The Link
Process, Material, People, Technology

What Is BPA?

A lot of businesses are now into change management. In order to deliver this they involve themselves in a number of TLAs (Three Letter Acronyms). Business Process Re-engineering (BPR), Business Process Modelling (BPM), Business Process Improvement (BPI), and what underpins it all Business Process Analysis (BPA). All of this appears to be the "new" science of making businesses perform better.

In fact it is an old science and has a number of other names and other descriptions. Accountancy firms have set up Procedures Manuals. Or in the laboratory world there are Standard Operating Procedures. And of course ISO 9000 and its derivatives of Quality Management or TQM are all in the same arena.

In simple terms, it is about looking at the business and setting down all the rules that are needed to run the business. Because businesses are complex, it is easy to look at the BAU (Business As Usual) model and note that there are some efficiencies that could be made; and in such a way improve the quality and financial capability of an organisation.

Why BPM?

Is there a difference between Procedures Manuals, SOPs and Business Process Models?

The answer is a most resounding YES.

When people try to write manuals, they try and think the process through. Write down all the instructions line by line and hope that they have not missed anything. Most manuals cover quite a lot of detail, but there is usually something missing. Very often what is missing is the link between one procedure and another. Assumptions are made that the reader understands how to take this leap.

With Business Process Modelling (or Business Process Mapping), a map of the business is made, and any missing links or unterminated processes become obvious. Not only that, but the very task of creating the model generates other "What if?" questions that inevitably improve the model on the way.

As such BPM is the ultimate tool to create the definition of how to run businesses efficiently and effectively.

More Background

In some respects, the concepts have been around for years. Noah must have used BPM when he created the ark. But there is an interesting (though not wholly apocryphal) story of how the whole method was brought up to date an initiated. It all started in the early 1900s.

The modern beginning was when the British Government started by trying to put quality into manufacturing about a century ago. Actually, it was a little bit more meaty than this. It was

the government trying to save the tax payers money - a laudable concept.

The government had agreed contracts with suppliers to produce munitions. It needed the munitions for the war effort. The manufacturers of the munitions would happily take a deposit, and if the government was lucky, it may get the munitions at some future date. But sometimes, the factory and the company producing the munitions went up in a puff of smoke. The explosive material blew up. The company disappeared with the factory. More important, so did the deposit.

The government thought that there must be a better way than this. It asked the factories to produce a definition of quality, risk and processes. Those companies that satisfied the quality criteria defined by the government won the orders. In this way less deposits were lost. This was the beginning of the quality management, risk analysis and process management in a formal way.

