



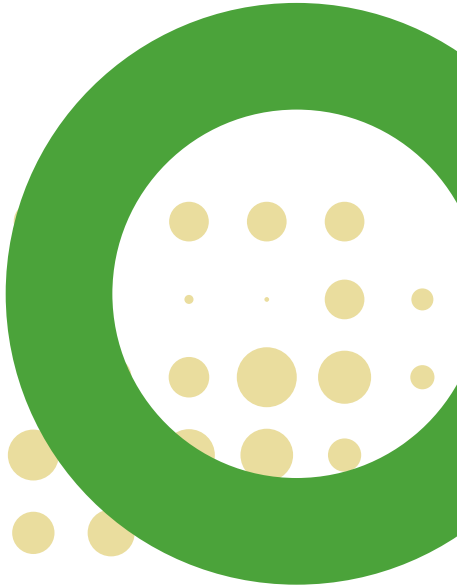
2022

Global Compensation and Scope of Practice Report for the Regulatory Profession

Executive Summary

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About This Report

The Regulatory Affairs Professionals Society (RAPS) has researched the work and compensation of regulatory professionals in the healthcare products sector for nearly 30 years. Conducted every two years, the Global Compensation and Scope of Practice Survey is the largest, most comprehensive study of these professionals. It results in original data and findings that are not available from any other source. This 2022 report presents analysis of more than 1,800 responses from individuals around the world.

The compensation data provide individual regulatory professionals, employers, recruiters and other stakeholders insight into the market value of regulatory work and expertise and allow comparison of differences in compensation based on variables such as job level, experience and education. The findings related to the work of regulatory professionals – the scope of practice – help us better understand their priorities and responsibilities and have helped RAPS track the evolution of the profession over time.

This year's survey questions were largely consistent with those of past years'. A review of past responses provided an opportunity to remove question options that were rarely selected. We also took the opportunity to rework or reword several questions to make them easier for respondents to complete. A few questions were added to address the effects of the global COVID-19 pandemic, including changes in the labor market and the Great Resignation trend in the US.

The information contained in this report represents complete and accurate compensation data on individuals working in the regulatory profession. The report is designed to allow organizations and individuals to compare their compensation levels and scope of practice to their peers.

This report shows compensation information for respondents based in the US, Canada and Europe. There was not enough data to show detailed results for other regions. Three-quarters of responses came from the US, allowing the most detailed aggregation of compensation data for US-based respondents.

These aggregations include:

- All US respondents
- Product most involved with
- Regulatory Affairs Certification (RAC)
- Years of regulatory experience
- Number of global full-time employees at organization
- Highest level of education completed
- Primary employer
- US Census division

As organizations and individuals compare their compensation information to that of peers, it is important to remember that the statistics published in this report should be regarded as guidelines rather than absolute standards. Since organizations will differ depending upon their location, size and other factors, any two organizations may offer their employees a reasonably attractive compensation package and yet be very different. For example, duration of employment and nature of prior experience will obviously influence the compensation offering for a particular individual. Thus, a deviation between any one organization's figures and a number appearing on a table in this report is not necessarily good or bad. It is merely an indication that additional scrutiny may be warranted.

This study was conducted for RAPS by Industry Insights Inc., an independent professional survey research firm located in Dublin, OH. The company specializes in conducting industry operating surveys, compensation and benefits studies, and member attitude surveys for professional and trade associations.

RAPS is proud to present the enclosed insights into the compensation levels in the regulatory profession. We wish to thank the professionals who submitted data for the study. Your support was essential in making this research a success.

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Survey Methodology

In May 2022, email invitations were sent to more than 100,000 regulatory professionals. In total, 1,818 completed online submissions were received by mid-July, representing a response rate of 1.8%. Submissions received after the final deadline and those with incomplete information were not included.

Upon receipt, all submissions were assigned a confidential identification number. All data were checked both manually and by a specially designed computer editing procedure. Strict confidence of survey responses was maintained throughout the course of the project.

A minimum of five responses was required to show data for any given category.

Final results were tabulated by Industry Insights Inc., and the report was completed in September 2022.

