

# Irish Medicines Board more than doubles productivity with assistance from IBM

## Overview

### ■ Business Challenge

*Paperwork-based processes at the Irish Medicines Board were growing to unmanageable proportions. With approvals for new medicines handled on a case-by-case basis, there was no overview of total workload and no way to identify and relieve the bottlenecks.*

### ■ Solution

*Working closely with IBM Global Business Services, the Irish Medicines Board redesigned the workflow of the approvals process and transformed the organisation structure. In parallel, the supporting IT specifications were drawn up, and a change management programme initiated to complete the move from paper systems to a fully electronic workflow solution.*

### ■ Key benefits

- *Total throughput of licensing activities has more than doubled*
- *Senior management team has a complete overview of workload status and individuals responsible*
- *Two-year backlog has vanished, helping to bring medicines to market more efficiently*
- *Staff have immediate visibility of their personal workload and responsibilities, including performance feedback and training opportunities.*



The Irish Medicines Board (the Board) is charged with the protection of public and animal health through the regulation of medicines, medical devices and healthcare products.

Based in Dublin, the 280 staff approve the quality, safety and efficacy of medicines available in Ireland, and participate in related processes in the European Union. The Board is also the Competent Authority for the implementation of EU and national legislation relating to medical devices, blood, blood components and tissues and cells.

Early in 2003, it was clear that the Board was drowning in paperwork. The process of seeking approval for medicinal product licensing consisted of multiple stages, often handled by separate departments, each generating a significant amount of paperwork at different stages within the process. With no overview

of total project status, it was almost impossible to co-ordinate the process or plan either departmental or individual workload.

Pat O'Mahony, Chief Executive Officer at The Irish Medicines Board, comments, "There was no way to take an overview of systemic problems. We were unable to pinpoint the true cause of the backlog. Did we have too much work for too few people, or were there duplications and inefficiencies in our processes? No-one knew, and we could not find out."

*"IBM Global Business Services has given us real, ingrained change backed up by excellent support, training and technology."*

*Pat O'Mahony, Chief Executive Officer  
Irish Medicines Board*

## Business benefits

- The Board has the necessary business tools to assist it in the effective regulation of medicines
- Introduction of workflow systems has helped eliminate a two-year workload backlog
- Total throughput of approvals for new medicines has more than doubled
- Senior management team has a complete overview of current project status and individuals responsible
- Staff have immediate visibility of their personal workload and responsibilities
- Metrics generated to help identify bottlenecks and improve performance
- Audit trails help keep in compliance with national and EU legislation
- Proactive management of workload and associated trend analysis

*“IBM Global Business Services was the ideal partner, offering both the management consulting and the technology capabilities.”*

*Suzanne McDonald, Director of IT and Change Management,  
Irish Medicines Board*

The challenge facing the senior management was immense: despite possessing highly skilled staff, the Board was struggling to perform and needed complete organisational transformation.

### Finding a solution

It was clear that paper-based systems were one of the key difficulties at the Board, and that an electronic infrastructure was the ultimate goal. Before approaching an IT solution, it was essential to understand and define the requirements and workflows, which in turn meant reorganising the Board's organisational structures.

Pat O'Mahony explains: “A medicine submitted for approval might involve both the medical and pharmaceutical teams, and that is how we were structured. Each team operated individually with little opportunity for co-ordinated management of the end-to-end process. We needed outside help to discover exactly where the problems lay, and what we could do about them. After completing a public tender exercise, we engaged IBM Global Business Services.”

The IBM consultants recommended that the Board restructured its teams to reflect the key components within the workflow process – an enormous shift for the organisation. All human medicines approvals would now go through a single process, with the medical, pharmaceutical and other teams being treated as operational units.

“The transformation affected everyone, and required an intensive engagement with the IBM consultants,” says Pat O'Mahony. “In the early stages it had very little to do with technology and everything to do with how we worked. The IBM consultants offered team and individual support for developing the new structures, which were tailored according to workflow. Our experience of engaging with IBM has been extraordinarily good, particularly the embedded consultants who worked at the Board's offices, and we were very keen to have them back at the next stage.”

### Restructuring the organisation

The initial project focused on the Human Medicines Licensing Group. This involved reorganisation of the department, design of a revised approvals process, development of a specification for a workflow system and design and implementation of the system.

The reorganisation created a unified human medicines department. All work on a specific approval falls into that department's responsibility, with a named individual case manager and group of assessors responsible for managing the process.

The restructuring gave the senior management team immediate visibility of the work queues for each application type and the resources assigned to those processes. The operational groups were now given approvals projects

simultaneously, so that work could progress in parallel, with an overall reporting process to eliminate duplication of work and duplication of effort. Staff could see project status, and, consequently, understand their forthcoming workload and commitments.

With the initial reorganisation complete, the next steps were to define the processes and workflows, which were still manual, and examine possible IT solutions to reduce paperwork and boost productivity.

Suzanne McDonald, Director of IT and Change Management, explains: “The reorganisation had shown what was possible, but we still needed to plan and allocate our work more effectively, and paperwork was not the way forward. We were looking for both a change in the way we worked and for the right IT infrastructure to make it possible. IBM Global Business Services was the ideal partner, offering both the management consulting and the technology capabilities.”

