



The nature of the pharmaceutical industry is changing as cost management and process efficiencies become critical to survival. Pharmatech.com, estimate that between 2012 and 2018, more than \$290 billion of sales would be at risk from patent expirations. Outsourcing is increasingly more common in the industry to help save costs. This often reflected in sourcing contractors.

The Contracting Model describes hiring individual contractors to quickly plug skill gaps and staff shortages during busy periods and to alleviate hiring/firing costs. This model is proven and works well. But benefits can be lost if the model slips into a more permanent approach. Typical problems are:

- Escalating costs.
- There is no Service Level Agreement (SLA) other than an agreement on the hours available to work.
- Increased overhead in managing several individual contractors to assign and track tasks.
- Knowledge is invested into contractors which can prolong their engagement.
- Any issues with this service are (conveniently) attributed to insufficient staffing.

The managed service is a vehicle for overcoming such problems. This is where a supplier assumes control of all or part of the execution of a service component on behalf of an organisation, for example, developing bespoke software. Whilst the regulated industry is accountable for the validated state and compliance of their computerised systems, it can still delegate the day to day activities of attaining and maintaining this state to a 3rd Party Supplier.

Computerised Systems Compliance as a Service (Cs CaaS) is a managed service where the supplier assumes control of all or part of the Computerised System Compliance need. The CS CaaS model yields all of the benefits of flexibility and skill access of the individual contractor model whilst overcoming the associated problems listed above.

Some key aspects of the CS CaaS approach are:

- 3rd Party Supplier manages the delivery model, pro-

cesses and tools: as the supplier is responsible for delivery there is no spike in costs for overtime hours from contractors, thus resulting in predictable out source costs.

- The regulated company defines the roles and responsibilities of their own staff and the interface to the supplier to ensure complete oversight of the service. The 3rd Party Supplier assumes the risk of service transition and operation of service – providing a complete workforce solution while ensuring efficient operation.
- Control is not ceded to the supplier – relationship and contractual commitments ensure that control (and accountability) of the service remains with the consumer.

Some of the key advantages of the CS CaaS managed service are:

- Provide key skills in GXP Computerised System Validation activities.
- Provide skills in new technologies and in non-Validation capabilities: software engineering tasks, SDLC processes and non-functional activities.
- Committed service for a committed price results in a lower cost operating model than internal staff or contractor models. Furthermore, price is focused on delivery value rather than on rate cards.
- Knowledge is documented and transferred back into the organisation via a Knowledge Transfer Plan.
- Free up internal staff to perform key tasks and activities.
- The supplier is highly incentivised to establish productivity measures required to meet the service commitment and ensure service acceptance. This manifests itself in the implementation of tools, processes and documentation. This is important as the supplier cannot afford the risk of not meeting the service commitment by relying on individuals.
- Through the application of a robust Quality Management System, the supplier will be able to deliver the services more reliably. The managed service model is structured to deliver a viable, low cost service offering to the organisation.

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Compliance as a Service is a cost effective approach to ensure the compliance of a Computerised System.

The key difference between the 2 models is that the under a CS CaaS approach the supplier is committed in delivering a complete service outcome at a predefined price, whereas the contractor is focused on the performance of a series of defined tasks against a set of bought hours.

A CS CaaS model delivers all of the skills access and flexibility of a contractor resourcing approach. However, because the managed service approach relies on management and process rigour, clients experience an elevation in service.

Introducing EmpowermentQE Compliance as a Service.

Operating within a managed service model is in our DNA: we have established tools, processes and documentation templates in our QMS that have with stood the test of time. We have always ensured knowledge transfer back into the client organisation as defined in the service contract. Our consultants have operated within the managed service model throughout Europe and the US during their software engineering and regulatory compliance careers and have successfully deployed the Compliance as a Service approach. Our approach is structured to deliver a viable, low cost offering to the regulated organisation.

EmpowermentQE advantages include:

- Vast experience of providing QA and CS CaaS for remote project teams that successfully increased quality and reduced project costs.
- Leverage key skills from the wider software engineering community in tandem with current GXP requirements.
- Defined SLA Key Performance Indicators (metrics) to measure our performance, improvements and return on investments. Providing you with the over-sight to ensure that your accountability requirement is met.
- Ensure concurrency with the latest technologies (e.g.

virtualisation, penetration testing, cloud computing, fault tolerant systems) – hands on expertise versus “Googled” expertise.

- Intellectual property remains your property and we operate an open door policy - full audit, full access to data and project artefacts at any time.
- Our robust risk management, reporting, change control and issue escalation ensures that you adopt a “management by exception” approach.

You can delegate all or part of the Computerised System Compliance into EmpowermentQE, such as:

- 3rd Party Computerised System Supplier Assessment or Audit.
- COTS tool selection and validation.
- Computerised System Validation Activities.
- Process Improvements.
- Computerised System SDLC process training.
- Independent Computerised System QA and nice testing.
- Consultancy to help with defining strategies.

Test our services for growth: try out our services by executing low-priority projects that carry minimum risks. After gaining a level of familiarity and confidence, nurture the relationship by engaging in larger projects.

Contact us to discover more about joint approaches, service over spill or quality focused leveraging of key skills.

EmpowermentQE is a QA, Technical Test and Validation consultancy that successfully cross pollinates skills and processes from the wider software engineering community to meet the needs of the regulatory user and the demands of 21st Century Computerised Systems Compliance.

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