



Mark Harris
BUSINESS DIRECTOR



Novartis

September 2012 - September 2014

Systems Project Management

"Mark was a key contributor to the new digital Telehealth programme at Novartis in Basel and his insight and experience made a notable contribution to the shaping of that programme."

Dominik Ziegler, Project Leader, Novartis Pharma

Challenge

Globally renowned healthcare and pharmaceutical company Novartis had identified a series of new business opportunities, one of which was Telehealth for COPD – mobile digital devices to be used in conjunction with a home terminal to:

- detect signs of patient deterioration
- monitor medication usage
- encourage patients to become more active

The system, comprising a bespoke home computer, a drug delivery medical device, monitoring devices, a mobile communication network and a back-end computer system for automatic analysis and medical reporting, required a Medical Devices Project Manager to help define the controls and documentation to meet all regulatory requirements.

Strategy

Mark acted as a principal point of contact with key technology and medical device contractors, developing robust project controls, establishing timescales for the completion of design and operations and creating and agreeing service agreements. Mark undertook successful contractual negotiations and intellectual property management and created and developed completely new processes and documentation on regulatory compliance, risk management, quality assurance and safety reporting processes.

Outcome

Key achievements in the project involved the delivery of a completely new range of technical, regulatory and supply chain template documents consistent with the stringent and highly risk-averse Novartis procedures. In addition, Mark successfully managed the company's relationship and ultimate legal disengagement with a failed home computer supplier company.



Regulatory compliance documents

Risk management processes

Safety reporting controls