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ASSESSMENT OF KNOWLEDGE AND PERCEPTIONS OF DRUG REGULATORY AFFAIRS AMONG PHARMACISTS AND PHARMACY STUDENTS

NALI HARIBABU*[1], T MADHAVILATHA[2], AUDINARAYANA NELAVALA[3], D JOTHIESWARI[4]

[1]II Year M.Pharmacy, Department of Drug Regulatory Affairs, Sri Venkateswara College of Pharmacy (Autonomous), RVS Nagar, Chittoor – 517127.

[2]Assistant Professor, Department of Pharmaceutical Analysis, Sri Venkateswara College of Pharmacy (Autonomous), RVS Nagar, Chittoor – 517127.

[3]Associate Professor, Department of Pharmaceutics, Sri Venkateswara College of Pharmacy (Autonomous), RVS Nagar, Chittoor-517127

[4]Professor & Principal, Department of Pharmaceutical Analysis, Sri Venkateswara College of Pharmacy (Autonomous), RVS Nagar, Chittoor – 517127

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Abstract

A vital part of the pharmaceutical industry, regulatory affairs (RA) includes important tasks such drug registration, product development, and post-marketing surveillance to guarantee the effectiveness, safety, and quality of pharmaceuticals. The purpose of this study was to assess Jordanian pharmacists' and pharmacy students' knowledge and comprehension of Regulatory Affairs and Drug Registration (DR). A structured questionnaire was used in a cross-sectional survey that was disseminated via social media, such as WhatsApp, to pharmacy students and pharmacists from different industries. Of the 411 respondents, 193 (47.0%) were pharmacists and the remainder respondents were students. The results showed that nearly half of the participants had little knowledge of the duties and obligations of RA professionals, and the majority of participants (77.4%) had not received any formal education related to RA during their undergraduate studies. The majority of responders underlined the necessity of better educational activities, including training courses, seminars, and lectures. Overall, the study reveals a sizable knowledge and awareness gap regarding regulatory affairs, indicating the necessity of adding RA-related courses to pharmacy curriculum and enhancing the function of regulatory organizations in order to better train next professionals.

Keywords: *Regulatory Affairs, Drug Registration, Pharmacists, Pharmacy Students and Awareness.*

***Corresponding Author**
Nali Hari Babu

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INTRODUCTION

One of the industries with the highest levels of regulation is the pharmaceutical sector, which demands rigorous adherence to regulations to guarantee the efficacy, safety, and quality of pharmaceuticals [1]. By overseeing medication research, registration, and post-marketing operations and serving as a liaison between pharmaceutical corporations and regulatory bodies like the USFDA, EMA, and CDSCO, Regulatory Affairs (RA) plays a critical part in this process [2]. Under the direction of the International Council for Harmonization (ICH), harmonized formats like the Common Technical Document (CTD) and electronic CTD (eCTD) have been developed to expedite international drug approval procedures. These frameworks make it easier for data about efficacy, safety, and quality to be submitted consistently across several regions, increasing productivity and cutting down on redundancy [3].

The clearance process is nevertheless impacted by issues including complicated regulatory standards, low understanding among pharmacy professionals, and quick technical innovations, despite improvements in regulatory systems and growing worldwide harmonization. Therefore, maintaining compliance, boosting professional competency in the pharmaceutical industry, and improving patient safety all depend on an awareness of regulatory affairs and its applications [4].

