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REVIEW OF RESPONSIBILITIES AND EXPECTATIONS FROM RA PROFESSIONALS

N. SHIVANI *, DR. MOHAMMED JAFFER SADIK, DR. D. VARUN.
DEPARTMENT OF PHARMACEUTICAL A REGULATORY AFFAIRS, SRI INDU INSTITUTE OF PHARMACY, SHERIGUDA (V), IBRAHIMPATNAM, TELANGANA, 501510

Abstract:
To obtain quantitative estimates of restrictions in participation, i.e., the performance of social roles, in patients with rheumatoid arthritis (RA). METHODS: Participation categories were selected from the International Classification of Functioning, Disability and Health (ICF) (preliminary) Comprehensive Core Set for RA. A literature search was performed utilizing PubMed and PsychInfo. Articles were included if: (1) performance in at least one of the participation categories was described; (2) patients with RA were compared to a healthy reference population or their performance over time was described; (3) published between 1995 and 2005; and (4) written in English. RESULTS: Seven participation categories were selected from the Comprehensive Core Set for RA, resulting in 50 articles included in the review. Almost all studies focused on remunerative employment (n = 30), recreation and leisure (n = 17), or both (n = 3). RA patients had an increased risk of being without a paid job compared to well adjusted reference groups (absolute difference 4% to 28%, odds ratios 1.2 to 3.4). Restrictions in employment occurred already within the early phase of RA and greatly among studies. Two years after diagnosis, disability benefits increased up to roughly 30% in some European cohorts. In the category of recreation and leisure most studies focused on socializing (n = 16). Patients with longstanding RA experienced a decrease in socializing (range, Cohen's d, -0.46 to -1.0), but changes over time were minor. CONCLUSION: RA patients experience restrictions in the performance of remunerative employment and in recreation and leisure (socializing). Due to the lack of studies, no conclusions on other ICF categories describing social roles could be made.

Corresponding author:
N. SHIVANI*
Department of Pharmaceutical Regulatory Affairs,
Sri Indu Institute of Pharmacy, Sheriguda (V),
Ibrahimpatnam, Telangana.
Email Id- shivaninomula51@gmail.com

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INTRODUCTION:

Regulatory Affairs (RA) is a critical function within the pharmaceutical, biotechnology, medical device, and healthcare sectors, responsible for ensuring that products comply with the complex regulatory requirements of various national and international markets. RA professionals act as a vital link between regulatory authorities and companies, facilitating the approval, launch, and maintenance of safe, effective, and high-quality healthcare products.

In today's globalized and highly regulated industry landscape, the responsibilities of RA professionals have expanded significantly. They are no longer limited to preparing and submitting regulatory dossiers but are now also involved in strategic decision-making, risk management, and lifecycle management of products. Regulatory professionals are expected to stay up to date with continuously evolving regulations, interpret them accurately, and guide cross-functional teams to ensure full compliance from product development through to post-marketing.

Moreover, the expectations placed on RA professionals have grown in scope and complexity. They are required to possess deep technical knowledge, regulatory intelligence, project management skills, and the ability to communicate effectively with both internal stakeholders and external regulators. Their role is essential not only for regulatory compliance but also for securing timely market access and ensuring patient safety.

This review seeks to explore the core responsibilities and evolving expectations of RA professionals, underscoring their indispensable role in the successful development and commercialization of pharmaceutical products.

Regulatory Affairs (RA) is an essential discipline within the healthcare industry that ensures that companies comply with all of the regulations and laws concerning their business. RA professionals are the backbone of product compliance, serving as the primary interface between pharmaceutical companies and regulatory authorities such as the US FDA, EMA, MHRA, TGA, CDSCO, and WHO.

Road safety – the paradigm prescriptive regime

The paradigm case of a prescriptive safety regime operates in the context of road safety. The aim of the authorities is to reduce the risk of road accidents, and to achieve this aim they specify certain driver behaviour, such as driving in accordance with speed limits and refraining from driving with blood alcohol above a certain limit. Furthermore, the regulators in this context, the police, devote considerable resourcesto enforcing these rules and the evidence is that this effort is remarkably successful: police campaigns aimed at catching drunken drivers and at enforcing speed limits have a significant effect in reducing road fatalities.3 This is a prescriptive regime that works.