Definitions

Average (mean): The arithmetic average obtained by adding the individual values for all responses to a particular question and dividing by the total number answering; a measure of central value that can be distorted by extreme high or low values.

Median: A measure of central value that is not affected by extreme values; calculated by arranging all responses in numerical order and selecting the value that falls exactly in the middle, with half higher and half lower.

25th Percentile: When responses are ordered from lowest to highest, the lower quartile is the response 25% from the bottom. In other words, 75% of the responses are higher than this measure.

75th Percentile: When responses are ordered from the lowest to highest, the upper quartile is the response 25% from the top. In other words, 25% of the responses are higher than this measure.



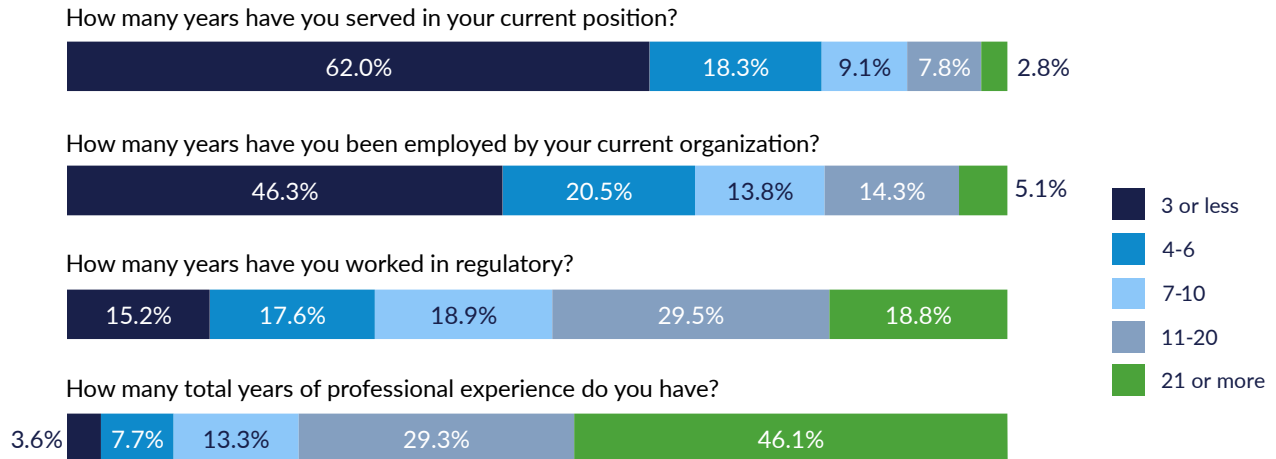


Executive Summary

Experience

The typical respondent has approximately 18 years of professional experience, with 10 of those in regulatory, up from 17 years of professional experience and 9 years in regulatory for respondents in 2020. They have been with their current employer for four years and in their current position for three years.