MATERIALS AND METHODS

Study Design, Setting, and Participants

Over the course of four months, from 2025, a descriptive cross-sectional study with an analytical component was carried out. The purpose of the study was to assess pharmacy professionals' and undergraduate pharmacy students' perspectives and understanding of Regulatory

Affairs (RA) and Drug Regulation (DR) [5]. Community pharmacies, hospital pharmacies, the pharmaceutical industry, and educational institutions were among the locations from which participants were gathered. The study team held professional workshops and academic meetings in addition to using internet platforms to distribute the survey. Participants who were at least eighteen years old and who were either: Pharmacists with a Bachelor of Pharmacy (B.Pharm) degree who are registered, or Students presently enrolled in a B.Pharm program in pharmacy [6]. To ensure consistency in educational background, those with advanced professional degrees, such as PharmDs, or those engaged in PharmD programs were excluded. Respondents were told that doing the questionnaire would take about ten to twelve minutes, and participation was completely voluntary. Development and Validation of Survey Instruments Following a thorough analysis of pertinent literature on regulatory affairs and pharmaceutical rules, a structured questionnaire was created [7]. A panel of subject matter experts from academia and the pharmaceutical sector evaluated the preliminary version of the questionnaire for comprehensiveness, relevance, and clarity [Table 1]. The necessary changes were made based on expert input to enhance readability and content authenticity. To verify the questionnaire's internal consistency and dependability, a pilot research was carried out on a small sample size (n = 20). After the pilot testing, a few minor changes were made. The final questionnaire was divided into three sections:

1. Demographic data, including age, gender, education, occupation, and experience
2. RA and DR-related knowledge assessment (multiple-choice and dichotomous questions)
3. A 5-point Likert scale from strongly agree to strongly disagree is used to assess perception.

Table 01: Structure of the Questionnaire

Section No.	Section Title	Description	Type of Questions
Section 1	Demographic Information	Age, gender, qualification, profession, experience	Multiple choice
Section 2	Knowledge Assessment	Knowledge about RA and DR concepts and practices	MCQs, Yes/No/I don't know
Section 3	Perception Assessment	Attitudes toward RA and DR	5-point Likert scale

Ethical Considerations

Prior to data collection, the Institutional Ethics Committee granted ethical approval for the study; all participants were informed of the study's purpose and objectives; confidentiality and anonymity were strictly maintained; no personally identifiable information was collected; before beginning the survey, participants had to provide electronic informed consent; they were free to withdraw at any time without facing any repercussions [8].

Sample Size Determination

Standard statistical formulas were used to determine the necessary sample size, taking into account a 50% response distribution, a 95% confidence interval, and a 5% margin of error. It was expected that 384 people would be the minimal sample size [Table 2]. Due to time restrictions and ease of access, a non-probability convenience sampling technique was used to find participants [9].

Table 02: Sample Size Parameters Used in the Study

Parameter	Value Used
Confidence Level	95%
Expected Frequency	50%
Margin of Error	5%
Design Effect	1.0
Minimum Sample Size	384
Sampling Technique	Convenience Sampling

Statistical Analysis

The Statistical Package for the Social Sciences (SPSS) version 26 was used to code and analyze the survey data. The data was summarized using descriptive statistics including means, standard deviations, percentages, and frequencies. To find correlations and determinants of knowledge levels, inferential statistical tests were used [10]. To find possible independent variables, a basic linear regression analysis was first carried out. The multiple linear regression model contained variables with a p-value of less than 0.20. A p-value of less than 0.05 was deemed statistically significant in the final model. Variance inflation factor (VIF < 5) and tolerance values (>0.2) were used to evaluate multicollinearity between variables [11].

RESULTS AND DISCUSSION

The survey was completed by 402 individuals in total. 53.2% of respondents were between the ages of 18 and 24, and 82.6% of participants were female. The remaining participants were undergraduate pharmacy students, with 45.5% of all responders being professional pharmacists. In terms of professional distribution, community pharmacies employed 28.1% of pharmacists, followed by academic institutions (10.2%), the pharmaceutical industry (5.1%), and wholesale drug stores (4.8%). About 22.3% had graduated during the previous one to three years, whereas 13.1% had four to eight years of experience. The 75.8% of the participants lived in metropolitan areas, and 68.4% of them had either finished or were enrolled in private pharmacy programs.

