



Dutch Association of Research Quality Assurance Professionals (DARQA)

Since its inception in 1981 the Dutch Association of Research Quality Assurance Professionals (DARQA) has been developing its role as the communication platform for Dutch and Flemish QA professionals. DARQA offers its 350 members an opportunity to bring their voice and vision to the industry's Good Practices: Good Laboratory Practice (GLP); Good Manufacturing Practice (GMP); Good Clinical Practice (GCP) and other recognised quality management systems related to the Life Science industry and organisations.

The background of its members is very diverse: originating from clinical/pharmaceutical/medical industries, laboratories, universities and research institutions, consultancies or other organisations that have an active interest in research and development. Lively interaction is also stimulated by the various professions of our members, like QA managers, auditors, clinical research associates, qualified persons, ICT professionals, consultants, academics, QC officers, study directors, project managers and managing directors. DARQA membership spans all levels of experience in the profession. New recruits benefit from the experience of the most senior members who are recognised internationally. This diversity is the sound basis for DARQA and facilitates the open exchange of knowledge, which is boosting the competence of its members and the companies they represent.

In 1981 DARQA was founded as a platform of GLP QA professionals, which formally became DARQA in 1992. In 1995 they were joined by the GCP association. In 1999, with the increased interest in 21 CRF Part II, an ICT interest group was formed. The European clinical trial directive initiated a fourth interest group in 2005, focusing on GMP. The interest groups organise at least two meetings annually to enable members working in their specialist sectors to have contact with other QA professionals in that area. However, all meetings are open to members of all interests, which enables a dialogue between QA professionals from multiple disciplines on areas of common interest. It also enables the mutual recognition of each interest in the interfaces between the disciplines they represent. More general topics like validation and risk management are frequent topics of the meetings, which offer QA professionals access to the process excellence available in all GxP disciplines.



For example, the pharmaceutical industry benefits from the more mature design risk management practice of the medical device industry. DARQA is still broadening its scope, currently focusing on GMP for hospital pharmacies, medical devices and the Investigational Medicinal Product supply chain. The Netherlands is a relatively small country, which enables members to frequently attend meetings. The meetings may be as conveniently short as one afternoon. Wherever possible the workshop format is used to stimulate open discussions and free transfer of knowledge and experience amongst the participants. Workshops address difficulties encountered in daily practice and how they have been solved at different companies. Also, the challenges new regulations impose on daily practice are the subject of workshops, from which members gain valuable implementation guidance.

DARQA is a recognised discussion partner for government inspectors. Occasionally its meetings are visited by the inspectors providing an informal opportunity to challenge each perspective and to validate ideas. By the well maintained relationship with the inspectors, DARQA also achieves a positive impact on the development of Dutch legislation and inspection practice.

With the advance of social media and other new means of electronic communication, DARQA is broadening the networking possibilities for its members. On the website forum www.darqa.org members are able to discuss current regulatory questions. Non-members can discuss topics with DARQA members at its LinkedIn group. The DARQA website is also used to disseminate draft European guidance documents open for consultation, providing members the opportunity to get involved in regulatory affairs.

Currently DARQA is launching a project to achieve status of centre of excellence for Quality Assurance. By inventorying competencies available throughout its members and increasing the platform opportunities to advocate them DARQA is strengthening its role as an advanced quality centre. In the case of new regulations or complex issues, DARQA may install special interest groups of experts that will investigate the best practices and report them in a white paper or a dedicated DARQA meeting. Also, means of marketing are exploited to establish DARQA as a recognised source of QA excellence in the market and the media. Opportunities for training and e-learning are also being investigated. A new era is dawning for DARQA, spawning new enthusiasm at its board and its members.



DISCUSS MORE AT DARQA'S WEBSITE FORUM:
www.darqa.org