Average Years

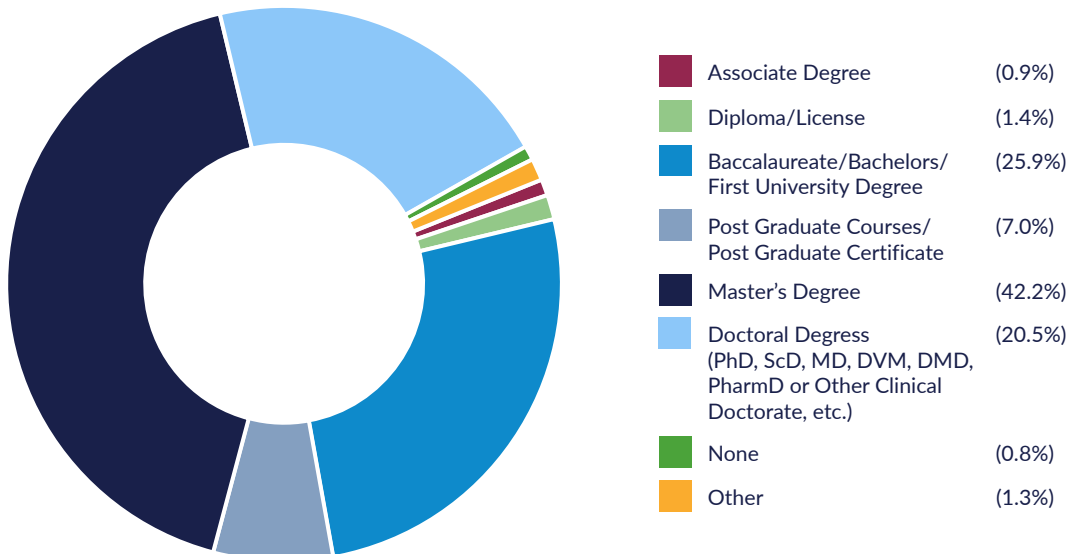


Most respondents worked in another profession or field before entering the regulatory profession. Common feeder fields include quality assurance/quality control (18.3%), research and development/product development (8.9%), life sciences research (7.1%) and laboratory sciences (6.7%).

Education

Regulatory professionals are a highly educated group. Nearly two-thirds (62.7%) of the respondents have a postgraduate degree, including 20.5% with a doctorate. Common areas of concentration include life/natural sciences (48%), engineering (17.8%), clinical science (14.8%), regulatory affairs (13.2%) and business/finance/economics (13%).

What is the highest level of university education that you have completed?

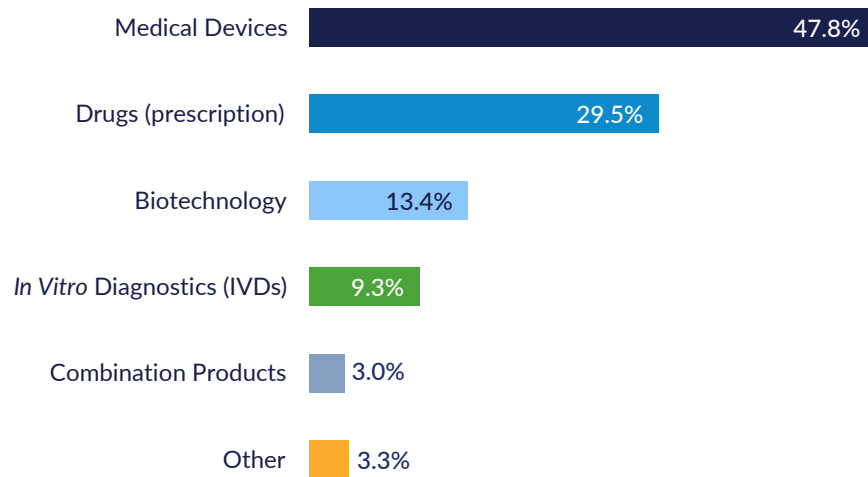


Scope of Practice

Products Most Involved With (Broad)

Respondents were asked to identify the product category they were most involved with from a detailed list. These detailed categories were collapsed into four broad categories for analysis:

- Medical Devices
- Drugs (prescription) – includes, generic drugs, innovative/brand-name pharmaceuticals, orphan products and active pharmaceutical ingredients (APIs)
- Biotechnology – includes biologics, biomaterials, biotechnology products and biosimilars/generic biologics
- *In Vitro* Diagnostics (IVDs)



Most Common Regulatory Functions Performed

Respondents were asked to choose the regulatory functions that comprise their typical week. Below are the top 5 regulatory functions. Please see pages 61-62 for a detailed list of regulatory functions performed by job title.

Top 5 Regulatory Functions Performed in a Typical Week

- 1 Regulatory Strategy
- 2 Submission
- 3 Project Management
- 4 Compliance
- 5 Writing/Medical Writing



Value and Recognition

Three-quarters (72.4%) of the respondents report senior management and executives are very aware or somewhat aware of the regulatory work they perform. Most (80%) also that report senior management and executives see regulatory professionals as either very important/valuable or somewhat important/valuable, up significantly from 56.5% in 2018.

Career and Job Motivations

Opportunity for career advancement was the most important factor in respondents' decisions to enter the regulatory profession, with 81.3% indicating it was very important or somewhat important. Other important factors include the diverse work of regulatory professionals (77.1%), ensuring the safety and effectiveness of healthcare products (77%), and job security in the profession (71.8%).

