

# 2016

## **SCOPE OF PRACTICE & COMPENSATION REPORT FOR THE REGULATORY PROFESSION**



REGULATORY AFFAIRS  
PROFESSIONALS SOCIETY  
*Driving Regulatory Excellence™*

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# Introduction

RAPS conducts the Scope of Practice & Compensation Survey of the Regulatory Profession every two years, and has fielded similar studies since 1990. For this year's iteration, regulatory professionals around the world who are involved with healthcare and related products were asked to complete an online survey between 1 March and 30 April 2016. The survey resulted in 3,358 usable responses from professionals in 56 countries. Respondents reported working with products including pharmaceuticals, medical devices and in vitro diagnostics (IVDs), biotechnology, nutritional and veterinary products. They reported being employed in industry, government agencies, academic and research settings, clinical research organizations (CROs), consultancies and other settings.

## Executive Summary

Regulatory professionals in the healthcare product sector are highly educated and tend to come into the profession with significant prior professional experience. Their work has become increasingly strategic. They influence their employers' overall strategic planning, and their expertise is valued as an important business asset. Their work on business-related tasks and responsibilities, which had increased over the past decade, has now stabilized. Most regulatory professionals work on multiple product types and with regulations of multiple countries or regions.

Compensation continues to trend upward, particularly for professionals at mid-level positions. Those same mid-level professionals also are gaining the largest salary advantage from attaining the Regulatory Affairs Certification (RAC) credential. The interrelated factors of job level, regulatory experience, highest earned degree and total professional experience have the greatest impact on compensation.

## Professional Profiles

Following are snapshots of the average regulatory professional at four common job levels.

### VICE PRESIDENT

- Average of 27 years professional experience
- Average of 19 years in regulatory
- Highest earned degree:
  - Doctorate: 29%
  - Master's: 43%
  - Baccalaureate: 22%
- 50% have RAC credential
- Supervises average staff of seven

### MANAGER

- Average of 18 years professional experience
- Average of 10 years in regulatory
- Highest earned degree:
  - Doctorate: 18%
  - Master's: 46%
  - Baccalaureate: 26%
- 47% have RAC credential
- Supervises average staff of two

### DIRECTOR

- Average of 23 years professional experience
- Average of 14 years in regulatory
- Highest earned degree:
  - Doctorate: 24%
  - Master's: 40%
  - Baccalaureate: 26%
- 54% have RAC credential
- Supervises average staff of four

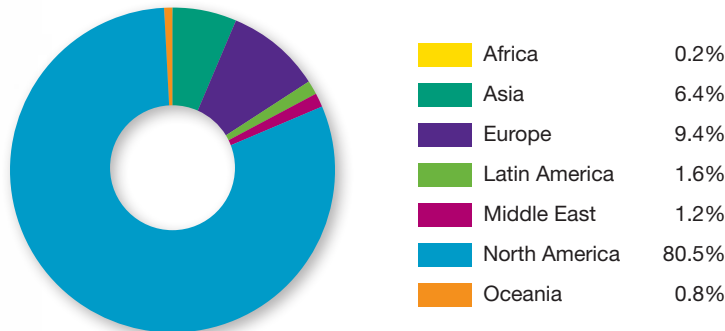
### SPECIALIST

- Average of 14 years professional experience
- Average of seven years in regulatory
- Highest earned degree:
  - Doctorate: 12%
  - Master's: 45%
  - Baccalaureate: 25%
- 38% have RAC credential
- Does not supervise direct reports

# The Respondents

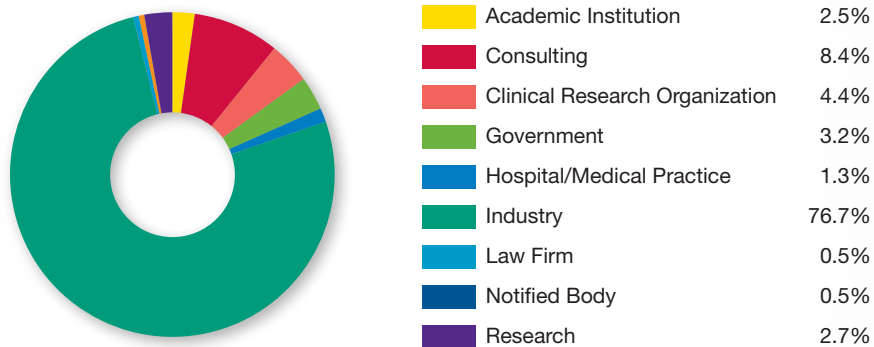
## Geographic Region

The majority of responses (80.5%) were from professionals in North America. Overall, 76% of respondents were based in the US. The largest proportion of respondents outside North America were those based in Europe (9.5%) and Asia (6.4%).



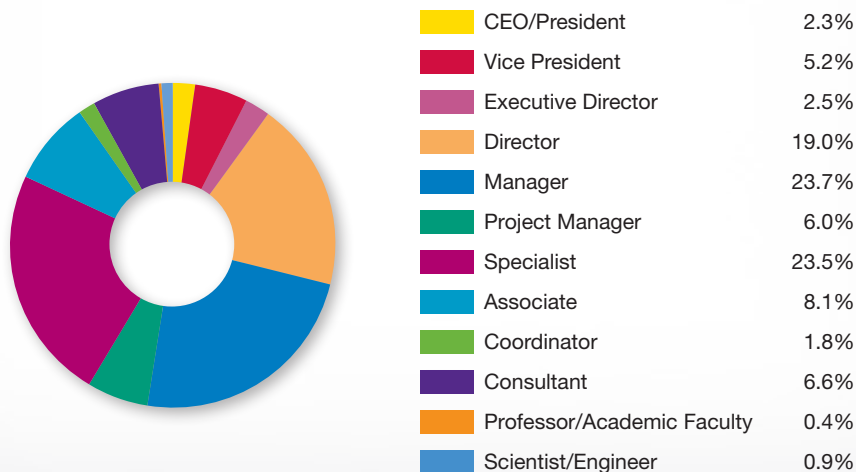
## Work Setting

The largest proportion of respondents (76.7%) reported being employed in industry, and 3.2% said they work for government or regulatory agencies. The distribution of respondents by employment setting closely mirrors the distribution seen over the last decade of undertaking these studies. Employer size ranged from fewer than 10 employees to more than 10,000 worldwide.



## Job Level

Respondents provided exact job titles and also were asked to classify their job level by 11 position titles. The 2016 survey added two new titles, executive director and professor/academic faculty. Based on responses, a 12th title, scientist/engineer, was added to the classifications. Respondents represent a range of job levels and job titles at proportions that closely reflect the distribution of regulatory jobs.