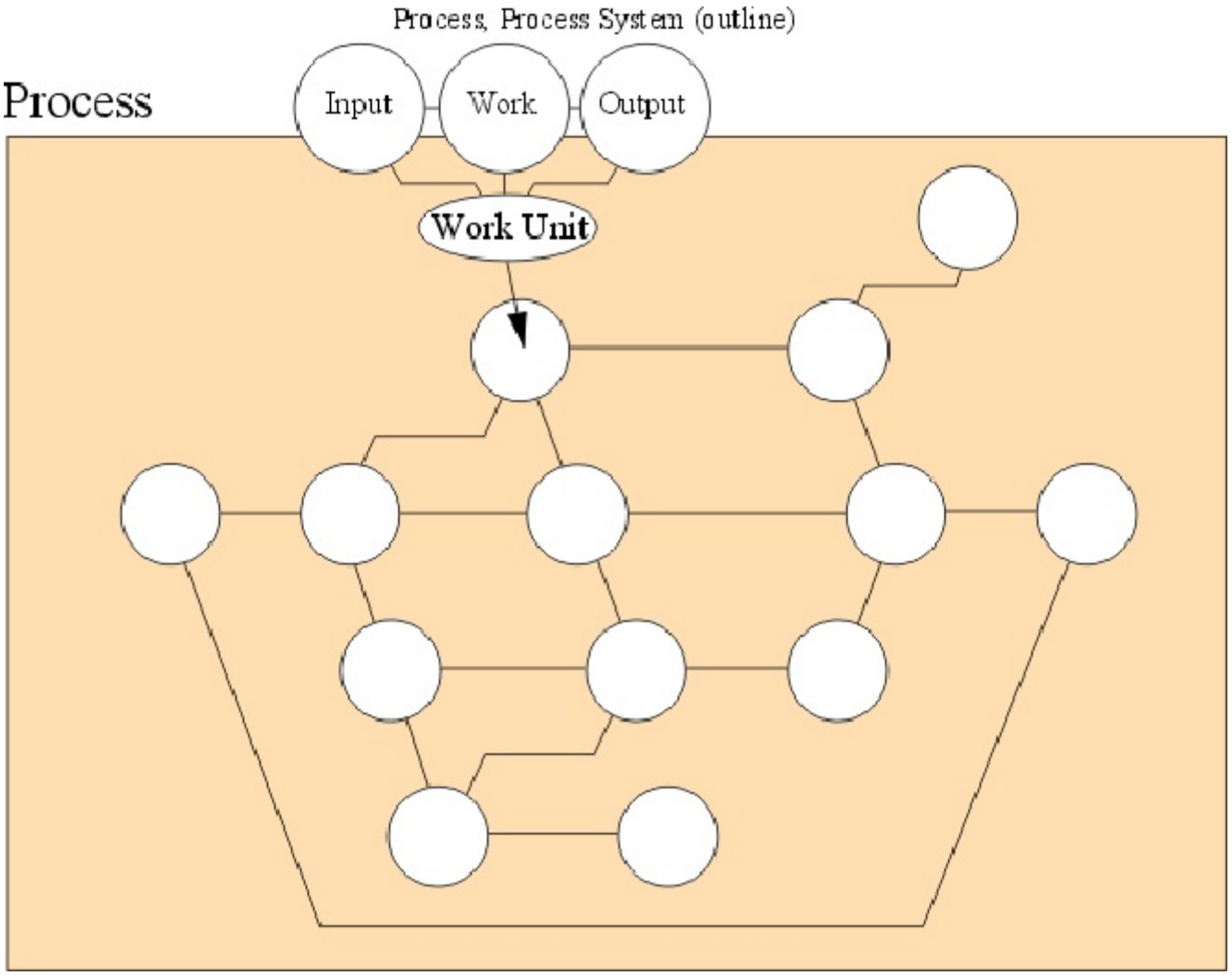
It is important to note that the government did not tell the manufacturers ***how*** to undertake their work. It asked for the manufacturers to show how they made their work ***conform to a quality standard***. The standard itself was even defined by the manufacturers. The accreditation of this was all that mattered.

Why Did It Produce The Results?

In order to understand why results were achieved, it is necessary to understand a little about the sorts of things that happen in process design.

We have already said that Business Process Analysis is all about writing down how the business works. And in a sense it is. But as we have already stated it is a little more than the description of the work. It is more than the procedures manual.

A large number of accounting companies make a fortune by writing business procedures. The procedure manuals are an excellent way of generating income and are part of the foundation of the ISO 9000 (and related numbers) accreditations. However, procedures are only part of a good process delivery. They are neither scientific, nor will they guarantee completeness. Only process analysis can do this. Process analysis is the art and science of drawing a flowchart of the business, and ensuring that all branches of the flowchart are defined. The following diagram gives some idea of the concept.



To summarise the diagram, there is at least one start point, and at least one end point. The diagram then shows the way through to the delivery of the defined process. The individual items are tasks or work units involving input, work and output. In a sense that is all there is to it. It is important to distinguish this from project plans or flowcharts. But that is a technical issue and is not addressed in this document. But an example of a difference is the decision making. The decision making is normally part of the task. A result is a decision, so the next step becomes clear - not part of another decision step.

Another way of looking at process maps is to put the tasks in “swim lanes” or “silos.” These are ways of organising the maps into either locations or responsibilities - the who does what, or the where does it happen. “Swim Lanes” are bands that go across the diagram, whereas “silos” run from top to bottom. A band defines a single area, and tasks may switch between areas. The use of the word area is vague on purpose. Area may mean responsibility - such as a person or role. However, it may also be used to mean location.

