Medical Device Industry

Survey Results

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Table of Contents

Attachments

1.0 Background

In partnership with medical device companies, a group of community colleges and technical colleges have formed the Medical Device Industry Education Consortium (MDIEC). The consortium is creating a learning and innovation network that is developing and delivering industry-endorsed education solutions for the medical device industry cluster. To better understand the industry's needs, the colleges have conducted focus group sessions and surveys involving 176 companies from seven regions of the country. Three quarters of the surveys were conducted in 2004, and the remainder were conducted in two regions of the country during 2005. The following report summarizes the findings from the survey results.

Colleges that Participated In the Survey of Medical Device Firms

Anoka-Ramsey Community College (MN)
Ben Franklin Institute of Technology (MA)
Community College of Allegheny County (PA)
Edmonds Community College (WA)
Gateway Technical College (WI)
North Orange County Community College (CA)
St. Petersburg College (FL)
Shoreline Community College (WA)

The survey feedback provided by industry executives identified critical education and training needs in a number of areas. As a result, the colleges are developing curricula to address the common educational needs of technicians involved with quality control, research & development, product development, manufacturing, and technology-related sales. Regulatory affairs courses have already been developed, and the colleges plan to develop additional courses and programs during 2006.

Funding for this initiative was primarily provided by the U.S. Department of Education's Fund for the Improvement of Postsecondary Education (FIPSE). The FIPSE funding was congressionally directed.

The MDIEC initiative is being managed by *CTC* Public Benefit Corporation, which is a 501(c)(3) organization that specializes in working with teams to solve complex economic development, workforce development, and technical problems.

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2.0 Medical Device Industry Overview

The medical device industry is a highly diversified cluster that produces a wide range of products, including basic thermometers, pacemakers for the heart, and advanced imaging systems. Medical device companies and their suppliers can be classified in a number of manufacturing-related industries, including wire, plastics, composite materials, electronics, and diagnostics/biologics. However, the majority of the industry's original equipment manufacturers are concentrated in the following areas.

1. Surgical and medical instruments
2. Ophthalmic goods
3. Laboratory apparatus
4. Electro-medical apparatus
5. Analytical laboratory instruments
6. Dental equipment and supplies

The medical device industry is growing rapidly and is vital to the global competitiveness of the United States. A 2004 report from the Advanced Medical Technology Association (AdvaMed) on the medical device industry reported America's production of medical devices and diagnostics at an estimated $77 billion in 2002.[1] Industry employment has grown steadily, reaching 349,571 employees in 2001. Industry employment has grown 26 percent over the ten-year period from 1992-2001.

The U.S. medical device industry is building on the country's strengths in bioengineering, biomaterials, genomics, computing and telecommunications to lead the world in medical device innovation and production. The United States accounted for 43 percent ($72 billion) of the global medical device and diagnostic industry sales ($169 billion) in 2000. The European Union ranked second ($35 billion / 21 percent) and Japan ranked third ($25 billion / 15 percent). In addition, the U.S. is the largest exporter of medical technology ($20.3 billion). Plus, U.S. exports have grown 110 percent over the ten-year period ending in 2003.

Companies within the medical device industry have traditionally provided a large portion of their technical training using in-house resources. This training has typically been non-standardized, expensive and job specific. The MDIEC colleges are developing education and training programs that can be delivered nationally using consistent industry-endorsed content and evaluation criteria.

3.0

[1] All of the industry statistics presented in this section were published in the following publication: Advanced Medical Technology Association. (2004). *The Medical Technology Industry at a Glance: 2004*.

Survey Results

Respondents were asked to provide information on the importance, demand and preferred delivery method for major job training areas related to the medical device industry. Results are segmented by size of company (in terms of level of employment), 12-month projected employment growth status and region. A copy of the survey instrument is included as Attachment A.

3.1 Sample Size and Description

Altogether, a total of 176 surveys were returned. There was significant variation in the number of responses received by region ranging from 8 to 55. Multiple responses were received from 17 companies.[2] Table 1 details the responses received by region.

Table 1 – Survey Responses Received by Region

Region	Survey Responses	% of Total Reponses
Allegheny (PA)	8	5%
Anoka-Ramsey (MN)	55	31%
Edmonds-Shoreline (WA)	23	13%
Gateway (WI)	8	5%
St. Petersburg (FL)	37	21%
Ben Franklin (MA)	22	13%
North Orange County (CA)	23	13%
TOTAL	**176**	**100%**

More than 50 percent (93 responses) of the responses were from companies with less than 50 employees. Figure 1 depicts the number of respondents by company employment level. Actual results are provided in Table 2.

