Spectrum Lecture Series 2018-2019

The History of DNA Sequencing and Applications for Diagnostic Testing for Cancer

Wednesday, February 27, 4:30 PM
Montgomery College
Germantown Campus
BE151

Dr. Joshua Levin
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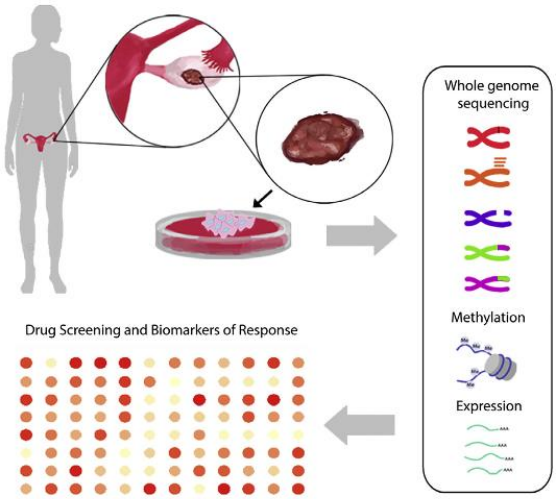
Personal Genome Diagnostics, Inc.



Abstract: The purpose of this talk is to describe how DNA sequencing is being used as a diagnostic tool for cancer, and the technological developments that made this possible. The first part of this talk describes the history and development of DNA sequencing technology and associated techniques such as the polymerase chain reaction (PCR), beginning with the identification of the structure of DNA in the 1950s. The first sequencing of a human genome was completed nearly 20 years ago, and since that time DNA sequencing technology has advanced by multiple orders of magnitude, facilitating the use of DNA sequencing as a diagnostic tool. The second part of the talk will discuss recent developments in the FDA approval of genetic tests for cancer tumor profiling and in directing therapeutic interventions. Personal Genome Diagnostics (PGDx), Inc. will be highlighted as a local company that that is developing diagnostic tests based on DNA sequencing for cancer detection in tissue and blood and identifying personalized therapy based on these DNA sequencing results.

Joshua Levin, Ph.D., RAC (US) is Associate Director, Manufacturing Quality at Personal Genome Diagnostics, Inc. (PGDx). In role at PGDx, Dr. Levin is responsible for overseeing the company's design control and risk management programs as well as ensuring that the PGDx Quality Management System is compliant with the ISO 13485:2016 standard and the FDA Quality System Regulation. Dr. Levin was previously a reviewer and postmarket team lead in the Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH, FDA where he was responsible for quality system reviews and compliance activities for IVD products. A significant part of Dr. Levin's work at FDA focused on working with clinical laboratories in the development of FDA-compliant Quality Management Systems to support FDA clearance and approval activities. Prior to his 8 years at FDA, Dr. Levin spent 15 years in R&D and process development in IVD and research products firms. Dr. Levin received his B.A. from Brandeis and his Ph.D. from Harvard.

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