TIPS AND TOOLS FOR STARTING A CAREER IN REGULATORY, QUALITY, OR CLINICAL

Skills and Basic Knowledge Needed
Preparation and Training
Resources

SDRAN
SAN DIEGO REGULATORY AFFAIRS NETWORK

Overview

- Minimum skills/knowledge needed
- Career preparation tips
  - Resume, Networking, Volunteering, Training/education, Interviewing
- Mentoring and internships
- Tools and resources

Minimum Entry-Level Skills Needed

- **Key skills: Writing, Interpersonal and communication skills, Project management, Attention to detail, Ethics**
- Strong oral/written communication skills
  - Write/edit technical documents; detail oriented
- Organizational skills to manage multiple, changing priorities
  - Handle/prioritize detailed tasks
  - Manage projects, meet deadlines; work on cross-functional teams
  - Review/analyze relevant data/information
- Think analytically/strategically
  - Research/locate relevant information

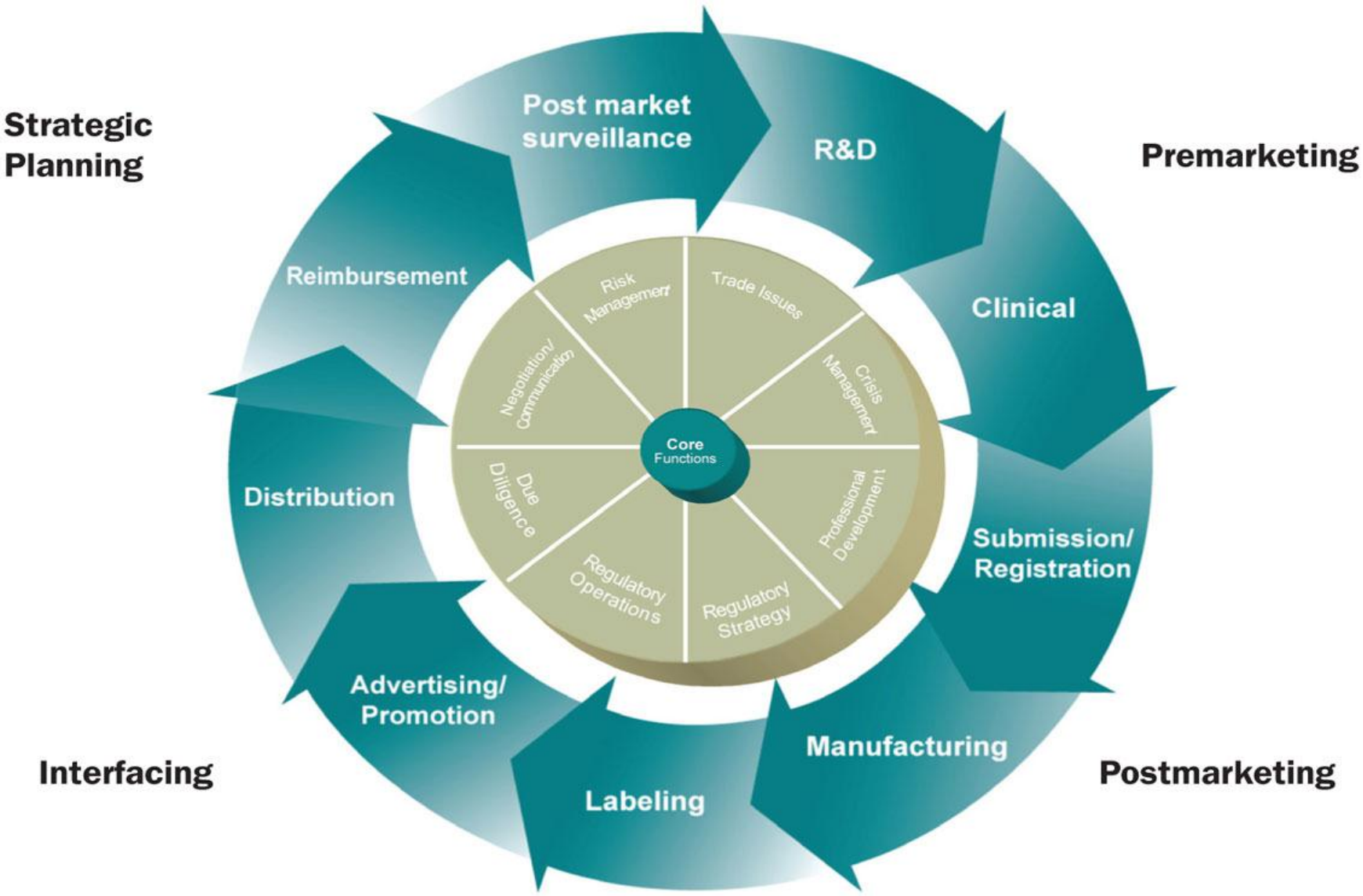
New to Regulatory, Clinical, Quality

- **Education**: Science, Engineering (Clinical: also Nursing, other Medical Professions)
- Not usually first industry job
  - QC may be first job
- **Bridging work experience**: Quality, Clinical/Medical, Regulatory, Toxicology, Manufacturing, Project Management
- **Job titles**: Coordinator, Associate, Specialist

What does Regulatory Professional Do?

- Understand/interpret/apply laws, regulations
- Monitor/report new regulatory requirements
- Advise company on regulatory compliance
- Prepare/manage regulatory submissions, communications with health authorities
- Maintain regulatory files, submission quality
- Participate on product development teams to develop regulatory strategies

RA Profession: Integral to the Healthcare Product Lifecycle



Regulatory Basic Knowledge Needed

- Regulatory, medical, scientific terminology
- Regulatory agency (structure, processes, personnel)
- Principles/requirements of device, drug laws
- Product lifecycle development: clinical, nonclinical, quality requirements (SOPs, GXPs)
- Submission types, requirements
- Electronic submission techniques
- Ethical concerns in human research, medical products risk/benefit, public health reporting

From RAPS *Regulatory Affairs Professional Development Framework*

RA Entry Level Responsibilities

- Maintain regulatory files
- Be current with regulatory procedures/changes
- Respond to RA information requests
- Assist in SOP development/review
- Investigate regulatory history of similar products
- Research submission requirements/options
- Assist monitoring project timelines
- Organize materials from nonclinical, clinical studies
- Coordinate/assist submission preparation
- Oversee quality control of regulatory documents
- Participate on product teams
- Compose routine correspondence to regulatory agency