The next projects, which led to the reorganisation of the medical devices and compliance departments, implemented additional systems for managing work, developed by the Board based on the redesigned processes created in partnership with IBM Global Business Services.

“The transformation programme was tough, and required a shift in mindset. The engagement with IBM Global Business Services was marvellous, and the consultants were very skilled people-managers, able to instil confidence in both the senior management team and the staff. In particular, the IBM consultants were able to convert their business proposals into meaningful technology specifications with a blend of business acumen and technical expertise.”

### **Achieving big results**

The IBM consulting team’s process identified two main activity types: large packets of work on approvals for new products, and smaller projects focusing on approvals for variations and renewals to existing products. A generic six-stage process – receive, validate, schedule, assess, complete and issue – is applied to all approvals. Every user now logs in to a central workflow system, which automatically displays their work responsibilities, actions required with timelines, and the process steps required.

Pat O’Mahony comments, “Using the new system, we can look at the total work queue by type, sector, team, date of arrival, individual and much more. With accurate data, we know that approvals productivity has risen by 122 percent.

“Previously we had no detailed management information on the bottlenecks in our processes. For example, it could be that we had a great technical assessor who was overloaded or another individual with capacity for new or different work streams. With the workflow system, we can see immediately where projects are stalling, and take action.

---

### **Key components**

- IBM Global Business Services  
– Strategy and Change Consultancy

*“The IBM consultants have a very good appreciation of the public sector environment and a huge work ethic, which I might summarise as an appetite to be the best in their field.”*

*Pat O’Mahony, Chief Executive Officer,  
Irish Medicines Board*

---

### **Transformation at a glance**

*With workload increasing and additional responsibilities, paper-based systems at Irish Medicines Board were unable to keep up with the pace of change. With new systems and processes designed in partnership with IBM Global Business Services, the Board has more than doubled its productivity in handling medicinal product applications. The organisation has been reinvigorated with a positive way to manage personal workloads while delivering an efficient service to the public and the pharmaceutical industry.*

“The system gives us high-quality information that shows what people are actually doing. In management terms this has transformed our capability to take on new work and use our resources efficiently. Each person has a performance assessment based on their workload and what’s expected of them, and in return we offer a colossal amount of support to help them meet their goals.”

The highly process-oriented approach has been built on the foundation of the reorganisation and workflow analysis, which, says Suzanne McDonald, accounts for a major part of its success.

“The technology gives the Board capabilities that would simply never have been possible with paper systems, and I don’t believe we could have achieved these results any other way,” she says.

“For example, we are able to examine trends and highlight difficulties. Are we slower in approvals processing, and why? Is the Board receiving poor-quality applications that are subsequently rejected? Or are we making mistakes in our capacity planning? With this system, created and tailored by IBM, we can identify areas that need attention and generate metrics to help us drive performance.”

### **No surprises**

One of the major changes at the Board has been the introduction of a ‘no-surprises’ work environment. From senior management to individual staff, everyone can see their appropriate

work tasks, project status and timelines – an enormous change from sifting through paper folders and discovering an urgent deadline.

“Capacity planning has been transformed, with views of forthcoming projects, milestones and key dates. The same system, almost as a by-the-way, can be used to predict the business impact of changes in regulations, as we can feed in the new milestones, resource requirements or legislative deadlines,” says Suzanne McDonald. “This allows the Board to release information in new ways to help us run a more efficient, more cost-effective service.”

Pat O’Mahony concludes, “IBM Global Business Services has become a true business partner for the Irish Medicines Board. The IBM consultants have a very good appreciation of the public sector environment and a huge work ethic, which I might summarise as an appetite to be the best in their field.

“IBM Global Business Services has given us real, ingrained change backed up by excellent support, training and technology. The real value to the Board has been the organisation, structures and procedures around successful change management. The resulting elimination of the backlog and 122 percent increase in productivity speak for themselves.”

### **For more information**

Please contact your IBM representative or IBM Business Partner. Visit us at: **ibm.com/gbs/uk**



### **IBM United Kingdom Limited**

PO Box 41  
North Harbour  
Portsmouth  
Hampshire  
PO6 3AU

The IBM home page can be found at **ibm.com**

IBM, the IBM logo and ibm.com are trademarks of International Business Machines Corporation, registered in many jurisdictions worldwide. A current list of other IBM trademarks is available on the Web at “Copyright and trademark information” at <http://www.ibm.com/legal/copytrade.shtml>.

Other company, product or service names may be trademarks, or service marks of others.

References in this publication to IBM products, programs or services do not imply that IBM intends to make these available in all countries in which IBM operates. Any reference to an IBM product, program or service is not intended to imply that only IBM’s product, program or service may be used. Any functionally equivalent product, program or service may be used instead.

All customer examples cited represent how some customers have used IBM products and the results they may have achieved. Actual environmental costs and performance characteristics will vary depending on individual customer configurations and conditions.

IBM hardware products are manufactured from new parts, or new and used parts. In some cases, the hardware product may not be new and may have been previously installed. Regardless, IBM warranty terms apply.

This publication is for general guidance only.

Photographs may show design models.

© Copyright IBM Corp. 2009 All Rights Reserved.