Figure 1 – Percentage of Respondents by Company Employment Level

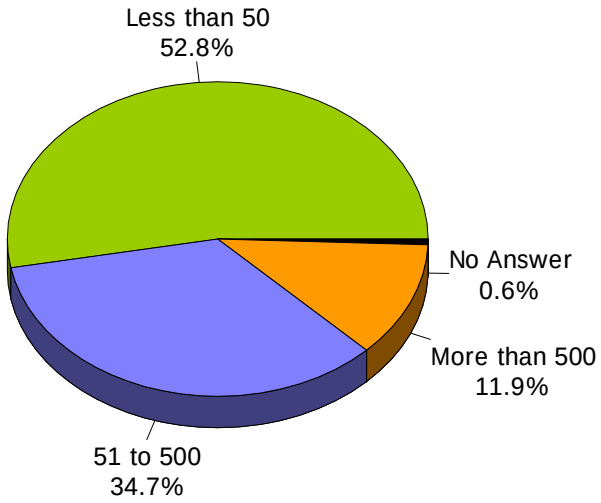


Table 2 – Responses by Company Employment Level

Employment Level	Survey Responses
Less than 50	93
51 to 500	61
more than 500	21
No Answer	1
TOTAL	**176**

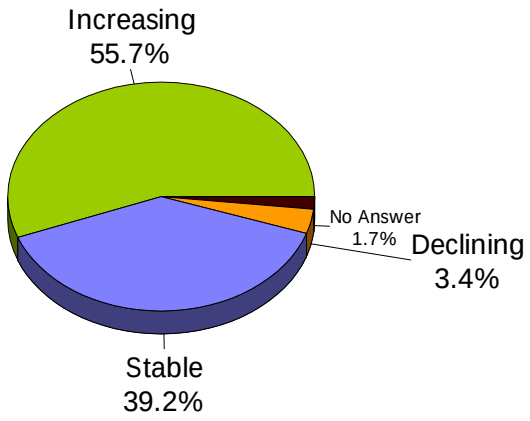
[2] A total of 44 responses were received from these companies.

Of the 176 responses, more than 50 percent (98 responses) projected increasing employment for the coming 12-month period. Figure 2 provides a percentage breakdown of the survey responses. Table 3 displays the actual results.

Table 3 – Responses by 12-Month Employment Level Projection

12-Month Employment Level Projection	Survey Responses
Increasing	98
Stable	69
Declining	6
No Answer	3
TOTAL	**176**

Figure 2 – Percentage of Respondents by 12-Month Employment Level Projection



3.2 Training Areas – Overview

Respondents were asked to provide information on the importance, demand and preferred delivery method for the following major job training areas related to the medical device industry.

- Clinical Research
- Documentation
- Health, Safety & Environmental
- Information Systems
- Logistical & Supply Chain
- Process Management
- Product Design or Development
- Project Management
- Quality Assurance/Quality Control
- R&D or Laboratory
- Regulatory Affairs
- Reimbursement
- Sales & Service
- Specialized Processes
- Specialized Equipment and/or Technologies

For more information on the write-in responses identifying specific specialized processes, equipment and technologies and other training areas, see Attachment B.

3.3 Training Areas – Importance

Respondents were asked to evaluate the importance of each training area in terms of the importance of education and training programs based on a 5-point scale (5=very important, 4=important, 3=neither important or unimportant, 2=unimportant, and 1=very unimportant). Survey results from this portion of the survey are displayed in Figure 3 and Table 4.