## Regulatory and Total Professional Experience

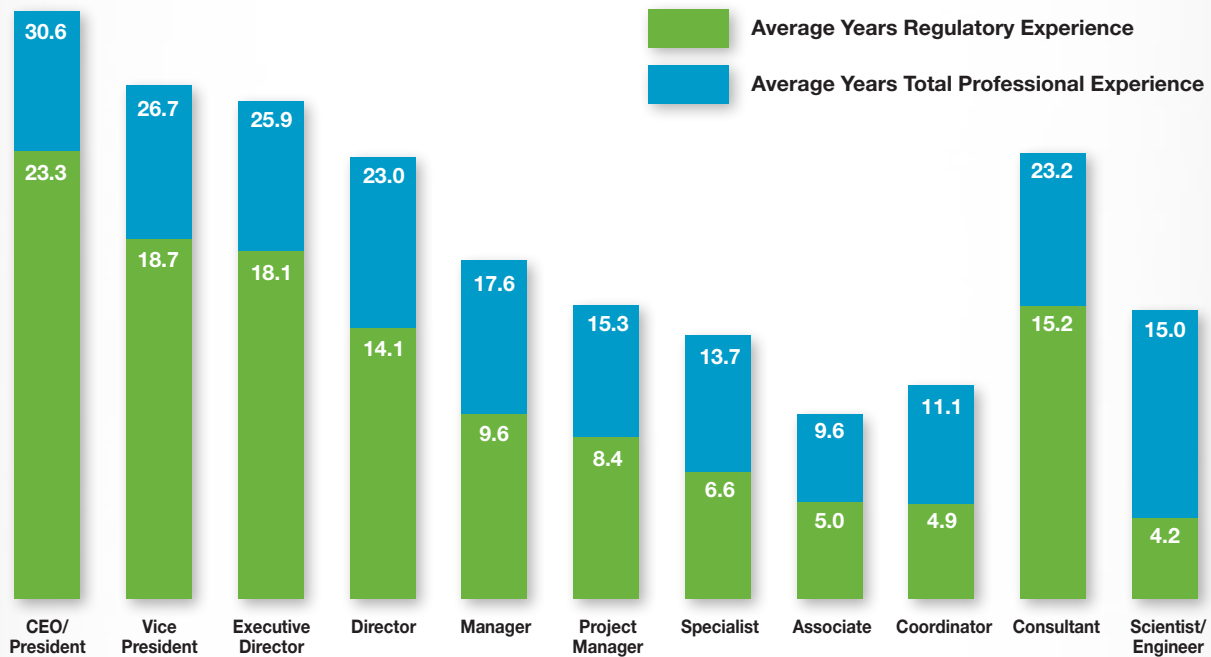
Regulatory experience and total professional experience are strongly linked to both job level and compensation for professionals around the world and in all work settings. More than 88% of regulatory professionals began working in another field before transitioning into regulatory. Overall, 75% worked in fields closely related to regulatory, such as research and development (R&D), quality assurance/quality control, laboratory sciences, engineering, clinical research or pharmacy/pharmacology.

>88%

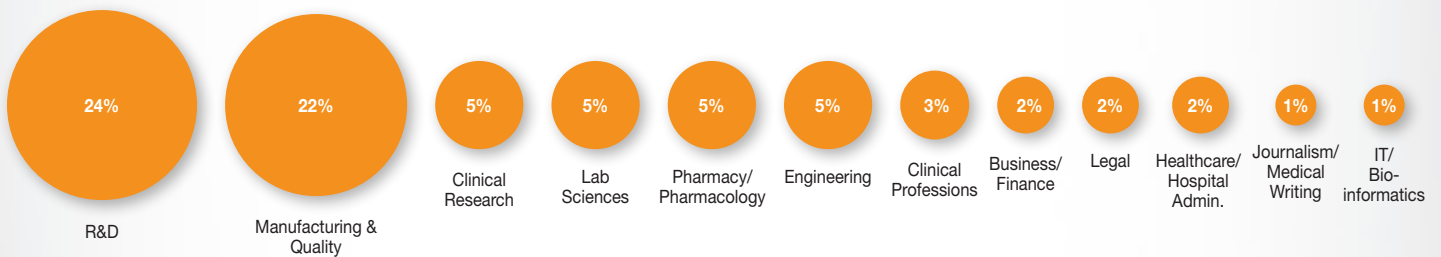
of regulatory professionals began working in another field before transitioning into regulatory.

Generally, those entering the regulatory profession come in with significant work experience. Typically, the ratio of total professional experience to regulatory experience is 2:1 or higher for professionals at the associate, manager and project manager levels. As they accumulate more regulatory experience relative to overall professional experience, the ratio decreases. For all respondents, the ratio is 1.7 to 1.

On average, professionals based in North America and Europe reported more regulatory experience than their counterparts in Asia and other parts of the world at most job levels. In many regions, including Asia and Latin America, this may be due to the relatively recent development of the regulatory profession and regulatory job functions there.



## Prior Professional Experience



## Education Background

More than 99% of regulatory professionals today hold a university degree. More than 42% have a master's degree (a 2% increase from 2014), and more than 20% have a doctorate. Most (more than 84%) hold a degree in a clinical discipline, science or engineering.



**48%**

Life Sciences



**21%**

Clinical Sciences/  
Public Health



**15%**

Engineering



**13%**

Business/Finance/  
Economics



**11%**

Regulatory Affairs



**9%**

Liberal Arts/  
Social Sciences



**3%**

Regulatory Science



**4%**

Technical Sciences



**3%**

Law

# Scope of Practice

## Key Findings

- Regulatory professionals at all levels are spending more time on regulatory strategy, regulatory intelligence and regulatory operations, and less time on preapproval activities.
- Time spent on business-related duties has stabilized.
- A majority of regulatory professionals have multiregional or worldwide responsibilities, but there are some regional variations.

From the broadest perspective, the work of regulatory professionals involves applying the regulations governing healthcare products to every stage of the lifecycle of these products. Stages include research and development (R&D), clinical testing, submission to regulatory agencies, manufacturing, marketing and postapproval monitoring. At each stage, important regulatory requirements must be thoroughly understood and steps taken to ensure compliance.

While there is a shared scope of practice seen among regulatory professionals employed in different work settings, the specific work of regulatory professionals reflects their employment settings and job levels. The responsibilities of regulatory professionals go well beyond product registration and compliance. Many professionals at all levels contribute to their organizations' strategies. At mid- and senior levels, they play important roles in business decisions shaped by regulatory requirements or with regulatory implications.

In this study, respondents were asked about the percent of time they spend working on various areas related to the product lifecycle, as well as business-related activities, including time spent on overall organizational strategy and decision making, department management, legal, involvement with risk management, due diligence, reimbursement and government affairs. They also were allowed to write in other job functions not included in the provided list. Over the history of this research, the latter has been an important source for identifying important, emerging job functions. For the 2016 survey, regulatory operations was added as a job function. Although closely related to regulatory strategy and regulatory intelligence, this function is an important and distinct area that is particularly important for industry-based professionals.

The most significant change in the scope of practice of regulatory professionals at all levels from the previous study is seen in the areas of regulatory strategy, intelligence and operations. Most professionals reported spending approximately one-third of their time in these areas, with a significant amount of time allocated to regulatory operations. While regulatory operations was reported under the "other" category in previous studies, it was not reported at the percentages of time or by the number of respondents as in the current survey.

It is also noteworthy that the increase in time allocated to regulatory strategy, intelligence and operations is partially offset by a decrease in time allocated to preapproval/approval functions. This may reflect a shift toward a more strategic approach to the work undertaken by regulatory staff and a greater integration of regulatory strategy, intelligence and operations into regulatory lifecycle management. In addition, business-related work among regulatory professionals, which grew over the past decade, appears to have stabilized at its current level.

74%

of professionals in North America,

66%

in Europe and

57%

in Asia report multiregional or worldwide responsibilities.