Professional Profiles – US Respondents

Below are summary results for the most common job titles in this year's survey.



Vice President

- 85% have 21 or more years of professional experience
- More than two-thirds have a postgraduate degree, including 34% with a doctorate
- 41% hold RAC
- Directly supervises seven people
- Works 50 hours per week
- 13% were promoted in 2021



Director

- 69% have 21 or more years of professional experience
- Two-thirds have a postgraduate degree, including 22% with a doctorate
- 48% hold RAC
- Directly supervises two people
- Works 47 hours per week
- 24% were promoted in 2021



Manager

- 73% have 11 or more years of professional experience
- Two-thirds have a postgraduate degree, including 22% with a doctorate
- 40% hold RAC
- Directly supervises one person
- Works 46 hours per week
- 28% were promoted in 2021



Project Manager

- 77% have 11 or more years of professional experience
- More than half have a postgraduate degree, including 8% with a doctorate
- 45% hold RAC
- No direct reports
- Works 44 hours per week
- 18% were promoted in 2021



Research Information Specialist

- 62% have 11 years or more of professional experience
- 40% have a postgraduate degree, including 12% with a masters
- 19% hold RAC
- No direct reports
- Works 44 hours per week
- 27% were promoted in 2021



Specialist

- 58% have 11 years or more of professional experience
- More than half have a postgraduate degree, including 11% with a doctorate
- 34% hold RAC
- No direct reports
- Works 44 hours per week
- 23% were promoted in 2021



Associate

- 46% have six or fewer years of professional experience
- More than half have a postgraduate degree, including 42% with a masters
- 17% hold RAC
- No direct reports
- Works 43 hours per week
- 25% were promoted in 2021

Compensation, US-Based Respondents

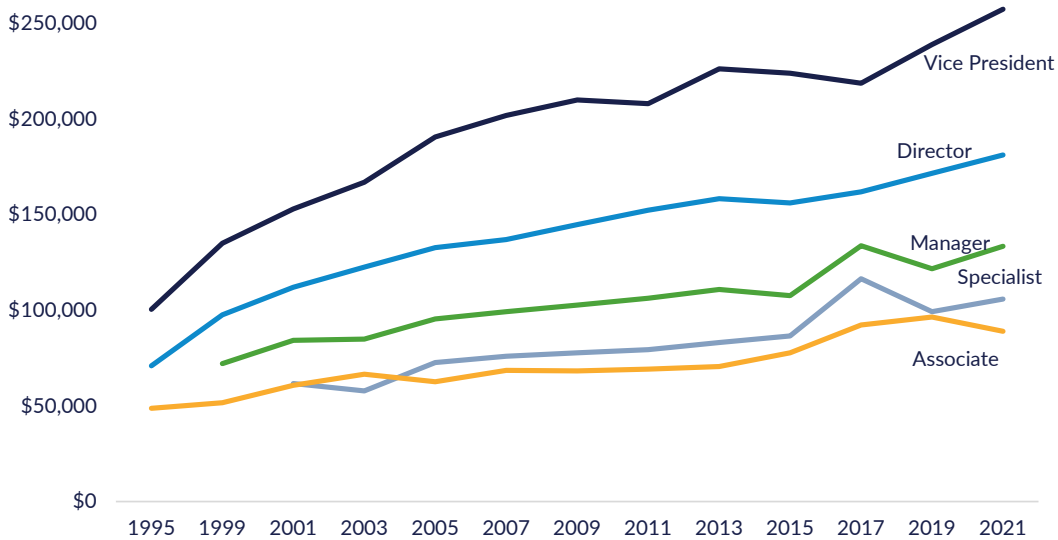
Average total compensation ranged from \$355,575 for vice presidents to \$101,294 for associates. Detailed compensation tables for each job title can be found in the Compensation by Job Title section of the report.

