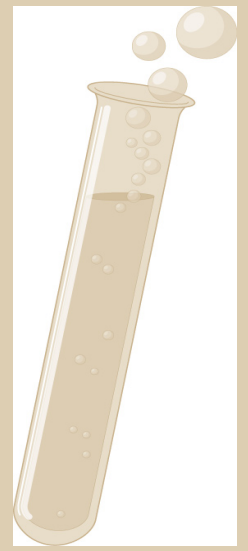


New Product Development Processes in a Laboratory Environment



From Possibility...

Developing a new product relies on the expertise of different areas of the business, sound project management and decision making based on accurate and relevant data. This is certainly required within the Bio Products Laboratory (BPL). BPL is a not for profit organisation wholly owned by the UK Government's Department of Health and an integral part of the NHS. BPL has been developing and manufacturing therapeutic plasma products for more than half a century and had recognised that they required a robust and effective cross functional project management approach to ensure improved performance in the developmental areas of the business. Their objective was to achieve higher success rates and shorter lead times for projects as well as ensuring joint working within their Research and Development, Medical, Technology Transfer and Business Development departments.

Whilst BPL had dramatically improved its operational efficiency, capability and capacity, strategic projects were still not being achieved in the shortest possible time frame and project management was a recognised weakness. Historically, investment into the developmental functions had been relatively small and projects had had a tendency to run late due to unforeseen delays and problems. This resulted in the product reaching the market later than planned. Improving the product development process and project management was critical to ensuring a strong and competitive product portfolio which in turn would enable the strategic achievement of a substantial patient base increase and long term viability.

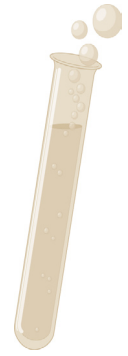
OUR APPROACH

Our approach was to initially carry out an effective diagnostic across the organisation. We met with team members and managers across R&D, Medical, Marketing, QA, QC, Production Support Unit and Production. As part of the diagnostic we also worked with the teams to value stream map the 'As-Is' product development process using the examples of two actual products that had been in development, namely Gammaplex and Factor X. This enabled us to ensure that we had not just picked up recent gripes but actual relevant issues (process and cultural) that the team had experienced and so were critical to the development process.

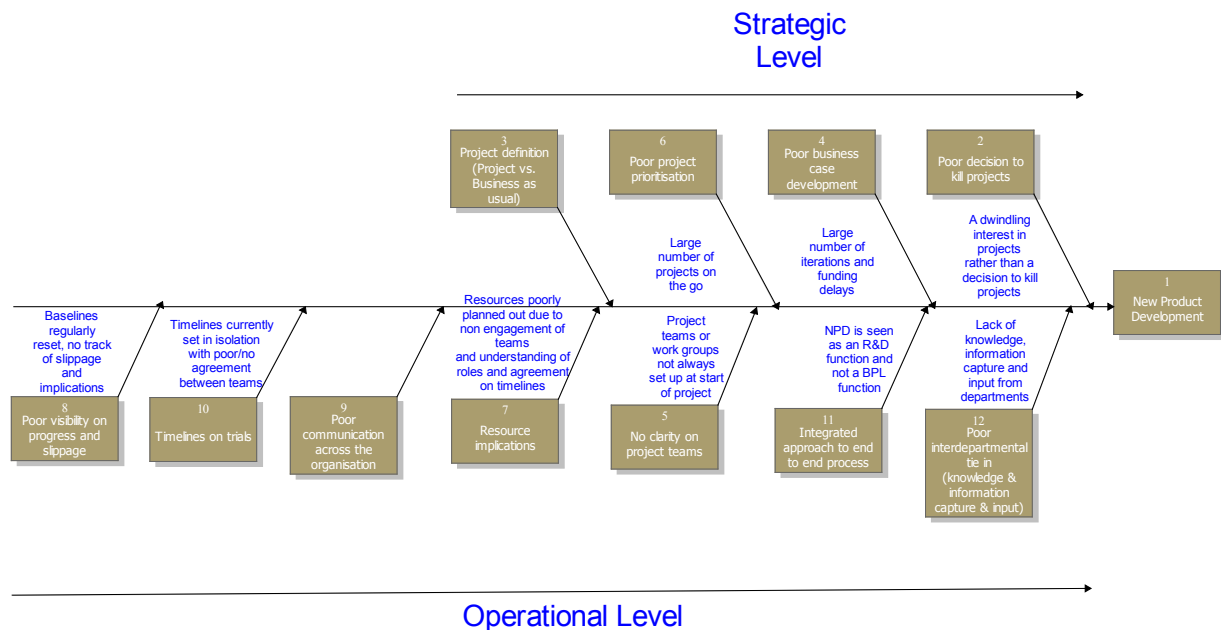
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The issues identified as a result of the diagnostic were:

