REGULATORY AFFAIRS: A BASIC NECESSITY

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AS SEEN IN THE PREVIOUS SEMINARS:

- Awareness of the regulatory environment is essential for successful auditing but with so many regulatory bodies in play, and the constantly changing playing field as new regulations appear on an annual basis, it is futile to believe that any one person can manage to keep up with all the details.
- Review and update of regulations actually requires a full-time team of people dedicated to nothing else but ensuring that the latest regulations are being circulated within the company and also have the ability to communicate directly with the authorities in order to obtain clarification, further details or register objections and/or complaints.

DEFINING A REGULATORY AFFAIRS DEPARTMENT:

- Regulatory Affairs (RA) acts as the interface between the pharmaceutical industry and the drug regulatory authorities across the world.
- Primarily involved in the registration of drug products in respective countries prior to their marketing.
- RA is an important part of the organizational structure of a pharmaceutical company, as internally it liaises at the interface of drug development, manufacturing, marketing and clinical research.
- RA is actively involved in every stage of development of a new medicine and in the post-marketing activities with authorized medicinal products.
- RA provides expertise and regulatory intelligence in translating regulatory requirements into practical workable plans.

JUSTIFICTION FOR RA:

- Due to constantly increasing regulatory obligations and new requirements as well as the globalization of the pharmaceutical market, the demands and responsibilities of regulatory departments is becoming more and more complex.
- Due to the still considerable differences in documentation requirements, regulatory procedures, ways of communication with the authorities, CMC regulations, importation regulations, etc., obtaining local regulatory knowledge is still the key to success in any new market.
- The proper implementation of regulatory guidelines and laws will improve the economic growth of the company as well as enhance safety.

THE SCOPE OF RA:

- The scope of the regulatory affairs group function spans the entire spectrum of product development, manufacturing, registration, post-marketing activities and lifecycle optimization. This span of involvement and responsibility is sometimes referred to as bench to bedside and beyond, from cradle to grave, from inception through lifecycle optimization, from laboratory to launch, etc. The regulatory team and professional hold a unique position of importance with impressive diversity in function and significant breadth and depth of responsibility.

WHY NOT OUTSOURCE RA:

- Identifying the right partner at the right time is vital to successful outsourcing of RA. This task is far more difficult than it first appears.
- There is an increasing trend towards outsourcing, which means that outsourced companies are representing many competing interests and long lineups.
- One size does not fit all. Whereas expertise may lay in a certain geographical area, the company may not be capable of handling other global authorities.
- Outsourcing does not bring the appropriate and required knowledge into the company.

DURING MY RECENT AUDITS:

- **Because of the limited capacity of companies I have dealt with in not having established RA Departments, the knowledge of SMEs on this particular subject matter has resulted in tremendous loss of time due to:**

  1. Not being aware of the regulations and wishing to argue their points endlessly.
  2. Not understanding that their product is to be licensed in a different country with different regulations that have to be met which have different requirements.
  3. Assessing their own experience as being more qualified than the regulatory requirements.
  4. Viewing the regulatory standards as suggestions rather than compulsory.
  5. Interpretation of the regulations according to their own thinking and not to mainstream understanding.
  6. Using Nationalism as an argument.

  By having an official Regulatory Affairs Department that is constantly advising and training company personnel to the new and foreign regulations this can all be avoided.