One specific feature of the regime is worth commenting on, to facilitate later comparison. The role of the regulator, the police, is one of deterring regulatory violations by the use of penalties. There is no expectation that police should use persuasion as a means of achieving regulatory compliance. Moreover, the focus is on deterring the regulatory violations, not on deterring the harm. While the police will always prosecute, if they can, following a serious accident, there is no presumption that such prosecutions have much effect in deterring dangerous driving, either by the driver prosecuted or by other drivers. Prosecutions after car accidents serve rather different purposes, such as satisfying public demand for retribution when someone is killed or seriously injured. The central preventive strategy in the road safety context is to identify and penalise violations that have not in fact resulted in harm.

The prescriptive regulation of industrial safety

Safety regimes in organisational contexts have also traditionally been prescriptive. Employee safety, for instance, was to be achieved by requiring employers to follow detailed sets of rules. The role of the industrial safety regulator was to ensure compliance with these rules. However, unlike the paradigm road safety regime, inspectorates did not typically seek compliance by penalising rule violators. Their first response to violations they discovered was generally to try to persuade violators to comply, even to negotiate for compliance, for example by giving violators time to comply. Only when they met with defiance did they resort to prosecution. The implication was that non-compliance was acceptable until an inspector challenged it; only after that might non-compliance lead to a penalty. This reliance on persuasion rather then deterrence goes back to the very outset of the industrial revolution.4

Apart from the issue of defiance, inspectorates in traditional prescriptive regimes have been more likely to prosecute when a violation has led to an accident, but here, as in the case of road safety, the real purpose of the prosecution is often retributive, aimed at satisfying public demand, rather than deterring further offences.5

Regulatory agencies offer various reasons for this generally conciliatory approach, largely to do with the scarcity of enforcement resources and the need to use them sparingly. They note, moreover that there are circumstances where compliance may not be possible or at least not practicable.6

Notwithstanding these reasons, the sociologists who first commented on this phenomenon saw it as a clear case of class bias, one law for the rich and another for the poor, or more precisely, one enforcement strategy for laws that applied toemployers, and another for the more conventional criminal law. The term white-collar crime was

coined to describe violations of laws designed to regulate business.7

AIM AND OBJECTIVE

AIM:

To critically examine the diverse responsibilities and evolving expectations of Regulatory Affairs (RA) professionals in the pharmaceutical and healthcare industries, highlighting their strategic role in ensuring regulatory compliance and product success.

OBJECTIVES:

1. To identify the key roles and responsibilities of RA professionals across various stages of the product lifecycle.
2. To understand the expectations of regulatory bodies, industries, and stakeholders from RA professionals.
3. To evaluate the impact of global regulatory changes on the functions of RA professionals.
4. To assess the skills, knowledge, and competencies required for effective regulatory management.
5. To explore the challenges faced by RA professionals and strategies to address them in a dynamic regulatory environment.

DISCUSSION

The regulatory environment in the South East Asian countries has certain characteristics that are similar but, in general, there are differences in systems and practices. Many of the regulatory agencies in the countries suffer from having rather weak infrastructures primarily due to limitedhuman resources. Some of the agencies have less than five staff in handling the registration matters of new drugs. As a result, the agencies traditionally performed mainly administrative work and simply endorse approvals of new drugs after other so-call advanced countries have previously approved them. This has set the scene for the existing approval systems in these counties depending heavily on the Free Sales Certificate or Certificate of Pharmaceutical Product (CPP) issued by reference or advanced countries for registration of new drugs. Most countries still have the problem of lack of consistency and transparency in the review procedure. In some countries we see improvement as more direct communications are becoming possible between regulator and the industry. The requirement of CPP from country of origin (COO) still remains a key barrier to the registration of new drugs in the region.

- Characteristics of regulatory environment
- Regulatory agencies: relatively weak infrastructure, Small resources, structurally different
  Standards of scientific guidelines not well established
- Diversity of approval timelines
- Diversity of regulatory requirements
- Requirement of CPP from COO or reference countries
- Lack of consistency & transparency but improving with more dialogues with industry

The regulatory agencies in the SE Asia countries have been organized differently and some changes have taken place in the recent years. The most significant change in the system was seen in Singapore. In 2001, the Singapore agency was reorganized into a statutory board known as the Health Sciences Authority that run in a corporative fashion. The agency has established two centers to deal with drug registration; the Centre of Pharmaceutical Administration (CPA) is the licensing body that performs administrative work related to drug registration & the Centre of Drug Evaluation (CDE) to perform scientific and medical evaluations of new drug applications. The CDE has established for the first time in-house capability for scientific and medical reviews of submissions and provide regulatory consultations to the industry. Due to the small number of staff available at the CDE, the center still have to rely heavily on external reviewers, many of them academic pharmaceutical and medical scientists from the local university.