## Time Allocation by Job Level

Values	CEO/ President	Vice President	Executive Director	Director	Manager	Project Manager	Specialist	Scientist	Associate	Coordinator	Consultant
Business Development/ Corporate Strategy	13.1%	10.4%	10.0%	5.6%	3.8%	4.8%	2.0%	1.4%	2.6%	3.7%	4.6%
Management	11.1%	11.8%	11.9%	8.8%	7.8%	8.2%	1.4%	2.1%	1.9%	4.2%	4.8%
Government Affairs/ Policy	2.6%	2.9%	7.0%	2.4%	2.3%	3.2%	1.9%	0.3%	2.2%	2.6%	2.2%
Legal	1.2%	1.6%	2.5%	1.0%	1.3%	0.9%	1.3%	0.3%	2.1%	2.6%	1.5%
Due Diligence	1.6%	1.6%	2.3%	1.7%	2.0%	1.7%	2.6%	2.7%	3.1%	2.2%	2.5%
Reimbursement/ HTA/Comparative Effectiveness	0.2%	0.8%	0.3%	0.3%	0.3%	0.6%	0.2%	0.3%	0.2%	0.8%	0.6%
Risk Management	2.4%	3.4%	3.1%	3.3%	3.3%	3.4%	3.6%	5.7%	2.5%	2.6%	5.0%
<b>Business-Related Total</b>	<b>31.9%</b>	<b>32.3%</b>	<b>36.7%</b>	<b>23.0%</b>	<b>20.6%</b>	<b>22.3%</b>	<b>12.8%</b>	<b>13.0%</b>	<b>14.2%</b>	<b>18.1%</b>	<b>20.3%</b>
Regulatory Strategy	13.8%	15.5%	18.1%	16.6%	13.0%	11.5%	11.7%	3.7%	12.0%	4.0%	12.2%
Regulatory Intelligence	5.5%	6.4%	8.7%	6.1%	6.3%	6.8%	6.6%	2.7%	7.9%	6.5%	7.1%
Regulatory Operations	7.6%	6.7%	5.7%	11.8%	14.7%	15.9%	15.6%	7.0%	21.0%	22.9%	14.0%
<b>Regulatory Strategy, Intelligence &amp; Operations Total</b>	<b>26.9%</b>	<b>28.6%</b>	<b>32.5%</b>	<b>34.5%</b>	<b>34.0%</b>	<b>34.2%</b>	<b>33.9%</b>	<b>13.4%</b>	<b>41.0%</b>	<b>33.4%</b>	<b>33.3%</b>
R&D	4.1%	5.2%	4.3%	5.3%	4.8%	6.4%	5.9%	22.2%	4.5%	3.7%	5.3%
Preclinical	0.9%	1.0%	0.5%	1.2%	0.9%	1.3%	0.8%	6.6%	0.7%	3.2%	1.0%
Clinical	5.0%	5.9%	3.7%	3.5%	2.5%	6.6%	2.4%	1.5%	3.2%	10.7%	4.0%
Domestic Registrations	2.3%	3.5%	2.3%	5.2%	5.6%	5.8%	8.0%	1.5%	6.2%	2.8%	4.6%
International Registrations	2.4%	2.4%	2.9%	4.5%	6.7%	3.3%	11.1%	1.0%	6.0%	2.1%	3.5%
<b>Preapproval/ Approval Total</b>	<b>14.7%</b>	<b>18.0%</b>	<b>13.7%</b>	<b>19.8%</b>	<b>20.6%</b>	<b>23.4%</b>	<b>28.2%</b>	<b>32.8%</b>	<b>20.6%</b>	<b>22.5%</b>	<b>18.4%</b>
Manufacturing	2.4%	2.0%	0.9%	1.7%	1.5%	2.0%	1.5%	5.8%	1.1%	1.0%	1.5%
Quality	6.3%	7.8%	3.2%	6.3%	6.8%	4.0%	5.4%	17.2%	4.9%	8.7%	7.0%
Domestic Compliance	8.3%	2.5%	2.3%	3.4%	3.8%	2.7%	4.6%	5.4%	3.4%	3.8%	5.6%
International Compliance	3.7%	1.9%	2.5%	2.4%	2.7%	2.0%	3.4%	3.5%	2.6%	3.4%	3.3%
Postmarketing	1.4%	2.1%	1.4%	2.0%	3.1%	2.9%	4.2%	2.6%	5.6%	3.4%	3.2%
Marketing	1.8%	2.3%	3.9%	3.9%	2.9%	1.5%	2.2%	0.3%	2.7%	1.4%	1.1%
<b>Postapproval Total</b>	<b>23.9%</b>	<b>18.7%</b>	<b>14.2%</b>	<b>19.6%</b>	<b>20.8%</b>	<b>15.1%</b>	<b>21.2%</b>	<b>34.9%</b>	<b>20.3%</b>	<b>21.7%</b>	<b>21.6%</b>
<b>Training/Education</b>	<b>2.2%</b>	<b>2.4%</b>	<b>1.8%</b>	<b>3.0%</b>	<b>3.7%</b>	<b>3.8%</b>	<b>3.7%</b>	<b>5.9%</b>	<b>3.9%</b>	<b>4.2%</b>	<b>4.9%</b>



## Time Allocation by Job Level and Work Setting

There are variations in time allocated to different areas depending on respondents' work settings. We have broken out time allocations for professionals working in government, industry, CROs, hospital settings and research. There were no significant variations by region.

		Vice President	Executive Director	Director	Manager	Project Manager	Specialist	Scientist	Associate	Coordinator
Government	Business-Related	100.0%	80.0%	33.1%	25.4%	39.6%	29.6%	17.0%	46.0%	5.0%
	Regulatory Strategy, Intelligence & Operations	0.0%	15.0%	35.6%	30.1%	27.2%	33.0%	20.8%	36.0%	35.0%
	Preapproval/Approval	0.0%	0.0%	8.2%	10.9%	13.5%	19.5%	24.0%	5.0%	0.0%
	Postapproval	0.0%	0.0%	21.1%	25.7%	15.1%	14.5%	25.8%	7.0%	50.0%
	Training/Education	0.0%	5.0%	2.0%	7.9%	4.6%	3.4%	12.5%	6.0%	10.0%
Industry	Business-Related	31.0%	35.8%	22.2%	19.1%	18.0%	11.7%	15.2%	11.9%	17.7%
	Regulatory Strategy, Intelligence & Operations	27.0%	31.4%	34.6%	34.0%	37.7%	33.5%	15.1%	41.2%	34.3%
	Preapproval/Approval	20.0%	14.8%	19.9%	21.5%	23.9%	29.5%	22.2%	20.8%	13.7%
	Postapproval	20.0%	15.0%	20.6%	21.7%	16.0%	21.9%	44.5%	22.4%	31.2%
	Training/Education	2.0%	1.8%	2.7%	3.4%	3.8%	3.3%	2.9%	3.6%	3.1%
CRO	Business-Related	46.3%	38.0%	31.2%	24.4%	34.8%	17.9%	3.0%	15.5%	10.0%
	Regulatory Strategy, Intelligence & Operations	29.4%	49.0%	35.9%	43.8%	17.5%	38.7%	0.0%	42.7%	42.5%
	Preapproval/Approval	13.8%	4.0%	23.0%	16.2%	35.6%	25.4%	72.0%	20.7%	30.0%
	Postapproval	6.9%	4.6%	6.7%	9.5%	7.9%	11.9%	0.0%	16.4%	12.5%
	Training/Education	3.8%	3.4%	3.2%	3.5%	4.2%	4.1%	25.0%	4.6%	5.0%
Hospital	Business-Related	37.5%	7.5%	27.0%	32.7%	37.0%	16.4%	10.6%	32.5%	25.0%
	Regulatory Strategy, Intelligence & Operations	32.5%	10.0%	18.0%	30.7%	48.5%	25.3%	26.4%	5.0%	24.4%
	Preapproval/Approval	5.0%	50.0%	16.7%	14.9%	7.5%	27.2%	26.5%	27.5%	21.4%
	Postapproval	20.0%	32.5%	30.0%	18.3%	4.0%	27.7%	35.3%	32.5%	25.5%
	Training/Education	5.0%	0.0%	8.3%	3.4%	3.0%	3.3%	1.3%	2.5%	3.7%
Research	Business-Related	21.0%	34.3%	23.4%	24.7%	21.0%	5.9%	0.0%	14.1%	7.8%
	Regulatory Strategy, Intelligence & Operations	18.0%	36.0%	33.7%	34.2%	43.0%	44.1%	0.0%	54.2%	25.2%
	Preapproval/Approval	35.0%	20.5%	21.5%	17.5%	21.0%	15.7%	70.0%	19.5%	51.0%
	Postapproval	22.5%	7.8%	17.4%	20.9%	10.0%	28.9%	10.0%	8.8%	5.0
	Training/Education	3.5%	1.5%	4.1%	2.8%	5.0%	5.4%	20.0%	3.5%	11.0

## Scope of Work: Geography

Many facets of regulatory work are multinational or even global in scope—from regulatory strategy and intelligence, regulatory submissions, surveillance to due diligence and other business-related activities. Thus, it is not surprising that many professionals report undertaking work that is multinational or worldwide in scope.