In terms of exposure to Regulatory Affairs (RA), a sizable percentage (74.6%) stated that they had not completed any official RA-related coursework throughout their academic career. In a similar vein, 69.2% of participants had never participated in training courses or workshops pertaining to drug regulation (DR) or regulatory affairs. Understanding of Drug Regulation and Regulatory Affairs. The 75.8% of participants correctly identified the term of

Drug Regulation (DR) and 76.9% were familiar with the idea of Regulatory Affairs (RA), according to the assessment of their definition knowledge. An assessment of participants' comprehension of RA's goals showed a generally high degree of awareness. Key objectives include guaranteeing medicine safety, upholding regulatory compliance, and streamlining product approval procedures were accurately identified by the majority of respondents [Table 03]. With a mean knowledge score of 2.36 ± 1.12 (out of 3) for RA goals, participants demonstrated a satisfactory degree of comprehension.

Knowledge of Roles of Regulatory Affairs Professionals

The participants' awareness of the duties of RA experts ranged from moderate to high. The percentage of right answers varied from 68.9% to 82.7%, with roles pertaining to guaranteeing adherence to regulatory criteria (cGMP, ICH, GCP, GLP) showing the highest awareness.

A fair level of awareness was indicated by the mean knowledge score for RA roles, which was 3.28 ± 1.87 (out of 5). Some misconceptions were identified, too; for example, 13.5% of participants thought that laboratory-based drug analysis was the responsibility of RA specialists [Table 04].

Knowledge of Pharmacovigilance

Only 46.7% of participants properly defined pharmacovigilance (PV) as the science pertaining to the identification, evaluation, monitoring, and prevention of hazardous medication effects.

On the other hand, 17.1% gave inaccurate answers and 36.2% stated they were ignorant of this crucial regulatory element [Table 05].

Table 03: Demographic Characteristics of Study Participants

Parameter	Category	n (%)
Age	18–23 years	212 (51.6)
	24–30 years	112 (27.3)
	31–40 years	40 (9.7)
	> 40 years	47 (11.4)
Gender	Male	62 (15.1)
	Female	349 (84.9)
Participant Type	Student (1st–2nd year)	20 (4.9)
	Student (3rd–5th year)	198 (48.2)
	Pharmacist	193 (46.9)
Occupation	Academia	47 (11.4)
	Drug Store	19 (4.6)
	Industry	18 (4.4)
	Pharmacy	109 (26.5)
	Student	218 (53.0)
Years Since Graduation	1–3 years	85 (20.6)
	4–10 years	50 (12.2)
	11–20 years	22 (5.4)
	> 20 years	36 (8.8)
	Still student	218 (53.1)
Nationality	Jordanian	337 (82.0)
	Non-Jordanian	74 (18.0)
Residence	Amman	318 (77.4)
	Other regions	93 (22.6)
Place of Study	Outside Jordan	12 (2.9)
	Jordan	399 (97.1)
University Type	Private	288 (70.1)
	Public	123 (29.9)
RA Course Exposure	No	318 (77.4)
	Yes	93 (22.6)
RA/DR Workshop Attendance	No	291 (70.8)
	Yes	120 (29.2)

Table 04: Knowledge Regarding the Goals of Regulatory Affairs (RA) Professionals Among Students and Pharmacists

Statement	Group	Yes n (%)	I Don't Know n (%)	No n (%)
Protection of human health	Students	171 (78.4)	39 (17.9)	8 (3.7)
	Pharmacists	171 (88.6)	12 (6.2)	10 (5.2)
	Total	**342 (83.2)**	**51 (12.4)**	**18 (4.4)**
Ensuring safety, efficacy, and quality of drugs	Students	175 (80.3)	31 (14.2)	12 (5.5)
	Pharmacists	176 (91.2)	12 (6.2)	5 (2.6)
	Total	**351 (85.4)**	**43 (10.5)**	**17 (4.1)**
Ensuring appropriateness and accuracy of product information	Students	177 (81.2)	34 (15.6)	7 (3.2)
	Pharmacists	175 (90.7)	14 (7.3)	4 (2.1)
	Total	**352 (85.6)**	**48 (11.7)**	**11 (2.7)**