Compensation By Job Title

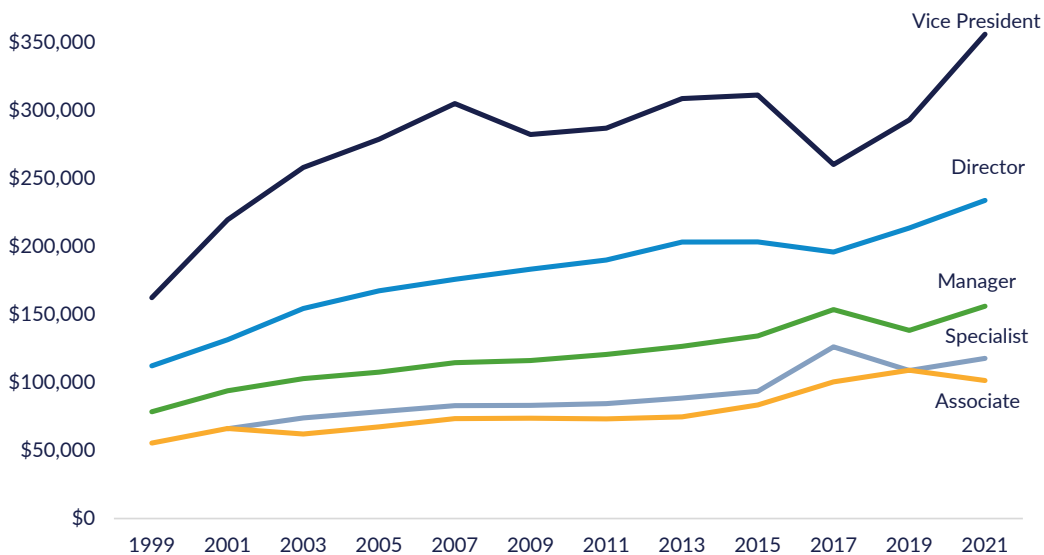
	Vice President	Director	Manager	Project Manager	Specialist	Associate	Regulatory Information Specialist
Total Compensation	\$355,575	\$233,574	\$155,873	\$149,318	\$117,615	\$101,294	\$121,186
Base Salary	\$257,189	\$181,048	\$133,380	\$127,856	\$105,741	\$88,961	\$102,917

