shows the spread over a range of different product lines. Average figures correspond to those in Fig 1.

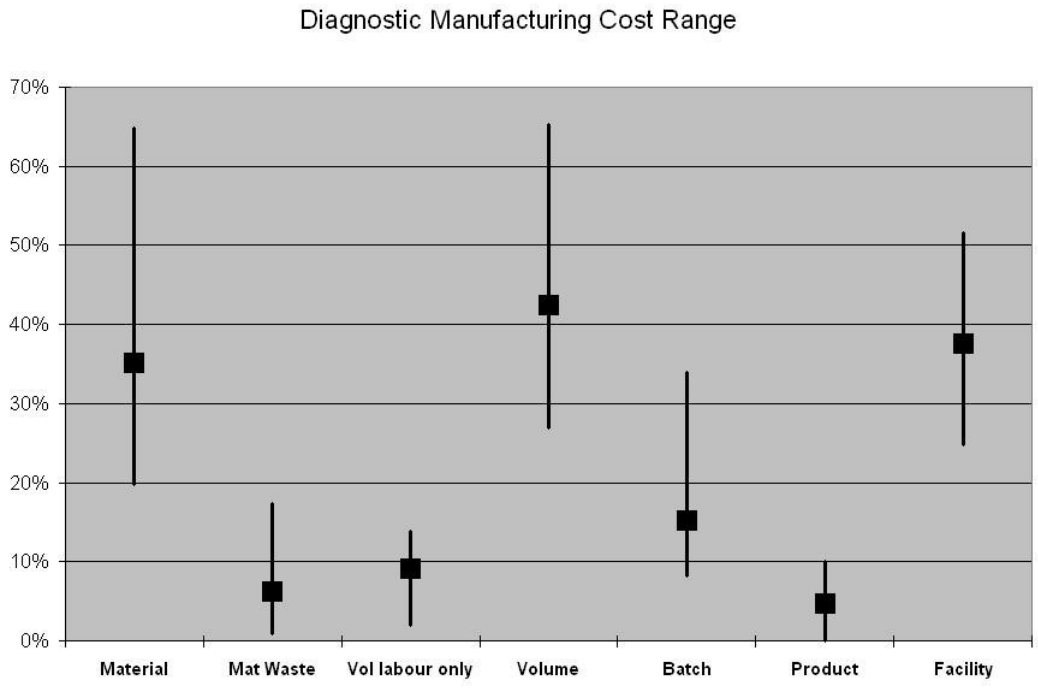

Fig 2

Inventory

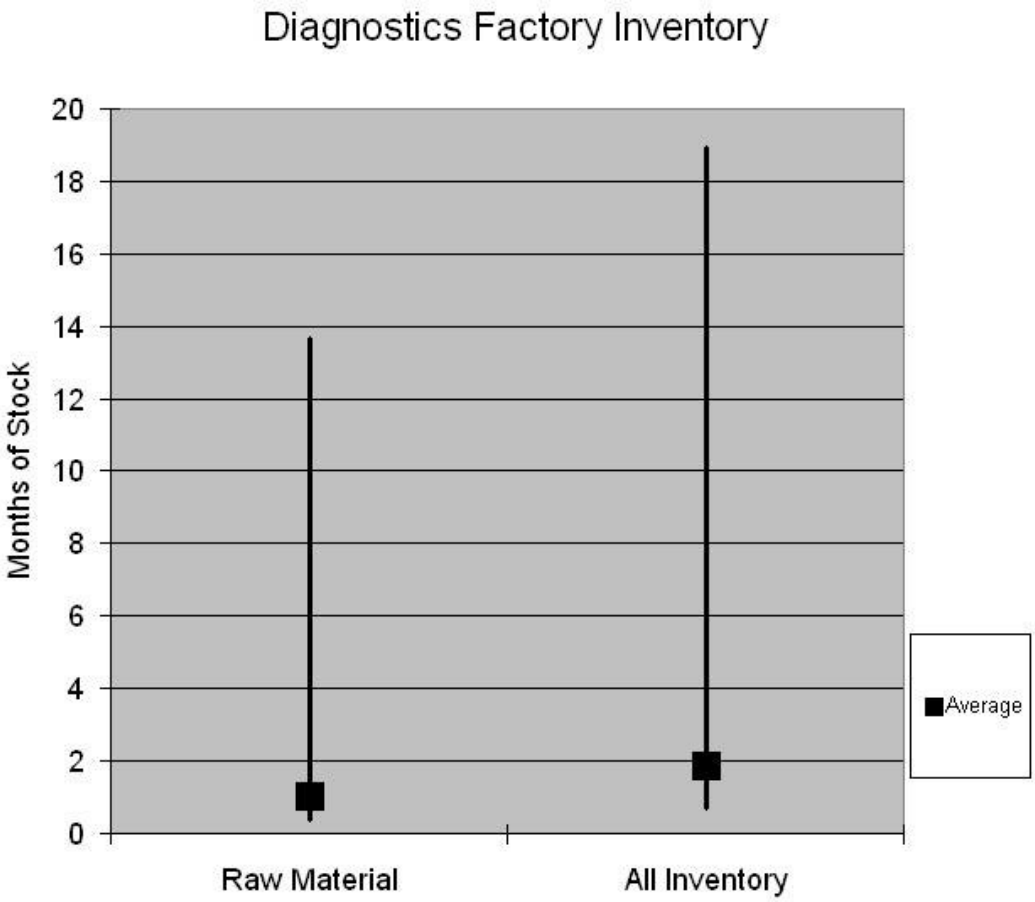

Fig 3

Fig 3 shows that the average raw material stock holding is about 1 month's worth and all inventory (raw material, WIP and finished goods at factory) about 2 month's worth. However, there is considerable variation. Some observations are:

- There are polarised views held by different managements as to whether high inventory levels are a problem
- Regulatory issues may mean holding finished goods for an extended period of time
- Raw materials may be rare and difficult to reproduce and so it may be necessary to hold high levels for strategic purposes
- Where inventory is low, it is because the product design allows it

Response Time

Response time indicates how quickly the factory would change its output with a change in demand, in the **absence** of expediting action. It takes account of batch frequency (more frequent batches shorten Response Time) and manufacturing lead time.

Arguably Response Time = 0 is the goal of Lean Manufactuting.

Further explanation and discussion of its business significance is done in another article viewable at www.HealthcareManufacturing.com.

Fig 4 shows the range for manufacture of diagnostic products.