Table 05: Participants' Knowledge Regarding the Roles of Regulatory Affairs (RA) Professionals

Statement	Group	Yes n (%)	I Don't Know n (%)	No n (%)
Act as a liaison with regulatory agencies	Students	150 (68.8)	58 (26.6)	10 (4.6)
	Pharmacists	165 (85.5)	20 (10.4)	8 (4.1)
	Total	**315 (76.6)**	**78 (19.0)**	**18 (4.4)**
Preparation	Students	140	54	24

of scientifically valid drug applications and dossiers		(64.2)	(24.8)	(11.0)
	Pharmacists	166 (86.0)	14 (7.3)	13 (6.7)
	Total	**306 (74.5)**	**68 (16.5)**	**37 (9.0)**
Ensuring compliance with cGMP, ICH, GCP, and GLP guidelines	Students	168 (77.1)	43 (19.7)	7 (3.2)
	Pharmacists	176 (91.2)	9 (4.7)	8 (4.1)
	Total	**344 (83.7)**	**52 (12.7)**	**15 (3.6)**
Providing regulatory expertise and strategic guidance	Students	138 (63.3)	59 (27.1)	21 (9.6)
	Pharmacists	148 (76.7)	30 (15.5)	15 (7.8)
	Total	**286 (69.6)**	**89 (21.7)**	**36 (8.7)**
Advising companies on regulatory policies and frameworks	Students	142 (65.1)	55 (25.2)	21 (9.7)
	Pharmacists	150 (77.7)	25 (13.0)	18 (9.3)
	Total	**292 (71.0)**	**80 (19.5)**	**39 (9.5)**

Participants' awareness of those who helped form the International Council for Harmonization (ICH) was found to be quite poor. Of the participants, only 25.3% (n = 104) correctly recognized the regulatory regions that were in charge. On the other hand, a tiny percentage of respondents chose the wrong combinations: 7.1% identified Europe, Australia, and the United States as contributors, 5.0% selected Japan, Australia, and the United States, and 6.2% selected Europe, India, and the United States. Interestingly, the majority of participants (56.4%, n = 232) indicated confusion by choosing "I do not know," suggesting a significant knowledge gap over international regulatory cooperative frameworks [Figure 6].

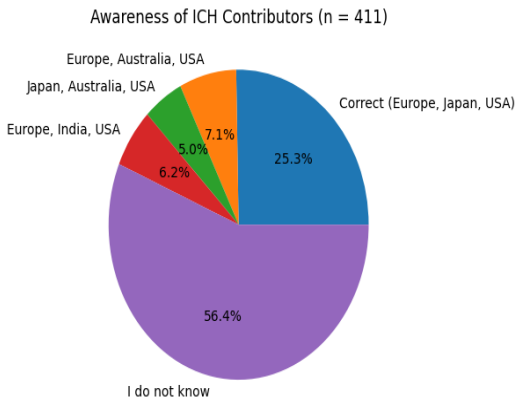
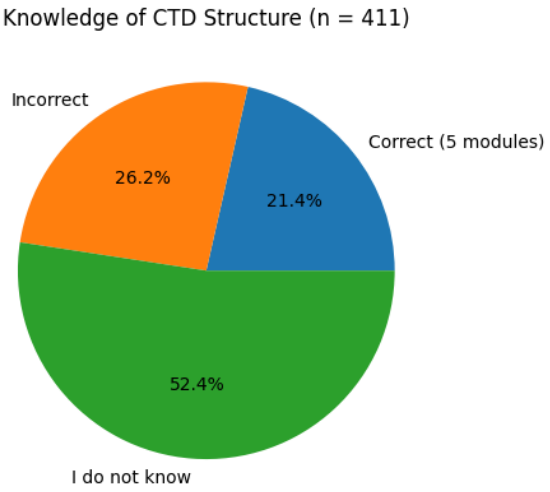


Figure 06: Knowledge of CTD structure among participants (n = 411).

