



## Continuing Education Units from CDG

### *Why Continuing Education?*

Medical devices are a fast-paced technology and, like Alice in Wonderland, we must run as fast as we can to stay in place. Professional development activities outside the realm of university credit courses provide unique opportunities for enhancing and expanding your professional skills. They provide focused learning, targeted to specific needs, and offered with technologies that are flexible in time and space.

Clinical Device Group offers unique training events for medical device pre-approval issues: including regulatory, clinical research, and biological safety. Presented in face-to-face seminars, online webinars, and online e-conferences, our training covers both basic and breaking skills in the global setting.

### *The Continuing Education Unit*

The Continuing Education Unit (CEU) is the internationally recognized method of quantifying the learning experience outside of the traditional classroom. Related to the contact hour, the most common module of educational experience, it is based on the International Association of Continuing Education and Training's definition of one CEU per 10 hours of contact time under responsible sponsorship, capable direction, and qualified instruction.<sup>1</sup>

Medical device companies require employees to continue their education and training in order to maintain the appropriate knowledge and skills to perform their jobs.<sup>2 3</sup> The primary purpose of the CEU is to provide a measurement and permanent record of the continuing educational accomplishments of an individual.

### *Continuing Education Quality Standards*

The National Council on Continuing Education and Training (NCCET) and the International Association of Continuing Education and Training (IACET) publish guidelines for quality standards of non-credit education.<sup>4 5</sup> As a member, Clinical Device Group adheres to these guidelines in all its educational events. The quality standards include:

### *Needs Assessment*

Behind every event is a needs assessment, by which our market research establishes the learning objective of the event. Our needs assessment activities include: 1) an Annual Survey of Clinical Research Practices,<sup>6</sup> 2) the Clinical Device Forum<sup>7</sup> (an online, global conversation about medical device pre-approval issues), 3) continuing research

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<sup>1</sup> See the International Association for Continuing Education and Training at [http://www.iacet.org/standards/intro\\_CG.htm](http://www.iacet.org/standards/intro_CG.htm).

<sup>2</sup> See ISO 13485—Quality Systems - Medical devices - Particular requirements for the application of ISO 9001, section 4.18—Training.

<sup>3</sup> See ISO 13488—Quality Systems - Medical devices - Particular requirements for the application of ISO 9002, section 4.18—Training.

<sup>4</sup> See <http://www.nccet.org/associations/2158/Abstract8%2D02%2Epdf>.

<sup>5</sup> See [http://www.iacet.org/standards/intro\\_CG.htm](http://www.iacet.org/standards/intro_CG.htm).

<sup>6</sup> See <http://www.clinicaldevice.com/survey.htm>.

<sup>7</sup> See <http://www.clinicaldeviceforum.com/>.

methodology, 4) participation in international standards development, and 5) personal contact with clients and customers.

### *Learning Objectives*

The learning objectives of each event determine the scope and depth of the event's content. We use it to assure that learners are presented with the right information and all the information they need for effectiveness in the workplace.

### *Relevant Content*

The content must be scientifically accurate, technologically current, ethically sound, and legally intact. It should enhance job skills and contribute to better work performance.

### *Qualified Instructors*

Instructors are skilled communicators who are professionally qualified in their fields. They are personally known to CDG for their knowledge, integrity, experience and contributions. Their curriculum vitae are on file and available on request.

### *Useful Materials*

Instructional materials are designed thoughtfully to maximize comprehension, demonstrate practical application through interactive learning, and serve as a resource for follow-up investigation. We take advantage of a variety of modern formats, including written text, slide presentations, hands-on workshops, web searches, interactive chats, and questions and answers.

### *Learner Feedback*

Learners are given the opportunity for evaluation and feedback. We use the feedback to improve future events, thus closing the learning-loop.

### *Learner Assessment*

Where our market research indicates a need, CDG offers management a method of learner assessment. These targeted examinations focus on the materials presented in an event, and provide a tool for managers to assess a learner's comprehension and ability to utilize the content in actual job applications.

### *Membership*

Clinical Device Group maintains active memberships in the International Association of Continuing Education and Training (IACET) and the National Council for Continuing Education and Training (NCCET).

### *Obtaining CEUs*

CEUs are available to those who participate in CDG events. For seminars, CEUs are issued to all attendees. For webinars, CEUs are available to the primary registered attendee and their colleagues who purchase related course materials (Attendee Kits). For e-conferences, CEUs are available for all persons who attend 80% or more of the event. For webinars and e-conferences, the primary registrant is responsible to complete a CEU application form indicating the eligible attendees and providing their full contact information. The application form may be found at <http://www.clinicaldevice.com/CertificateRequest.htm>.

### *CEU Registry*

CDG maintains a permanent registry of CEUs issued back to 1997. Learners may contact us at any time at 1-773-489-5706 to obtain a transcript of their educational history at Clinical Device Group.