

Keeping your Balance: How lessons from the factory can optimise capacity in PV Operations

Imagine that you are running a business-critical global process where the workload is steadily mounting, the pressure for improved productivity and efficiency is increasingly evident, and where the need to meet onerous compliance requirements is paramount. Nothing unusual in that you might think. But, what if you had no clear visibility of future workload, no exact handle on how many people were actually working for you, and little idea of how long it took them to complete their tasks? In that case, how would you know if you had enough people, or too many? Wandering around the office to have a look will only get you so far because most of your staff are working in other parts of the world and, besides, everyone always looks busy. They're clever, highly educated and well motivated people too; surely they wouldn't be doing anything other than their very best, would they? Besides, you keep getting told by the team leaders, some of them anyway, that there simply aren't enough people to do the required work and that if you don't increase capacity soon you will fail to remain compliant with the regulatory timescales and then you'll be in trouble. Needless to say, your boss is unsympathetic and far from granting you extra resources is expecting you to cope with what you have. You suspect he'd actually like you to manage with even fewer people and you think he may be wondering if you're actually capable of doing this job in the first place. You're not sleeping well.

Welcome to the world of pharmacovigilance operations.

Being responsible for managing the case handling function in a major pharmaceutical organisation is a crucial job as it is intimately involved in protecting both patient safety and the company's reputation; as well as being inherently interesting from a physician's perspective. However, there are times when you feel more like a factory manager than a doctor; and not a very effective factory manager at that.

Perhaps it's time to take a medical approach to your problems. If your department were a patient what symptoms would they present and how might they be cured?

Your department's list of symptoms might look something like this:

- The volume of cases is increasing by between 15% and 20% year on year
- Reporting timelines imposed by regulators apply constant pressure
- There is a clamour for more resources
- There is a demand for more efficiency
- The business is closing more deals with License Partners and the resulting PV Agreements add more complexity
- You don't know how many people you need in the department, and you're not entirely sure exactly how many you have in the first place
- Morale is lower than ideal; people are leaving because they're either bored or overworked, and finding good replacements is becoming increasingly difficult

It looks like a serious case of non-management of capacity. This is a thoroughly unpleasant condition and one which is regrettably common in the industry. If left untreated it will lead to escalating costs, non-compliance and possibly even, I'm sorry to say, surgery at the top of the department.

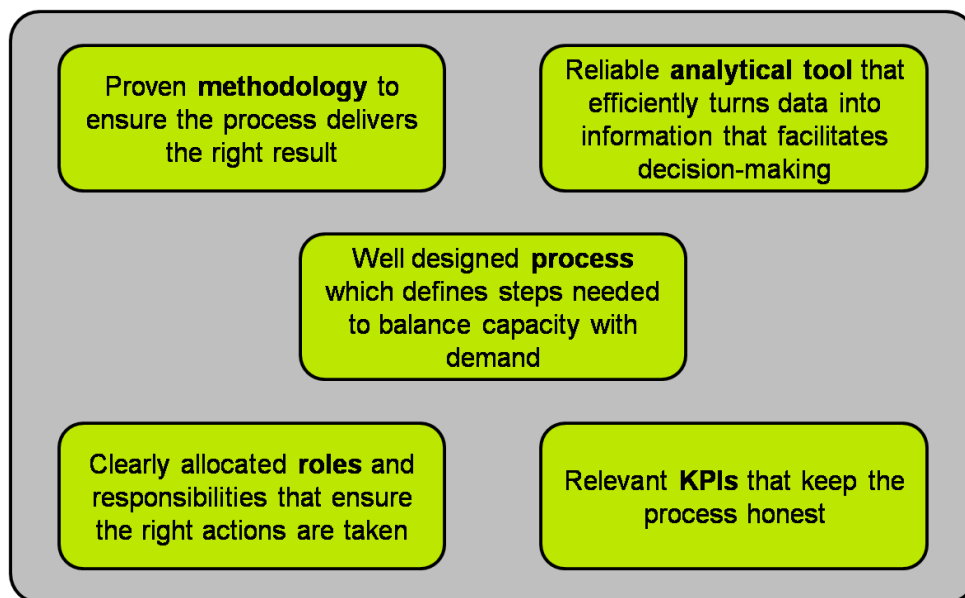
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Fortunately it is treatable. By borrowing a well-proven methodology from another discipline and customising a tool to suit the particular needs of the job, the department can be returned to rude health in next to no time. You'll find the methodology in any well-run production facility which should be no surprise; the reason your job sometimes feels more like that of a factory manager is that in many ways, that's exactly what it is. Stuff comes in (raw materials); you use people and technology to process it (making things); and it goes out the other end (finished goods). Your job is to make all of that happen effectively and efficiently. Of course, having a thorough understanding of the work content helps (just like most production managers know what their machines actually do), but it's not the whole story by any means.

If you were to invite any decent factory manager to run the case handling operation for you there's a good chance that they would focus first of all on the management of capacity, and do a pretty good job of it. Now, you might not want to leave them there for too long in case they start breaking things, but they should be able to at least understand the capacity issues.

There are five key elements to any effective capacity management process, and these are shown in the diagram below.

