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WHAT MAKES PROFESSIONAL CERTIFICATION VALUABLE?

In recent years, there has been a proliferation of certification programs within the pharma/biotech/devices world. Some are broad-based, such as project management (e.g., the Project Management Institute's PMP). Others, for example, clinical monitoring and clinical data management, are industry-specific. Regardless of the profession, there are heated debates as to the meaning and value of certification. Opinions vary tremendously, and often depend on the profession, the goals and quality of the certification, and the credibility of the authoring organization.

FACTORS THAT CAN AFFECT THE PERCEIVED VALUE OF CERTIFICATION

Certification is the process by which an individual demonstrates his or her level of expertise in a field, usually by taking an exam. Certification programs are usually developed by professional societies as a means of identifying those who have higher qualifications. They are particularly useful for jobs, such as data management, where the job definition varies and where there are few targeted academic programs and a limited published body of knowledge. In these cases, a certification program can help to clarify the role, identify the associated knowledge base, and define expected proficiency levels.

Much of the "value" debate comes from different perceptions of what certification says about an individual, and that depends upon many factors. Few are objective, which fuels the arguments. They include:

- **Credibility** of the certifying organization.
- **Clarity** and fairness of exam questions.
- **Exam difficulty** — if everyone can pass, it is not a differentiator.
- **Relevance** of exam questions to daily job activities.
- **Knowledge vs. experience** — i.e., the ability to use judgment to apply the knowledge appropriately in real-world settings.
- **Correlation with performance** — i.e., the peer community must see that certification correlates with greater skill and value to the company.

CLINICAL CERTIFICATION

To add value, a certification program must address these issues and more. The Certified Clinical Data Manager (CCDM) program developed by the Society for Clinical Data Management provides a useful illustration. For clinical data management (CDM), certification is a way to help define the profession. There is little generally accessible published material, its definition varies, there are no dedicated diploma programs and, indeed, its worth to companies is still regularly challenged. The certification

program, along with the publication of the organization's Good Clinical Data Management Practices document, is changing these perceptions.

The exam was developed by a large team of experts over several years. A test development company was also involved to ensure test validity. The beta version was taken by a range of people, from experts to people from outside the field. This improved the correlation between level of knowledge and total score, and allowed the "pass" score to be set. The target was to identify those who met minimum requirements of education or experience and had a working knowledge of most areas of data management. The initial version was published in 2005, and a revised version in late 2008. To date, about 360 people have taken the final versions.

Several elements contribute further to the exam's credibility. Many of those who took the test, including senior data managers, reported that it was unexpectedly difficult. The questions draw on an array of expected skills, and require the application of judgment to diverse situations. Certification lasts for three years, at which time candidates must either retake the exam or provide evidence of sufficient CEUs to requalify. A new program encourages companies to support certification by rewarding them with recognition and discounts based on the percentage of their eligible staff who are certified. The jury is still out on the long-term success of the CCDM program, but early indicators seem positive.

In the end, the value of certification depends upon the quality of the exam and the degree to which it is adopted. If it is perceived to be fair, representative of both experience and knowledge, and accessible to all who are qualified to take it, employers and peers will be more likely to react positively. To remain so, it must be updated as technology and practices evolve. Taken with evidence of formal education and experience, certification can be a useful tool in identifying those who are more likely to continue to grow professionally and add value to their companies.

Editor's Note: The 2009 SCDM Annual Conference will be held October 4-7 at the Westin Seattle in Seattle. For more information, visit scdm.org.

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New York Hilton, New York
Thursday, May 7, 2009
Reception: 10:30 a.m.
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Registration Deadline:

Thursday, April 23, 2009
Member: \$200
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