Regulatory Agencies in South East Asia:

- Malaysia : Drug control authority, NCE unit
- Indonesia: National Agency of Drug & Food Control
- Philippines: Bureau of Food & Drugs, Department of Health
- Thailand : Thai FDA, Drug Control Division
- Singapore: Health Science Authority (HSA)

Clinical Trials in South East Asia

Asia is increasingly being recognized as an important base for R&D. Many multi-national research-based pharmaceutical companies are beginning to see the potential of Asia in contributing to drug development. Several companies and CRO's have established their trial monitoring organizations and built facilities in Asia to perform trials to international standards and meeting regulatory requirements. The large patient pool available for trials in Asia has potential for faster patient recruitment, and hence trials involving Asia medical centers may contribute to shortening the development time of new drugs. A recent review has discussed the challenges and benefits of conducting drug development clinical trials in SE Asia (2).

Many companies have already successfully conducted many drug development global studies in SE Asia. With close clinical trial monitoring and professional project management, many medical centers particularly those located in major cities could perform high quality GCP studies and they often can compete very favorably in terms of patient recruitment and costs with other centers in the Europe, USA or Latin America.

For the past many years, although SE Asian countries had demonstrated their capabilities in performing clinical trials, there were still many issues which discouraged companies from bringing in Phase II and III studies to the region. One of the issues was the long clinical trial approval process. It sometimes took longer than 6 months for an approval to be granted in some countries and hence limits their participation. With the joint efforts of industry, hospital and regulatory authorities, there has been a steadily improvement in shortening the timelines lately.

In some countries nowadays, IRB and regulatory submissions could be done simultaneously and this has significantly improved the overall timeline for new trial start-up. In general, the approval timeline now is 3 to 4 months in South East Asia and for most trials it is acceptable for them to join. The average timelines for clinical trial approvals in the 5 ASEAN countries were shown in the table .

Clinical Trial/Study Report

A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report (see the ICH Guideline for Structure and Content of Clinical Study Reports).

Comparator (Product)

An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.

Compliance (in relation to trials)

Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements.

Confidentiality

Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

Contract

A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

Coordinating Committee

A committee that a sponsor may organize to coordinate the conduct of a multicentre trial.

Coordinating Investigator

An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial.

Contract Research Organization (CRO)

A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

Direct Access

Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor’s proprietary information.

Documentation

All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

Essential Documents

Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Independent Data-Monitoring Committee (IDMC) (Data and Safety Monitoring Board, Monitoring Committee, Data Monitoring Committee)

An independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

Impartial Witness

A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject’s legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

Independent Ethics Committee (IEC)

An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

The legal status, composition, function, operations and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in this guideline.

Informed Consent

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

Inspection

The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).

Institution (medical)

Any public or private entity or agency or medical or dental facility where clinical trials are conducted.

Institutional Review Board (IRB)

An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Interim Clinical Trial/Study Report
A report of intermediate results and their evaluation based on analyses performed during the course of a trial. Investigational Product

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Investigator

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Investigator / Institution

An expression meaning "the investigator and/or institution, where required by the applicable regulatory requirements".

Investigator's Brochure

A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects (see 7. Investigator's Brochure).

Legally Acceptable Representative

An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

Monitoring

The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s)

Monitoring Report
A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs.

- Multicentre Trial
- A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.
- Nonclinical Study
- Biomedical studies not performed on human subjects.
- Opinion (in relation to Independent Ethics Committee)
- The judgement and/or the advice provided by an Independent Ethics Committee (IEC).

Original Medical Record
See Source Documents.
Protocol

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.

Protocol Amendment

A written description of a change(s) to or formal clarification of a protocol.

Quality Assurance (QA)

All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

Randomization

The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

Regulatory Authorities

Bodies having the power to regulate. In the ICH GCP guideline the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections (see 6.2.29). These bodies are sometimes referred to as competent authorities.

6.2.49 Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)

Any untoward medical occurrence that at any dose:

- results in death,
- life-threatening,
- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability/incapacity, or
- congenital anomaly/birth defect

Source Data

All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Source Documents

Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

Sponsor

An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.

Sponsor-Investigator

An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

Standard Operating Procedures (SOPs)

Detailed, written instructions to achieve uniformity of the performance of a specific function.

Sub investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

Subject/Trial Subject

An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

Subject Identification Code

A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial related data.

Trial Site

The location(s) where trial-related activities are actually conducted.

