Infosys ASM offerings in R&D, Safety & Regulatory (RDSR)

Research, Development, Safety & Regulatory (RDSR) is a core function that drives sales for IP-driven life sciences organizations by creating new and safe drugs. This function encompasses the pharma supply chain from molecule discovery to clinical trials and safety / compliance. Life sciences companies are facing multiple challenges with their existing IT solutions:

- High cost of maintenance and enhancements for custom developed or COTS applications
- Lack of well-defined governance model that can help track and monitor support and maintenance KPIs
- Lack of a scalable model with flexibility to add new applications and retire applications to align with business objectives
- Need for process and tool standardization

Infosys leverages its existing application support and maintenance (ASM) experience and enhances the value by creating IT and business specific differentiation. This is based on optimized execution, integrated offering, domain capability and product capabilities.

Key ASM services offered

1. R&D, Safety and Regulatory application support and maintenance (ASM) services
2. Regulatory compliance services and regulatory submissions platform
3. Portfolio rationalization, application decommissioning, content migration, and archival services
4. Transformation, business analysis, and consultation services
5. Focus on implementing and supporting diverse set of industry leading products like Argus, ArisG, Lab Information management products, ELN products etc. across RDSR value chain.

<table>
<thead>
<tr>
<th>Drug Discovery</th>
<th>Drug Development</th>
<th>Clinical Trials</th>
<th>Regulatory &amp; Submissions</th>
<th>Pharmacovigilance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labvantage</td>
<td>Accelrys Lab Notebook</td>
<td>GCDSTRACK</td>
<td>ECTD Xpress</td>
<td>AERS/Argus Safety</td>
</tr>
<tr>
<td>Biobook</td>
<td>LIMS Products</td>
<td></td>
<td>Viewpoint Submissions Management</td>
<td>Empirica</td>
</tr>
<tr>
<td>Discovery 360</td>
<td>eLN Process Notebook</td>
<td>Oracle Clinical/RDC</td>
<td>Rosetta Phoenix</td>
<td>ArisG</td>
</tr>
<tr>
<td>Activity Base</td>
<td>Symyx – Renaissance</td>
<td>Philips Telemetry</td>
<td>Lorenz DocuBridge</td>
<td>Medidata Rave</td>
</tr>
<tr>
<td>Laboratory Data Archive</td>
<td></td>
<td></td>
<td>ISI Toolbox</td>
<td></td>
</tr>
<tr>
<td>Aperio Spectrum</td>
<td>Quovadx Integrator</td>
<td></td>
<td>Oracle LSH</td>
<td></td>
</tr>
<tr>
<td>Pathology Data Systems</td>
<td>Thesaurus Management System</td>
<td></td>
<td>MediData CTMS</td>
<td></td>
</tr>
</tbody>
</table>
ASM practice highlights

- **Global reach** – 24x7 coverage available using operations spread across the globe to service the application
- **Optimized portfolio** – proven portfolio rationalization capabilities, retirement and archival services
- **Enhanced flexibility in SLAs** across different business functions
- **Consolidated destination for all services** – namely L1, L2, and L3 consulting, migration, data integration, Business Intelligence and Analytics

Benefits to our clients

- **Reduced total cost of compliance** – 30 to 50 percent leveraging value GDM and integrated shared services model
- **Improved adherence to regulatory requirements** – leveraging focuses COE on compliance and business analytics expertise – ensuring 99 to 100 percent compliance
- **Integrated end-to-end capability** – capability across RDSR value chain including some of the most critical COTS platforms and custom applications across service lines. Partnerships with key software vendors to support the capability

ASM services for a leading global pharma company

ASM services for one of the world’s largest pharmaceutical company based in the US – with operations in over 100 countries and many leading brands across a large number of therapies.

- Infosys has a successful engagement with the customer since 9 years providing ASM services for over 340 applications in the Drug Research, Development, Safety, Regulatory and Medical domains
- Team consists of over 300 members, handling nearly 4000 tickets every month
- Support for 32 business critical apps and 80+ COTS applications. 40 percent validated and GxP applications across value chain
- Savings of $110,000 in the first year of contract for new application addition due to economy of scale built in the model

Portfolio rationalization for a leading global pharma company

A pharma giant in the US had to undergo organizational transformations. One of the objectives was to reduce IT maintenance costs by identifying applications that can be retired or consolidated.

- Application portfolio rationalization for over 300 applications
- Over 20 recommendations on decommissioning and technology upgrades
- Savings of $550,000 due to application rationalization and decommissioning
- Improved business and technical quality of portfolio achieved through retirement and consolidation of over 20 applications

Success stories: