

Your Extended Digital Engineering Arm to Build Innovative Medtech Solutions

As the momentum of digital transformation in the medical devices and healthcare industry continues, COVID-19 has accelerated the need for connected healthcare and remote monitoring of patients. Medical device companies are now looking for innovative, meaningful and cost-effective medical device solutions that work seamlessly in an era of patient-centric connected healthcare. Further, they want to maximize the value of their data through robust data analytics and AI-based solutions. Medical device companies are also emphasizing efficient and modern UI/UX design for their medical device software to deliver enhanced product quality and enriched user experience. At the same time, nuances of regulatory compliance in different geographies, cyber security issues and time-to-market continue to be top priorities for all the leading medical device manufacturers.

Mphasis works as the extended arm for medical device organizations to provide digital product engineering services. We enable transformation, new product R&D and end-to-end product and platform engineering solutions across several specialties such as imaging diagnostics, clinical diagnostics, surgical and therapeutic applications, connected medical devices and remote patient monitoring.

For analytical instrumentation OEMs, we help enable instrument data acquisition and post processing of acquired data and facilitate interoperability of instruments and data systems from multiple OEMs, through development of instrument drivers. Through our solutions, the OEMs can realize usage of these instruments in regulated environments at Pharmas and CDMO/CROs for Drug Discovery, Manufacturing and QC.

Transformation through Digital Innovation

Our innovative solutions, coupled with digital transformation services such as cloud, AI/ML, data analytics and cyber security, enable medical device companies to capitalize on next-generation MedTech solutions such as:

- Cloud-based patient data access - medical images, surgical videos
- Data- and analytics-driven clinical decision-making
- Deep learning-enabled healthcare diagnostics
- Future-ready CX involving AR/VR/MR
- IoMT-based patient and device analytics

Service Offerings



End-to-End Product and Platform Development & Sustenance, for your class I, II and III products based on ISO 13485 standards and IEC 62304 guidelines ensuring highest quality control and smoother regulatory compliance



Development of SAMD and SIMD solutions such as connected mobile apps (SAMD) for visualizing the imaging data from your diagnostic and surgical devices & embedded software (SIMD) within medical device



Seamless connectivity solutions such as instrument drivers and bridge layers enabling interoperability among devices and acquisition systems in a pharma lab. Also, HL7 FHIR & DICOM standard based interoperability solutions for connectivity of medical devices with the hospital enterprise systems.



Laboratory informatics services to enable lab automation in pharma and CDMO through EBR, CSV and LIMS implementation. We also enable the integration of instrument software with LIMS to move from paper to paperless labs.



Cyber security of medical devices and analytical instruments – Offerings include cyber security consulting services, risk advisory services, security design and operation solutions, embedded device security, infrastructure security, data security, and risk and vulnerability solutions.



Regulatory compliance and data integrity services - Our end-to-end solutions for device manufacturers ensure compliance with regulatory standards and guidelines issued by FDA (USA), MDR (EU) and TGA (AUS).



Digital health technology services, based on Cloud, AI/ML and cyber security, image analytics, Cloud migration and modernization.



Cognitive Quality Engineering (CQE) - Our AI/ML platform enables clients to take decisive actions in planning product releases through cognitive models based on product configurations, test assets and past test results. It is used for medical device testing and Healthcare & Life Sciences software testing, with a strong focus on regulations and standards compliance.

Platform Solutions



Cloud-based platforms e.g., to facilitate live surgery capture and broadcast, analytics for aggregated COVID19 testing data



Healthcare data platform for patient workflows, image transfer and analysis across multiple application areas for Dental, ENT, Neuro, Ophthalmology



ALTA platform - for ensuring an uninterrupted supply chain for pharmas and device OEMs



DeepInsights™ - for AI-based image analytics



Bridge layer platform - to enable interoperability of multi-OEM instruments with multi-OEM data systems

Success Stories



Transformation of security features through 'Security by Design' for a leader in ophthalmology devices

Through secure coding and robust access control, static code analysis and design elements, we enabled a leading ophthalmology device manufacturer to comply with FDA security requirements in record time. Our bottom-up approach of applying security standards reduced the need for frequent security patches, slashed maintenance costs and associated risks by 30% and achieved 'zero' security testing bugs in the device software.