Unexpected Adverse Drug Reaction

An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product) (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

Vulnerable Subjects

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as

medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

Well-being (of the trial subjects)

The physical and mental integrity of the subjects participating in a clinical trial.

Principles of ICH GCP

6.3.1 Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

- Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
- The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
- The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
- Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
- A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/ favourable opinion.
- The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
- Each individual involved in conducting, training, and experience to perform his or her respective task.
- Freely given informed consent should be obtained from every subject prior to clinical trial participation.
- All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
- The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
- Investigational products should be manufactured, handled, and stored in accordance with

applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.

- Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Institutional

review board/Independent ethics committee (IRB/IEC)

Responsibilities

✓ An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects.

Special attention should be paid to trials that may include vulnerable subjects.

✓ The IRB/IEC shouldobtainthefollowingdocuments:trialprotocol(s)/amendment(s),written informed consent form updates that the investigator proposes for use in the trial, subject recruit -ent procedures (e.g.advertisements),written information to be provided to subjects, Investigator

Brochure (IB), available safety information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing quali -fications and any other documents that the IRB/IEC may need to fulfil its responsibilities.

The IRB/IEC should review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed and the dates for the following:

- ✓ approval/favourable opinion;
- ✓ modifications required prior to its approval/favourable opinion;
- ✓ 3 disapproval / negative opinion; and
- ✓ termination/suspension of any prior approval/favourable opinion.
- ✓ The IRB/IEC should consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB/IEC requests.

Composition, Functions and Operations

The IRB/IEC should consist of a reasonable number of members, who collectively have

the qualifications and experience to review and evaluate the science, medical aspects, and ethics

of the proposed trial. It is recommended that the IRB/IEC should include:

- ✓ At least five members.
- ✓ At least one member whose primary area of interest is in a nonscientific area.

- ✓ At least one member who is independent of the institution/trial site.
- ✓ Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter.
- ✓ A list of IRB/IEC members and their qualifications should be maintained.
- ✓ The IRB/IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).

Procedures

The IRB/IEC should establish, document in writing, and follow its procedures, which should include:

- ✓ Determining its composition (names and qualifications of the members) and the authority under which it is established.
- ✓ Scheduling, notifying its members of, and conducting its meetings.
- ✓ Conducting initial and continuing review of trials.
- ✓ Determining the frequency of continuing review, as appropriate.
- ✓ Providing, according to the applicable regulatory requirements, expedited review and approval/favourable opinion of minor change(s) in ongoing trials that have the approval/favourable -pinion of the IRB/IEC.
- ✓ Specifying that no subject should be admitted to a trial before the IRB/IEC issues its written approval/favourable opinion of the trial.
- ✓ Specifying that no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favourable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only loistical or administrative aspects of the trial (e.g., change of monitor(s),telephone number.
- ✓ Specifying that the investigator should promptly report to the IRB/IEC: Deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects
- ✓ Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial.
- ✓ All adverse drug reactions (ADRs) that are both serious and unexpected.
- ✓ New information that may affect adversely the safety of the subjects or the conduct of the trial.
- ✓ Ensuring that the IRB/IEC promptly notify in writing the investigator/institution concerning:
  - ✓ 1 Its trial-related decisions/opinions.
  - ✓ The reasons for its decisions/opinions.
  - ✓ Procedures for appeal of its decisions/opinions.

Records

The IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of the trial and make them available upon request from the regulatory authority(ies).

The IRB/IEC may be asked by investigators, sponsors or regulatory authorities to provide its written procedures and membership lists.

Investigator

Investigator's Qualifications and Agreements

- ✓ The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies).
- ✓ The investigator should be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor.
- ✓ The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

Adequate Resources

- ➢ The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.
- ➢ The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.
- ➢ The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

Medical Care of Trial Subjects

- ➢ A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.
- ➢ During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a

subject for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.

Communication with IRB/IEC

- Before initiating a trial, the investigator/institution should have written and dated approval/favourable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects.
- During the trial the investigator/institution should provide to the IRB/IEC all documents subject to review.
- Compliance with Protocol
- The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies) and which was given approval/favourable opinion by the IRB/IEC. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.
- The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.

Investigational Product(s)

- Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.
- Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product(s) accountability at the trial site(s) to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution.
- 3The investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol.
- Randomization Procedures and Unbinding

The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s)

CONCLUSION:

Regulatory Affairs (RA) professionals play a critical and multifaceted role in the pharmaceutical, biotechnology, and healthcare industries. They act as a vital bridge between regulatory authorities and organizations, ensuring that products meet all legal and scientific requirements for safety, efficacy, and quality.