Figure 1: Capacity Management Process – the Five Key Elements



Process

The core of the approach is the process itself. The aim of the process is to produce and agree a single data set that is as reliable as possible and that can be used to plan in such a way as to maximise the chance of balancing capacity with demand. The main steps in this process include the following:

- Form a consensus of forecast demand, based on history and known future events
- Confirm headcount and capabilities

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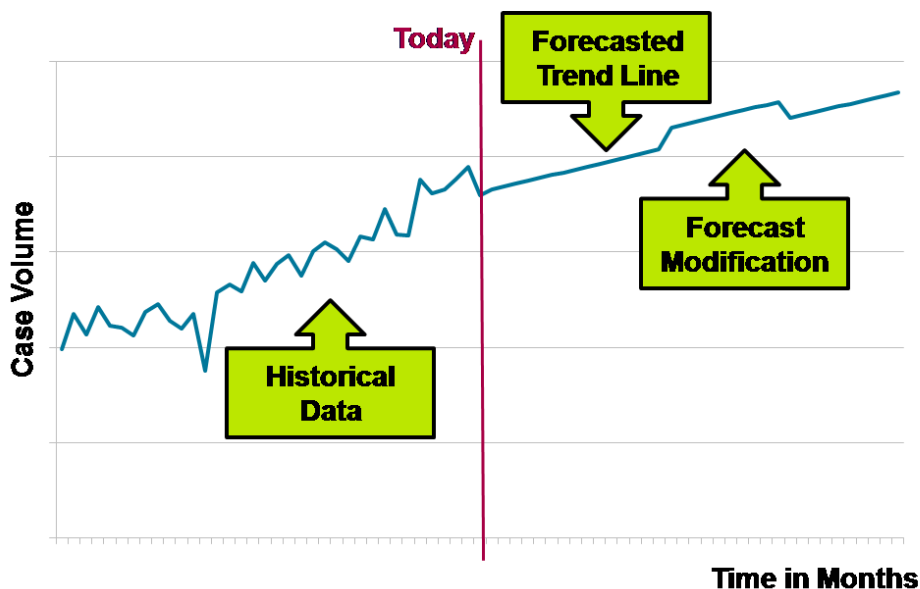
- Confirm case processing times
- Run capacity model
- Review capacity model output with key stakeholders in a single capacity management meeting
- Run scenarios on capacity tool to optimise plan, confirming actions needed to balance workload and capacity
- Agree and implement capacity plan

The process is structured and disciplined. It revolves around a regular, drumbeat meeting which is typically held monthly and which sets capacity for the next twelve months. The meeting agendas are fixed, the attendees are known, and the decision making criteria well understood.


Methodology

There are some supply chain managers who become so obsessed with forecast accuracy that they spend huge efforts searching for ever increasing precision rather than working within the natural limitations of their organisation's ability to predict the future. But there is a law of diminishing returns here and these optimistic managers are, more often than not, frustrated with the results. When we translate our borrowed methodology from the supply chain into the world of adverse event reporting we must be careful not to make the same mistake. It turns out that the most reliable forecasts can be based on historical trends modified for known future events. The graph below shows a sample of real data that was used to create a modified forecast that accurately enough predicted future demand. Modifications are made for events such as unblinding clinical trial data, entering a new market, starting a post market study, opening an AE reporting phone line, or withdrawing a product.

Figure 2: Historical and Forecast Case Volume



Whereas the forecast looks at future workload, it is also important to have good enough information about capacity itself. There are two elements to this: headcount and activity times. The



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most accurate way to determine activity times is to carry out a sampling exercise. Typically this involves looking at a statistically significant number of cases handled within a representative time period, say, a week, and recording how long each step takes for each case. This sample needs to cover all case types: serious/non-serious and initial/follow-up. The times should be validated by management and signed off by all parties involved. This brings real ownership to the numbers so that people know that the calculations of capacity will be reliable and transparent. Interestingly, this level of analysis may also reveal something about the case handling process itself. In one client, we discovered that as much time was spent checking the reports as actually creating them in the first place!

This kind of activity sampling feels a bit foreign to many people in pharmacovigilance operations, but imagine trying to run a factory without knowing how long each process step takes. You wouldn't be able to do it, not effectively anyway, and it's the same with case handling.

Roles

Depending on size and complexity, a dedicated capacity manager may well be needed to pull together the forecast from different parts of the business (Clinical, Marketing etc) and ensure that the process is properly administered. They will need to be accountable to the Head of Single Case Processing who, in turn, will have overall accountability for the whole process. It is essential that someone has this clear accountability and that he or she is sufficiently senior in the organisation to achieve consensus-based recommendations that will then be implemented by the relevant managers. Ensuring that business rules are maintained and that a regular meeting happens effectively, month after month, requires a certain tenacity of approach and is not to be taken lightly. The concept may be straightforward but making it happen is another matter altogether.

The key stakeholders in the process typically include the Head of PV Operations, Head of Safety, Head of Local Affiliates, Capacity Manager, and Resource Owners. These are the people that need to attend the monthly meetings and contribute to the accuracy of the data and the interpretation of the scenario planning.