- There was a disconnect between internal teams. For example, between the BPL Exec team and the NHSBT Board there was a lack of clarity on what was required for the business case and feedback on progress of the product
- There were discrepancies in how projects were defined; whether they were new projects or business continuity and this impacted on the way the projects were managed
- There was a lack of clarity on who the project teams were at the start of the process and this impacted on effective communication about progress and what would be needed from different departments as well as decision making at critical points within the project plan
- There was no clear process to prioritise projects and so key stages in the process such as scheduling batch manufacture of a product in preparation for clinical trials would be delayed as another project would jump the queue. Also projects would suffer from a lack of resource allocation which would cause delays
- Lack of co-ordination of projects, visibility of progression and slippage meant that interest in a project would dwindle when it was more appropriate to kill the project
- Due to the lack of a visible and effective project management process there was poor project review and decision points, poor realistic estimation of timelines, lack of effective communication across the organisation, gantt charts used as KPIs in isolation and the resetting of baselines
- Projects were also going on that were not on any radar



These issues were broken down to be addressed at the strategic level and the operational level.

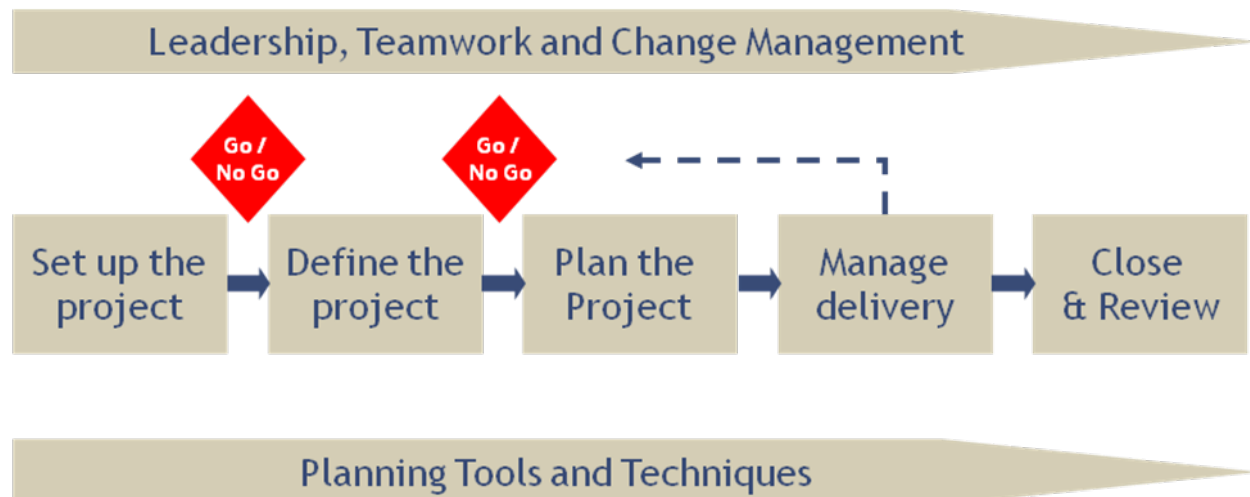


To Actuality...