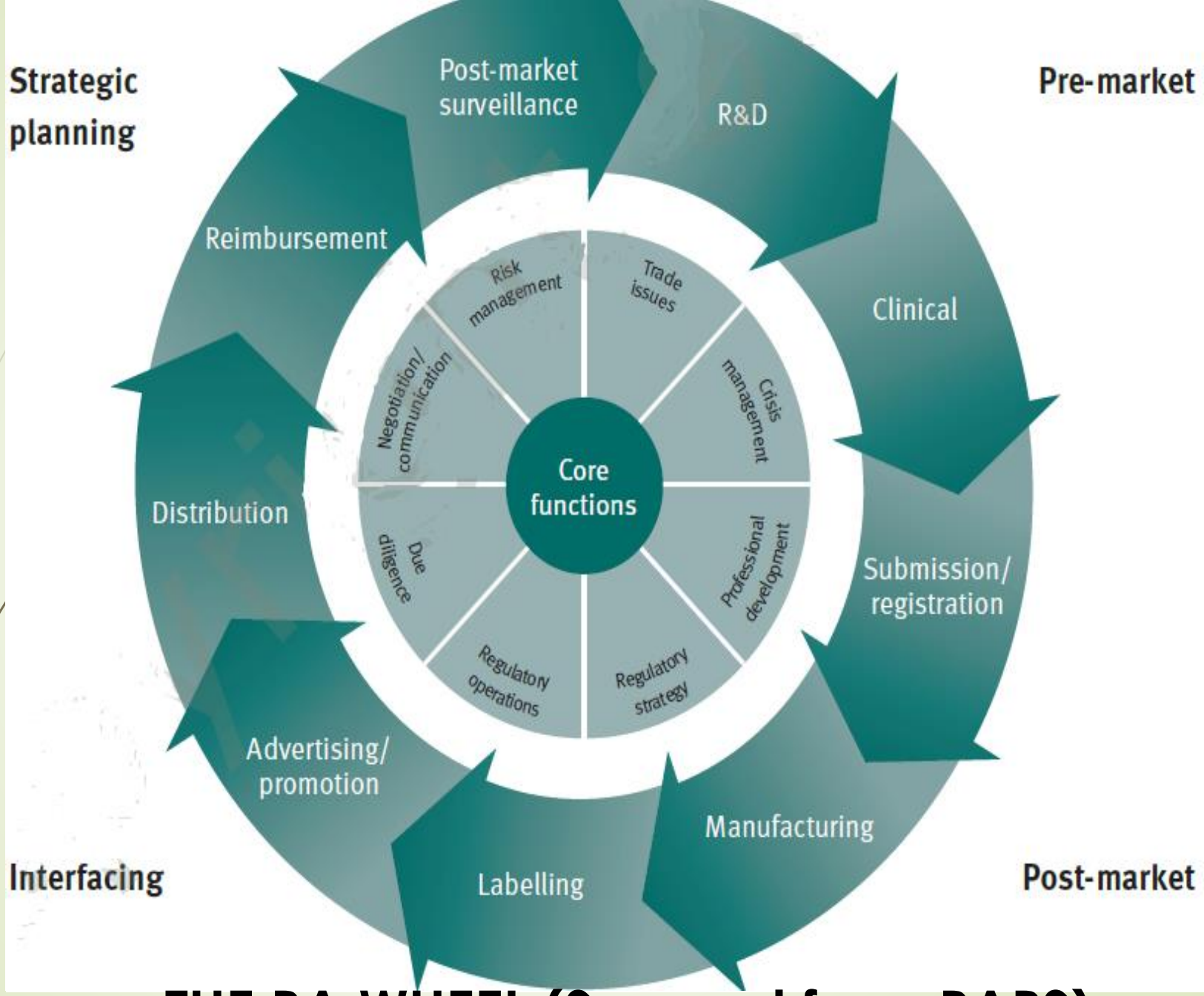
RA AND QA ARE NOT A MATCH:

- There is a continuing trend to include quality assurance (QA) under the umbrella of RA or vice versa, and in fact at some companies many positions at higher levels are designated as RA/QA positions.
- While it is inherent that RA functions in a role to ensure compliance and overall quality of regulated products, it must be cautioned that this reporting structure has associated risk associated, as QA must function independently and this is not possible if it has the role of RA in submitting products for approval by the regulatory authorities and reporting directly to management.
- Where auditing of regulatory functions is required, QA cannot obviously audit itself so the marriage of the two should be strictly avoided.

GLOBAL REGULATORY BODIES:

COUNTRY or REGION	REGULATORY BODY
USA	Food and Drug Administration (FDA)
UNITED KINGDOM	Medicines and Healthcare Products Regulatory Agency (MHRA)
AUSTRALIA	Therapeutic Goods Administration (TGA)
INDIA	Central Drug Standard Control Organization (CDSCO)
CANADA	Health Canada
EUROPE	European Medicines Agency (EMEA)
JAPAN	Ministry of Health, Labour & Welfare (MHLW)

RA INVOLVEMENT:



THE RA WHEEL (Sourced from RAPS)

DEALING WITH EXTERNAL FACTORS:

- **Politics:**
  1. As recently seen in China, politics can directly affect the production and release of product, not based on actual findings but because of public pressure placed on government.
  2. RA can intercede, providing government with factual information rather than hearsay.
- **Media:**
  1. It was also evident how the media played a role in fueling the public to make assumptions on the safety of vaccines.
  2. RA would liaise with Media in order to ensure they had up-to-date facts and information.

