BioPharma Regulatory Affairs
Graduate Education Program

College of Pharmacy
The University of Georgia

Division of Outreach and Nontraditional Education

www.RA.Rx.UGA.edu
Regulatory Affairs
Careers

Overview
Regulatory Affairs Careers

Who Hires Regulatory Affairs Professionals?

Industry
- Pharmaceutical Companies
- Biotech Companies
- Medical Device Companies
- Contract Research

University/Healthcare
- Academic Programs
- Continuing Education
- Applied Research
- Clinical Research

Government
- FDA
- NIH
- CDC
- USDA
- EPA
- OSHA

Trade Associations
- Pharmaceuticals
- AdvaMed
- MDMA

Law Firms
- Patent & Regulatory
- Compliance experts
- Lobbyists
Roles for RA Professionals

- New Product Development
  - Member of Project Teams
  - Submissions Strategy/Pathways

- Product Submissions & Marketing Applications
  - IND
  - IDE
  - NDA/ANDA
  - 510(k)
  - PMA
  - PDP
  - BLA
Roles for RA Professionals

- Maintenance/Marketing Support
  - Post-Marketing Compliance
  - Complaints Administration/MDR
  - Pharmacovigilance
  - Advertising and Promotion Review
  - Labeling Reviews
  - FDA/Regulatory Agency Inspection Interface (US & International)
  - Annual and Periodic Reports to Regulatory Agencies
Essential RA Skills

• Academic/Education
  ➢ Technical/Healthcare/Scientific Disciplines
  ➢ BS...MS...Pharm.D...Ph.D./MD...DVM

• Knowledge and Competency in Laws & Regulations
  ➢ US
  ➢ International

• Communications Skills
  ➢ Verbal
  ➢ Written
  ➢ Negotiation
  ➢ Diplomacy

• Transferable Skills
  ➢ Research Experience
  ➢ Project Management
  ➢ Critical Thinking Ability
  ➢ People Skills
  ➢ Supervisory Experience
  ➢ Leadership Skills
  ➢ Budgetary Experience
  ➢ Project Planning & Strategy
  ➢ Problem-solver
  ➢ Calm Under Pressure
Essential RA Skills

• Experience
  ➢ Industry Related: highly desired to required, depending on position
  ➢ Technology Specific Experience: drugs, biologics, IVDs, medical devices and animal health products
  ➢ External Relations: regulatory agencies, national and international
Regulatory Affairs Career Opportunities
Respondents by Work Setting

- Industry: 77%
- Research Organization: 2%
- Academia: 2%
- Consulting: 11%
- CRO: 4%
- Government/Notified Body: 3%
- Hospital/Medical Practice: 1%
Respondents by Job Level
Educational Background

- Life Sciences: 50%
- Clinical Sciences: 18%
- Engineering: 14%
- Business: 14%
- Regulatory Affairs: 13%
- Social Sciences: 7%
- Regulatory Science: 4%
- Technical Sciences: 4%
- Public Health: 3%
- Law: 3%
Prior Professional Experience

- R&D: 26%
- Manufacturing & Quality: 21%
- Clinical Research/Biostatistics: 8%
- Lab Sciences: 7%
- Engineering: 6%
- Pharmacology/Pharmacy: 4%
- Medicine/Nursing/Public Health: 3%
Closely related to job level are regulatory experience and total professional experience. More than 90% of regulatory professionals began working in another field before transitioning into regulatory; 75% worked in fields closely related to regulatory.
## Compensation

