Managed Service Solution for Pharmaceutical Annual Product Review (APR)

2012 to Present

CLIENT PROFILE

Client Reference ID	CA-JCP-012
Product Classes Manufactured	Cosmetic, Medical Device, OTC Pharmaceutical
Number of Employees	12,000 +
Number of Client Sites	Five (5) plus approximately 50 external manufacturers
Operating Scope	Regional
Annual Revenue	$6-8 Billion (est.)

CLIENT BUSINESS SITUATION

Client was experiencing multiple problems with its Annual Product Review (APR) process for its externally manufactured products, which included OTC Pharmaceuticals, Cosmetics, and Medical Devices (See Note). Client was also exceeding its budget for the execution of APR activities. Client had **approximately 325 APR reports** that need to be completed annually, for products manufactured across approximately 50 External Manufacturing sites (EMs). EMs were often late with the information they were required to compile and submit, and the Client frequently needed to follow-up with the EMs about the information submitted, and reconcile issues and questions pertaining to submitted data. There was not a strong control framework for what APRs needed to be completed, nor a precise definition of when they were due. APRs were not drafted to consistent standards and levels of quality, and were consistently completed and approved late. In addition, the APR function was plagued by loss of knowledge and expertise as the temporary workers performing the function were frequently replaced.

Note: Client produced multiple regulated products under one quality system; therefore, all Client's products were included in the Annual Product Review process.

CLIENT BUSINESS PAIN

The Client Quality Assurance staff was expending significant effort directing the day-to-day activities of the temporary workers to obtain timely reports and remain “in compliance”. There was little time to focus on the actual report content and evaluate any noted product quality and manufacturing issues. The APR function was costing more than it should, and delivering suboptimal outcomes. Compliance risks from an inspection review were well-known, and acknowledged. Eventually, the deficient process and poor APR quality led to a 0% on-time completion rate for APRs, resulting in the creation of a CAPA to address the issues.

SOLUTIONS PROVIDED / SERVICES DELIVERED

Initially, Compliance Architects® was asked to provide project-based consulting resources to work in staff augmentation roles in lieu of the temporary staff assignments. Assigned consultants had a much higher level of experience and capability in analyzing data and information and drafting APR documents than previous temporary personnel. After a year of success with more experienced personnel driving the APR process, Compliance Architects® then changed the game by scoping and delivering an innovative set of APR capabilities under a **Managed Service delivery model.** This innovative approach has resulted in a significant improvement in the level of operational control, compliance and document quality outcomes. In order to provide improved document, process and compliance outcomes at a reduced cost, the solution needed to include elements of “**People, Process, and Technology**” as part of the solution delivered:

People: The managed service is now staffed with full-time experts in GMPs, quality systems, FDA-regulated manufacturing, Annual Product Reviews, and technical writing.

Process: Extensive process improvements were developed, reviewed with the client, and implemented. Templates, requirements and standards for report writing were developed and implemented, along with a peer review process to promote quality and consistency across APRs. New processes for reviews by client Quality Engineers and Directors were introduced. Expectations and formal requirements for source data delivery from the EM sites were updated and communicated. Service Level metrics were introduced to measure the timeliness and quality of deliverable at key stages of the APR process, and a Service Governance model was deployed to manage service performance, address service issue and govern change management.

Technology: A Compliance Architects® provided SharePoint-based portal was scoped, configured and deployed to manage the overall process for APR report development and completion. The portal manages data and information

submissions from the EM partners; manages tasks for Quality Engineer and Director reviews and approvals; and provides a repository for final/approved reports. Real-time metrics dashboards show the status of all active reports, making it easy for the Compliance Architects® team and Client management to focus on issues requiring attention. The portal also provides data to support the reporting of monthly service level metrics.

BENEFITS REALIZED

Key Success Metrics:

- **Reduction** in total annual cost of service (over three years) from $1 million + to approximately $600,000, **a 40% reduction in cost to the client!**
- **Improvement** in on-time-completion of APRs to consistent achievement of **100% on-time-completion**.

Transition to a Managed Service for the APR process for this leading OTC healthcare company was a significant deviation from normal company practices, but also, a significant success! Trust in our firm as a preferred service provider played a large role in their willingness to adopt this service model. The Client has realized significant benefits in improved consistency of documents; improved process definition and governance; and overall, a significantly improved compliance profile. On-time completion of APR reports improved steadily as process improvements were introduced, and has been consistently at 100% since the deployment of the full solution. Collaboration between the Compliance Architects® writers and Client staff has grown stronger over time, yielding additional benefits in terms of lower rework and higher levels of report quality.

Client References Available Upon Request.
For more client success stories, visit: compliancearchitects.com/success-stories/

Want more details about this story? Contact us to set up a meeting: 888.734.9778

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