

## Case Study 3

### **New Product Development**

I was very excited when I was invited by Kodak to head up a major part of their Vitro Immunoassay analyser development project.

The project was truly multinational with the development of the analyser being based in Rochester, in upstate New York and the chemistry work being based in Buckinghamshire in the UK. The actual manufacturing and filling of the reagents was planned for Cardiff.

The part of the programme that I took care of was the development of the consumable components that would be used to deliver the reagents into the analyser.

Previously in non-automated assays the reagents would simply be delivered to the customer in bottles. Now they had to be packaged to be fully machined accessible with no customer intervention and they had to be multi-occasion use. Of course the cost targets were set aggressively and we were seeking to deliver the automated assay at a lower purchase price than the existing manual version. Some of the challenges were:

Need to change from glass to plastic containers to be able to produce more complex shapes

Need to be able to prevent evaporation of liquid reagents once containers were open.

Need to change from a developer reagent from a solid plus liquid formulation to a binary liquid. Here it was also required to increase the shelf life from 3 days to 12+months

All materials to be recyclable.

All reagent assemblies to have easy machine interfaces and be reliable in operation. (i.e. to behave as fully engineered components in the analyser)

We also took a strategic decision not to make the delivery system look expensive. We had concerns that the customer would see this as throwing away value when the empty cassettes were disposed of.

I formed a team consisting of machine designers, some of the guys who worked on film cassette design, chemists working on the reagents from the UK, production and process engineers as well as QA and QC and marketing folks. These people were drawn from several sites around the world. As we developed we added supplier expertise directly into this core project team. We also added dedicated project planning and document control to form a very strong back-office function.

One of the first things that became clear during the concept phase was that we were going to have to re-engineer a lot of the assembly systems which were

really traditional bottle filling and closing lines. Additionally we needed to build a specialized robotic cell to make one of the key disposables.

In a project of this size control of the plan and configuration control of the part designs are of equal importance so we established design control from a very early stage. The QA reps were charged with this task directly in a break with tradition where their role is often seen as policing or advisory.

Design for manufacture was also high on our list and we spent a long time critiquing the designs we had and considering, not just the component manufacturability but the use and the filling or processing of the components as well.

In the end we hit most of our design goals with the components largely being made from relatively cheap styrene or polypropylene. We developed self seal techniques for the liquid holding containers which we backed up with pierceable seals for longer term transport and storage stability and security. We also built a clean cell to make our main disposable in the middle of our chosen moulding partners' factory (And provided the required staff training for it to be operated correctly).

The key to managing a project of this size is to set up well defined structures in the team and to ensure that everybody is driving towards the same targets. This might sound obvious but it requires a lot of translation to ensure that each specialist function is seeing their part of the project as a part of the whole. The breaking down of traditional silo's is essential and getting the teams to focus on the total cost of delivery and optimising this rather than each department striving to optimise just its own part is essential. This in itself needs caution as the team can become so strong that it appears as the threat to those departments it interacts with.

Of course communication both within the team and to the wider world of the rest of the project and then the organisation is essential. This programme was so large as to necessitate its own internal press office and even a regular published news letter to which all sub project teams contributed.

People development and trust are also key factors. In a project based in so many locations the project manager cannot be everywhere at the same time and it would be arrogant to assume that personal supervision would make a difference. Therefore it is important to establish good structures and find the right people for each task. Once this was done a lot of the PM role was about mentoring and encouraging those team members to achieve their full potential.

The project delivered 2 reagent carrying assemblies (one with 10 sub components and one with 3) 2 new filling lines, 1 robotic moulding cell and 14 moulding tools.

Each moulding process was fully validated and due to the engineering approach that was adopted we were able to miss out the traditional prototype tooling stages and move from design to production tooling immediately. In the case of the robotic cell this was done to give an initial output of 48 million pieces per year and used a 48 cavity mould. Most of the other tooling was more modest in terms of its cavitation with 4 cavities being the norm.

The project was always under time pressure from the overall programme as many other projects were demanding materials or test pieces to get their own development activity rolling.

In such a large project the PM also needs to give consideration to the end phase. I had taken many people away from line tasks for 2 years. Of course their function had been backfilled quite quickly so it was important to make sure they were re-integrated back into the organisation as the project drew to a close. (Not surprisingly a lot also spread their wings and moved on to greater things at this time.)

The Vitro Immunoassay product finally launched after 5 years although the consumables project had a two and a half year life within the overall development programme. Indeed by the time of product launch “consumables 2” the scale up of capacity was already fully underway to meet the planned product growth in the 2<sup>nd</sup> and subsequent years after launch.