

Press Release

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Manuel Fernández joins 2cureX as Director of Quality Assurance and Regulatory Affairs.

2cureX, a company pioneering the use of 3D micro-tumors (tumoroids) for drug sensitivity testing in patients with cancer, announced today a new member of its management team, Manuel Fernández. Manuel will use his many years of experience to lead the critical QA / RA function.

The operations of all *In Vitro Diagnostics* (IVD) companies have been deeply impacted by the transition from the former IVD-D regulatory environment to the new one (IVD-R). The company has therefore established a new position – Director, Quality Assurance and Regulatory Affairs – to ensure 2cureX continues to operate according to the highest standards, and that its products and services are designed, developed, tested, manufactured, marketed, and distributed in compliance with the relevant regulations in the different markets.

A very experienced professional

Manuel Fernández has nearly 30 years' experience in Diagnostics and Medical Devices. His academic background is in mechatronics, robotics and automation engineering, as well as biomedical engineering. Throughout his career he has led QA / RA functions in several companies, becoming an expert in all relevant ISO norms. He has deep knowledge of the regulatory landscapes in Europe, US, China and Asia Pacific, and has worked with Notified Bodies and competent regulatory authorities in major countries. He is a certified FDA-MDSAP Auditor, certified ISO 13485, ISO 27001 and ISO 9001 Lead Auditor, certified FDA-Clinical Investigator Inspector and certified FDA Pharmaceutical QMS Auditor, among others.

A critical part of the overall competitive strategy

“We are very excited about Manuel joining us” says Fernando Andreu, CEO of 2cureX. “In the new regulatory landscape, QA / RA has become a critical part of the overall competitive strategy, and Manuel's comprehensive and global experience within the Medical Device, Diagnostics and Software industries will be a great asset for the company”.

Manuel: “It is a pleasure for me to join the 2cureX Team. The IndiTreat® tests are opening an all-new category of IVD devices, and I am thrilled to be part of this journey, helping bring 2cureX operations to the highest quality standards and guiding future IndiTreat® products and services smoothly through the regulatory system”.

Compliance with the new IVD-R

2cureX has launched three IndiTreat® tests in the last nine months – IndiTreat® mCRC Start, IndiTreat® mCRC Extend and IndiTreat® mCRC Explore –, each aimed at guiding medical treatment of patients with metastatic colorectal cancer. From May 26th 2022, the company has a 4-year period to adapt the related regulatory files of these tests to the new IVD regulation (IVD-R). Products launched after May 26th 2022 will need to be compliant with IVD-R and gain regulatory approval before being placed in the market, a process for which the company has been preparing thoroughly in the last year.

For more information about 2cureX:

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About 2cureX

2cureX is a leader in cancer drug sensitivity testing and has developed the IndiTreat® (Individual Treatment) family of tests. Starting from a sample of the patient's tumor, IndiTreat® creates thousands of 3D replicas (tumoroids) and predicts the tumor response to the different available drugs, providing the physician with valuable information to make the treatment decisions.

The portfolio of IndiTreat® tests is aimed at optimizing treatment decisions in patients with metastatic colorectal cancer (IndiTreat® mCRC Start for first line of therapy, IndiTreat® mCRC Extend and IndiTreat® mCRC Explore for third line). Additional tests are under development to cover other stages of colorectal cancer as well as other gastrointestinal cancers.

According to several reports, the total yearly expenditure in cancer-related *In Vitro Diagnostic* (IVD) tests exceeds 17.5Bn USD worldwide, from which 2.5 Bn USD are tests directly related to therapy decision making, with a CAGR of 12.7%. Despite this, only one third of all cancer treatments are supported by one of these tests. IndiTreat® aims at filling this gap and making Precision Oncology available to all cancer patients.

The company is listed on Nasdaq First North Growth Market in Stockholm (symbol: "2CUREX"). For more information about 2cureX visit www.2cureX.com

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Attachments

[Manuel Fernández joins 2cureX as Director of Quality Assurance and Regulatory Affairs.](#)