Only 7.2% of respondents reported work focused on a single country, although this varies by region. In Asia, 16.4% of respondents work only on country-specific functions, with an additional 27% focused regionally on Asia and nearly 57% involved with multiregional or worldwide regulatory work.

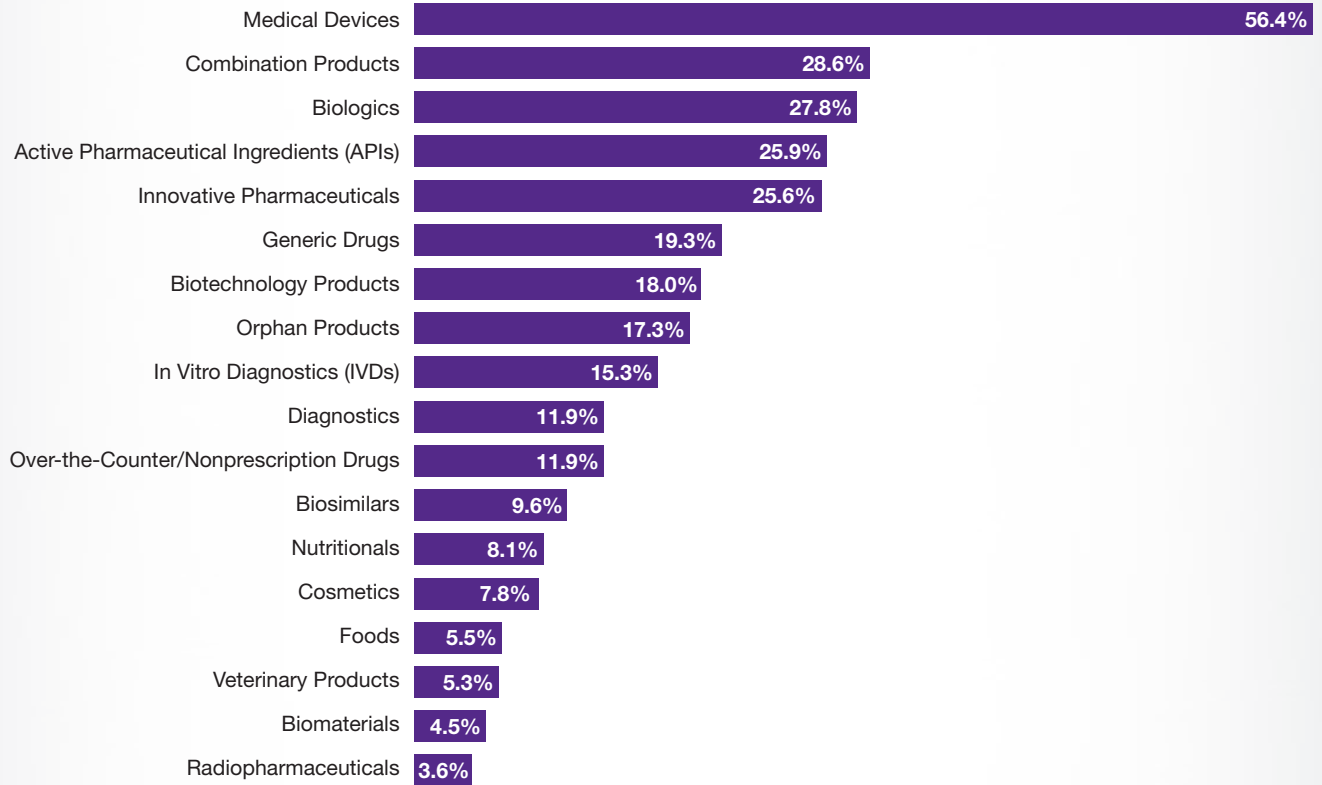
In Europe, 11% report working on regulatory functions for a single country, 13.7% focus on European issues only, and 66% reported multiregional or worldwide responsibilities. In North America, 74% report multiregional or worldwide responsibilities and just 5.8% report a single-country focus.

## Scope of Work: Product Types

Respondents reported working with a range of regulated healthcare and related products, with 56% working with medical devices and IVDs; 55% working with pharmaceuticals, 15% with biologics or biotechnology products and 14% with medical foods or nutritional products. More than 70% of respondents reported working for an organization involved with multiple types of products.

>70%

of respondents reported working for an organization involved with multiple product types.



# Compensation

## Key Findings

- Regulatory professionals at mid-level positions, including manager, project manager, specialist and associate, saw a steady increase in salaries.
- The compensation advantage of having Regulatory Affairs Certification (RAC) has grown for mid-level professionals.
- Regulatory experience is now having a greater impact on compensation than highest-earned academic degree.

The regulatory profession continues to pay well, and while some other fields have been negatively impacted by changes within the healthcare product industries and general economic trends, salaries for regulatory professionals showed a general upward trend.

Compensation information collected includes base salary, the amount of bonuses and other cash compensation for 2015, as well as the amount of base salary increase from 2014 to 2015.

## Factors Shaping Compensation

Regulatory professionals' pay is affected most by several interdependent factors, which have been stable drivers of compensation for more than a decade and affect compensation for professionals around the globe. The strongest factor affecting compensation is job level, but others also have an effect. Regulatory experience has emerged as a more critical factor influencing compensation than highest earned degree. The most important factors are:

- job level
- regulatory experience
- highest-earned degree
- total professional experience
- Regulatory Affairs Certification (for mid-level positions)

Total compensation of regulatory professionals may include bonuses and other cash compensation, including stock options. In addition to base salary, 67.2% of regulatory professionals working full time received bonuses, and 30% received other cash compensation in 2015. Bonuses were reported by professionals in all regions and at nearly all job levels.

## Base and Total Compensation by Job Level: US-Based Professionals

		Average	25th Percentile	50th Percentile	75th Percentile	90th Percentile
Vice President	Base	\$223,616	\$180,000	\$220,000	\$261,250	\$300,000
	Total	\$308,389	\$200,000	\$263,000	\$355,000	\$499,500
Executive Director	Base	\$202,050	\$178,900	\$207,500	\$235,650	\$256,300
	Total	\$306,655	\$218,773	\$297,500	\$391,500	\$481,200
Director	Base	\$156,020	\$131,625	\$155,000	\$175,000	\$200,000
	Total	\$203,119	\$143,309	\$182,010	\$236,750	\$302,103
Manager	Base	\$118,491	\$98,000	\$115,000	\$130,000	\$148,000
	Total	\$134,019	\$104,600	\$125,000	\$149,081	\$178,000
Project Manager	Base	\$102,215	\$85,000	\$100,000	\$118,000	\$134,500
	Total	\$112,174	\$89,500	\$110,950	\$130,500	\$156,000
Specialist	Base	\$86,529	\$68,000	\$83,000	\$98,875	\$115,000
	Total	\$93,376	\$70,000	\$86,750	\$106,000	\$125,640
Associate	Base	\$77,709	\$60,000	\$75,000	\$89,750	\$109,200
	Total	\$83,386	\$63,120	\$80,000	\$94,000	\$115,180
Coordinator	Base	\$60,561	\$50,000	\$59,000	\$69,000	\$80,154
	Total	\$62,620	\$52,000	\$61,000	\$72,750	\$83,000

Average base compensation for all US-based regulatory professionals at all levels was \$122,711. Average total compensation was \$150,422.