For example, in a cell banking application, the swim lanes could include the office (where paperwork is received and handled), the laboratory (where most of the work takes place), the freeze rooms (where stocks are held and accounted for). In the IVF field, then we can

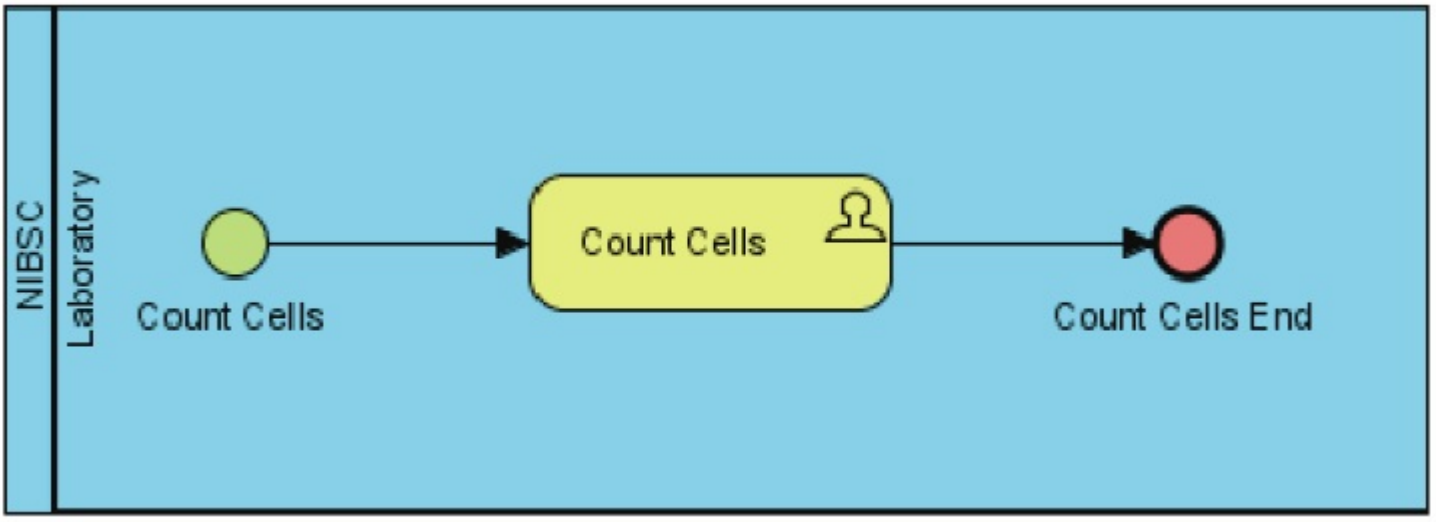
consider lanes for consulting rooms, operating theatres, even lanes for individual hoods (an ICSI hood for example).

But lanes could also be used for authority - the embryologist, the clinician, the nurse and so-on.

Task Analysis

Using process analysis, we eventually get down to task analysis. This looks at the input, the work undertaken and the output. When undertaking full analysis, it should also include a rationale for the work.

The input to tasks can be a variety of items, but will include the disposables used. Using process modelling, this allows the disposables (and their contents like media, virus additives, and biological materials such as sperm or eggs). A typical task description might contain:



Count Cells

Name	Value
Id	1
Version	0.1
Language	English
Data Based XOR Gateway Markers Visible	False
Show Lane Header	0
Show Id Option	0

Summary

Name	Documentation
Count Cells	The vacutainer tubes should be scanned to ensure that they are all of one Accession Number. The operator will need to count the cells under a microscope, and enter this count (in millions) onto the system.
Count Cells	
Count Cells End	
Laboratory	
NIBSC	

Details

Count Cells

Name	Value
Start Quantity	**1**
Suppress Join Failure	**False**
Enable Instance Compensation	**False**
Process Type	**None**
Documentation	The vacutainer tubes should be scanned to ensure that they are all of one Accession Number. The operator will need to count the cells under a microscope, and enter this count (in millions) onto the system.

Input Sets

Vacutainers

The vacutainers have been barcoded to identify them for this task. The bar codes are read to identify them for this task, and to ensure that they are all associated with one Accession Number.