The overall structure of the organisation also needs to be considered. Some organisations split their workforce by geographic regions, while others prefer ownership by therapeutic areas in order to deepen specialisation and make them more 'efficient' at handling the work. Some specialisation is undoubtedly useful, but this comes at a price: some teams become overloaded, while others have insufficient work to keep them busy. Whatever the structure, a degree of multi-skilling and visibility of workload, allows managers to re-allocate resources in order to achieve balance. This ensures that bottlenecks don't threaten compliance and under-utilisation doesn't impose an unacceptable burden on costs.

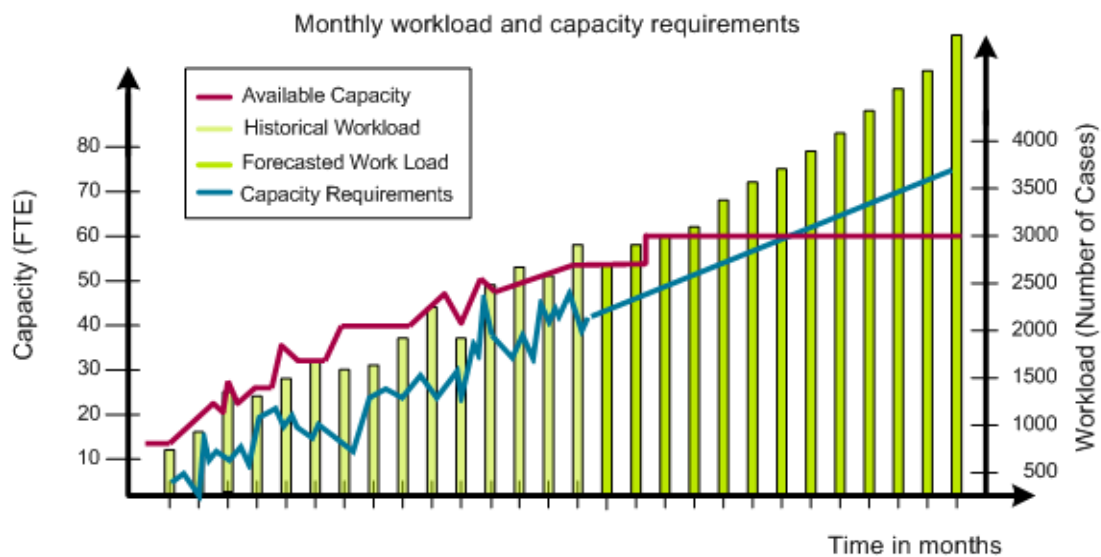
Analytical Tool

The process will only effectively manage capacity if decisions are based on reliable data. The data will only be accessible, in the form of useful information, with a purpose-made tool. The whole process will be much more difficult without an efficient way of extracting data from various sources, intelligently manipulating it and presenting different scenarios for decision making purposes. Typically, volumes by case type need to be downloaded from the safety database and

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used in conjunction with activity times by case type and role, headcount per team, historical volumes, and known future changes. The three key variables of volume, headcount and activity times can then be adjusted to create scenarios upon which capacity management decisions will be based.

Figure 3: Analytical Tool Output (Cases per Month)




The chart above shows typical output from a forecasting and analysis tool which has identified the point at which currently available capacity for Single Case Handling will be unable to manage the workload. As this is some time in the future, in this case, management will be able to take the appropriate decisions to avoid the problem of overloading the operation and missing regulatory timelines.

KPIs

All processes need relevant metrics to make sure that they are delivering the requirements and continuously improving. The four most obvious measures to be used in capacity management are:

1. Productivity: Calculated as the number of cases completed per team and role within a given time period. This metric may also be used to express cost.
2. Forward load: This will usually be expressed as a percentage of available hours that can be loaded with planned work. If future workload is higher than available capacity then productivity needs to improve, or resource redeployed, or capacity increased (or some combination of all three). If it is lower there may be an opportunity to redeploy resources into different roles, or to reduce costs.
3. Forecast accuracy: Learning how to improve the accuracy of the modified forecast will enhance the reliability of the planning, and this can only be achieved through measurement
4. Reporting compliance: Measured as the proportion of cases completed within the regulatory timelines



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As normal, the metrics will have locally set targets and will form a key part of the monthly meeting and management review process.

WCI has designed and implemented capacity management processes in many environments, including the case handling department of PV operations. We have developed forecasting and analytical approaches and tools that are robust, configurable, easy to operate, and effective. The consequences of embedding an effective capacity management process is that it provides the framework for balancing resources, managing costs, maintaining compliance, eliminating backlogs and, as a consequence, improving morale. So much so that the Head of PV at a top 20 Pharma company which implemented a process such as this commented, *“I was always being asked for more resources for the Case Handling Process – it turns out we had enough overall resource, they just weren’t assigned to the correct tasks.”* Sounds like capacity management at work, doesn’t it?!

For more information on how WCI can help you manage your capacity in order to match supply with demand, and help you sleep better at night, please contact Neil Richards (neil.richards@wcigroup.com) or Paul Beaumont (paul.beaumont@wcigroup.com)