Collaborate with regulatory bodies to obtain medicine approval (right response*). To examine the formulation's active ingredient content. To conduct medication product stability studies. To oversee the formulation's manufacture ▪ I don't know Only 88 participants (21.4%) correctly identified that the Common Technical Document (CTD) is divided into five modules, according to an assessment of participants' knowledge on the CTD. On the other hand, 26.1% of participants gave false answers, while the majority (52.3%) chose "I do not know," indicating a lack of expertise [Figure 07].

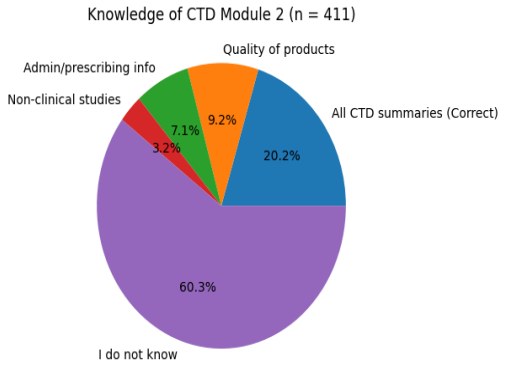
Subsequent assessment of participants' comprehension of particular CTD modules revealed low awareness. Just 20.2% (n = 83) of respondents correctly identified Module 2's connection to CTD summary. On the other hand, the majority (60.3%) chose "I do not know," while 9.2% thought it had to do with the quality of pharmaceutical items, 7.1% connected it to administrative and prescribing information, and 3.2% connected it to non-clinical studies [Figure 8].

In a similar vein, just 16.5% (n = 68) of respondents correctly identified Module 3's connection to pharmaceutical product quality. Participants had misconceptions: 6.8% thought it had to do with CTD summaries, 6.6% thought it had to do with clinical research, 4.1% thought it had to do with non-clinical studies, and 2.9% thought it had to do with administrative and prescription information. A significant percentage (63.0%) chose "I do not know" to indicate ignorance [Figure 09].



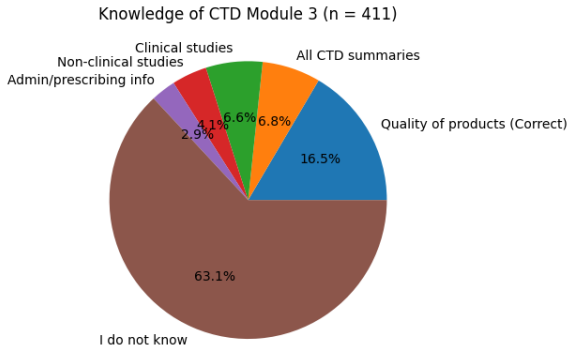
- CTD is divided into five modules (correct answer*)
- Incorrect responses regarding CTD structure
- I do not know

Figure 07: Knowledge of CTD structure among participants (n = 411).



- All CTD summaries (correct answer*)
- Quality of pharmaceutical products
- Administrative/prescribing information
- Non-clinical studies
- I do not know

Figure 08: Participants' awareness regarding CTD Module 2 (n = 411).



Pharmaceutical product quality (right response*) Every CTD summary Research studies. Non-clinical research Information related to administration and prescription I have no idea.

Figure 09: Knowledge of CTD Module 3 among participants (n = 411).

When participants' sources of information about Regulatory Affairs (RA) were evaluated (Fig. 4), electronic websites were the most often used source (53.3%), followed by academic institutions (50.1%). There were fewer reports from other sources, such as friends, pharmaceutical businesses, and social media. When participants' general knowledge of RA and Drug Regulation (DR) was assessed, the percentage of right answers varied depending on the item. "Common Technical Document (CTD) is a format set by the ICH" had the lowest right response rate (44.4%), while "Active pharmaceutical ingredient (API) is not related to drug substance" had the highest (74.2%). The participants' average general knowledge score was 3.34 out of 6 (SD = 2.31), suggesting a modest level of comprehension.

