Infosys®
Navigate your next

INFOSYS PHARMA REGULATORY COMPLIANCE

Pharmaceutical and life sciences companies are among the most heavily regulated industries in the world. The regulatory environment is continuously changing in response to the effects of globalization, emerging markets, new technologies, and rising demands of both patients and regulators. Some of the key business drivers that compel organizations to focus more on quality and compliance requirements include:

- Close scrutiny by regulators, and heavy penalties associated with non-compliance
- Pressure to optimize the cost of compliance and minimize risk exposure
- Maintain market standing and brand reputation

Infosys has a dedicated team of experienced professionals and a suite of service offerings that can cater to your organization's quality and compliance requirements.

Infosys pharma regulatory compliance offerings

Infosys quality and compliance offerings are categorized as – pharma IT compliance and pharma domain compliance. Pharma IT compliance provides the following:

Compliance advisory

- Process definition / compliance framework
- IT legacy process modernization

Compliance management

- Quality and compliance management (build and run)
- Continuous compliance improvements

Audit management

- Hosting internal and external audits
- Internal assessments (sustenance)

Validation services

- Validation consultancy
- Project quality management
- LIMS / eLN validation

Mobile medical applications consultancy

- Mobile application classification (medical / non-medical)
- Mobile medical application categorization (I, II, III)
- Regulatory requirements for mobile medical applications

Pharma domain compliance provides the following:

Regulatory submissions

- Regulatory guidance interpretation
- Regulatory submission strategy

Clinical supply chain management

- Validation planning and guidelines
- Implementation of standard and data conversions

Digital marketing

- Governance, performance reporting

Regulatory compliance value proposition

Accelerators

- Pharma IT process tool kit is a ready-to-use process tool kit that is compliant to pharma regulations
- IT audit tool is a predefined audit tool to prepare and execute audits
- Tools / solutions include regulatory submission platform, IT control matrix, LIMS validation package, mobile medical apps validation package

People

- 20+ senior consultants with an experience of more than 10 years in the pharma industry
- 40+ consultants with an experience of 7 – 10 years in the areas of CSV , audit support and IT compliance
- 40+ associate consultants with an experience of 4 – 7 years in the areas of CSV, change and release management, and audit support
- 30+ consultants and senior consultants with experience in compliance for regulatory submissions, HCP spends, digital marketing, and clinical trials

Engagement

- Providing validation services to 4 out of the top 10 pharma companies
- Providing validation services to 3 medical devices companies
- Providing compliance advisory, audit support and domain compliance services to 3 out of the top 10 pharma companies
- Managing compliance sustenance activities within 3 pharma companies

Benefits derived by our clients

- HCP spend disclosures –
  - *Track reporting requirements*
  - *Data cleansing as per business rules*
- Reduced total cost of compliance
- Improved adherence to IT regulatory controls
- Better control over compliance risks
- Reduced number of failures in external audits / inspections through an efficient audit function
- Faster turnaround time in outsourced service areas

Key success stories

Validation consultancy

Infosys was engaged to provide validation services for the entire set of regulated applications of a top pharma client. Our services included:

- An analysis of the existing validation methodology of the client and process definition
- A risk-based validation approach, which helped the client save 15 percent more effort than what was internally estimated
- Based on project experience, the client setup a validation CoE to cater to future needs. The projected savings for validating future projects through this CoE lies between 15 – 20 percent
- A streamlined process for documentation saved the client more than 10 percent effort in recreating documents, which was required for this program

IT compliance for shared services

The client had a siloed model for managing IT with little or no standard processes, where 100+ vendors supported the portfolio of 2,000+ applications. Infosys was involved in setting up the compliance function:

- It helped reduce the number of findings each year in the internal and external audits – from 10 non-compliances in 2008 to zero compliances in 2012
- It set up a unified process model and created an effective auditing framework
- It defined control points to review and approve through the lifecycle of the project – a) stage gate reviews b) production acceptance reviews, and c) effective change management process

For more information, contact askus@infosys.com

Infosys®
Navigate your next