US Compensation Trends

Average Base Compensation: US-Based Professionals

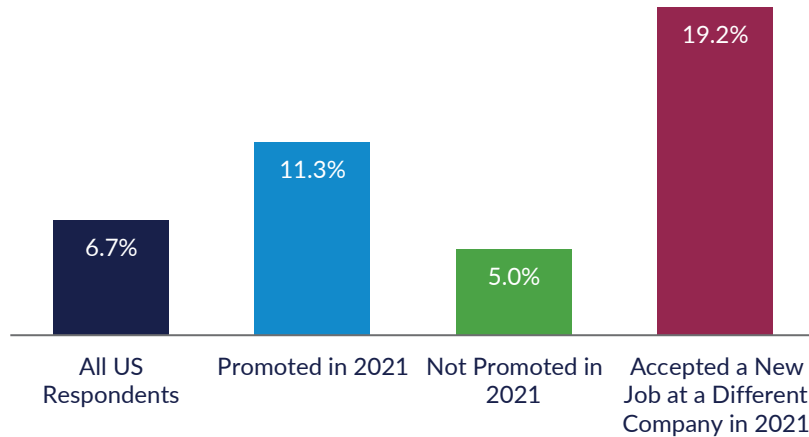


Average Total Compensation: US-Based Professionals



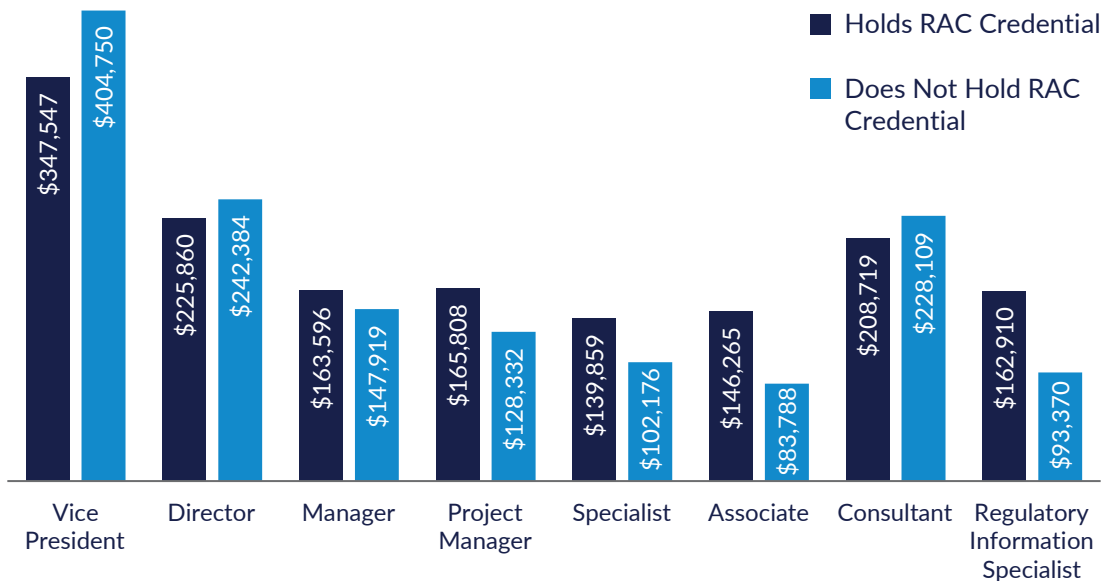
Base Salary Increase (2020 to 2021)

On average, US respondents reported base salary increases from 2020 to 2021 of 6.7%. More than one in five respondents (22.8%) were promoted in 2021. As expected, professionals who were promoted experienced higher base salary increases (11.3%) than those not promoted (5%). Respondents accepting a new job in 2021 received the largest increase in base salary of 19.2%.



Certification

Hold a Regulatory Affairs Certification (RAC) credential made a difference in compensation for US-based respondents at most job levels. Overall, those with a RAC credential earn 7.5% more than those without it. Associates with a credential made 75% more than those without it.



Global Full-Time Employees at Organization

Compensation tended to be higher for US respondents at large organizations, although the results were not completely consistent. Directors at organizations with 10 to 49 employees earned a median total compensation of \$186,784 compared to \$242,523 for those working at organizations with 10,000 or more employees.

	Vice President	Director	Manager	Project Manager	Specialist	Associate	Regulatory Information Specialist
1-9	*	*	*	*	*	*	*
10-49	\$295,100	\$186,784	\$119,250	*	\$94,328	*	*
50-99	\$361,381	\$176,255	\$120,430	*	\$92,820	\$76,860	*
100-999	\$402,229	\$240,491	\$153,945	\$179,981	\$125,418	\$109,898	\$169,829
1,000-4,999	\$300,214	\$249,527	\$157,966	\$118,443	\$109,798	\$99,096	\$94,350
5,000-9,999	\$378,163	\$253,561	\$166,716	*	\$124,695	\$133,732	\$159,667
10,000 or more	\$388,973	\$242,523	\$165,322	\$146,451	\$118,234	\$97,115	\$120,181