- Assist in preparing for meetings with regulatory agency

From RAPS *Regulatory Affairs Professional Development Framework*

What does Clinical Professional Do?

- Safeguard clinical trial patient safety
- Ensure clinical data quality
- Ensure ethical conduct of clinical trials
- Ensure regulatory compliance
- Ensure research projects completed on time, on target, on budget
- Prepare/manage adverse event submissions
- Maintain regulatory files, ensure clinical trial file quality
- Participate on product development teams to develop clinical strategies
- Coordinate with clinical sites, monitors, CROs, DSMBs, clinical investigators
- Conduct internal/external training sessions
- Manage clinical trial databases
- Conduct internal/external GCP audits

From ACRP *Association of Clinical Research Professionals Development Pathway*

New to Clinical Affairs

- Education: Science, Nursing, Other Medical Professions
- Not usually first industry job
- Bridging work experience: Medical, Regulatory, Quality, Project Management
- Understand healthcare product development, clinical uses
- Responsibilities: coordinate, support technical, scientific clinical activities
- Job titles: Coordinator, Associate, Specialist

Clinical Basic Knowledge Needed

- Regulatory, medical, scientific terminology
- Clinic/Hospital Environment (structure, processes, personnel)
- Principles/requirements of device, drug laws
- Product lifecycle development: clinical research, nonclinical, quality requirements (SOPs, GXPs)
- Submission, clinical document types, requirements (health authorities, IRBs, DSMBs)
- Electronic data capture, management
- Good documentation practices

From ACRP *Association of Clinical Research Professionals Development Pathway*

Clinical Entry Level Responsibilities

- Maintain, review, audit case report forms, clinical trial files
- Database entry
- Stay current with regulatory procedures
- Assist in SOP, CRF, informed consent development, review
- Coordinate with clinical sites
- Assist project timeline monitoring
- Organize documents/records from clinical sites
- Assist adverse event or clinical report preparation
- Oversee quality control of regulatory documents
- Ensure ethical treatment of clinical study subjects
- Participate in risk management activities

From ACRP *Association of Clinical Research Professionals Development Pathway*

New to Quality Assurance

- Education: Science, Engineering
- Not usually first industry job (QC may be first job)
- Bridging work experience: Clinical, Regulatory, Manufacturing, Toxicology, Project Management
- Understand healthcare product development
- Responsibilities: coordinate/support technical, scientific quality activities
- Job titles: Coordinator, Associate, Specialist

