

AMAAL MOHAMMED KHALLIL AI SHA'AR

TEL (MOBILE) : 0780046640 Jordan

Personal Information

Marital status : Married.

Nationality : Jordanian.

Date of Birth : December 25, 1963.

Place of Birth : West Bank



Objective

To do my best in every field, and to improve as much as I can

Education

DBA student at The World Islamic Sciences and Education University, since 2/2022-Present.

MBA (Master of Business Administration)/ Arab Open University/Jordan Branch/2018-2020

ILLAFTrain Certified Professional Trainer (CPT) Program, 2017/Dubai

Diploma of Packaging Technology, the institute of packaging (UK/Jordan branch); 2001.

Bachelor of Pharmacy - University of Jordan - 1986

General Secondary School Certificate - Science Branch - Hay Al-Arman School, Jordan – 1981

Training

1. Inter country workshop on Validation of Expiry Dates of Drugs –Philadelphia Hotel, Amman - Jordan, March 29 - April 1 1993.
2. AUPAM 5th Symposium on Stability Studies - Al Sham Hotel, Damascus - Al Sham, 15 - 16 Jun 1994.
3. Win Word 2.0, Dar Al Dawa, Na'ur - Jordan, 14 - 18 August 1995.
4. Seminar on the international TQM (Total Quality Management) Measurement Models: Analysis, Comparison & Criticism, JEDCO, Amman-Jordan, 3 September 1995.
5. Workshop on Pharmaceutical Statistic - Jordan Pharmaceutical Association, Amman - Jordan, 9 - 24 September 1995.
6. Course on Time Management - International Center for System &Management Sciences, Amman - Jordan, 13 - 22 Jan. 1996.
7. AUPAM 8th Symposium on Pharmaceutical Biotechnology – Regency Hotel, Amman - Jordan, 14 - 15 May 1997.
8. Regulatory & Scientific Issues in Drug Product Development University of Jordan of Science & Technology, Irbid - Jordan, 27 –28 May 1997.
9. Course on GMP - Dar Al Dawa, Na'ur - Jordan, 21 - 22 Jun 1997.

10. Course on ISO9000 Requirements Standards, Dar Al Dawa, Na'ur – Jordan, 16 Jun 1997.
11. Seminar on Documentation, Dar Al Dawa, Na'ur - Jordan, 28 October 1997.
12. Workshop on Writing SOP's, Dar Al Dawa, Na'ur - Jordan, 10 November 1997.
13. Seminar on GMP, Dar Al Dawa, Na'ur - Jordan, 11 November 1997.
14. DIA Workshop on Drugs Registration Requirements in the EU. Radisson Sas Hotel, Amman - Jordan, 23 - 24 Feb. 1998.
15. The eighth Jordanian Pharmaceutical conference, Jordan Pharmaceutical Association, Amman - Jordan, 6 - 8 May 1998.
16. AUPAM 9th Symposium on Bioequivalence studies, Radisson Sass Hotel, Amman - Jordan, 27 - 29 May 1998.
17. Workshop on Internal Auditing, Dar Al Dawa, Na'ur - Jordan, 5 –9 Sept. 1998.
18. Workshop on Preparation of Registration File for Europe JEDCO, Amman – Jordan, 24 - 26 October 1998.
19. Seminar on Trading with the European Union, Intercontinental Hotel, Amman, Jordan, on Sunday 29 November 1998.
20. Seminar on Future trends on production & packaging of food products, JEDCO, Amman- Jordan, 3 December 1998.
21. Workshop on Bar Code Technology, JEDCO, Amman - Jordan, 27 July 1999.
22. Seminar on Training Concept, Dar Al Dawa, Na'ur - Jordan, 10 October 1999.
23. Course in Civilian Emergency, Dar Al Dawa, Na'ur - Jordan, 16 –19 October 1999.
24. Seminar on the Development of Pharmaceutical Industry, Dar Al Dawa, Na'ur - Jordan, 10 November 1999.
25. Continues Improvement Tools and Techniques, Dar Al Dawa,Na'ur – Jordan, 28 November - 5 December 1999.
26. Seminar on the Closure-Container System, JEDCO, Amman – Jordan, 5 June 2000.
27. Course on Accounting for Managers, Dar Al Dawa, Na'ur- Jordan, 3 – 17 September 2000.
28. Lecture on the Operations of Export and Transport, Dar Al Dawa, Na'ur- Jordan, 4 October 2000.
29. Lecture on Budgeting, Dar Al Dawa, Na'ur-Jordan, 31 November 2000.
30. Lecture on Balance basic service course, Dar Al Dawa, Na'ur-Jordan, 16 April 2001.
31. New Trends in Pharmacy Education, Jordan University of Science and Technology, faculty of pharmacy, Thursday, April 26, 2001.
32. Basics for successful conversation, Dar Al Dawa, Na'ur-Jordan, 22 July 2001.