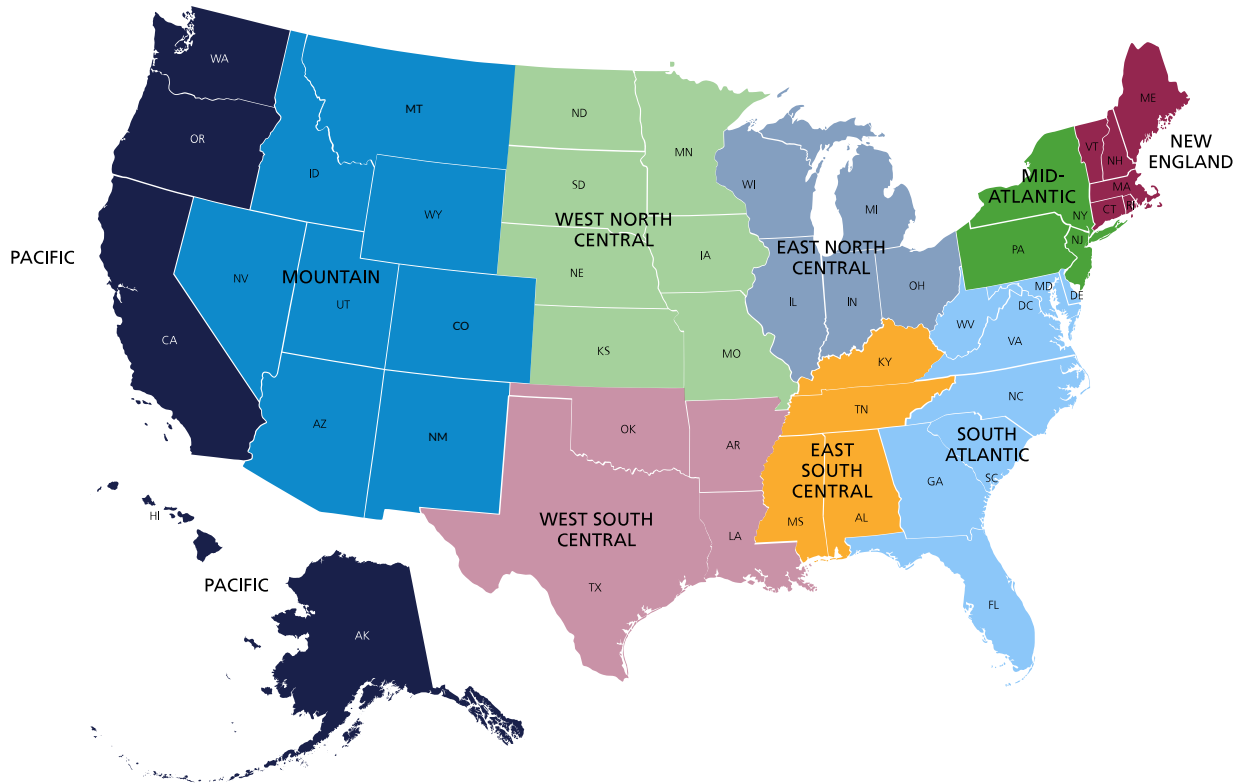
Highest Level of Education

Educational achievement did not show a strong correlation with compensation. Note: data for respondents at the vice president level are based on a relatively small dataset.

	Vice President	Director	Manager	Project Manager	Specialist	Associate	Regulatory Information Specialist
Bachelor's Degree	\$325,978	\$222,166	\$150,860	\$145,983	\$101,986	\$72,616	\$101,260
Postgraduate Courses	\$333,500	\$231,502	\$155,057	*	\$114,747	*	*
Master's Degree	\$332,088	\$226,480	\$155,291	\$142,360	\$125,514	\$105,775	\$128,797
Doctorate Degree	\$405,059	\$263,406	\$164,507	\$209,925	\$137,771	\$152,618	\$191,221

US Census Division

Compensation results by US census division showed no clear correlation that applied to every job title. However, respondents in the New England and Pacific divisions tended to report the highest compensation for most job titles.



	Vice President	Director	Manager	Project Manager	Specialist	Associate	Regulatory Information Specialist
New England	\$473,291	\$275,483	\$175,313	\$147,153	\$125,044	*	*
Mid-Atlantic	\$383,222	\$253,777	\$143,892	\$167,214	\$110,151	*	*
South Atlantic	\$275,964	\$216,460	\$153,792	\$149,740	\$117,819	\$122,524	\$134,062
East North Central	\$338,696	\$207,361	\$147,499	\$106,657	\$101,581	\$73,136	
East South Central	*		\$136,000	*	*	*	*
West North Central	*	\$190,131	\$181,215	*	\$120,607	*	*
West South Central	*	\$171,600	\$133,259	*	\$96,405	*	*
Mountain	*	\$216,705	\$143,954	*	\$104,131	\$53,708	*
Pacific	\$347,717	\$262,244	\$161,574	*	\$127,379	\$95,730	*