Quality Basic Knowledge Needed

- Regulatory, medical, scientific terminology
- Regulatory agency (structure, processes, personnel)
- Principles/requirements of device, drug laws
- Product lifecycle development: clinical, nonclinical, quality requirements (SOPs, GXPs)
- Quality system requirements (cGMP, QSR, ISO, ICH)
- Electronic documentation management
- Good documentation practices
- Basic audit techniques

Quality Entry Level Responsibilities

- Maintain department files
- Stay current with quality procedures
- Assist in SOP development, review
- Collect, review, analyze quality data
- On-going compliance evaluation (or assessment)
- Assist in internal audits
- Track product events, complaints, recalls
- Oversee quality control of quality records, documents
- Present quality data to project teams, management
- Participate in risk management activities

CAREER PREPARATION SUMMARY

- Revise resume to show transferable skills
- Update LinkedIn profile
- Networking, Volunteering
- Mentoring, Internship, Training
- Related work experience (e.g., clinical, QA, project management)
- Prepare for interview

Preparation within Your Company

- Talk with supervisor about long-term goals
- Try to transfer within your company
  - Talk with your manager or HR department about your interest
  - Volunteer to help
- Some companies have cross-training programs for short-term assignments or part-time work in other departments

Resume Preparation

- For career change, include Objective
  - Focused on job applying for; not just any job
- Bullets, not paragraphs
  - Readability important; simple format
  - Tailor to specific job with keywords
- List accomplishments, include numbers
- Highlight relevant, transferable skills/experience
  - For example: Project management, Report writing
- List relevant courses, training
- Show what you know about regulations, therapeutic area
- Other ways to show commitment to career change: memberships, certification, classes/seminars

Networking

- Use your connections
- Be your own advocate
- Describe yourself professionally
- Describe opportunities you are interested in
- Prepare “elevator pitch” or sentence about yourself
  - Short version, Longer version, Audience specific
- Take advantage of networking opportunities at meetings
  - Meet other professionals at local programs; Ask for introductions
- Network on LinkedIn

Volunteering

- Great way to network; meet other professionals
- **Regulatory**
  - SDRAN - volunteer on committee, speak at program
  - RAPS – write article for Focus, speak at program, join planning committee
- **Quality**
  - ASQ - volunteer on committee, speak at program
- **Clinical**
  - SDCRN - volunteer on committee, speak at program
  - ACRP - write article, speak at program, join planning committee

Training to Improve Knowledge, Credentials

- Educational programs/seminars/webinars
  - SDRAN, OCRA, RAPS, ASQ, ACRP, SDCRN programs
- University classes (certificates, masters programs)
- Certifications
  - RAPS RAC - US, EU exams (SDRAN Study Group)
  - ACRP Clinical Research Associate certification
    - SDCRN Study Groups
  - ASQ – CBA, CMQ/QE, CPGP, CQA, CQE, etc.
- FDA website: CDER, CDRH Learn

Interview Preparation

- Find what skills most important for position; show your experience fits
- Describe how you handled related situation
- Research company products, competitors, management, etc.
- Practice interviewing
- Be confident, professional
- Formulate S.T.A.R. (Situation, Task, Action, and Result) responses

Interviewing Tips

- Don't have an attitude
- Dress professionally
- Watch body language
- Be prepared (do homework about position, company, typical questions)
- Focus
- Don't talk money
- Be yourself
- Follow up with thank you email

Phone Interview Tips

- Typical phone interview 20-30 minutes
- Print copy of resume, cover letter, job posting
- Prepare list of questions
- Assemble talking points, company research
- Record professional voice mail message on phone
- Answer with your name
- Have water available
- Use landline if possible; if using cell phone, have charger handy
- Eliminate distractions
- Have calendar handy to schedule follow up interview
- Ask about next steps; send thank you

Skype Interview Tips

- Look at camera, not screen
- Dress professionally like for in-person interview
- Quiet location with good lighting; ready early
- Check internet connection and familiarize yourself with Skype's features in advance; practice with friend
- Close other programs on computer
- Smile to bring energy/excitement to your voice
- Pay attention to body language; good posture
- Pause before answering in case of lag
- Same follow up as phone interview

SDRAN Mentoring

- Career development advice from experienced professionals
- Further develop career goals
- Resume critique
- Identify skill/training gaps
- Describe different jobs
- Help with networking

SDRAN Internship

- Work with industry to provide internship opportunities in regulatory, quality, clinical, project management
- Meaningful short term work experience
- Learn from experienced manager
- May provide experience to qualify for entry-level position
- Try out new career path

Where are the Jobs?

