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 ~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
- Vendor Management
- GxP Systems Management
- Business and Operational Oversight
- Related Support Systems & Tools
- Budget Planning and Negotiations
- System Training and User Support
- ID, Eval, Qual, Selection, Impl, Validation
- System Managed Services
- Technical Point of Contact (Internal)
- Audit Inspection Readiness (Systems)
- 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