



**Survey Results -
How Corporate Officials in the Drug and Medical Device
Industries View Certifications and Higher Education for
Regulatory and Quality Professionals**

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Compliance-Alliance in cooperation with Dr. Frances Richmond, Director of the Department of Regulatory Science Program in USC's School of Pharmacy, distributed a questionnaire to professionals in the drug and medical device industries to find out how they view certifications and higher education.

Respondents Profile

Over 330 professionals responded. More than half of the respondents worked for firms with more than 2000 employees, 27% worked for firms with 100 - 1999 employees, and 12% worked for firms with less than 100 employees. The most common title was manager, but presidents through regulatory associates answered the questions. Respondents had a diversity of experience and education in FDA regulated industries, but most were relatively experienced. More than 67% reported being in the field for more than 10 years, and 19% reported being in the field from five to ten years. While most of the respondents had a bachelors degree, 40% had a masters degree, and 9% had a doctorate. Twenty seven (27)% had obtained ASQ certification, and 20% had obtained RAC certification.

Ability to Hire Employees

Eighty five (85) percent of the respondents reported that they have input when their firm hires new personnel.

Educational Requirements for Hiring

Eighty five (85) percent of respondents reported that their firm required applicants for quality and regulatory positions to hold a bachelor degree as a pre-requisite for employment. Other prerequisites included:

- ASQ certification 9%
- Masters degree 6%
- RAC certification 7%
- Certificate from a college our university 4%
- Doctorate 2%

Many firms take continuing professional education into consideration when determining which individuals to promote. For example, respondents reported that their firms consider the following degrees/certifications:

- Masters degree 42%
- RAC certification 36%
- ASQ certification 33%
- Bachelor degree 32%
- Doctorate degree 22%

A majority of firms provide financial assistance for their employees to pursue the following educational programs:

- Masters degree 65%
- RAC certification 62%

- Bachelor degree 61%
- ASQ certification 59%
- Certificate program 54%
- Doctorate program 41%

Interest in Online Programs

Over one third of the respondents who were interested in pursuing a masters or doctoral program were interested in classes being offered on-line. Specifically 43% wanted the entire program to be given on-line, and 37% wanted the program to be given on-line with two weeks of instruction provided in a classroom setting.

Competence Expected of Individuals Holding a Doctorate in Regulatory Affairs

The potential introduction of a doctoral program motivated us to question the skill-sets that might be expected. Responses highlighted that individuals with a Doctorate in Regulatory Affairs would generally be expected to possess the following:

- Knowledge of FDA and ISO Requirements 90%
- Ability to communicate & persuade relevant audiences 74%
- Skills in leadership and management 74%
- Ability to assemble a regulatory submission 67%
- Understanding the role of relevant organizations 60%
- Ability to set up a quality or manufacturing system that complies with cGMPs 56%
- Understanding of government operations 46%
- Knowledge of business operations 40%
- Knowledge of emotional intelligence 33%
- Ability to calculate the cost of poor quality 32%
- Skills in foreign languages 09%

Other skills respondents suggested would be helpful include:

- Computer skills
- Diplomacy in addressing controversial issues
- Ethics
- Financial management skills
- Law
- Listening skills
- International requirements
- Negotiation skills
- Problem solving
- Project management
- Reimbursement
- Research methods and regulations
- Science/mathematics
- Team building
- Writing skills

Conclusion

In order for medical device and drug firms to manufacture safe and effective products, personnel in these firms need to understand:

- The technology,
- The needs of their customers,
- The government's regulatory requirements, and
- How these requirements relate to their firm's operations.

To be effective in their jobs, knowledge of the product environment must be complemented by interpersonal and management skills. While experience certainly plays an important role for quality and regulatory officials, formal education can also be a key part of the process.