## Average Base Compensation by Job Level and Regulatory Experience: US-Based Professionals

	25+ years	20–24 years	15–19 years	10–14 years	6–9 years	3–5 years	1–2 years	< 1 year
Vice President	\$222,239	\$242,733	\$235,870	\$187,058	\$190,300	\$176,000	N/A	\$252,000
Executive Director	\$227,467	\$208,156	\$189,877	\$212,857	\$176,000	\$125,000	N/A	N/A
Director	\$173,229	\$164,434	\$163,862	\$154,444	\$140,517	\$145,411	\$124,455	\$178,750
Manager	\$136,714	\$130,117	\$125,598	\$116,075	\$130,240	\$105,520	\$97,176	\$107,872
Project Manager	N/A	\$119,085	\$105,640	\$111,293	\$102,086	\$99,952	\$90,747	\$57,500
Specialist	\$89,000	\$101,514	\$101,238	\$109,276	\$89,525	\$80,840	\$71,115	\$77,713
Associate	\$81,200	\$146,000	\$97,176	\$84,148	\$86,886	\$74,318	\$70,664	\$66,189
Coordinator	N/A	N/A	N/A	\$69,553	\$67,250	\$49,654	\$57,041	\$64,000
Scientist	N/A	N/A	\$205,700	\$103,545	\$80,000	\$82,500	\$92,667	\$64,667

## Average Base Compensation by Job Level and Highest Earned Degree: US-Based Professionals

	Doctorate	Master's	Postgrad	Baccalaureate	Associate
Vice President	\$228,960	\$222,059	\$213,850	\$224,909	\$180,000
Executive Director	\$223,756	\$196,376	\$188,400	\$190,783	N/A
Director	\$161,863	\$157,207	\$147,735	\$151,589	\$151,167
Manager	\$133,302	\$120,300	\$104,914	\$111,304	\$101,364
Project Manager	\$106,150	\$105,114	\$94,655	\$99,944	\$76,200
Specialist	\$88,515	\$85,758	\$91,477	\$87,451	\$73,716
Associate	\$92,352	\$77,948	\$79,911	\$70,488	\$63,600
Coordinator	\$58,193	\$61,714	\$76,750	\$57,514	\$46,000
Consultant	\$185,475	\$121,095	\$104,167	\$133,823	N/A
Scientist/Engineer	\$94,267	\$82,959	N/A	\$80,500	N/A
<b>Total</b>	<b>\$140,024</b>	<b>\$122,607</b>	<b>\$117,661</b>	<b>\$115,351</b>	<b>\$91,075</b>

## Compensation Trends: US-Based Professionals

RAPS has collected compensation, scope of practice and demographic information on thousands of US-based professionals since 1995 and is thus able to study trends over a 20-year period.

Among US-based professionals, base salaries have increased by an average of 3.3% per year, with slightly larger annual increases seen among senior and executive level positions. Base salaries among consultants increased by an annual average of 6.4% from 1999 to 2015.

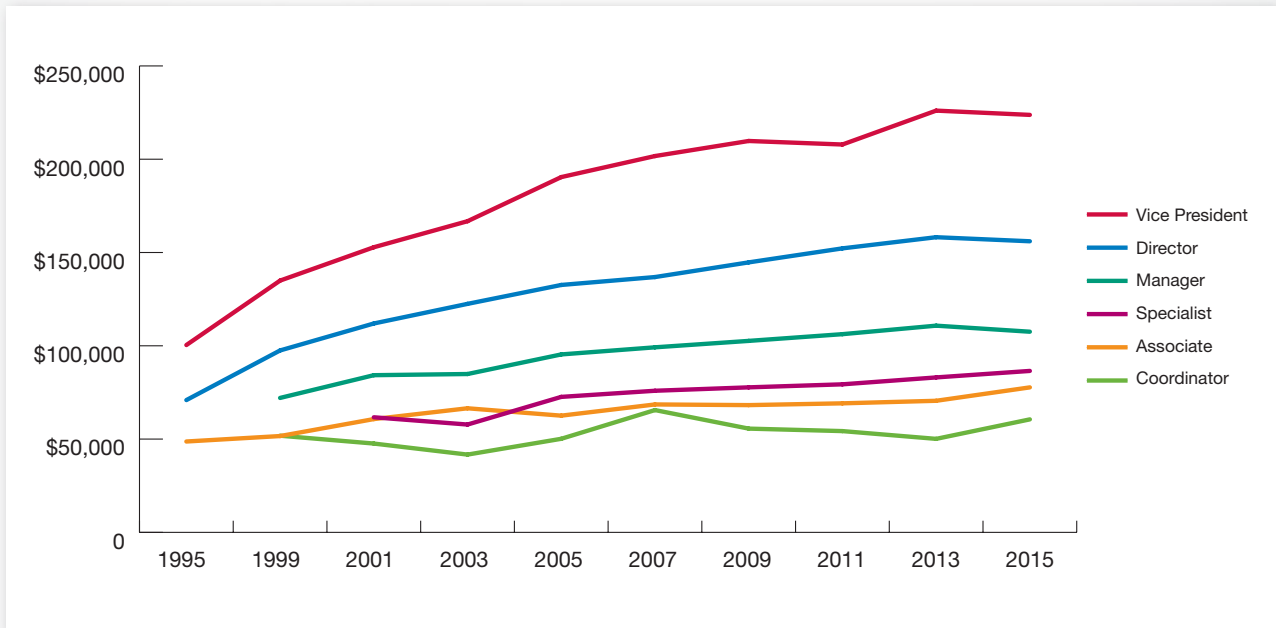
Total compensation has grown by an average of 3% per year since 1995, with higher growth among vice presidents (4.6%) and directors (4%). Total compensation shows variability over the 20 year window, reflecting, in part, economic conditions. Total compensation at senior and executive levels (vice president and director) increased by less than 1% between 2013 and 2015. However, mid- to lower level positions showed stronger increases, with a 3% yearly increase from 2013 to 2015 for managers and specialists. Associate and coordinator levels increased at an annual rate of 6% and 12% respectively. This may reflect the demand for regulatory professionals at these levels as well as the experience and training of professionals at these levels.

