Annex 1:

DETAILED REQUIREMENTS OF QUALITY AND REGULATORY EXPERIENCE FOR QA/RA LEADER

The person's knowledge of the regulatory requirements within the medical device industry is crucial to establish whether or not the candidate is qualified as a QA/RA Leader Medical Devices. The following theoretical and practical requirements should, at the very least, be met, in addition to an approved certification exam in order to obtain a certificate.

Alternative 1)

Completed university degree or equivalent education within science, medicine, pharmacology, engineering or other relevant subject and at least two years' professional work experience in the areas of Regulatory or Quality Management systems in relation to the medical device industry.

Alternative 2)

Five years' professional work experience in the areas of Regulatory or Quality Management systems in relation to the medical device industry.

Alternative 3)

At least two years' professional work experience and completed relevant education in the areas of Regulatory or Quality Management systems in relation to the medical device industry.