According to participants' opinions about RA and DR, 38.9% of respondents agreed or strongly agreed that RA-related content should be included in pharmacy curricula. While a sizable majority (81.5%) agreed that more seminars, training programs, and educational activities relating to RA and DR are necessary, a greater percentage (74.4%) felt that pharmacists were unaware of RA.

None of the independent variables had a significant impact on the knowledge scores pertaining to the objectives of RA, according to multiple linear regression analysis. However, having previously attended RA/DR-related courses ($p = 0.012$) and being a pharmacist ($p = 0.022$) were linked to considerably higher knowledge ratings for the tasks of RA professionals. Furthermore, there was a significant positive correlation ($p < 0.001$) between general knowledge ratings and attendance at RA/DR-related lectures (Table 10, 11 & 12).

Table 10: Participants' General Knowledge Regarding Regulatory Affairs (RA) and Drug Regulation

Statement	Group	True n (%)	I Don't Know n (%)	False n (%)
A generic drug is not comparable to an innovator drug	Students	137 (62.8)	67 (30.7)	14 (6.4)
	Pharmacists	155 (80.3)	25 (13.0)	13 (6.7)
	Total	**292 (71.0)**	**92 (22.4)**	**27 (6.6)**
Drug Master File (DMF) definition	Students	103 (47.2)	96 (44.0)	19 (8.7)
	Pharmacists	119 (61.7)	62 (32.1)	12 (6.2)
	Total	**222 (54.0)**	**158 (38.4)**	**31 (7.5)**
CTD is a set of specifications for drug registration dossier	Students	98 (45.0)	112 (51.4)	8 (3.7)
	Pharmacists	107 (55.4)	77 (39.9)	9 (4.7)
	Total	**205 (49.9)**	**189 (46.0)**	**17 (4.1)**
API is not related to drug substance	Students	150 (68.8)	61 (28.0)	7 (3.2)
	Pharmacists	155 (80.3)	28 (14.5)	10 (5.2)
	Total	**305 (74.2)**		

Notes:

- **Correct answers are highlighted under "True"**
- **S = Students (n = 218)**
- **P = Pharmacists (n = 193)**

DISCUSSION

In order to guarantee that pharmaceutical products fulfill safety, quality, and efficacy regulations, regulatory affairs (RA) is essential. Global drug registration procedures are now more uniform because to the adoption of harmonized frameworks like the Common Technical Document (CTD), created by ICH. Jordan's dedication to regulatory harmonization is demonstrated by the Jordan Food and

Drug Administration's (JFDA) alignment with these international standards.

The results of this study show that pharmacists and pharmacy students have a basic comprehension of RA and Drug Regulation (DR), especially with regard to basic principles. Technical aspects like pharmacovigilance and CTD structure still have deficiencies, though. Participants used self-learning techniques and digital platforms to expand their knowledge despite having little formal training in RA.

The study further emphasizes the value of ongoing professional development by showing that those who have previously participated in RA training or seminars had superior understanding. Despite being moderate, pharmacovigilance knowledge is still lower than in some other nations, suggesting that more work needs to be done. Overall, the findings point to the necessity of encouraging training programs and incorporating RA and pharmacovigilance into pharmacy curriculum in order to improve understanding and proficiency in this area.