Total compensation for US professionals has grown by an average of

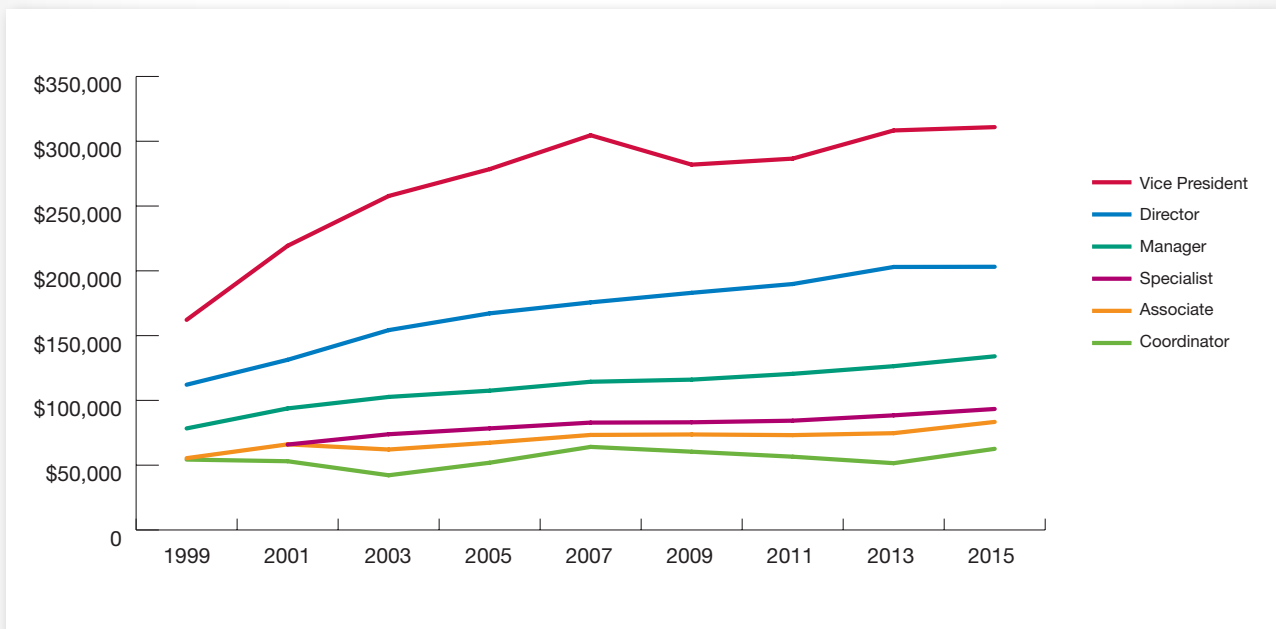
3%

per year since 1995.

## Base Compensation: US-Based Professionals



## Total Compensation: US-Based Professionals



## Base and Total Compensation by Job Level: Europe-Based Professionals

		Average	25th Percentile	50th Percentile	75th Percentile	90th Percentile
Vice President	Base	€179,394	€111,125	€157,550	€222,638	€318,000
	Total	€242,448	€130,375	€185,050	€256,945	€478,021
Executive Director	Base	€137,697	€128,915	€140,000	€145,525	€153,630
	Total	€165,983	€161,090	€163,000	€167,500	€190,420
Director	Base	€114,718	€78,837	€107,950	€151,250	€188,500
	Total	€137,565	€84,914	€131,475	€201,500	€230,515
Manager	Base	€72,835	€48,000	€65,000	€92,000	€121,600
	Total	€79,774	€50,000	€70,000	€100,000	€139,304
Project Manager	Base	€58,331	€29,988	€55,000	€76,625	€114,510
	Total	€61,698	€30,245	€58,500	€84,425	€115,990
Specialist	Base	€45,464	€33,486	€42,545	€58,400	€70,324
	Total	€47,271	€33,500	€46,000	€62,600	€73,113
Associate	Base	€46,329	€35,827	€42,228	€57,250	€67,098
	Total	€48,184	€37,298	€43,728	€57,250	€68,748

## Average Base Compensation by Job Level and Regulatory Experience: Europe-Based Professionals

	25+ years	20–24 years	15–19 years	10–14 years	20–24 years	6–9 years	3–5 years	1–2 years	< 1 year
Vice President	N/A	€255,000	€248,425	€142,875	N/A	€82,550	N/A	N/A	N/A
Executive Director	€165,000	€145,000	€131,077	€140,000	N/A	€120,650	N/A	N/A	N/A
Director	€157,239	€139,000	€126,050	€109,846	€100,000	€69,333	€78,975	€43,250	N/A
Manager	€16,300	€92,286	€83,444	€70,172	N/A	€75,319	€69,432	€59,585	€110,000
Project Manager	€94,000	€114,300	N/A	€46,125	N/A	€45,850	€34,000	€62,250	€92,500
Specialist	N/A	€48,823	€81,625	€44,097	N/A	€52,969	€39,789	€38,163	€39,644
Associate	N/A	€100,000	N/A	€58,000	N/A	€41,565	€42,085	€39,460	€70,000
Coordinator	N/A	N/A	N/A	N/A	N/A	N/A	€40,640	€12,000	N/A
Scientist	N/A	N/A	N/A	N/A	N/A	€54,000	N/A	N/A	N/A

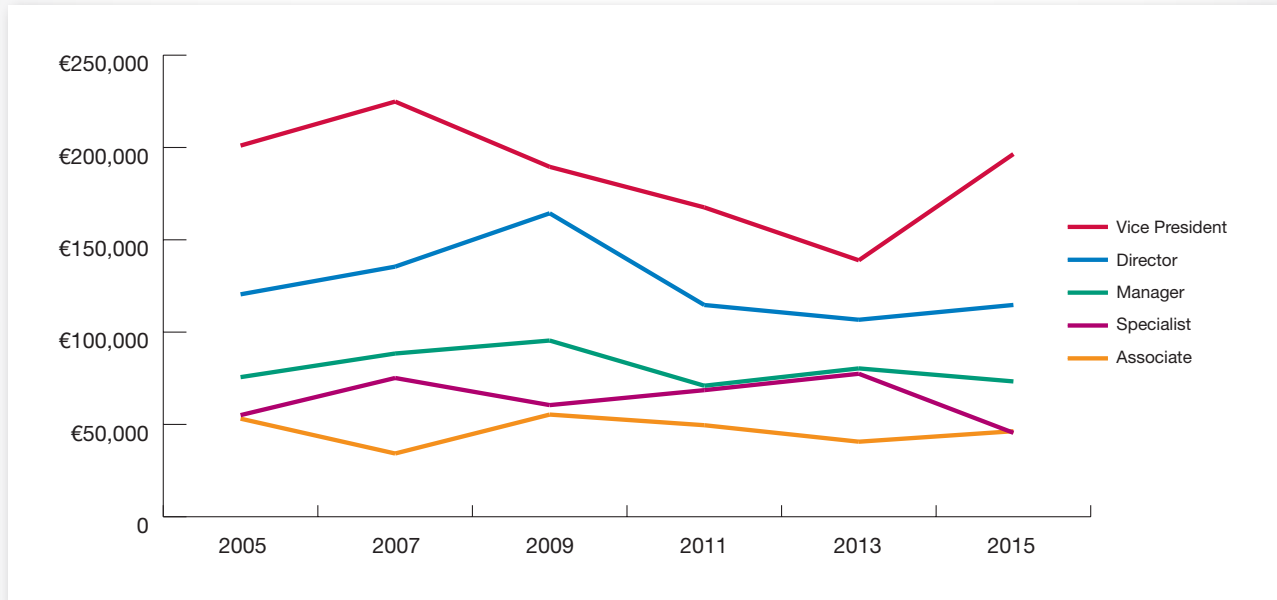
## Average Base Compensation by Job Level and Highest Earned Degree: Europe-Based Professionals

	Doctorate	Master's	Postgrad	Baccalaureate	Diploma	Associate
Vice president	€275,033	€139,700	€120,650	€150,000	N/A	N/A
Executive Director	€130,325	€130,727	N/A	€146,050	€165,000	N/A
Director	€140,588	€96,894	€121,617	€87,335	€114,000	N/A
Manager	€71,210	€74,067	€69,375	€77,235	€74,403	€57,500
Project Manager	€66,238	€54,842	N/A	€62,667	€3,000	N/A
Specialist	€70,507	€41,380	€28,866	€41,555	€68,000	€95,250
Associate	€44,864	€45,051	N/A	€53,045	N/A	N/A
Consultant	€55,500	€53,050	€50,000	€45,000	N/A	N/A
Scientist	N/A	€54,000	N/A	N/A	N/A	N/A
<b>Total</b>	<b>€92,563</b>	<b>€67,649</b>	<b>€68,505</b>	<b>€67,210</b>	<b>€84,623</b>	<b>€70,083</b>