### Average Base Compensation Increase 2012–2013

<table>
<thead>
<tr>
<th>Role</th>
<th>Africa</th>
<th>Asia</th>
<th>Europe</th>
<th>Latin America</th>
<th>Middle East</th>
<th>North America</th>
<th>Oceania</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEO/President</td>
<td>16.7%</td>
<td>4.1%</td>
<td>10.0%</td>
<td>10.0%</td>
<td>5.8%</td>
<td>27.5%</td>
<td></td>
</tr>
<tr>
<td>Vice President</td>
<td>6.3%</td>
<td>4.3%</td>
<td>4.6%</td>
<td>4.6%</td>
<td>4.9%</td>
<td>14.5%</td>
<td></td>
</tr>
<tr>
<td>Director</td>
<td>9.6%</td>
<td>4.1%</td>
<td>7.4%</td>
<td>16.7%</td>
<td>4.2%</td>
<td>5.3%</td>
<td></td>
</tr>
<tr>
<td>Manager</td>
<td>2.5%</td>
<td>13.4%</td>
<td>4.6%</td>
<td>14.2%</td>
<td>10.1%</td>
<td>5.3%</td>
<td></td>
</tr>
<tr>
<td>Project Manager</td>
<td>3.0%</td>
<td>9.7%</td>
<td>3.0%</td>
<td>5.0%</td>
<td>4.1%</td>
<td>3.0%</td>
<td></td>
</tr>
<tr>
<td>Specialist</td>
<td>8.3%</td>
<td>10.2%</td>
<td>3.6%</td>
<td>16.7%</td>
<td>4.8%</td>
<td>4.7%</td>
<td></td>
</tr>
<tr>
<td>Associate</td>
<td>15.0%</td>
<td>7.2%</td>
<td>10.4%</td>
<td>24.5%</td>
<td>5.3%</td>
<td>2.9%</td>
<td></td>
</tr>
<tr>
<td>Coordinator</td>
<td>30.0%</td>
<td>3.9%</td>
<td>12.9%</td>
<td>0.0%</td>
<td>2.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultant</td>
<td>10.0%</td>
<td>43.3%</td>
<td>6.2%</td>
<td>5.3%</td>
<td>39.0%</td>
<td>7.1%</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>5.1%</td>
<td>13.0%</td>
<td>4.5%</td>
<td>11.9%</td>
<td>12.5%</td>
<td>4.8%</td>
<td>5.3%</td>
</tr>
</tbody>
</table>
Compensation Trends-Base

Compensation Trends, US-Based Professionals

- Vice President
- Director
- Manager
- Specialist
- Associate

Base Compensation (US$)

$0 $50,000 $100,000 $150,000 $200,000 $250,000

1999 2001 2003 2005 2007 2009 2011 2013

2014 Scope of Practice & Compensation Report for the Regulatory Profession
Compensation Trends-Total

The graph above illustrates the total compensation trends for different roles between 1999 and 2013. It shows the increase in compensation for roles ranging from Vice President to Associate over the years. The lines represent the total compensation (in US$) for each role, with Vice President leading the highest compensation and Associate showing the lowest increase compared to other roles.
## Base Compensation by Job Level-US

<table>
<thead>
<tr>
<th>Job Level</th>
<th>Compensation ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vice President</td>
<td>$227,357</td>
</tr>
<tr>
<td>Director</td>
<td>$158,607</td>
</tr>
<tr>
<td>Manager</td>
<td>$110,833</td>
</tr>
<tr>
<td>Project Manager</td>
<td>$102,542</td>
</tr>
<tr>
<td>Specialist</td>
<td>$83,012</td>
</tr>
<tr>
<td>Associate</td>
<td>$70,687</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td><strong>$126,163</strong></td>
</tr>
</tbody>
</table>

Source: 2014 Scope of Practice & Compensation Report for the Regulatory Profession
Average Base Compensation

