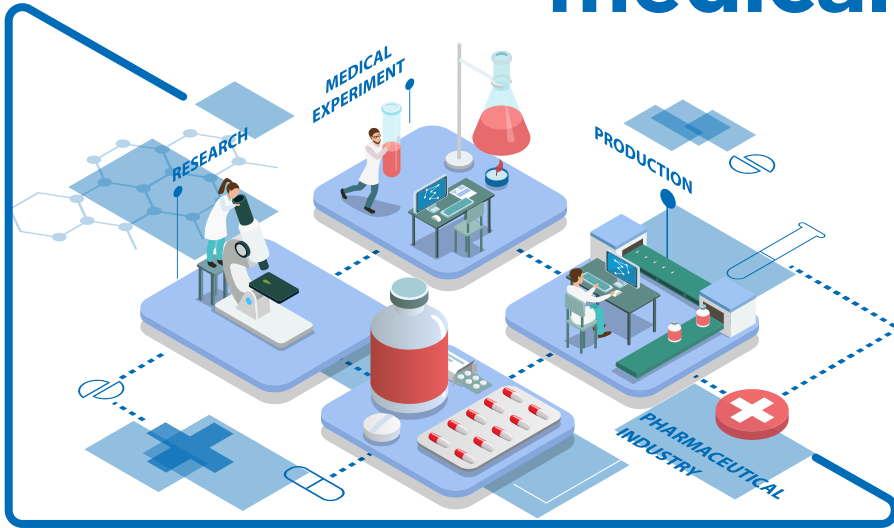


Pharmacovigilance and medical Information services



Transforming patient safety & inquiry management through innovative and integrated services

Pharmacovigilance (PV) and drug safety services focus on assisting our clients through the developmental phase to the post-marketed phase to ensure their products meet regulatory requirements and maintain their safety profile. HCL Technologies possesses decades of PV and medical information experience including seasoned industry experts to operational excellence at global scale. The experience allows HCL Technologies a unique position to monitor the product safety needs from intake to regulatory reporting globally and in multiple regulatory environments.



Medical Information Contact Center

HCL Technologies has a deep history of delivering successful medical information services to our pharma clients. From medical information inquiry management to adverse event and product complaint intake and triage, HCL delivers the full spectrum of medical information program services. Our team of healthcare professionals is exceptionally well prepared to address our clients' customers in an efficient manner. HCL Technologies drives further value by providing our clients with actionable insights, automated processes, comprehensive reporting, and an ever-present emphasis on the quality of the interactions we handle. Combined with our strict adherence to industry compliance, HCL offers our clients high-quality services along with the peace of mind that HCL is making their business, our business.

Key Offerings



HCL Advantages

Healthcare Heritage: ◀

42 years of experience in building trusted customer relationships with healthcare clients

Globally integrated, regionally focused engagement models provide in-region support and capture regional nuances

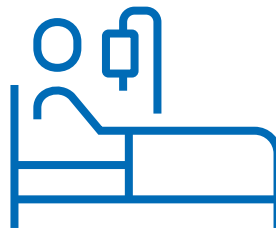
Multilingual support across various channels including inbound and outbound phone and web interactions

Social media monitoring for adverse events, product quality complaints, Off-label use identification, and reporting misinformation

Next-gen contact center solutions by leveraging automation, conversational intelligence, artificial intelligence, and machine learning capabilities

Quality and Compliance: ◀

Dedicated compliance team, quality management system, non-conformance system, ZERO 483s with FDA audits, ISO 9001:2015 certified, ISO 13485:2016 certified, fully compliant in HIPAA, EU Privacy and GDPR.



Pharmacovigilance (PV) Services

Since 1995, HCL Technologies has been delivering end-to-end PV services. Our comprehensive service portfolio includes global case processing, regulatory submissions, regulatory reporting, aggregate reporting, signal detection, QPPV, regulatory intelligence, literature searches, and hosted safety database solutions. The services are flexible to fit into clients' current business processes, to help them manage their PV and drug safety needs. PV services also include Argus database expertise in implementation and hosting, configuration, and upgrades of the Oracle Argus Safety database.

Offering 1

Pharmacovigilance Consulting-

PV Overall Strategy, PV Industry trends and transformation roadmap.

Offering 2

Pharmacovigilance Operations-

Case processing (hosted or clients' database), clinical trials (CT) and post-marketing (PM), proprietary PV intake platform for global receipt of safety information, aggregate report writing, support, and more.

Offering 3

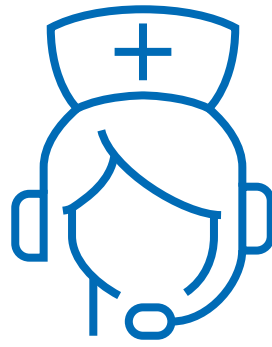
System Implementation &

Integrations- Hosting of global Argus platform implementation and system integrations and Argus Safety. Argus upgrades, MedDRA and WHO drug upgrades, and safety data migration

Offering 4

Technology Capabilities:

Experience with various system Integrations, analytics, Axway, SAS, and BI



HCL Advantages

Specialized in ◀
Pharmacovigilance: 27 years of experience in building and executing customized, high quality, and compliant PV programs

Oracle premium partner: ◀
HCL Technologies Argus Database Safety systems analysts are Oracle certified implementation specialists.

Healthcare professional ◀
model: Licensed healthcare professionals with extensive clinical and therapeutic expertise combined with leadership experience producing high-quality services and expert management oversight.

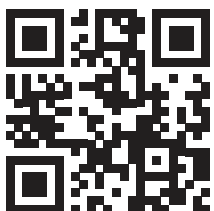
Quality and Compliance: ◀
Dedicated compliance team, QMS System, Non-conformance System, ZERO 483s with FDA audits, ISO 9001:2015 certified, ISO 13485:2016 certified, fully compliant in HIPAA, EU Privacy, GDPR, and Standard Contractual Clauses (SCC).



HCL Technologies (HCL) empowers global enterprises with technology for the next decade today. HCL's Mode 1-2-3 strategy, through its deep-domain industry expertise, customer-centricity and entrepreneurial culture of ideapreneurship™ enables businesses to transform into next-gen enterprises.

HCL offers its services and products through three lines of business - IT and Business Services (ITBS), Engineering and R&D Services (ERS), and Products & Platforms (P&P). ITBS enables global enterprises to transform their businesses through offerings in areas of Applications, Infrastructure, Digital Process Operations, and next generation digital transformation solutions. ERS offers engineering services and solutions in all aspects of product development and platform engineering while under P&P. HCL provides modernized software products to global clients for their technology and industry specific requirements. Through its cutting-edge co-innovation labs, global delivery capabilities, and broad global network, HCL delivers holistic services in various industry verticals, categorized under Financial Services, Manufacturing, Technology & Services, Telecom & Media, Retail & CPG, Life Sciences, and Healthcare and Public Services.

As a leading global technology company, HCL takes pride in its diversity, social responsibility, sustainability, and education initiatives. As of 12 months ending on December 31, 2021, HCL has a consolidated revenue of US \$ 11.48 billion and its 208,000 ideapreneurs operate out of 52 countries. For more information, visit www.hcltech.com



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