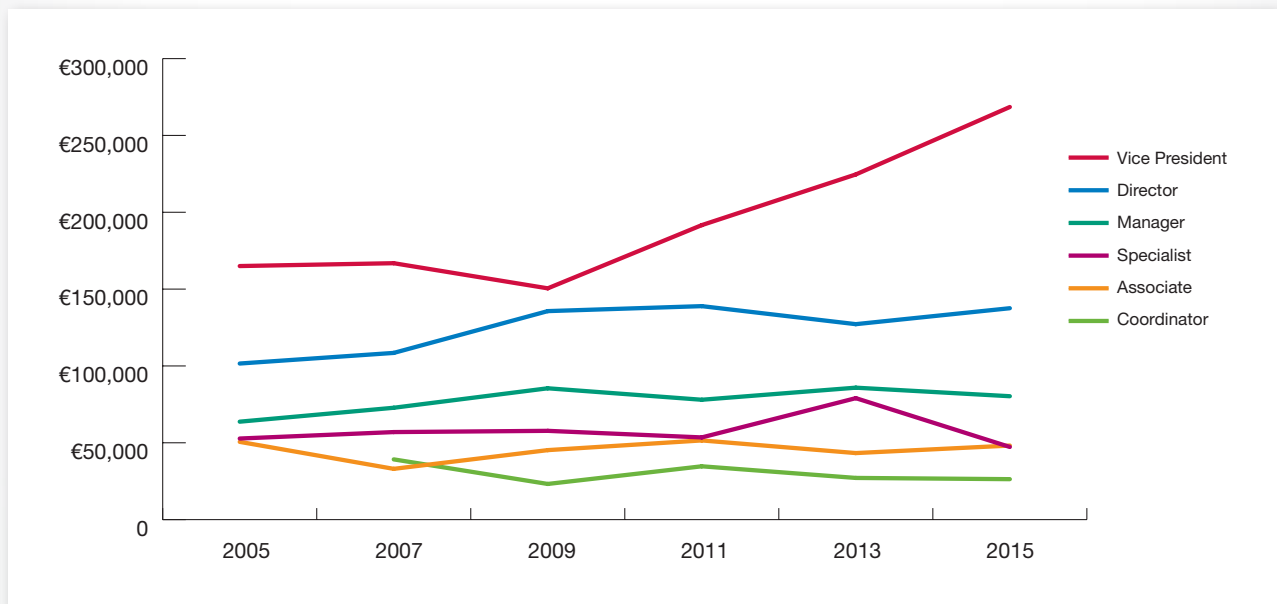
## Compensation Trends: Europe-Based Professionals

Data from a sample of hundreds of Europe-based professionals are available for a 10-year timeframe. Compensation trends among professionals in Europe are more difficult to interpret, due in part to variations in the mix of countries of the respondents in each year's survey, as well as fewer responses compared with the US. Overall, base salaries of European professionals have shown only moderate growth over the past 10 years. In contrast, total compensation increased by an average annual rate of 4.1%, with total compensation at the vice president level increasing by more than 11% from 2005 to 2015.

## Base Compensation: Europe-Based Professionals



## Total Compensation: Europe-Based Professionals



## Compensation: Other Regions

### Base and Total Compensation by Job Level: Canada-Based Professionals

		Average	25th Percentile	50th Percentile	75th Percentile	90th Percentile
Director	Base	\$130,400	\$111,750	\$127,500	\$157,000	\$164,500
	Total	\$157,427	\$118,500	\$153,000	\$198,300	\$229,000
Manager	Base	\$95,547	\$82,360	\$94,000	\$105,000	\$130,000
	Total	\$104,367	\$87,000	\$100,258	\$126,250	\$138,700
Project Manager	Base	\$90,077	\$75,000	\$87,000	\$100,000	\$116,400
	Total	\$101,779	\$80,000	\$95,000	\$106,000	\$139,400
Specialist	Base	\$73,062	\$60,375	\$69,500	\$81,491	\$93,810
	Total	\$78,101	\$62,750	\$75,500	\$90,250	\$102,036
Associate	Base	\$93,577	\$70,000	\$88,500	\$107,500	\$139,260
	Total	\$99,175	\$77,500	\$90,250	\$117,250	\$147,500

Figures in Canadian dollars

### Base and Total Compensation by Job Level: China-Based Professionals

		Average	25th Percentile	50th Percentile	75th Percentile	90th Percentile
Director	Base	¥537,500	¥340,000	¥475,000	¥672,500	¥929,000
	Total	¥668,750	¥391,250	¥582,500	¥860,000	¥1,184,000
Manager	Base	¥313,875	¥217,500	¥271,000	¥360,000	¥425,000
	Total	¥379,075	¥264,500	¥339,000	¥441,250	¥500,500
Project Manager	Base	¥286,000	¥220,000	¥350,000	¥350,000	¥404,000
	Total	¥333,340	¥260,000	¥390,000	¥400,000	¥483,220
Specialist	Base	¥103,302	¥57,200	¥60,000	¥127,200	¥187,000
	Total	¥120,758	¥62,200	¥68,000	¥153,000	¥238,800

### Base and Total Compensation by Job Level: India-Based Professionals

		Average	25th Percentile	50th Percentile	75th Percentile	90th Percentile
Director	Base	\$52,524	\$28,170	\$33,500	\$83,750	\$105,000
	Total	\$66,324	\$29,995	\$43,650	\$107,625	\$136,250
Manager	Base	\$60,056	\$11,750	\$22,850	\$33,000	\$63,500
	Total	\$62,845	\$12,875	\$25,475	\$37,500	\$68,412
Specialist	Base	\$40,656	\$6,811	\$10,500	\$19,150	\$100,000
	Total	\$45,232	\$8,400	\$12,004	\$26,128	\$113,216
Associate	Base	\$7,918	\$4,175	\$5,000	\$7,979	\$10,259
	Total	\$8,225	\$4,175	\$6,385	\$8,088	\$10,259

Figures in US dollars



## Base and Total Compensation by Job Level: Oceania-Based Professionals

		Average	25th Percentile	50th Percentile	75th Percentile	90th Percentile
Manager	Base	\$103,979	\$78,500	\$96,000	\$127,500	\$141,940
	Total	\$117,926	\$78,750	\$119,000	\$150,000	\$175,193
Specialist	Base	\$109,353	\$90,209	\$101,470	\$135,000	\$153,200
	Total	\$113,832	\$93,621	\$103,000	\$136,500	\$163,000
Associate	Base	\$87,250	\$70,250	\$84,500	\$101,500	\$109,600
	Total	\$99,750	\$76,000	\$88,500	\$112,250	\$134,300

Figures in Australian dollars

## Base and Total Compensation by Job Level: Singapore-Based Professionals

		Average	25th Percentile	50th Percentile	75th Percentile	90th Percentile
Director	Base	\$242,150	\$185,950	\$225,800	\$282,000	\$321,600
	Total	\$348,050	\$243,400	\$317,600	\$422,250	\$512,700
Manager	Base	\$132,143	\$106,000	\$144,000	\$150,000	\$170,000
	Total	\$151,291	\$123,000	\$168,000	\$180,000	\$190,000
Project Manager	Base	\$80,000	\$45,000	\$60,000	\$105,000	\$132,000
	Total	\$96,000	\$47,500	\$65,000	\$129,000	\$167,400
Specialist	Base	\$65,114	\$49,300	\$70,200	\$72,500	\$91,800
	Total	\$79,066	\$50,332	\$77,200	\$103,500	\$130,800
Associate	Base	\$36,083	\$16,560	\$48,000	\$52,356	\$56,942
	Total	\$38,435	\$19,320	\$48,000	\$60,000	\$60,214