EFFECTIVE PROJECT MANAGEMENT

Based on the issues identified as part of both the diagnostic and the workshops, we worked together with representatives from all the teams to develop solutions which would streamline the process, reduce interruptions and delays and enable better process flow. Our focus was on operational level improvements which would feed into enabling effective strategic decision making. We used a simple to use project management approach, covering the lifecycle from initial ideas for setting up a project, through to close-out,

learning and review (as shown below). To address the issues found at the diagnostic stage the priority was to have defined process roles at each stage, clear process steps that were relevant and timely, defined review and go/no-go points at key decision points. This process would be owned across all participating departments.



The phases and activities we developed with the team within the new product development process incorporate sound, effective project management principles. These activities are now owned and carried out across R&D, Medical, Marketing & Business Development and Technology transfer. Some examples are outlined below;

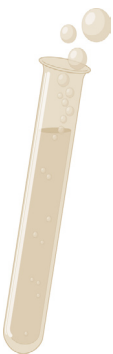
New Idea captured or generated

- An impact assessment is carried out
- Resource requirements are estimated and assessed
- Information required to move ahead is identified and collected
- Dependencies across the organisation and beyond are identified
- Patent search is carried out to assess whether there is a gap and, therefore a market
- Partnering requirements are identified and sounded out

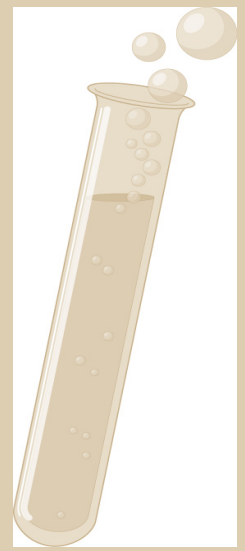
Initial Feasibility Assessment

- Teams work in partnership to identify whether this is a new business opportunity and where it fits with the business strategy
- Business Risk is assessed
- Marketing supply the competitor and market information to ensure there is a market to sell to
- Mechanisms for change control and rationale are identified as well as a mechanism for identifying risk and information sharing

In addition, the new approach has been redesigned cross functionally with the teams to incorporate and clearly define the role of the governance group, structure of clinical trials, technology transfer and manufacturing requirements, and communication protocols. Also, the rationale behind decision making, inputs and information flows and the criteria for the gate process. Defining all these elements enables effective and evidenced decision making at an operational and strategic level and will enable effective evaluation post project to ensure improvements can be identified and applied in the future.



New Product Development Processes in a Laboratory Environment



THE BENEFITS

The products that BPL develops have enormous significance and benefits in the field of medicine. BPL also has expertise in different areas across the organisation that it recognised were not being utilised effectively in the development of new products.

In working with the teams involved in this process BPL now have the following

- An integrated approach to an end to end product development process
- Effective project prioritisation and resourcing allocation
- Understanding from all concerned including the BPL Exec of what is required, by whom and when to ensure the product goes to the market at the right time
- Improved communication processes across the organisation
- Improved visibility through the use of the information centre on timelines, progress and slippage and the means to address and resolve issues
- A new committee structure which has a dual role in reviewing progress and decision making within the projects as well as deciding on future and no go projects. This has enabled improved decision making by the Exec level due to access to robust project management data
- A clearly defined new product development process which is cross functional, incorporates the principles of effective project management and is owned in partnership by members of the project team

“Ad Esse overcame the barriers to change in the various teams by adopting a very effective style of listening and inclusion into the change process. This meant that the participants were open and honest in the assessment of the current system and its weaknesses and open minded to the new process. This was incredibly important in getting the buy-in of key people involved in the product development process”

Jane Martin, Marketing Director, BPL.

FURTHER INFORMATION

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PHONE: +44 (0) 845 366 8528 EMAIL: seriousfun@ad-esse.com WEBSITE: www.ad-esse.com