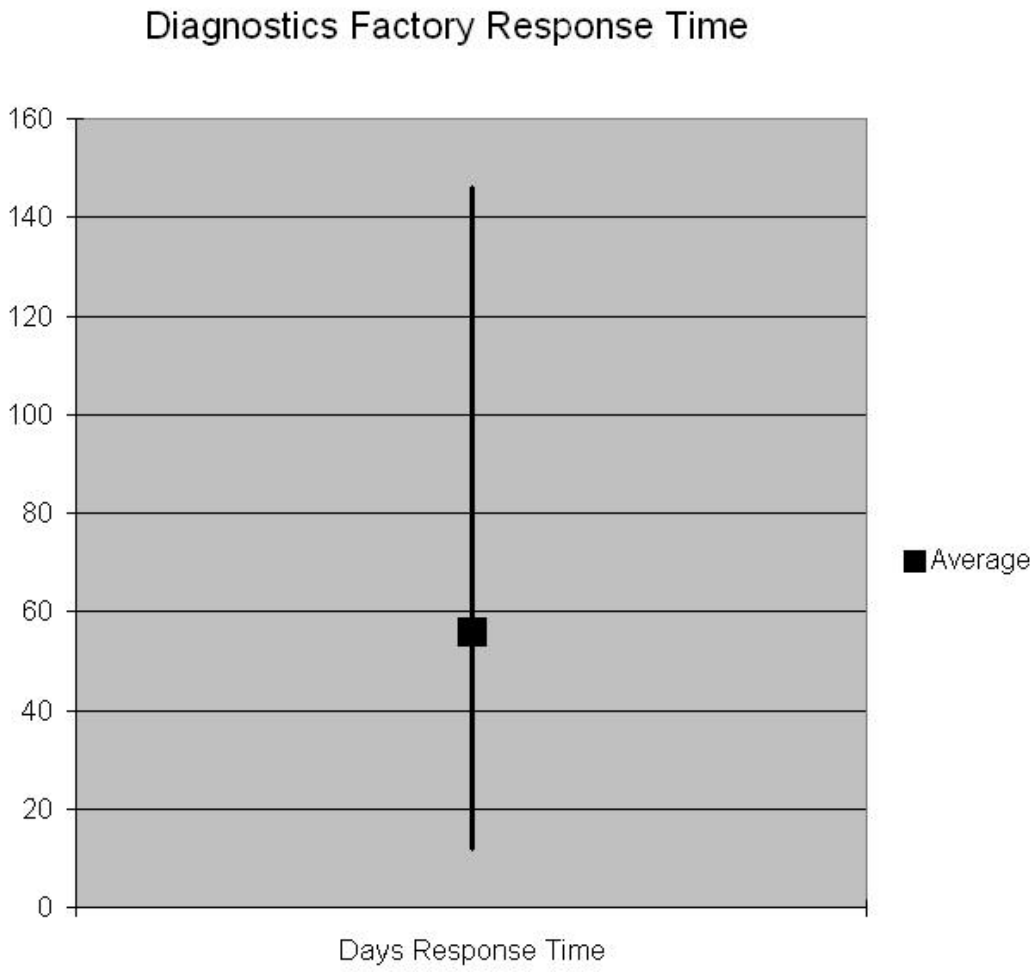

Fig 4

56 days is typical.

Response time is an indicator of the likelihood of going out of stock. In the healthcare business, after product recalls, this is usually the most serious operational default.

Business Realities

Most healthcare supplies businesses have these features:

- End user consumption is uniform through the year
- Delivery reliability is a major customer requirement
- Quality must be guaranteed
- Distributors add variation to demand
- Purchasing troughs in the winter and summer holidays distort true demand
- Health budget restrictions create a downward pressure on prices

For diagnostics, there are particular issues:

- Users prefer to hold large stocks of one batch in order to avoid batch to batch variation
- A wide product range is important to the decision to purchase the diagnostic system
- Shelf life considerations are more likely to restrict stock holding than problems of finance or obsolescence

Opportunities

Putting together the business realities and typical operational performance, we can suggest 8 opportunities for improvement:

1. **Reduce response times** by inserting stocking points immediately after process steps with problematic first pass approval rates. This will increase inventory levels at this point, but it should then be possible to reduce inventory downstream (possibly at distributors). The reduction in stock holding downstream is made possible by the more reliable supply that the upstream stocks promote. The improvement will thus be seen in both response time and inventory.
2. **Reduce batch size** to reduce response times further. This would normally increase cost. So, you will need to perform changeover reduction improvements in key processes in order to bring those costs back down again.
3. **Increase batch size** if it can be done without increasing response time. Possibly increase factory inventory whilst reducing distributor stock. (potential 15% of cost)
4. **Reduce the amount of valuable material supplied to the customer** to achieve the desired effect (potential 30% of cost).
5. **Reduce batch related effort** generally (potential 15% of cost)
6. **Consolidate** facilities (potential 13% of cost)
7. **Reduce material waste** (potential 7% of cost)
8. **Design out** the need for expensive strategic raw materials

There is one area that most people try to address, but we suggest that it should not be a priority:

- Automation of volume related tasks, unless it is for quality or capacity reasons. The capital investment and engineering effort needed rarely justify the cost savings that ensue. This is because there is usually so little cost involved in "volume related" activities in diagnostics manufacturing.

Better still is to be aware of these issues when designing the product and processes for its manufacture and distribution.

More ideas at www.healthcaremanufacturing.com