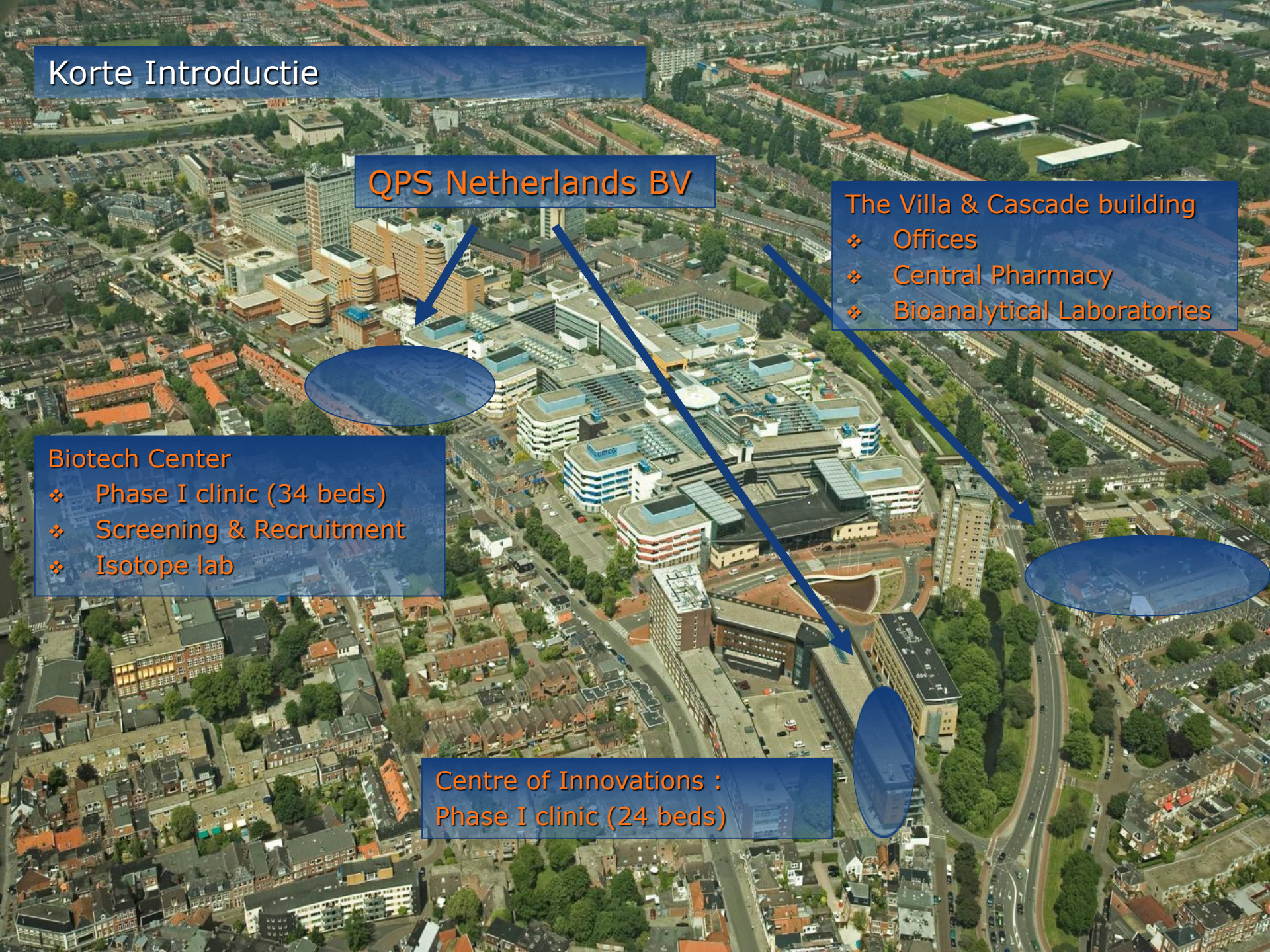
QPS helps you navigate

Responsibilities

Delegation and Communication

Marleen Beijl, 05 oktober 2016


Korte Introductie
QPS Netherlands BV
The Villa & Cascade building
Offices
Central Pharmacy
Bioanalytical Laboratories
Biotech Center
Phase I clinic (34 beds)
Screening & Recruitment
Isotope lab
Centre of Innovations :
Phase I clinic (24 beds)

Responsibilities Sponsor

5.1.1

The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented, and reported in compliance with the protocol, GCP and the applicable regulatory requirements

5.2.1

A sponsor may transfer any or all of the sponsor's trial related duties and functions to a CRO but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control


Signature

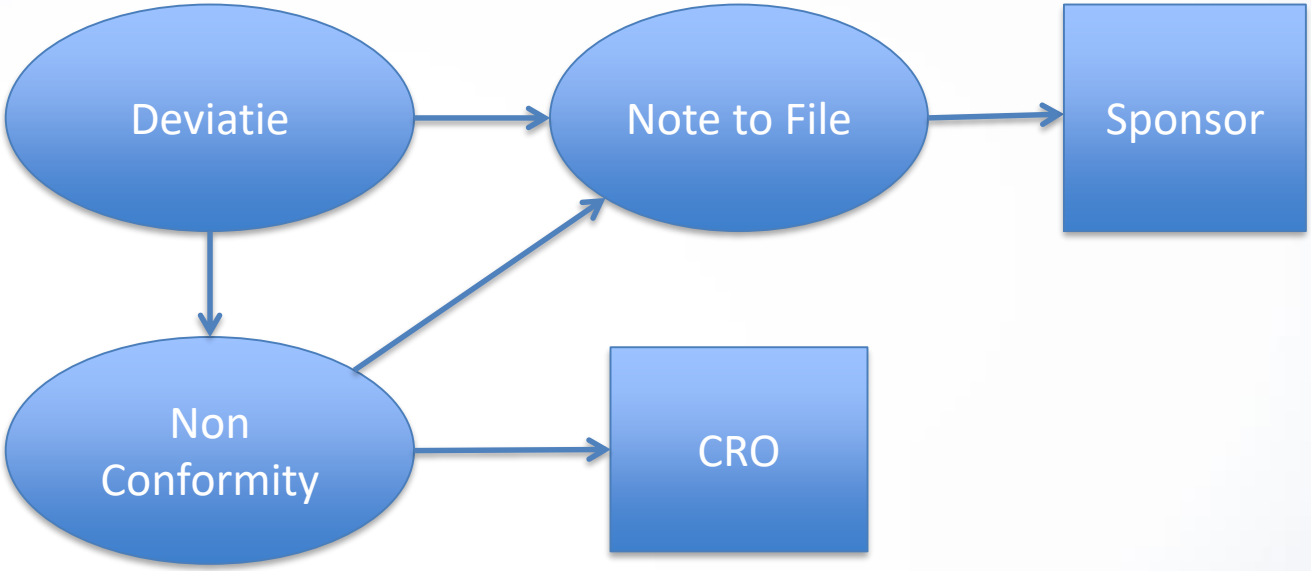
Responsibilities Investigator

4.2.3

The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

4.5.2

The investigator should not implement any deviation from or changes of the protocol without agreement by the sponsor and prior review and documented approval from the IEC of an amendment, except where necessary to eliminate an immediate hazard to trial subjects, or when the change involves only logistical or administrative aspects of the trial


Deviatie
Note to File
Sponsor
Non Conformity
CRO

Kwaliteit door Samenwerking