Achieving high trust levels for a leading ophthalmology device software brand

We successfully re-classified the devices according to the Regulation 2017/745 (MDR) Annex VIII in record time to ensure the client met the acceptance criteria for Market Registration to operate in 4 EU countries. Through a comprehensive process of technical gap assessment, risk assessment, labeling and conformity assessment, post-market surveillance plan and all regulatory submissions, we enabled fast delivery to reduce time-to-market and enhanced the brand's trust factor.



Automating and streamlining of surgical workflow for a surgical microscopy device OEM

We developed an iPad application to remotely access and control the state-of-the-art microscope and its image capturing parameters. This enabled the live stream of surgical procedures for Dental, ENT and Neurosurgery with minimal latency – with data masking for enhanced safety and privacy. The client could increase their market penetration with leading products and improve their time-to-market.



Enhancing device connectivity through software modernization for a leading device manufacturer

Undertaking complete ownership of product development, enhancement and modularization of legacy code for a leading device manufacturer, we increased device efficiency and utility through software modernization for seamless connectivity between devices and cross-vendor data sharing.

Compliant with HL7 FHIR interoperability standards, our solution delivered easy transmission of data amongst the devices so that our client's customers could offer a unique consultation experience.



Delivering a 25% saving in development time for a global leader in the Lifesciences industry through reduced hardware dependency

We successfully designed and developed Linux-based Liquid Chromatograph (LC) emulators for a leading player in the global Lifesciences industry. Using virtual machine-based Linux and hardware-based ARM processor, we enabled the client to save development time by ~25% for each driver. Through reusable frameworks for all instruments and emulators in automation testing, and preventive measures in addressing issues, we significantly reduced associated efforts and costs.



Improving speed of processing to enhance LIMS performance for a US based industry leader in analytical instrumentation & innovative software solutions

We enabled HL7 standard interfacing for LIMS software and its full implementation for a leading player in analytical instrumentation & software solutions company resulting in improved speed of processing of worklists and uploading of results. Through additional HL7 segments, performance optimization of the required parts of codes, and improved options of sending results we could achieve faster processing of worklists and uploading of results to LIMS.

Why Mphasis?

- **“One Team” approach** with dedicated MedTech and Lifesciences subject matter experts (SME), compliance specialists, certified professionals for standards to provide customized solutions in line with regulatory standards and compliance requirements
- **Customer Centric Investments**
 - Investments in IP, Solution Accelerators, COEs, upskilling and cross-skilling of teams for faster deployment and higher engagement ROI for clients.
 - Medical and Analytical instruments lab to create infrastructure and technology for development and testing
 - State-of-the-art Lab setup to support end-to-end product testing and supports customer environment
 - Deep focus and investments in chosen sub-verticals including SMEs in product development, cloud, data, analytics and cyber security
- **Quick POCs and demos**, showcasing delivery excellence through transparent governance, metrics driven digital dashboards and talent-next platform
- **Research and innovation center** (NEXT Labs) to build Next-gen solutions
- **Rich ecosystem of 100+ technology partners** & bringing disruptive innovation through Sparkle Lab, an incubation center for contextual innovative solutions in partnership with academic institutions and startups

About Mphasis

Mphasis' purpose is to be the *“Driver in the Driverless Car”* for Global Enterprises by applying next-generation design, architecture and engineering services, to deliver scalable and sustainable software and technology solutions. Customer centricity is foundational to Mphasis, and is reflected in the Mphasis' Front2Back™ Transformation approach. Front2Back™ uses the exponential power of cloud and cognitive to provide hyper-personalized ($C = X2C^2 = 1$) digital experience to clients and their end customers. Mphasis' Service Transformation approach helps 'shrink the core' through the application of digital technologies across legacy environments within an enterprise, enabling businesses to stay ahead in a changing world. Mphasis' core reference architectures and tools, speed and innovation with domain expertise and specialization, combined with an integrated sustainability and purpose-led approach across its operations and solutions are key to building strong relationships with marquee clients.

[Click here](#) to know more. (BSE: 526299; NSE: MPHASIS)

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