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BAKUL PATEL is the Director of Digital Health Division, at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel is responsible for providing leadership, development, implementing, execution, management and setting strategic direction and regulatory policy and coordinate scientific efforts for digital health, software and emerging technologies.

This includes responsibilities in leading the development on policies for mobile health, health information technology, cyber security, medical device interoperability, and medical device software.

Mr. Patel, in 2013, created the term “software as a medical device” (SaMD) and under his leadership the *International Medical Device Regulators Forum* (IMDRF) established the globally harmonized definition of SaMD. Mr. Patel subsequently led global regulators at IMDRF to create and author the globally harmonized regulatory framework for SaMD documents. The concepts, principles and vocabulary created in harmonized regulatory framework has been used as a foundation and adopted by medical device regulatory bodies in the European union, Japan, Canada, Brazil, Australia and in the USA by US-FDA.

Mr. Patel is the FDA liaison between the Federal Communications Commission (FCC) and the Office of the National Coordinator (ONC).

Mr. Patel is currently leading the effort for the agency in developing an innovative software precertification program in collaboration with all stakeholders to reimagine a regulatory approach for Digital health that aims for patients and providers to have timely access to safe and effective digital health products.

Prior to joining FDA, Mr. Patel held key leadership positions in the telecommunications industry, semiconductor capital equipment industry, wireless industry and information technology industry. His experience includes Lean Six Sigma, creating long and

short-term strategy, influencing organizational change, modernizing government systems, and delivering high technology products and services in fast-paced, technology-intensive organizations. Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.