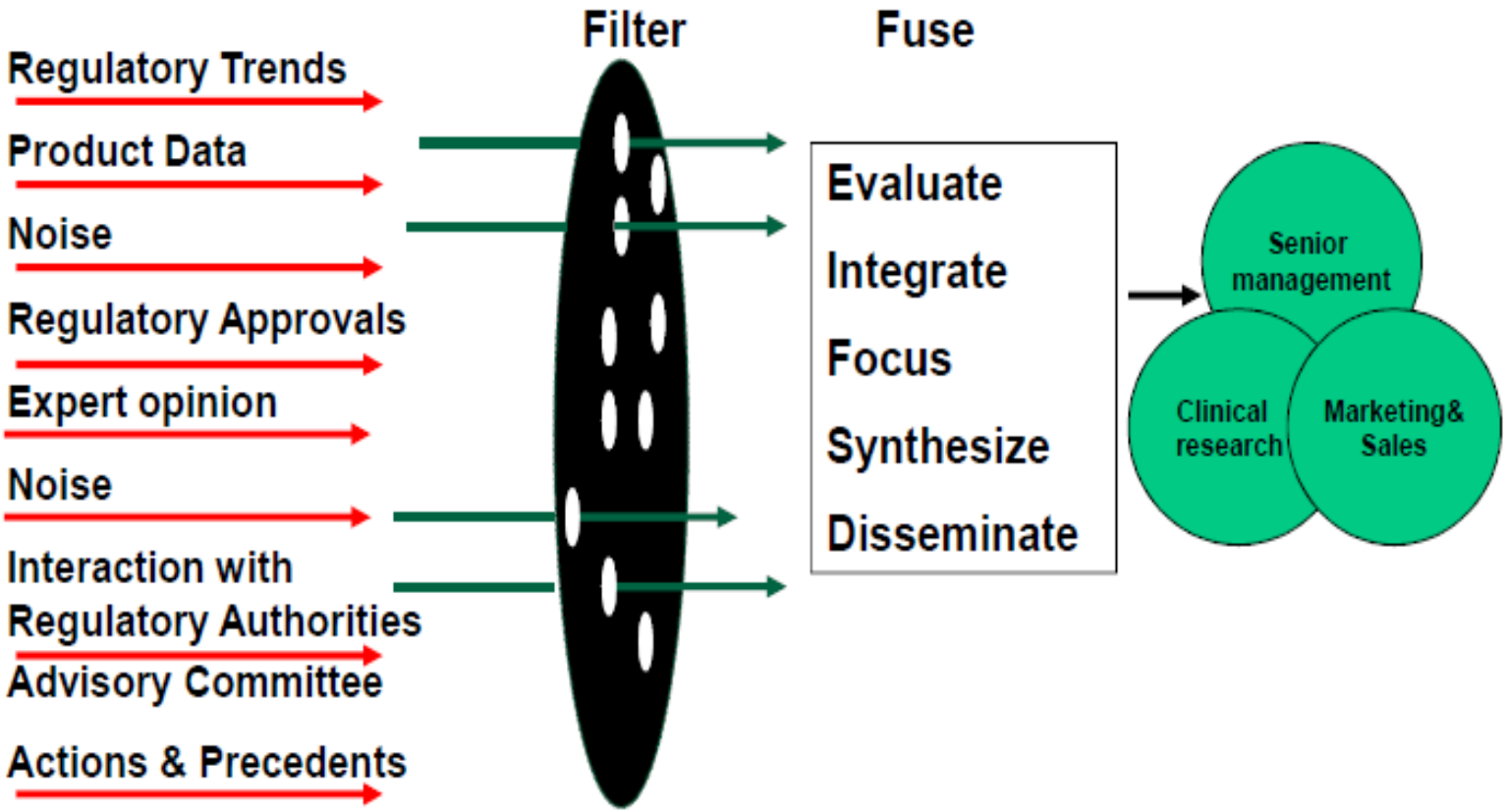
ROLES AND FUNCTIONS OF REGULATORY AFFAIRS:

- **PRIMARY ROLES**
  1. The Regulatory Affairs departments of life-science companies ensure that their companies comply with all of the regulations and laws concerning their business.
  2. Externally it is the key interface between the company and the regulatory authorities, interfacing during drug development, manufacturing, marketing and clinical research.
  3. It prepares and submits the relevant regulatory dossiers to health authorities.
  4. Consultations with the appropriate regulatory agencies, for example Scientific Advice procedures in the European Union (EU) or pre-IND meetings with the FDA, as part of the milestones in product development

ROLES AND FUNCTIONS OF REGULATORY AFFAIRS:

- **SECONDARY ROLES**
  1. Regulatory Affairs can play a key role in guiding drug development strategy in an increasingly global environment.
  2. It prepares and submits the relevant regulatory dossiers to health authorities ensuring the data is communicated in the proper manner.
  3. Attend the meetings and manage all communication with the regulatory agencies
  4. Provide advice on necessary adaptations to development plans and target product profiles.
  5. Involved in the life-cycle management of a product.

RA AS THE REGULATORY FILTER:

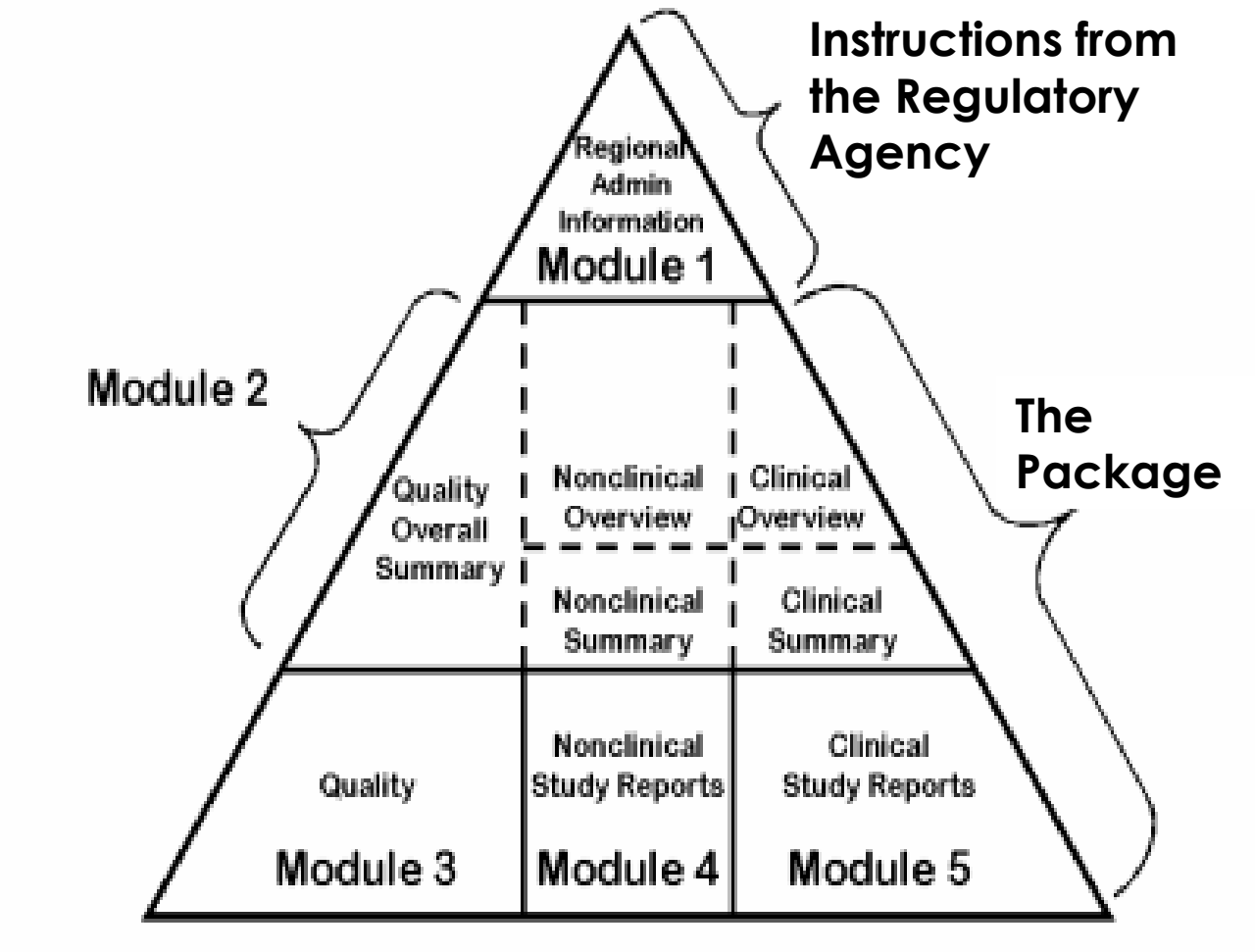


Source: Miller L, Cocchetto D. The Regulatory Affairs Professional in the „Hot Seat“ in Drug Development Process. DIA, Vol.31, 1997.

THE 6 CORNERSTONES OF RA:

CORNERSTONE	DETAILS
1. Product Development	Develop the global strategy. Liaise with authorities. Review regulatory submissions.
2. Regulatory Compliance	Develop the manufacturing process strategy to meet regulatory requirements. Support site inspections.
3. Regulatory Intelligence	Assess and predict emerging trends and possible changes in policies, regulations and guidelines. Communicate with external industry partners to shape future trends.
4. Promotion and Advertisement	Create promotional materials that are accurate and competitive. Submit materials for regulatory review. Ensure promotions are within legal parameters.
5. Regulatory Submission	Compilation and electronic publishing. Ensure document standards are met. Assemble all submission.
6. Product Labeling	Develop product labeling. Ensure accuracy and compliance of the label.

RA PUTS TOGETHER THE SUBMISSION PACKAGE:



RA PERFORMANCE MEASURES:

- **Anticipate the questions the Authorities will raise:**
  1. Analyze the Gaps that are present in completing the package.
  2. Coordinate the processes a project from inception to submission
  3. Obtain additional data and/or information as required.