Figure 3 – Percentage of Respondents by Importance of Training Areas

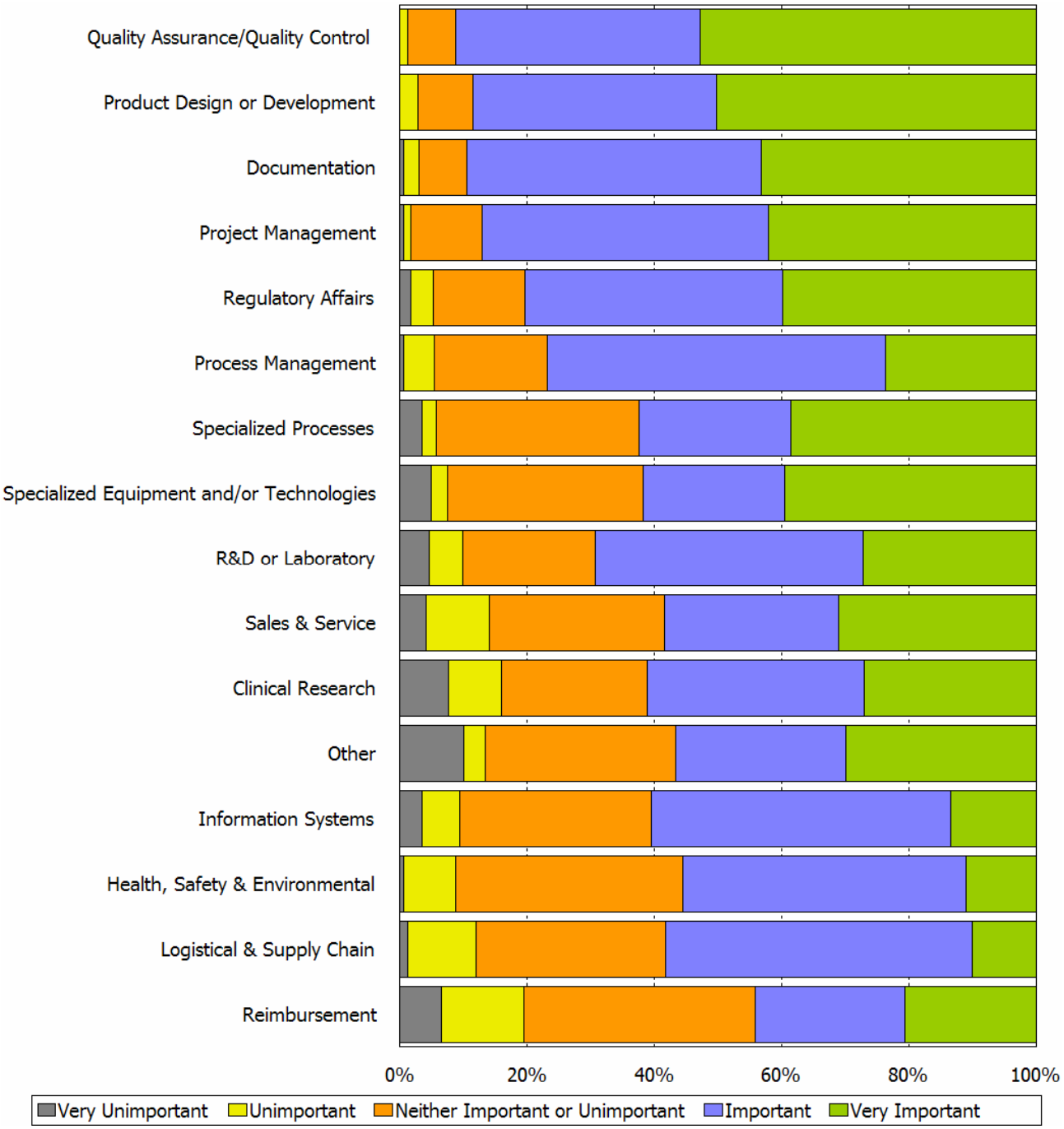


Table 4 – Responses by Importance of Training Areas

Training Area	Very Important 5	Important 4	Neither Important or Unimportant 3	Unimportant 2	Very Unimportant 1	Total Responses	Average Rank
Quality Assurance/Quality Control	91	66	13	2	0	172	4.43
Product Design or Development	88	67	15	5	0	175	4.36
Documentation	74	79	13	4	1	171	4.29
Project Management	72	77	19	2	1	171	4.27
Regulatory Affairs	69	70	25	6	3	173	4.13
Process Management	40	90	30	8	1	169	3.95
R&D or Laboratory	47	73	36	9	8	173	3.82
Sales & Service	53	47	47	17	7	171	3.71
Clinical Research	46	58	39	14	13	170	3.65
Information Systems	23	80	51	10	6	170	3.61
Health, Safety & Environmental	19	76	61	14	1	171	3.57
Logistical & Supply Chain	17	81	50	18	2	168	3.55
Reimbursement	35	40	62	22	11	170	3.39
Specialized Processes*	34	21	28	2	3	88	3.92
Specialized Equipment and/or Technologies*	32	18	25	2	4	81	3.89
Other*	9	8	9	1	3	30	3.63

*These training areas are listed separately because they received less than 66 percent of the total number of responses received by the other training areas.

