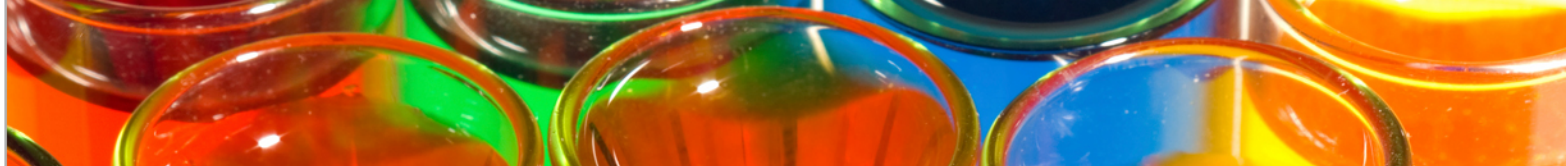




MassBio
MASSACHUSETTS BIOTECHNOLOGY COUNCIL

Regulatory Affairs: Find, Hire, Retain

Thursday January 26, 2017



Regulatory Affairs: Find, Hire, Retain

Speakers:

- **Stephen F. Amato**, PhD, MBA, RAC (US/EU), Program Director, Regulatory Affairs for Drugs, Biologics and Medical Devices, Northeastern University
- **Craig Gassman**, MS, Associate Director, Regulatory Informatics, Operations, and Technology, Karyopharm Therapeutics Inc.
- **James Sullivan**, Lead, Regulatory Affairs - New Product Development, GE Healthcare Life Sciences
- **Jodi Symes**, Senior Recruitment Consultant, Foundation Medicine

Moderator:

- **Lauren Celano**, MBA, Co-Founder and CEO, Propel Careers (Moderator)

Why Regulatory Affairs?

- MassBioEd focuses on researching hiring issues in biopharma
 - All reports free and accessible on our website
- Industry survey last spring identified Reg. Affairs as top “pain point” of hiring managers
- Goal: to highlight regulatory affairs workforce development concerns through labor market data and insights from industry/academia

Regulatory Affairs Report's Key Findings

- 65% growth in non-management regulatory professionals at Mass. biopharma companies between 2012 and 2015
- Online listings for regulatory openings requiring <2 years' exp. were **halved** between 2013 and 2016
- Increases in pay is concentrated in positions requiring more experience; wages at the lower end of the distribution fell $\sim 7\%$ in inflation-adj. terms
- Only **10%** start directly in Reg. Affairs – up from **2%** at the start of the decade

Shameless Plug

- MassBioEd is partnering with Regis College to offer *Overview of Health Product Regulation*, beginning **Feb. 8th**
 - Rundown of regulators, regulations, and their interplay with industry across product development stages, for those interested in transitioning into a career in regulatory affairs
 - Offered at a reduced rate
 - Earn 3 graduate credits

Regulatory Informatics, Technology, and Operations

OPERATIONS

Submission Management

Business Process Engineering

Document Publishing

Cross-Functional Alignment

Submission QC

Submission Standards Awareness

Planning and Timeline Management

Departmental SOPs
(Submissions)

Template Management

Systems-based SOPs
(non-Core IT)

Technical Troubleshooting
(PDF, Word, etc.)

TECHNOLOGY

System Management & Training

GxP Systems Management

Related Support Systems & Tools

System Training and User Support

System Managed Services

Audit Inspection Readiness
(Systems)

Vendor Management

Business and Operational Oversight

Budget Planning and Negotiations

ID, Eval, Qual, Selection, Impl, Validation

Technical Point of Contact *(Internal)*

License Management

INFORMATICS

Content Management

Metrics and Information

Regulatory Information Management
(RIM)

Submission and Related Informatics

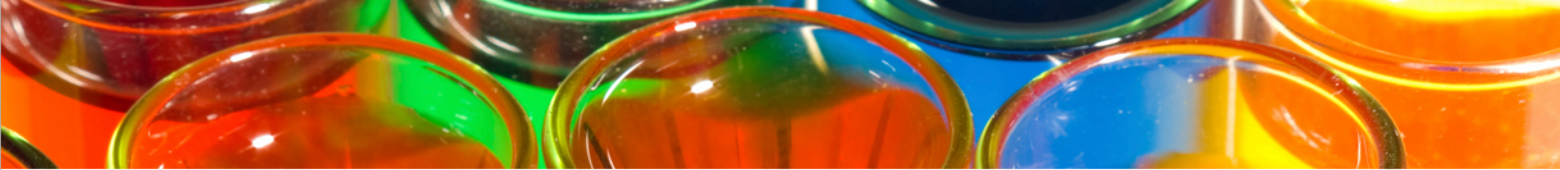
Document Management
(eDMS)

Regulatory Intelligence

Industry Policy and Influence
(Technical Focus)

Conference, Webinar & Educational Speaking Roles

Guidance Interpretation & Public Commenting Periods



Upcoming **2017** MassBio Forums

Feb 28: Rare Disease Day at the State House: The Role of Patient Advocacy Organizations in Advocating for Drug Approvals; **L&R**

March 9: Governance and Board Recruiting: Building a strong foundation for nonprofit success; **NonProfit**

March 16: The Expanding Role of CROs in External Innovation; **CRO/CMO**

March 23: Drugs are from Venus, Devices from Mars: The Value of Understanding Opposites; **MedDev**