- **Communications:**
  1. Internally – with all departments and management
  2. Externally – the assessors, experts, agencies
- **Controlling resources:**
  1. Ensure materials are available as required.
- **Time Management:**
  1. Ensure that milestones are met.
  2. Keep project on track.
  3. Done right the first time.

THE CHARACTERISTICS OF AN RA PERSON:

- TEAM MANAGER AND PLAYER
- GOOD COMMUNICATION SKILLS
- MULTI-DISCIPLINED
- DILIGENT
- DECISIVE
- COMMERCIAL SENSE
- LEADERSHIP SKILLS
- MULTI-TASKING
- GOOD TIME MANAGEMENT SKILLS
- SOCIAL SKILLS
- PROACTIVE AND FORWARD THINKING

TYPICAL RA JOB DESCRIPTION:

- The review, evaluation, and compilation of files and reports for submissions
- Provide project team representation and direction in managing information from/to other departments (including R&D, Manufacturing, Quality Assurance, Quality Control, Medical Affairs, Marketing, and Clinical Affairs) regarding Regulatory submissions
- The preparation of outlines, summaries, status reports, graphs, charts, tables and slides for distribution and communication to other departments.
- Review of technical and clinical documentation and recommend changes for labeling, manufacturing, marketing, and clinical protocol for regulatory compliance.
- Researches and analyzes regulatory information and determines acceptability of data, procedures, and other product-related documentation presented in support of product registration.
- Responsible for the timely completion of regulatory projects and submission of documentation to regulatory agencies.
- Develops and maintains current regulatory knowledge and keeps abreast of regulatory procedures and changes. May provide regulatory guidance to project teams and junior staff.

HIRING THE RIGHT PEOPLE:

- **CANDIDATE ONE: THE RELATED PROFESSIONAL:**
  1. Most of the Regulatory Affairs professionals have a degree in either pharmacy or medicine or another relevant life science or health subject.
- **CANDIDATE TWO: THE RA GRADUATE:**
  1. The European Centre of Regulatory Affairs Freiburg, EUCRAF with its Postgraduate Master Course offers for the first time in Europe an education with a special focus on biopharmaceutical-related Regulatory Affairs.
  2. TOPRA as The Organization for Professionals in Regulatory Affairs offers a special MSc in this field with lectures taking place in UK.
  3. A post-graduate master course in regulatory affairs is also offered by DGRA, the German Society for Regulatory Affairs with lectures taking place in Bonn, Germany and by the University of Wales.

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