From this review, it is evident that RA professionals are expected to:

- Ensure compliance with national and international regulations throughout the product lifecycle.
- Develop and submit regulatory documentation, including dossiers, variation applications, and responses to queries.
- Stay updated with constantly evolving regulations and interpret them for internal teams.
- Support cross-functional collaboration, guiding R&D, quality assurance, marketing, and production on regulatory strategies.
- Manage product approvals and maintain licenses and registrations across different markets.
- Uphold ethical standards, accuracy, and transparency in all regulatory communications.

In conclusion, the responsibilities of RA professionals go beyond documentation—they are strategic advisors, compliance experts, and key contributors to product success in global markets. Their evolving role requires not only technical expertise but also agility, communication skills, and a proactive mindset to adapt to regulatory changes and safeguard public health.

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1. It is sometimes argued that “accidents” are not really accidental since they have causes (for example, the Esso Longford trial judge; see my Lessons from Longford: The Trial (CCH: Sydney, 2002). However, this interpretation is at odds with the more common meaning of accident as an unintended and undesired

outcome. In this article I shall use the term accident to mean unintended and undesired outcome.

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4. Carson, W (1970) 'White-collar crime and the enforcement of factory legislation', British Journal of Criminology, Vol 10, pp 383-398.
5. Hutter, B (1997) Compliance: Regulation and Environment, Clarendon Press, Oxford, p 221.
6. Hutter, op cit, p17.
7. Sutherland, E (1949) White Collar Crime, Dryden, New York.
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9. Grabosky, P and Braithwaite, J (1986) Of Manners Gentle: Enforcement Strategies of Australian Business Regulatory Agencies, Oxford University Press, Melbourne, p203.
10. References to this research will be found in Hopkins, A (1995) Making Safety Work: Getting Management Commitment to Occupational Health and Safety, Allen and Unwin, Sydney, chapter 6.
11. Ayres, I and Braithwaite, J (1992) Responsive Regulation, Oxford University Press, New York.
12. Gunningham, N and Johnstone, R (1999), Regulating Workplace Safety: Systems and Sanctions Oxford University Press, New York, p 25. See also: http://www.minerals.nsw.gov.au/__data/page/1696/gunninghampaper.pdf, p7.
13. 13 For a good discussion on the role of prescription see Breslin, P (2004) 'Performance versus prescriptive approaches to OHS in the Victorian construction industry, Journal of OHS – ANZ, 20(6), pp 563-571.
14. The EU Framework Directive (1989), Article 5, states as follows: 1. The employer shall have a duty to ensure the safety and health of workers in every aspect related to the work……..4. This Directive shall not restrict the option of Member States to provide for the exclusion or the limitation of employers' responsibility where occurrences are due to unusual and unforeseeable circumstances, beyond the employers' control, or to exceptional events, the consequences of which could not have been avoided despite the exercise of all due care. The Robens principle is thus consistent with this Directive.
15. In reality, when general duty requirements are enacted it may be some time before prescriptive legislation is repealed or modified.
16. These requirements are referred to as process standards. In some circumstances, performance standards, which specify precise targets to meet, eg noise levels, may also be contained in regulations. See Bluff, E and Gunningham, N 'Principle, process, performance or what? New approaches to OHS standards setting, in Bluff E, Gunningham N and Johnstone R (eds) OHS Regulation for a Changing World of Work, The Federation Press, Sydney, pp 12-42.
17. In the case of performance standards, such as permissible noise levels, the idea of compliance remains perfectly meaningful. Indeed the idea of going beyond compliance takes on a particular meaning in this context, namely, achieving a performance better than that required by the standard. See Gunningham, N Kagan, R and Thornton, D (2004), 'Social license and environmental protection: Why businesses go beyond compliance', Law and Social Inquiry, 29 (2): 307-34
18. Hutter, op cit p 94.
19. Hutter, op cit pp 95-6.
20. http://www.hse.gov.uk/enforce/emm.pdf
21. The Australian National Offshore Petroleum Safety Authority states in its strategic plan that safety cases will be checked to ensure that they are consistent with "good oil field practice", p 6.
22. Appleton, B (2001) 'Piper Alpha' in Kletz, T Learning from Accidents. 3rd ed, Gulf, Oxford, pp 196- 206; Hopkins, A (2000) Lessons from Longford: The Esso Gas Plant Accident, CCH, Sydney; Hopkins, A (2005) Safety, Culture and Risk: The Organisational Causes of Accidents, CCH, Sydney.