Approximately 70 percent of the responses ranked all training areas as important or very important. This may reflect a general high-level of importance of training to the medical device industry.

Using statistical analysis of variance (ANOVA) to compare average importance rankings, there is no significant statistical variation found in any of the results from the regions or by either company size or employment growth projection category. Actual results by region, company size and employment growth projection category are provided in Attachment C.

3.4 Training Areas – Demand

Respondents were next asked to identify their company's estimated demand for training in terms of the number of employees in the next 12 months who would require training by training area. The survey results are provided in Figure 4 and Table 5.

Figure 4 – Demand for Training by Training Area in Number of Employees Estimated to Require Training in the Next 12 Months

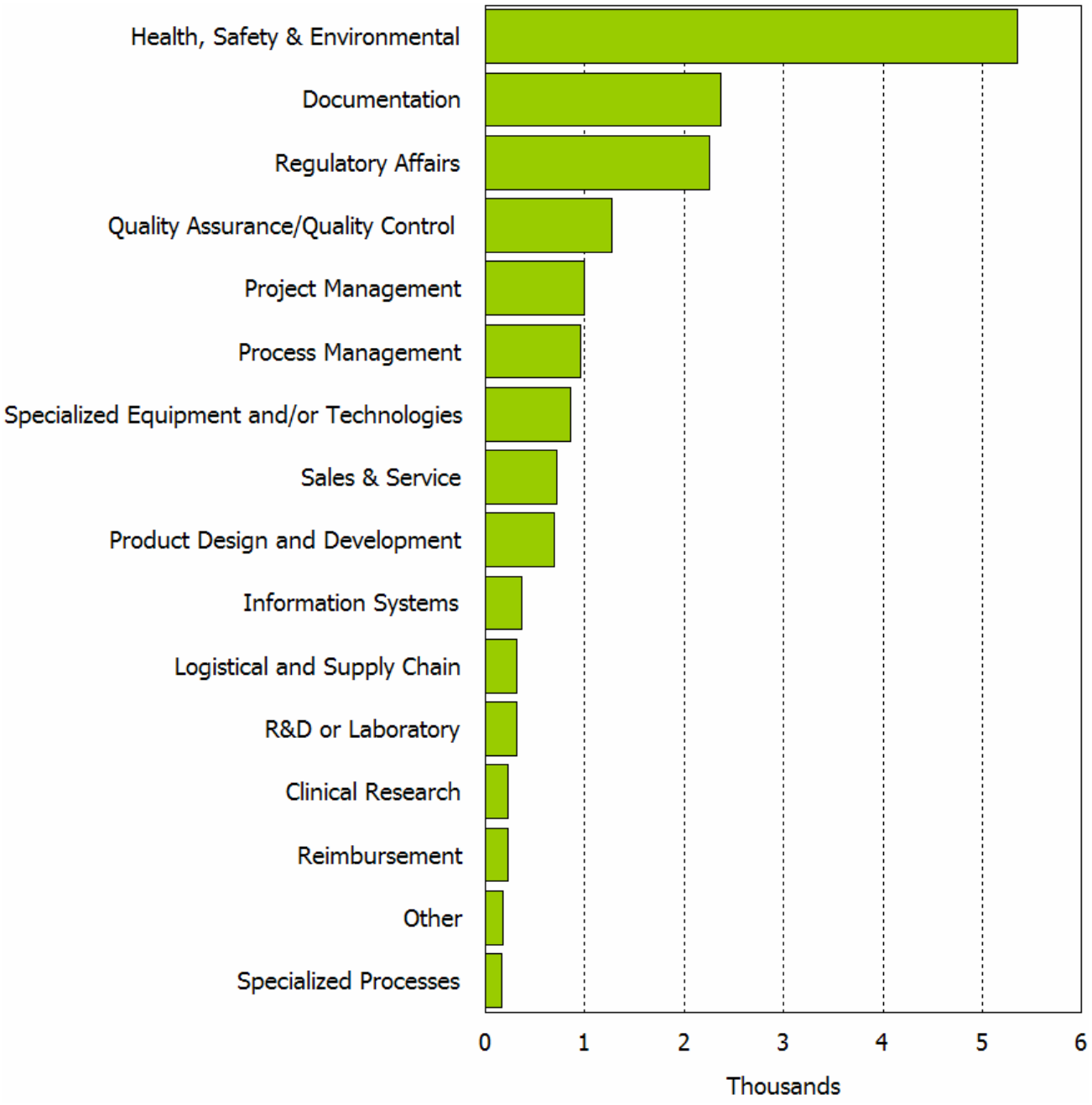


Table 5 – Responses by Training Demand

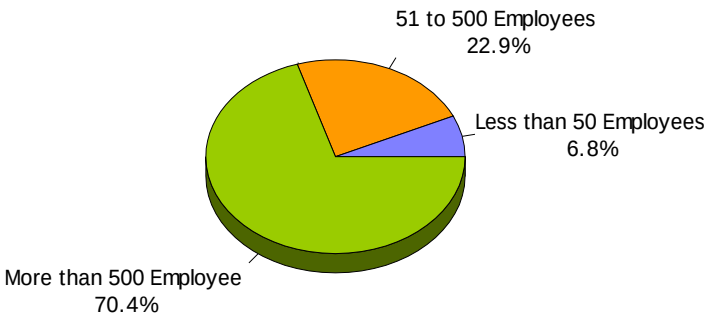
Training Area	Demand	% of Total Demand
Health, Safety & Environmental	5,355	31%
Documentation	2,362	14%
Regulatory Affairs	2,256	13%
Quality Assurance/Quality Control	1,273	7%
Project Management	989	6%
Process Management	955	6%
Specialized Equipment and/or Technologies	861	5%
Sales & Service	712	4%
Product Design and Development	688	4%
Information Systems	367	2%
Logistical and Supply Chain	321	2%
R&D or Laboratory	318	2%
Clinical Research	229	1%
Reimbursement	228	1%
Other	176	1%
Specialized Processes	170	1%
TOTAL	**17,260**	**100%**

There is a significant variation in the demand for training by training area. The top 3 training areas comprise 58 percent of the total demand for training. However, the level of demand is significantly dependent upon the responses of a few large employers. For example, one company recorded a demand for *Health, Safety & Environmental* training that comprised more than 40 percent of the reported demand for that area. Another large company reported more than 30 percent of the total demand for training for *Documentation*. Even though only accounting for slightly more than 11 percent of the survey responses, companies with more than 500 employees comprised 70 percent of the demand for training. Figure 5 and Table 6 present an overview of this data. More detailed results are in included in Attachment C.

Table 6 – Responses by Demand for Training by Company Size

Company Size	Demand	% of Total
Less than 50 Employees	1,114	7%
51 to 500 Employees	3,766	23%
More than 500 Employees	11,585	70%
TOTAL	**16,465**	**100%**

Figure 5 – Percentage of Respondents by Demand for Training by Company Size



Using statistical analysis of variance (ANOVA), there were a few minor statistically significant variations found in the demand for training between the various regions as described in the following list. Actual results

by region, company size and employment growth projection category are provided in Attachment C.