- Industry (Biotech, medical devices, pharmaceutical)
- Government (FDA headquarters or field office)
- Contract Research Organization (CRO)
  - Various locations, positions including regulatory, quality, and clinical
- Hospital or university
- Contract or temporary job
- Transfer within company

Summary

- Prepare for career change:
  - Resume update
  - Interviewing skills
  - Training/education
  - Networking/volunteering

- Following are resource slides

Helpful Tools and Resources

San Diego Regulatory Affairs Network (SDRAN)
www.sdran.org

- Monthly educational programs on regulatory topics
- Mentoring – new mentees accepted annually
- Internships – new opportunities posted as available
- Job listings posted regularly
- RAC study groups (every summer)
- Networking at programs, other events
- Resource links
- Volunteer on committee
- Join SDRAN LinkedIn Group

Helpful Tools and Resources

Regulatory Affairs Professionals Society (RAPS) www.raps.org

(some of these links may only be available to RAPS members)

- Education, training
- Certification (RAC)
- Publications including Fundamentals of Regulatory Affairs books
- Career information http://www.raps.org/your-career.aspx
  - Job listings; Career fairs
- Salary Calculator http://www.raps.org/2012-scope-of-practice-compensation-report/salary-calculator.aspx

Helpful Tools and Resources

- More RAPS Tools:
  - *Regulatory Affairs Professional Development Framework* *http://www.raps.org/Portals/0/Documents/PDF_Framwork_Whitepaper.pdf*
  - *The Pipeline for Regulatory Talent* *http://www.raps.org/portals/0/documents/report_May11_Talent_Pipeline.pdf*
  - *2012 Scope of Practice & Compensation Report for the Regulatory Profession* *http://www.raps.org/2012-scope-of-practice-compensation-report.aspx*
  - *Strategies for your Career: Finding YOUR Pathway into Regulatory (free webinar)* *http://connect.raps.org/raps/communities/resources/viewdocument?DocumentKey=24f0a64b-0cfe-474c-bfe3-5b42a13d4008*
  - Professional Levels http://www.raps.org/Your-Career/Regulatory-Career-Advancement-Guide/About-Regulatory/Professional-Levels.aspx

Helpful Tools and Resources

LinkedIn www.linkedin.com

- Update your profile
  - Your career advertising space
  - Professional photo
- Add connections
- Join Groups, post discussions, comments to show your expertise, ask for recommendations
- Search Jobs, People, Companies
- Network; prepare for interview

University Programs

- SDSU Regulatory Affairs program (online) http://interwork.sdsu.edu/cbbd/regaffairs/regaffairs.htm
  - Advanced Certificate in Regulatory Affairs
  - Master of Science in Regulatory Affairs
- USC Regulatory Affairs program (online) http://regulatory.usc.edu/
  - Masters in Regulatory Science
  - Doctorate in Regulatory Science
- UCSD Extension (many classes online) http://extension.ucsd.edu/programs/index.cfm?vAction=certDetail&vCertificateID=79&vStudyAreaID=4
  - Regulatory Affairs Essentials Certificate
  - Regulatory Affairs for the Biomedical Industry

More University Programs

- CSUF Clinical Trials Project Management Certificate http://extension.fullerton.edu/professionaldevelopment/Certificates/Clinical-Trials
- CSUDH Quality Assurance program
  - BS in Quality Assurance http://www.csudh.edu/bsqa/
  - MS in Quality Assurance http://www.csudh.edu/msqa/
- Life Science Certificate Programs www.extension.ucsd.edu
- Clinical Regulatory Affairs and Clinical Affairs at http://www.nu.edu/OurPrograms/SchoolOfHealthAndHumanServices/HealthSciences/Programs.html.

Job Listing Boards

- Medzilla http://www.medzilla.com/
- Biospace http://www.biospace.com/jobs
- FierceBiotech http://www.fiercebiotech.com/jobs/
- Indeed http://www.indeed.com/
- Monster http://www.monster.com/
- Simply Hired http://www.simplyhired.com/
- Glass Door http://www.glassdoor.com/index.htm
- CareerBuilder http://www.careerbuilder.com/