Compensation, Europe-Based Respondents

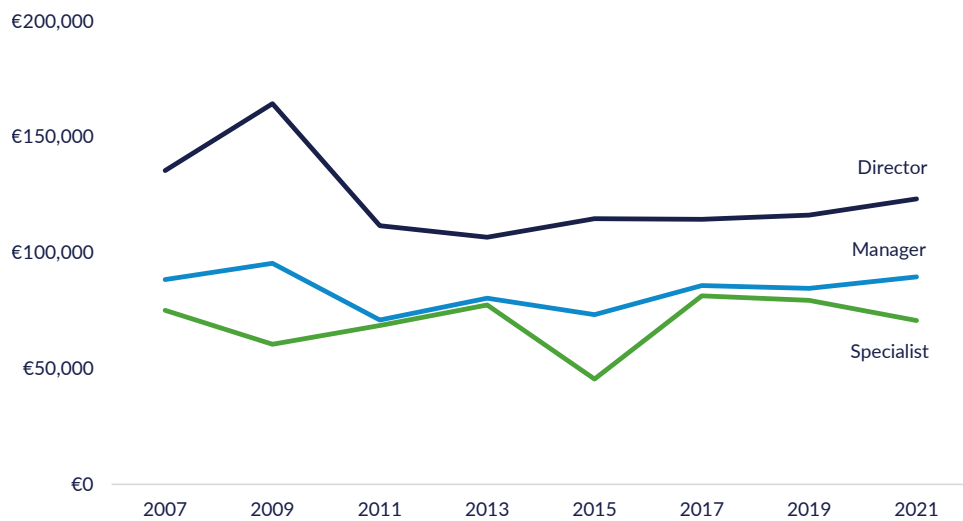
Average total compensation ranged from €154,694 for directors to €91,395 for specialists. Detailed compensation tables for each job title can be found in the European Compensation by Job Title section of this report. Average total compensation for Directors and Managers has increased by 9% and 12%, respectively over the past two years while total compensation for Specialists showed a slight decrease.

Compensation By Job Title

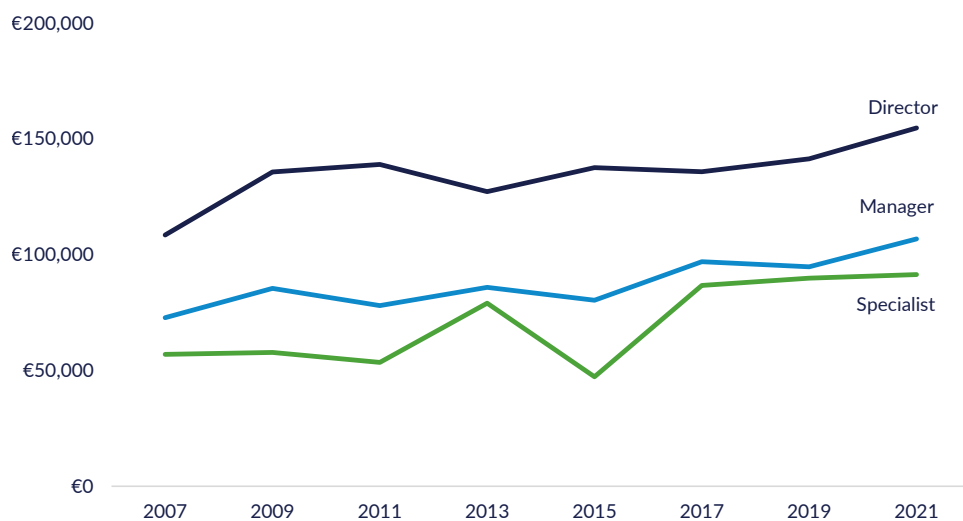
	Director	Manager	Specialist
Total Compensation	€154,694	€106,788	€91,395
Base Salary	€123,240	€89,588	€70,706

European Compensation Trends

Average Base Compensation: Europe-Based Professionals



Average Total Compensation: Europe-Based Professionals



Compensation, Canada-Based Respondents

Average total compensation ranged from \$183,793 for directors to \$92,300 for associates.

Compensation By Job Title

	Director	Manager	Project Manager	Specialist	Associate
Total Compensation	\$183,793	\$135,432	\$117,746	\$95,608	\$92,300
Base Salary	\$150,578	\$117,592	\$107,330	\$90,408	\$83,444

Note: Shown in Canadian dollars



