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Rafeek Fahmy Shokry Atallah

Personal data:

Nationality: Egyptian
Military service: Final exemption
Date of Birth: 2 May 1984

Education:

- PhD degree of Pharmaceutical Sciences (Analytical Chemistry), Faculty of Pharmacy, Cairo University (12/2017) "Analytical study of some compounds containing phenolic group".
- Master degree of Pharmaceutical Sciences (Analytical Chemistry), Faculty of Pharmacy, Cairo University (4/2013) "Analytical study of some compounds containing amino group". Excellent grade in premaster courses.
- Bachelor Degree of Pharmaceutical Sciences, Faculty of Pharmacy, Cairo University (5/2006), very good grade with honor 84.37%. Excellent in Analytical Chemistry courses.
- School: Patriarchal College, Ramses, Cairo.

Current positions:

- ICH Expert; Q6(R1) EWG Revision of the specifications guidelines, since 6/2024.
- Technical Advisor at marketing authorization Central Administration of Pharmaceutical Products Egyptian Drug Authority (EDA) since7/2020.
- Certified Trainer at Center for Continuing Professional Development, EDA teaching members of pharmaceutical companies and CTD assessors how to understand and implement WHO, ICH, EMA, FDA guidelines and Pharmacopoeia requirements to achieve the objectives of our regulatory authority. For example, some training lectures to Egyptian companies' managers and members:
    - Training Program on Risk Management according to updated ICH Q9 Guideline

& its application in CTD file for prequalification by WHO or FDA and EMA Approval & during Pharmaceutical Products Lifecycle (2&3/2024)

- Pharmaceutical Development of Generic Drug Products according to ICH & WHO guidelines for successful Prequalification dossier submission (5 days 12/2023) teaching; impurities, ICH M7, leachables and extractables, microbiological attributes and compatibility.
- Preparation of CTD files according to Prequalification requirements & EMA /FDA approval; six lectures (5&6/2023)
- WHO medicine prequalification CTD, development and implementation; three lectures (9/2022 repeated 1/2023).
- Validation of analytical procedures and statistics course (5/3/2021 repeated 26/7/2021).
- Understanding and setting the specifications on chirality and polymorphism (28-29/6/2021). Setting specifications to active pharmaceutical ingredients and inhalation products (8-11/4/2021 repeated 1/2022).
- Applying the new ICH M7 guideline on mutagenic impurities, nitrosamines and leachables courses (18-21/2/2021 repeated 10/2021, 2/2022).
- Drug master file specifications and manufacture according to ICH Q11 (9/2021).

- Member of EDA stability committee since 7/2024, responsible for reviewing stability critical quality attributes, analytical methodology and their validation.
- Statistics responsible at EDA stability shelf-life extension program.
- Member of EDA working group for updating ICH M4Q(R2) since 4/2023.

Work experience:

- 17 years of experience in many fields of drug regulatory authority such as marketing authorization, product testing, license and regulatory inspection;
  - marketing authorization: as CTD module 3 quality assessor and setting specifications to emergency use COVID-19 drugs (e.g. Remdesivir, Favipiravir, Ivermectin,.. active ingredients and finished products) at EDA (since 3/2020)
  - Many activities during the work at National Organization for Drug Control and Research, NODCAR Agouza branch (5/2007-3/2020 continuously) including; technical manager, quality assurance internal auditor, member of nonconformity committee for more than 5 years and also member of technical evaluation committees for the purchase tenders of chemicals, data integrity and laboratory instruments, besides the work as

pharmaceutical product laboratory analyst. Also performed proficiency testing from USP (2014), from National Institute for standardization (2011) and participate in NODCAR inter-laboratory comparison.

- Pharmaceutical companies laboratories licensing establishments: Zad industrial Pharma (4/2018), Orchidia (2/2018), Ultimate Pharma (5/2017), ACDIMA International hormones line (5/2016), Wadi Elneel Benta Pharmaceutical Company (1/2016), International company for medical necessities, Asyut (12/2015), Minapharm, Haidylena, Rhein-Minapharm (2012-2013).
- Regulatory inspections: GMP auditor for many national and multinational companies; Saja Pharmaceuticals (1/ 2020), Pharo Pharma (9/2019), Sanofi Aventis supplements (7/ 2019), Novartis (7-2019), Chemipharm (6/2019), Kahira Pharmaceuticals (3/2019), Sanofi Aventis (2/ 2019), El-Mottahedoon Pharma (1/ 2019), Allmed (1/ 2019), Napco Pharma (5/ 2018), Eva Pharma (9/ 2017). GMP audit in the quality control laboratories of Memphis, El Arabeya Company For Pharmaceutical and Chemical Industries and The Packaging and Medical Supplies Company (Mapk) with the Administrative Control Authority of Egypt (2/2017).