HitopaqueTubes

These are not identified at this stage, but it may be useful to add a bar code to these. There are likely to be no more than two of these tubes.

PBS

PBS Media is used for this process. It is likely that this comes in 400ml bottles of which only 10ml is used, and the rest is thrown away. The bottle should have been barcoded, and this should be checked for this task. The bottle should never have been used before.

Output Sets

CountTube

Is this an input?

The tube enters the task as an empty unused barcoded tube. It exits the task as the product of this task.

CellCount
The number of cells (in millions) is requested from the operator.
Viable%
The percentage of good cells is requested of the operator.
NonViable%
The number of bad cells is calculated as 100 - Good% and displayed.
CryoTubeNumber
This is calculated from the number of cells. The normal rate is 5 million per tube. So the number of cells is divided by 5, rounded up to the next nearest whole number and offered as the suggested number of tubes. The operator may change this.
FreezeTubes
The number of tubes to freeze is normally 1. This should be offered to the operator, but the operator may change this.
ImortaliseTubes
The number of tubes for imortalised cells is normally one less than the total number of tubes. This is calculated. If the number of freeze tubes is greater than one, then the number of imortalise tubes is reduced by the corresponding amount.
DMSO
Each tube should contain 4ml of material. The amount of DMSO will be 10% of this final volume. So the amount required will only depend upon the number of tubes.
FreezeMedia
The amount of media required for both processes is calculated as follows. This is handled by example.

Suppose that there are 30 million cells, then this will equate to 6 (that is 30/5) cryotubes. This would normally lead to 1 freeze and 5 imortalised tubes. But let us suppose that the operator chose 3 of each.

The final requirement is to have 1 ml of material in each tube. But to be safe, we will add 0.5ml as a total media requirement (0.5 is a constant whatever the quantity of tuves). So we need 3.5 ml of final material. This means that for the frozen cryotubes, we need 0.35 ml of DMSO. As we have 4ml of material, we only have 2ml of white cells to make up 3.5ml of material for freezing. So we need 1.15ml of media for the freeze portion (2 + 0.35 + 1.15 = 3.5).

For the imortalising tubes we need 1.5 ml of media (2 + 1.5 = 3.5).
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For the imortalising tubes we need 1.5 ml of media (2 + 1.5 = 3.5).

References

C:/Argus/NIBSC/Screens/ScreenImages/Screen5.jpg
This screen logs information provided by the operator.

The operator enters the number of cells in millions (say 30).

The operator enters the % Viable cells.

The system calculates and displays
% Non viable (100 - % Viable)
Number of cryotubes require (millions / 5)
Number of tubes to freeze (default 1)
Number of tubes to Immortalise (Total - Freeze)
Media and DMSO requried (see main text)

The user will be allowed to change:
Use number and Freeze number

Computer Controlled Processes

Processes may be manually undertaken, run by computers, or manually undertaken and controlled by computer systems. The EPCoT ARGUS system offers the latter approach.

As may be seen from the above extract documentation, there is significant detail to show how the task is to be handled. From this type of information, with the correct modelling tools, the information is collected and used by an intelligent system to run the process. EPCoT has such a system - its CERTainty Engine and the ARGUS processor - together these take the documentation and create system processes that control the laboratory tasks. This ensures that material is labelled correctly and that the correctly labelled vessels are used appropriately through the process.

What all of this does is bring together all of the factors - the people, the location, the materials and the technology to deliver a process controlled solution.

There are a number of advantages to this. First the documentation is always up to date. As the documentation controls the process, the documentation must be up to date in order to control the process. For the EU Tissue Directive, this will deliver a number of advantages in that it will ensure that the documentation does match what is being operated, and that the documentation is revision controlled.

We all understand that processes change. As such, when they are changed, the documentation is first updated to reflect the new change, and the software automatically responds by using this as the control mechanism for ensuring the laboratory delivers appropriately.

How Do I Move Forward to QA?

Business Process Management, and particularly the use of this to drive computer controlled laboratory systems are the way forward to improving quality assurance.

EPCoT Systems Limited is an innovative organisation that delivers a world class solution. To ensure that you are delivering quality assured processes, contact EPCoT Systems Limited to find out how you can take advantage of this technology.

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