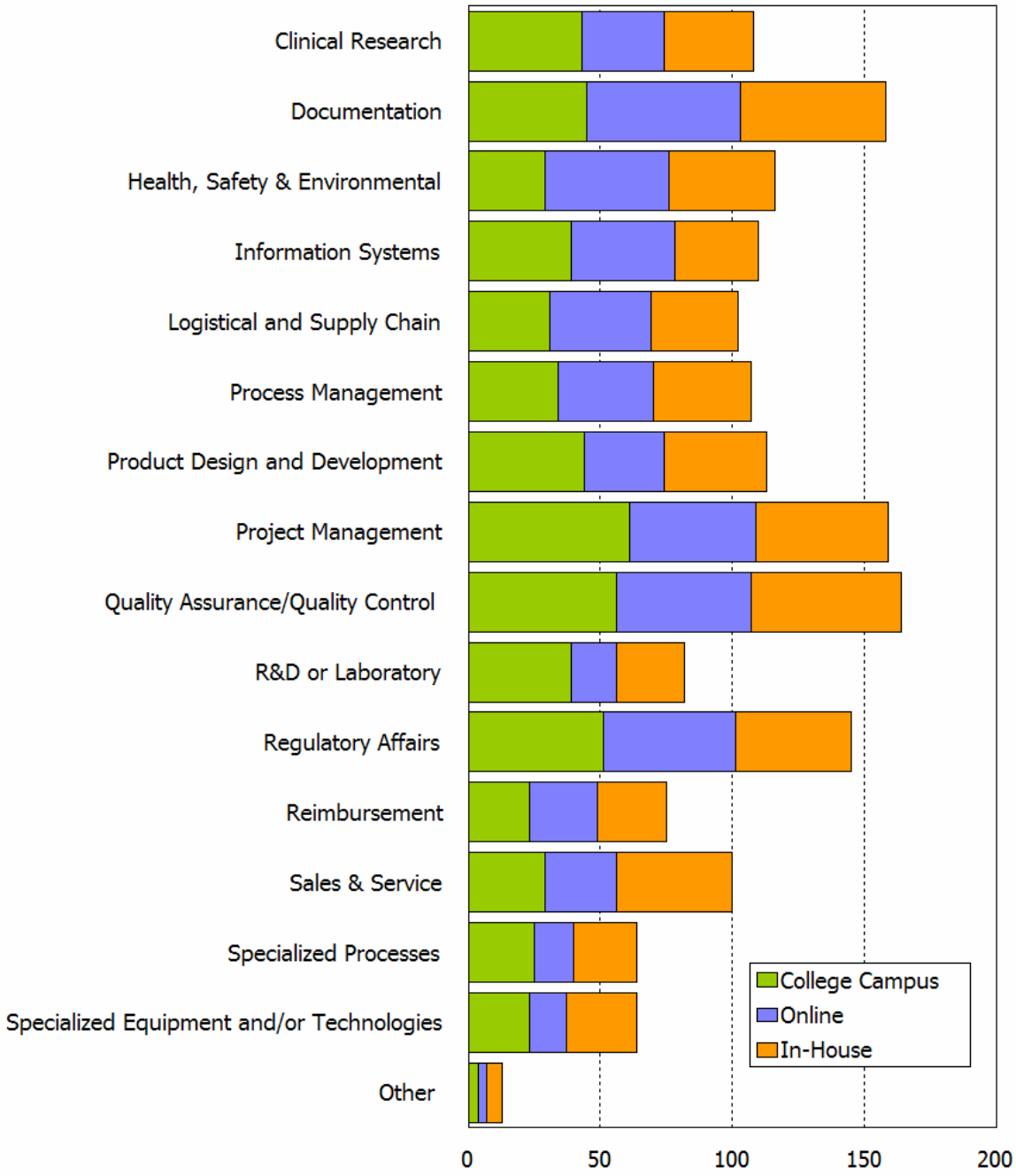
As one might expect, the higher the training area is ranked in importance, the greater the demand for training in that area. Figure 6 displays a scatter plot of the aggregated average importance rank on a 5-point scale (5=very important to 1=very unimportant) by the demand for training in terms of the 12-month projected number of employees needing training. As the scatter diagram indicates, after removing the outlying data point for the *Health, Safety & Environmental* training area, the relationship is linear in nature. The Pearson product-movement (PM) correlation coefficient for the data set is -.67, indicating a moderately-strong positive linear relationship.

Figure 6 – Scatter Plot of Training Area Importance vs. Demand

3.5 Training Areas – Delivery Method Preferences

Finally, respondents were asked to identify their delivery method preferences. Respondents selected the type of training delivery method preferred (College Campus, Online or In-House) for each training area. Multiple selections were allowed for each training area. Results from the survey are provided in Figure 7 and Table 7.

Figure 7 – Percentage of Responses by Training Delivery Method Preference



Note: Respondents were allowed to select multiple responses.

Table 7 – Responses by Training Delivery Method Preference

Training Area	College Campus	Online	In-House
Clinical Research	43	31	34
Documentation	45	58	55
Health, Safety & Environmental	29	47	40
Information Systems	39	39	32
Logistical and Supply Chain	31	38	33
Process Management	34	36	37
Product Design and Development	44	30	39
Project Management	61	48	50
Quality Assurance/Quality Control	56	51	57
R&D or Laboratory	39	17	26
Regulatory Affairs	51	50	44
Reimbursement	23	26	26
Sales & Service	29	27	44
Specialized Processes	25	15	24
Specialized Equipment and/or Technologies	23	14	27
Other	4	3	6

Actual results by region, company size and employment growth projection category are provided in Attachment C.