- Pharmacist at the Import Unit, the Egyptian Pharmaceutical Trading Company, Shobra, Cairo (2006-2007).

Academic experience:

- Teaching analytical chemistry courses of various analytical techniques and Process Analytical Technologies. (electrochemistry, instrumental, water analysis) at Faculty of Pharmacy Fayoum University (from 2 to 6/2019).
- Supervision on quality control practical course at Faculty of Pharmacy Ahram Canadian University (from 9 to 12/2018).
- Conducting oral examination at Faculties of Pharmacy; Tanta university (6/2023), Ahram Canadian University (1/2020), Fayoum, Tanta, Ein Shams Universities (6/2019) and Cairo University (6/2018, 6/2019).

Publications:

PhD

1. Comparative stability-indicating chromatographic methods for determination of 4-hexylresorcinol in pharmaceutical formulation and shrimps. *Journal of Pharmaceutical and Biomedical Analysis*, 145, 2017, 386-398.

2. Successive ratio subtraction coupled with constant multiplication spectrophotometric method for determination of hydroquinone in complex mixture with its degradation products, tretinoin and methyl paraben. *Spectrochimica Acta Part A: Molecular and Biomolecular Spectroscopy*, 157, 2016, 116–123.
3. Stability-indicating chromatographic determination of hydroquinone in combination with tretinoin and fluocinolone acetonide in pharmaceutical formulations with a photodegradation kinetic study. *RSC Advances* 5, 2015, 43178-43194.

Master and other:

4. Chromatographic Determination of Aminoacridine Hydrochloride, Lidocaine Hydrochloride and Lidocaine Toxic Impurity in Oral Gel. *Journal of Chromatographic Science*, 54 (4), 2016, 492–499.
5. Chromatographic determination of clopidogrel bisulfate; detection and quantification of counterfeit Plavix® tablets. *Bulletin of Faculty of Pharmacy, Cairo University*, 52 (1), 2014, 91–101.
6. Stability-Indicating HPLC and RP-TLC Determination of Cefpirome Sulfate with Kinetic Study. *Chromatographia*, 76 (17-18), 2013, 1141-1151.
7. Stability indicating HPLC and spectrophotometric methods for the determination of bupropion hydrochloride in the presence of its alkaline degradates and related impurity. *Bulletin of Faculty of Pharmacy, Cairo University*, 50 (1), 2012, 49-59.

International publications awards from Cairo University.

Training courses and conferences:

- Training course from ICH on Guidelines Q8, Q9, Q10, Q11, Q12 (three days 7/2023)
- Training of Trainers course by Dr. Osama Mosallam (six days 11/2022)
- Leadership course at National Training Academy (NTA) including public speaking, effective communication, strategic planning, coaching, emotional intelligence, human resources, projects management, follow-up and evaluation, crisis management, digital transformation, Egyptian National security (one month 3,5-2022)
- CTD modules 2 and 3 course at NODCAR 28/10 – 20/11/2019.
- Participant in the Global Forum for Higher Education and Scientific Research at Al-Masa Capital (5-6/2019).
- Risk management course at the National Quality Institute (3-7/6/2018).
- Analytical Chemistry Instrument conference by Technoscient company for lab and optical

products (2/2018).

- Attending GMP courses at the Central Administration of Pharmaceutical Affairs (8/2017).
- Good Laboratory Practice at the Egyptian Society for Quality (1/2017).
- Equipment Qualification lecture at NODCAR (7/2016).
- Training course on UHPLC Agilent 1290 from Agitech company (8/ 2015).
- Ion chromatography conference by Agitech company. (6/2015)
- Analytical method validation course at The Egyptian Society for Quality (1-2/4/2015).
- QMS ISO 9001:2008 Internal Audit training course at Engineering & Quality Experts (EQE) (28/2-1/3/2012).
- Developing and Implementing OHSAS 18001/2007 training course at The Egyptian Society for Quality (15-18/1/2012).
- HPLC columns applications, TLC and HPLC instruments from PSI Company (10/5/2011).
- Understanding and Implementing ISO/IEC 17025: 2005 from Egyptian Accreditation Council EGAC (14-17/1/2008).

Undergraduate training at Amoun Pharmaceutical Company and Cancer Institute (6/2005).

Foreign languages, computer skills and Personal interests:

Very good in in English, good in French and very good in ICDL.

objective in research, critical thinking, teaching updated international pharmaceutical guidelines to link academic with industrial fields.

Personal interests in philosophy and history.