Figures in Singapore dollars

## Base and Total Compensation by Job Level: Taiwan-Based Professionals

		Average	25th Percentile	50th Percentile	75th Percentile	90th Percentile
Manager	Base	\$781,164	\$426,164	\$770,000	\$1,125,000	\$1,350,000
	Total	\$818,222	\$475,722	\$835,000	\$1,177,500	\$1,371,000
Specialist	Base	\$691,600	\$628,500	\$750,000	\$837,500	\$860,200
	Total	\$731,140	\$688,750	\$804,700	\$845,000	\$951,700
Associate	Base	\$717,160	\$467,000	\$708,000	\$958,160	\$1,242,848
	Total	\$979,328	\$519,856	\$893,000	\$1,352,472	\$1,806,922

Figures in New Taiwan dollars

## Average Base Salary Increase by Region, 2014–15

In addition to providing specific figures for their base and total compensation for 2015, respondents also were asked to report any increase in base salary from 2014 to 2015. According to this self-reported data, base salary increased by an average of 5.9% in that period. The smallest rate of base salary increase was reported among professionals in North America (5.4%), although slightly larger salary increases were reported among lower- to mid-level professionals. More than 10% of regulatory professionals worldwide reported base salary increases of 10% or more. Only 7.8% reported no base salary increase.

Respondents reported an average base salary increase of

# 5.9%

from 2014 to 2015.

	Africa	Asia	Europe	Latin America	Middle East	North America	Oceania	All Regions
<b>CEO/President</b>	N/A	N/A	6.3%	N/A	20.0%	5.1%	N/A	5.6%
<b>Vice President</b>	N/A	19.5%	2.4%	10.0%	6.1%	4.2%	2.5%	4.4%
<b>Executive Director</b>	N/A	3.5%	4.9%	25.0%	N/A	5.7%	N/A	6.3%
<b>Director</b>	N/A	7.6%	4.3%	5.3%	8.0%	5.3%	N/A	5.4%
<b>Manager</b>	7.0%	11.8%	4.7%	12.6%	12.9%	5.1%	7.2%	5.8%
<b>Project Manager</b>	N/A	9.2%	5.4%	N/A	10.0%	5.5%	40.0%	5.9%
<b>Specialist</b>	10.0%	10.2%	6.0%	16.6%	9.3%	5.3%	3.6%	6.0%
<b>Associate</b>	29.0%	9.5%	8.1%	6.0%	15.0%	6.3%	3.3%	6.9%
<b>Coordinator</b>	N/A	15.0%	8.8%	11.8%	N/A	5.6%	N/A	7.1%
<b>Consultant</b>	12.0%	12.4%	4.5%	7.8%	N/A	7.7%	4.3%	7.8%
<b>Scientist/Engineer</b>	N/A	N/A	0.0%	N/A	N/A	5.6%	N/A	5.4%
<b>All Job Levels</b>	<b>14.5%</b>	<b>10.5%</b>	<b>5.2%</b>	<b>13.4%</b>	<b>9.6%</b>	<b>5.4%</b>	<b>6.2%</b>	<b>5.9%</b>

# The RAC Credential



## Key Findings

- RAC compensation advantage has grown to 11%
- significant advantage at mid-level, disappears at senior level
- significant advantage beginning to emerge among professionals in Europe

RAC holders on average earn

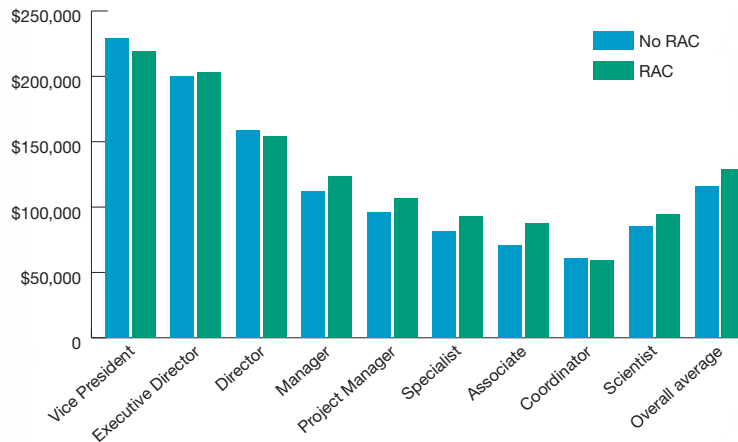
# 11%

more in base salary than non-RAC colleagues.

Nearly 46% of survey respondents reported having the Regulatory Affairs Certification (RAC) credential, the only post-academic professional credential specifically for those in the healthcare product regulatory field. The RAC is most common among professionals in North America, where 52% hold the credential, followed by 32% in Oceania and 26% of respondents in Asia. More than 18% of European professionals reported holding the RAC.

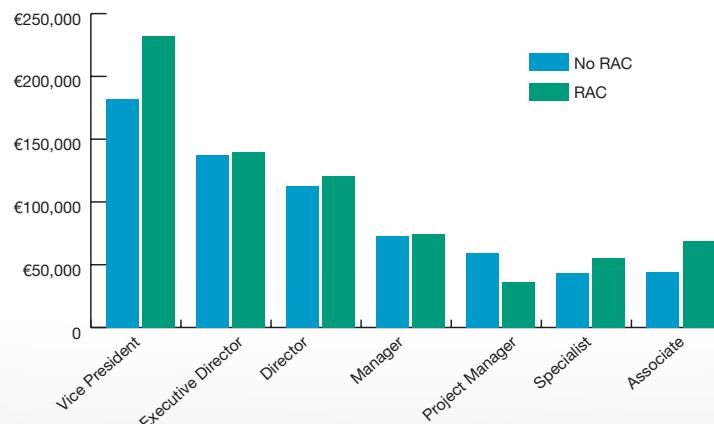
The RAC has been positively linked to compensation among North America-based professionals for many years. Overall, RAC holders on average earn 11% more in base salary than non-RAC colleagues. The impact on compensation is most apparent among mid-level professionals where the differential between RAC holders and non-credentialed personnel is 10% for managers, 10.6% for project managers, 14.3% for specialists, 24.4% for associates and 11% for regulatory scientists/engineers.

## Base Compensation for US-Based Professionals: RACs vs. non-RACs



The RAC credential also is correlated with higher compensation in other regions, including Europe, where RAC holders on average earned 21.6% more than non-credentialed professionals. This difference was evident at every job level other than project manager. While the overall number of respondents in Europe is smaller than for North America, the significant salary advantage of RAC in Europe could signal the beginning of a trend that bears watching.

## Base Compensation for Europe-Based Professionals: RACs vs. non-RACs



## Methodology

Data for RAPS' 2016 *Scope of Practice & Compensation Report for the Regulatory Profession* were collected through a global survey administered on a secure, independent website from March through April 2016. The survey was open to all professionals involved in the regulatory process for healthcare and related products. No information was collected that identified individual respondents or their employers. All information, including background demographics, compensation and scope of work were self-reported by the respondents.

Most questions on the 2016 survey were the same as those used in previous studies, allowing for direct comparisons across years. RAPS has conducted the Scope of Practice & Compensation Survey every two years since 1990.

### Response, Confidence Intervals and Measurement Error

There were 3,358 usable responses to the survey. A response was considered usable if it included job title, scope of practice variables, compensation data and geographic location. Responses that did not include these data elements were not used. It was not possible to verify information with respondents so some responses that appeared to be significantly out of range with other similar respondents were not included in compensation calculations.

Based on the total number of responses to the survey, the margin of error is estimated to be less than 2% at a confidence level of 95%. The same margin of error and confidence level applies to data from US-based respondents. This means that for overall analyses and for results reported for US-based respondents, one can be 95% confident that the figures in individual data cells are within +/- 2 percentage points of the figures for regulatory professionals fitting similar criteria.



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