

## **PDS Consultants: Context of the Organisation**

PDS Consultants (the trading name of PDS Computer Software Ltd) is a technology business which provides specialist software and consulting services dedicated to the use of computers in regulated industries (predominantly pharmaceutical research and medical device manufacture).

The purpose of the organisation is to establish and maintain an industry-wide reputation for providing a unique range of products and services aimed at managing safety data within a regulatory context. From this platform, strong operating profits are achieved which will eventually underpin the value of its assets as part of a controlled exit strategy.

We have established close, long term relationships with our clients (both end user organisations and third party suppliers to those organisations). We develop all of our products in house which we supply directly to our clients.

We are a single person business which uses sub-contractors. However, in the absence of a succession policy, we are following an exit strategy which aims to avoid impacting our customers through a controlled transfer of software assets, along with their support and onward development, to a larger organisation. This is scheduled to take place during 2018.

We are members of a consortium (eTRANSafe) which has been selected to deliver a European Union Horizon 2020 project relating to translational safety. This is a 5-year project which involves a combination of software and consulting. In line with the exit strategy, our software assets will be divested during the course of the project which will allow the Managing Director to continue on a consulting basis until project completion and beyond. Brexit is considered to have zero impact on the business.

The management is aware of the necessity to monitor the business environment and the company's position within it. As part of the management review procedure, any changes to the context of the organisation and the needs and expectations of all interested parties are discussed and documented and their impact considered in terms of both risk and opportunity.

The Management Team, comprising the Managing Director and an external Quality Management specialist, have established, documented, implemented and are continually improving our quality management system in accordance with the latest revision of the ISO 9001 quality standard.

We hold regular management review meetings where we highlight areas of risk regarding the development and delivery of products and services and take appropriate mitigating action. This is augmented by a schedule of internal audits and corrective actions.

The company is aware of, and acts proactively to ensure adherence to, all relevant external standards and regulations as well as ensuring that our products and services meet our customers' requirements in full.