



The Realtime Group of Companies

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Case Study – Cytology System

The Challenge:

Provide Verification and Validation services to a start-up company developing a device intended to collect and prepare cervical-vaginal cytology specimens for Pap stain-based screening for cervical cancer. The Cytology System's Pap Test produces slides are intended to replace conventionally prepared Pap smear slides.

The Solution:

The Realtime Group immediately facilitated a formal Hazard Analysis in accordance with ISO 14971, the international standard for Application of Risk Management to Medical Devices. The Realtime Group also collected all marketing-level and system-level requirements specifications and began development of a trace matrix from 'parent' specifications to 'child' specifications (and eventually down to test cases).

To address the manufacturing and process aspects, Realtime developed comprehensive validation test protocols. For the larger, critical systems, protocols were developed in the Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) format. For other, less critical systems, a tailored approach to validation was developed commensurate with the size and quality impact of the system, including computer system validation procedures.

The Realtime Group was also an essential partner in preparation of Pre-Market Application (PMA) to the FDA. The company was approved by the FDA to market the product in 2006.



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To Learn More About this Product:

The Cytology System product, automates the preparation of cellular specimens in the cytology laboratory. Sophisticated automation engineering makes the Cytology System unique on the market. It delivers significant benefits to pathology laboratories, including lower costs, greater throughput capacity, consistency of test results, and the capability to handle many different specimen types.

The Realtime Group is a leading medical device and aerospace engineering & product development firm that was instrumental in supporting the customer in achieving FDA approval to market the Cytology device. The Realtime Group has been in the trenches of supporting clients get products through the FDA approval cycle. There is no better company to have as a partner than The Realtime Group.



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