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

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Doctorate</th>
<th>Master's</th>
<th>Post Grad</th>
<th>Bachelor's</th>
<th>Associate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vice President</td>
<td>$243,339</td>
<td>$223,542</td>
<td>$241,988</td>
<td>$206,105</td>
<td>$145,000</td>
</tr>
<tr>
<td>Director</td>
<td>$169,812</td>
<td>$155,056</td>
<td>$158,273</td>
<td>$155,029</td>
<td>$153,636</td>
</tr>
<tr>
<td>Manager</td>
<td>$117,962</td>
<td>$110,158</td>
<td>$112,502</td>
<td>$110,178</td>
<td>$96,808</td>
</tr>
<tr>
<td>Project Manager</td>
<td>$101,044</td>
<td>$108,386</td>
<td>$104,387</td>
<td>$96,645</td>
<td>$110,000</td>
</tr>
<tr>
<td>Specialist</td>
<td>$92,379</td>
<td>$81,639</td>
<td>$85,323</td>
<td>$79,980</td>
<td>$77,433</td>
</tr>
<tr>
<td>Associate</td>
<td>$76,257</td>
<td>$73,149</td>
<td>$70,909</td>
<td>$65,358</td>
<td>$71,275</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td><strong>$148,025</strong></td>
<td><strong>$123,559</strong></td>
<td><strong>$133,563</strong></td>
<td><strong>$115,302</strong></td>
<td><strong>$107,214</strong></td>
</tr>
</tbody>
</table>

While the data presented in the table above are for US-based professionals, a similar effect is evident in other regions, with higher degrees typically associated with higher salaries.
The RAC Credential Factor

Base Compensation for US-Based RACs vs. non-RACs

2014 Scope of Practice & Compensation Report for the Regulatory Profession
Scope of Work: Product Types and Geography

Product Line Involvement*

- **55.9%** Medical Devices
  - **44%** Pharmaceuticals/Biotech
    - **27.3%** APIs
    - **26.4%** Innovative Rx
      - **21.5%** Generic Rx
  - **32%** Combination Products
    - **26.6%** Biologics
    - **19.7%** Biotech
    - **9.5%** Biosimilars
    - **4.7%** Biomaterials
  - **29.2%** IVDs
  - **17.5%** Orphan Products
  - **17%** Foods/Nutritionals
  - **15%** Veterinary Products

*Because many respondents work with multiple product lines, percentages do not add up to 100%
Educational Background

- Nearly all professionals (99%) have university degrees, and 69% pursued postgraduate studies. More than 40% hold master’s degrees and 20% have doctorates. Most regulatory professionals (94%) hold degrees in the sciences, a clinical discipline or engineering. Degrees or certificates in regulatory affairs or regulatory science are becoming more common.

Compensation and Factors Shaping Compensation

• The regulatory profession continues to pay well, and salaries for regulatory professionals maintained a general upward trend. Regulatory professionals’ pay is affected most by several interdependent factors: job level, regulatory experience, highest-earned degree, total professional experience and whether they hold the Regulatory Affairs Certification (RAC) credential (US-based professionals with the RAC earn 10.6% more).
RAPS Position Postings 2014

<table>
<thead>
<tr>
<th>Position and Company</th>
<th>Internal Number</th>
<th>Salary</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Affairs CMC Manager-Merial a Sanofi company</td>
<td>RACMCMER05</td>
<td>Open</td>
<td>Duluth, Georgia</td>
</tr>
<tr>
<td>Project Regulatory Affairs Manager</td>
<td>1001</td>
<td>Open</td>
<td>Manchester, New Hampshire</td>
</tr>
<tr>
<td>Regulatory Affairs Manager</td>
<td>7152014</td>
<td>Open</td>
<td>Kennesaw, Georgia</td>
</tr>
<tr>
<td>ASSOCIATE DIRECTOR REGULATORY AFFAIRS US Abbott</td>
<td>14000003K7</td>
<td>Open</td>
<td>Santa Clara, California</td>
</tr>
</tbody>
</table>

http://regulatorycareers.raps.org/jobs
# RAPS Position Postings 2014

<table>
<thead>
<tr>
<th>Position</th>
<th>Company</th>
<th>Internal Number</th>
<th>Salary</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Affairs / Quality Assurance Manager</td>
<td>Alpha-Tec Systems, Inc.</td>
<td>RAQA</td>
<td>Open</td>
<td>Vancouver, Washington</td>
</tr>
<tr>
<td>Director, Quality and Regulatory</td>
<td>McKesson</td>
<td>86979</td>
<td>Open</td>
<td>United States</td>
</tr>
<tr>
<td>Regulatory Affairs Manager</td>
<td>CryoLife</td>
<td>7152014</td>
<td>Open</td>
<td>Kennesaw, Georgia</td>
</tr>
<tr>
<td>Associate/Senior Associate, Regulatory Operations</td>
<td>Intarcia Therapeutics, Inc.</td>
<td>03</td>
<td>Open</td>
<td>Hayward, California</td>
</tr>
</tbody>
</table>

