Working closely with MHRA personnel, Accenture has significantly strengthened the UK medicines and medical devices regulator’s position in an increasingly competitive marketplace. Agile methods, technologies and tools are automating, streamlining and accelerating the processes that help the MHRA fulfil its mandate. Workflow is already more flexible.

More transparent documentation has greatly enhanced visibility. Impacts are now clearly measurable. As the DevOps platform for continuous automated testing spreads across the organisation, the MHRA will be able to deliver better, faster business outcomes for its pharmaceutical industry customers, and higher quality assessments will improve public safety.
The Medicines & Healthcare Products Regulatory Agency (MHRA) is an executive agency of the UK’s Department of Health and Social Care, responsible for ensuring the efficacy and safety of medicines and medical devices.

Originally formed in 2003, it incorporates both the National Institute for Biological Sciences (NIBSC) and the Clinical Practice Research Datalink (CPRD) and employs more than 1300 people.
Tasked with regulating medicines, medical devices and blood components for transfusion in the UK, the MHRA has come under mounting pressure in recent years to raise its game.

Its Sentinel case-management system handles product licensing, clinical trials, pharmacovigilance, and a host of more granular processes. But the system, which has been in place for more than a decade, is too inflexible and cumbersome to deal efficiently with the surge in demand for faster drug licensing, better pharmacovigilance, and higher public-safety standards. Processes are fragmented. Because multiple teams use different tools and legacy methods, approvals take far too long. Poor transparency can lead to communications gaps and traceability nightmares.

The MHRA remains a market leader, but it faces mounting pressure to improve, especially as plenty of its peers have improved their service. The UK agency now has the opportunity to re-orientate itself towards a more global, emerging-markets focus. In a highly competitive marketplace, that will require a faster-paced, more interactive model, led by technology.
The MHRA has been an Accenture client for more than 15 years. We built the agency’s Java-based Sentinel system some 12 years ago and have continued to manage it, along with more than 15 other, loosely integrated 3rd party applications.

In late 2016, when the MHRA decided to transition away from the traditional, linear approach to case management that Sentinel represents and towards a more iterative, agile way of working, we were in pole position to help them. Since April 2017, when we began working together on the transformation, we have dedicated a team of around 40 professionals (based in India as well as in the UK) who are implementing new technology capabilities that use and promote the DevOps platform.

Our engagement has comprised both an Agile Delivery Assessment and the implementation of a DevOps framework that aims to optimise IT delivery by straddling the divide between development and operations and that the MHRA wants all its suppliers to adopt.
AGILE MATURITY ASSESSMENT

In February 2017, by interviewing key stakeholders from across the organisation, we sought to assess the MHRA’s agile “maturity” across 6 parameters and along a 5-step maturity curve where 1 = Ad Hoc and 5 = Agile Process Excellence (See Fig. 1).

We found that although some agile processes were in place, the MHRA’s maturity was still very greenfield and nowhere near the agency’s ambition to achieve enterprise-wide agile sponsorship and governance. On the basis of our findings, we worked with the MHRA to produce a roadmap, with projects classified by both priority and complexity.

Based on the assessment across the 5 separate parameters listed below, the MHRA’s maturity curve is between ad-hoc and basic and this has been determined by where each parameter lies along the Agile Maturity curve.

- Agile Leadership
- Agile Methods & Tools
- Agile Delivery
- People & Community
- Agile Enablement Support
- CI

(1) Ad-Hoc
- No Enterprise-wide capability or support for Agile Development exists

(2) Basic
- There is identified local Agile Sponsorship and Governance in place.
- Agile Processes are in use. Some Agile roles are defined.
- Rolling wave planning is not in place. Sprints are groomed as they occur.
- Informal Release planning
- Some Test Automation and Continuous Integration is in use across the Enterprise
- Some Agile Processes are measurable

(3) Emerging
- Enterprise-wide Sponsorship and Governance is emerging.
- Agile Roles & Processes are well defined.
- Rolling Wave planning has started. N+3 Sprints are groomed. N+1 Releases are planned.
- Continuous Integration and some Test Automation is in use across the Enterprise.
- Agile Processes are measurable. Some metrics are in place.

(4) Managed
- Enterprise-wide Agile Sponsorship and Governance is in place.
- Agile Process measurement is used to drive improvement & innovation.
- Rolling Wave Planning in place. >N+2 Releases are Planned.
- Continuous Integration and Automated Testing is used by all teams.
- Data, metrics, and best practices process improvement.

(5) Agile Process Excellence
- A learning organization is in place.
- Development & Business are aligned in their use of agile methods to achieve higher quality and business value.
At the same time, we assessed the requirements for a DevOps platform that would standardise development across the organisation and prevent suppliers from adopting their own individual toolsets. The MHRA asked us to recommend a single tool set, and to tell them which tools could be introduced to add immediate value, and which would take longer to do so.

We introduced our open-source, Cloud-based ADOP DevOps platform, a tools environment for continuous applications testing, release and maintenance, and deployed it to create immediate value for the MHRA by boosting quality and improving documentation and visibility; key considerations for the client. Tools deployed include Jira and Confluence, both of which are designed to enhance collaboration and build scale.

We demonstrated long-term value add through continuous improvement/continuous development (CI/CD) to enable build-and-deploy automation. We also introduced reusable cartridges to facilitate the rapid creation of technology sets.
I never thought we would have sight of a “wireframe” mock-up of our new system so early in the process. Within weeks, Clinical Trials Unit (CTU) staff were able to give feedback on the look and feel of our new case folder. I have been involved in other projects where it took years for the users to actually have sight of the potential end product.

Martin O’Kane
Head of Clinical Trials Unit, MHRA
THE FIRST BIG PROGRAMME: CLINICAL TRIALS

The first large delivery programme to utilise the full DevOps capability is the Clinical Trials programme, which is scheduled to go live in early 2019.

The DevOps platform and agile processes enable rapid prototyping and greater business involvement. Indeed, the business is driving the system and not the other way around, helping to break down the traditional development/operations divide. The business, furthermore, has already seen tangible benefits. These include:

- A document management functionality that gives operators access to more information and wider access to documents on a single screen with minimal mouse clicks.
- Real-time integration with the Cloud finance system enables the instantaneous creation of invoices and greater visibility of payment status.
- Surfacing of legacy data within the new application to simplify the deployment process and enable early recognition of benefits.
- Successfully executed four Sprints, defining 407 requirements (Jira stories) and 631 tasks (Jira tickets) fully traceable to the 35 components delivered, of which 23 are reusable for future planned delivery programmes.
- All components built are implemented using automated code deployment for consistency of access across the environment landscape. This will reduce defects and eliminate discrepancies between test phases. Automated test scripts that enable continuous validation and visibility of application behaviour following changes will enhance visibility and traceability. Sprint retrospective meetings have recognised a 30 percent productivity increase, thanks to continuous evolution and lessons learned.
GOING FORWARD

Clinical Trials is just the first of many applications that will soon, thanks to reusable technologies, run on the DevOps platform. Meanwhile, we have helped the MHRA transition from a risk-response mindset to a continuous development way of working. Our tools and methodologies have established the structure and governance that the MHRA needs to sustain and bolster its reputation as a premium regulator globally. Going forward, we will continue to work together to expand and refine the DevOps processes and tooling so that they align with constantly changing business processes, particularly in regard to support operations.
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