**Qualities of a good RA professional**  
Ø  Authoritative  
Ø  Team Player  
Ø  Decisive  
Ø  resourceful  
Ø  Good Communication Skill  
Ø  Analytical Skill- Ability to evaluate the strengths and weakness of the technical and legal options open to a company.  
Ø  Good Informational Technology skills  
Ø  Negotiating Skills  
Ø  Able to reapply scientific and regulatory principles  
Ø  Ability to work with other disciplines  
Ø  Flexible- Always willing to learn.

**Responsibilities of Regulatory Affairs Department**  
Ø  Keep in touch with international legislation, guidelines and customer practices  
Ø  Keep up to the date with a company’s product range  
Ø  Ensure that a company’s products comply with the current regulations.  
Ø  The Regulatory Affairs professional’s job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating.  
Ø  Formulate regulatory strategy for all appropriate regulatory submissions for domestic, international and/or contract projects.  
Ø  Coordinate, prepare and review all appropriate documents for example dossier and submit them to regulatory authorities within a specified time frame in conjugation with the organization.  
Ø  Prepare and review of SOPs related to RA. Review of BMR, MFR, change control and other relevant documents.  
Ø  Monitor the progress of all registration submission.  
Ø  Maintain approved applications and the record of registration fees paid against submission of DMF’s and other documents.  
Ø  Respond to queries as they arise, and ensure that registration/ approvalare granted without delay.  
Ø  Impart training to R&D, Pilot plant, ADl and RA. Team members on current regulatory requirements.  
Ø  Advising their companies on the regulatory aspects and climate that would affect proposed activities. i.e. describing the "regulatory climate" around issues such as the promotion of prescription drugs and Sarbanes-Oxley compliance.  
Ø  Manage review audit reports and compliance, regulatory and customer inspections.  
Ø  Regulatory Affairs professionals help the company avoid problems caused by badly kept records, inappropriate scientific thinking or poor presentation of data. In most product areas where regulatory requirements are imposed, restrictions are also placed upon the claims which can be made for the product on labelling or in advertising.  
Ø  Have a duty to provide physicians and other healthcare professionals with accurate and complete information about the quality, safety and effectiveness of the product.

**Regulatory Affairs Profession**  
The (Healthcare) Regulatory Affairs Profession is still an emergent profession but has two major international professional membership societies:  
The Regulatory Affairs Professionals Society, RAPS,  
The Organisation for Professionals in Regulatory Affairs, TOPRA,  
In Canada, the major professional membership society is: The Canadian Association of Professional Regulatory Affairs, CAPRA,

**Roles of regulatory affairs professionals**

Regulatory Affairs advisor plays important portfolio in Health Authority as well as Pharmaceutical Industry.

Role of Regulatory Affairs Professionals in Health Authorities (HA):

a) Evaluation of MAA:

1.Evaluation of Marketing Authorization Application i.e. New Drugs Application, New Biologics Application, Medical Device and Cosmetics application, Generic Application, Clinical Trial Application, Variation Application, Drug Master Files for API, Excipients and Packaging Materials, Site Master File for GMP inspection.

2.Issuance of Evaluation comments/ Exigencies to Manufacturers

3.Managing variation application, post approval changes and keeping record of annual update

4.Post Marketing Approval Management

5.Issuance of Marketing Authorization Approval, GMP, and GCP approval certificate

6.Managing MAA On-line and up-gradation towards common technical document format

b)Input for guidelines and guidance documents:

1.Issuance of guidelines & guidance documents for Quality, Safety, Efficacy and

Pricing Control as well as CTD for implementation

2.Collaboration with Global and Regional Harmonization units for exchange of technical knowledge, developing guidelines as well as allotting mutual recognition status for technical documents, GMP status and product approval

Part of foreign trade delegation to facilitate smooth management of Pharmaceutical business within countries and minimising barrier by reducing duplicate generation of technical data and timeline for evaluation and approval by respecting each other regulatory framework c)Inspection:

1. Performing GMP Audit for Drug Manufacturing Site, GCP Audit for Clinical Study Site and Bio-equivalence Centre, and issuing certification confirming approval status.

d)Support to Pharmaceutical Manufacturers:

1.Supporting Manufacturer in defining drug development pathway during Pre-NDA meeting and providing comments / confirming development pathway

2.Time to time meeting with pharmaceutical manufacturers association to discuss ongoing challenges, technical issues, guidelines/ guidance documents discussion and future development

e)Monitoring of Drug Safety and Efficacy:

1.Monitoring Drug Safety by collecting Pharmacovigilance data and reviewing drugs in markets time to time by reviewing labels and taking appropriate action accordingly

2.Monitoring Clinical Trials as well as approving study results for next phase of study

3.Allowing speedy or fast track designation for essential drug to patient population

**Role of Regulatory Advisor in Pharmaceutical Industry:**

a) Define Regulatory Strategy for drug development: Based on the intended market; regulatory strategist plays an active role in below areas

1.Critical role during selection of Drug products for specific market

2.Be a part of Business development, Marketing and Project team meeting

3.Defines the type of application in consultation with specified Health Authority i.e. New Drug or Generic Application

4.Meet Health Authority/ies to define Clinical Regulatory Pathway

5.Based on that prepares Global Regulatory Plan (GRP) defining Chemistry, Manufacturing and Control (CMC), Clinical and Non-Clinical Requirements

6.Advise Research and Development (R&D) team to develop product at laboratory scale matching regulatory criteria. In case of Generic drug, regulatory strategist advise which Reference Listed Drug (RLD) to be used, Test Criteria and Specifications for Active Pharmaceutical Ingredient (API) and Drug

Product for different kind of dosage forms, Stability data requirement of specified climatic zone (Zone I-IV) for Drug substance and Drug Product, Analytical Validation requirement, in-vitro equivalence data

7.Support in terms of executing validation batches at manufacturing location, defining batch size, number of batch sizes, criteria and justification for specification, evaluation of technical data

8.Bio-equivalence (BE) or Bio-Availability (BA) criteria- defining study protocol and getting concurrence from respective health authority

9. Labeling Requirement- for Generic submission, replica of innovator labeling information. In case of new drug, labeling to be based on actual Clinical and non clinical study

10.Applying for Site inspection for Good practices confirmation. For Manufacturing site- GMP certification, For BE and Clinical Site- GCP certification

**Major Regulatory Authorities**

|  |  |
| --- | --- |
| Country | Regulatory Authority |
| India | Central Drugs Standard Control Organization  Drug controller general of India (DCGI) |
| US | Food and Drug Administration (US FDA) |
| UK | Medicines and Health care products regulatory Agency (MHRA) |
| Australia | Therapeutic Goods Administration (TGA) |
| Japan | Japanese Ministry of health, Labour and Welfare (MHLW) |
| Canada | Health Canada |
| Brazil | Agency Nacional degradation Vigilancia Sanitaria (ANVISA) |
| South Africa | Medicines Contol Council (MCC) |
| Europe | European Directorate for Quality of Medicines (EDQM) |
|  | European Medicines Evaluation agencies (EMEA) |