[http://regulatorycareers.raps.org/jobs](http://regulatorycareers.raps.org/jobs)
<table>
<thead>
<tr>
<th>Position</th>
<th>Location</th>
<th>Salary</th>
</tr>
</thead>
</table>
| Biomedical Equipment Support Specialist GS-1601-7/9 (Target GS-11) **Sarah R. Parker**  
**Phone:** (727)398-6661x15663  
**Email:** SARAH.PARKER3@VA.GOV | Bay Pines, FL     | $44615 - $57982    |
| RTIDS Technical Services Specialist           | Alachua, FL       | H26: 16.92-$22.00  |
| Center Director, Clinical Research Services   | All locations     | Open               |
| Alfred I. DuPont Hospital for Children, Wilmington  
**paul.garfinkel@nemours.org**                  |                   |                    |
| Clinical Research Technician                  | Orlando, FL       | Open               |
| Center for Pharmacogenomics & Translational Research-Job #6458 |                    |                    |
## Open Positions-GA 2014

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Location</th>
<th>Employer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Coverage &amp; Compliance Specialist</td>
<td>Atlanta, GA</td>
<td>Gentiva Health Services</td>
</tr>
<tr>
<td>Principal Quality Specialist - Clinical</td>
<td>United States</td>
<td>Allergan, Inc</td>
</tr>
<tr>
<td>Regulatory Affairs Associate</td>
<td>Atlanta, GA</td>
<td>Quest Group</td>
</tr>
<tr>
<td>Regulatory Affairs Associate, International</td>
<td>Alpharetta, GA,</td>
<td>EndoChoice</td>
</tr>
<tr>
<td>Regulatory Affairs Manager</td>
<td>Kennesaw, GA</td>
<td>CryoLife</td>
</tr>
</tbody>
</table>
## Open Positions-GA 2014

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Location</th>
<th>Employer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head of RA Pharmaceutical New Projects</td>
<td>Duluth, GA</td>
<td>Merial</td>
</tr>
<tr>
<td>Post Market Surveillance Technical Leader</td>
<td>Roswell, GA</td>
<td>Kimberly-Clark</td>
</tr>
<tr>
<td>Trade Compliance Specialist III</td>
<td>Atlanta, GA</td>
<td>Tyco</td>
</tr>
<tr>
<td>Clinical Application Specialist</td>
<td>Atlanta, GA</td>
<td>Cochlear</td>
</tr>
<tr>
<td>Managing Director, Brand Strategy</td>
<td>Atlanta, GA</td>
<td>American Cancer Society</td>
</tr>
<tr>
<td>Procurement Specialist</td>
<td>Atlanta, GA</td>
<td>Sterling-Hoffman Life Sciences</td>
</tr>
</tbody>
</table>
# Open Positions-GA 2014

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Location</th>
<th>Employer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field Service Specialist</td>
<td>Atlanta, GA</td>
<td>Sterling-Hoffman Life Sciences</td>
</tr>
<tr>
<td>Clinical Development, Manager</td>
<td>Midwest</td>
<td>Monster-UU - tz03051AT</td>
</tr>
<tr>
<td>Associate Account Manager</td>
<td>Atlanta, GA</td>
<td>SterilMed</td>
</tr>
<tr>
<td>Regulatory Affairs Coordinator-UDI</td>
<td>Covington, GA</td>
<td>C. R. Bard, Inc.</td>
</tr>
<tr>
<td>Senior Manager, Regulatory Affairs</td>
<td>Atlanta, GA</td>
<td>JDC Group</td>
</tr>
<tr>
<td>VP of Regulatory Affairs</td>
<td>Atlanta, GA</td>
<td>Sterling-Hoffman Executive Search</td>
</tr>
</tbody>
</table>

3/18/2015