Table 11: Participants' Perception Regarding Regulatory Affairs (RA) and Drug Regulation (DR)

Statement	Response	Students n (%)	Pharmacists n (%)	Total n (%)
Pharmacy schools in Jordan should introduce RA	Strongly Agree	51 (23.4)	44 (22.8)	95 (23.1)
	Agree	40 (18.3)	25 (13.0)	65 (15.8)
	Neutral	86 (39.4)	49 (25.4)	135 (32.8)
	Disagree	31 (14.2)	54 (28.0)	85 (20.7)
	Strongly Disagree	10 (4.6)	21 (10.9)	31 (7.5)
RA roles are well known among pharmacists	Strongly Agree	47 (21.6)	35 (18.1)	82 (20.0)
	Agree	51 (23.4)	28 (14.5)	79 (19.2)
	Neutral	84 (38.5)	46 (23.8)	130 (31.6)
	Disagree	34 (15.6)	52 (26.9)	86 (20.9)
	Strongly Disagree	9 (4.1)	30 (15.5)	30 (7.3)
There is a lack of awareness about RA	Strongly Agree	117 (53.7)	132 (68.4)	249 (60.6)
	Agree	70 (32.1)	57 (29.5)	127 (30.9)
	Neutral	21 (9.6)	24 (12.4)	45 (10.9)
	Disagree	9 (4.1)	5 (2.6)	14 (3.4)

Table 12: Assessment of Factors Affecting Knowledge Scores Among Study Participants

Parameter	Category	Goals' Knowledge Score (β, p[a])	Goals' Knowledge Score (β, p[b])	Knowledge Score (β,	Knowledge Score (β,	Knowledge Score (β,	Knowledge Score (β,
Age	≤ 23 years	Ref.	—	Ref.	—	Ref.	—
	≥ 24 years	0.073, 0.164	-0.032, 0.661	0.153, 0.003	0.025, 0.728	0.136, 0.010	0.019, 0.793
Gender	Male	Ref.	—	Ref.	—	Ref.	—
	Female	0.063, 0.206	0.064, 0.230	0.054, 0.276	—	-0.025, 0.608	—
Participant Type	Students	Ref.	—	Ref.	—	Ref.	—
	Pharmacists	0.157, 0.001	0.131, 0.078	0.220, ≤0.001	**0.168, 0.022[s]**	0.175, ≤0.001	0.137, 0.055
Place of Study	Outside Jordan	Ref.	—	Ref.	—	Ref.	—
	Jordan	-0.011, 0.818	—	-0.038, 0.445	—	-0.018, 0.719	—
University Type	Private	Ref.	—	Ref.	—	Ref.	—
	Public	0.035, 0.474	—	0.015, 0.760	—	0.025, 0.620	—
RA Course During Study	No	Ref.	—	Ref.	—	Ref.	—
	Yes	0.049, 0.318	—	0.046, 0.357	—	0.192, ≤0.001	0.061, 0.311
RA/DR Lectur	No	Ref.	—	Ref.	—	Ref.	—
	Yes	0.123, 0.012	0.102, 0.0	0.178, ≤0.	**0.131, 0.0**	0.290, ≤0.	**0.228, ≤0.0**

es or Workshops			56	001	**12[s]**	001	**01[s]**

Notes:

- **β = Regression coefficient**
- **[a] Simple linear regression**
- **[b] Multiple linear regression**
- **[s] Statistically significant (p ≤ 0.05)**
- **Ref. = Reference category**

CONCLUSION

According to the survey, pharmacy students and practicing pharmacists in Jordan have a moderate understanding of Regulatory Affairs (RA) and Drug Regulation, with significant gaps in important areas such CTD structure, pharmacovigilance, and international regulatory systems. Although there is some fundamental awareness, there is still a lack of thorough comprehension. The results highlight the necessity of improving RA education and training because attending lectures and workshops greatly raises knowledge levels. These gaps can be filled by incorporating RA into pharmacy courses and encouraging ongoing professional development. In general, raising awareness and implementing educational programs are crucial to producing qualified personnel who can handle the expanding demands of the pharmaceutical regulating industry.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTION

All are contributed equally

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ETHICAL CONSIDERATIONS AND INFORM CONSENT

Not Applicable

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