33. Social security act (law) and its application, Dar Al Dawa, Na'ur-Jordan, and 23 - 26 July 2001.
34. ISO 9001:2000, (SGS), Dar Al Dawa, Na'ur-Jordan, Meeting Hall, 18 - 20 September 2001
35. Workshop on Export for Europe JEDCO & Talal Abu Kazalah, Amman – Jordan, 8-9 October 2001.
36. Workshop on Registration requirements in MOH, Amman Hotel, 2 March 2002.
37. Ten keys for successful, Mosque of Abdullah King, Amman-Jordan, May 2002.
38. Brain Rules, Mosque of Abdullah King, Amman-Jordan, May 2002.
39. Leadership & Executive Management Skills, Na'ur Jordan, Dar Al Dawa, Meeting Hall, 1-3 July 2002.
40. GCP course, POSIC conference Hall, Royal Scientific Society RSS Amman Jordan 25/01/04
41. Development a strategic planning for registration in EU, HAYAT AMMAN HOTEL, 26-27/01/04.
42. Oral presentation, Amra HOTEL, 04.
43. Project management, Al Royal Hotel, 26-28/07/04
44. GCP course, Na'ur-Jordan, Dar Al Dawa, Meeting Hall, 5-8/12/04
45. Knowledge creation company, Na'ur-Jordan, Dar Al Dawa, Meeting Hall, 02/06/05
46. CTD format & Technical writing Workshop, Na'ur-Jordan, Dar Al Dawa, Meeting Hall, 30/11-01/12/05
47. New regulation for particle measurements in pharmaceutical industry, Na'ur-Jordan, Dar Al Dawa, Meeting Hall, 21/03/06
48. Log transformation of bioequivalence data and normality assumption, Na'ur-Jordan, Dar Al Dawa, Meeting Hall, 10/05/06
49. Train the trainer, 50 hours, since 05/05/07- 23/05/07
50. Project management, Jordan Society for Quality, Amman, 16/05/07 and 30/05/07.
51. Pillars of Excellence, Marmara Hotel, Amman, 16/06/07.
52. Bilcare Ltd., India/JFDA workshop (packaging and stability), Cosmodar Premises, Na'our. 08/09/07.
53. CTD format (modules 1-5), 23-25/10/2007. Dar Al dawa, Na'our.
54. USP3rd regional scientific meeting, 29-31/10/2007, Kempinsky Hotel, Amman.
55. Datafarm e-CTD, 14/10/08, Crown Plaza Hotel, Amman.
56. Facilitating clinical trials in MENA region conference, 23-24 October 2008, Kempinski hotel, Amman.

57. USP Fourth Annual Science meeting, November 30-December 1, 2008. Sheraton Amman, Jordan.
58. CGMP workshop, February 25-26, 2009, Grand Hyatt Hotel, Amman-Jordan.
59. Pharmacovigilance and Risk management workshop, 19-20 may 2009. le Meridian hotel Amman -Jordan
60. Arab CTD conference (AUPAM), May 30-31,2009, Radisson SAS, Amman-Jordan
61. Batch record review July 1, 2009. Grand Hyatt Hotel, Amman- Jordan
62. JFDA workshop on stability requirements, October 24/2009. Bristol Hotel Amman.
63. Negotiation and Managing Conflict in the workplace. March 29, April 6 and April 8, 2010.DAD training hall.
64. The third JAPM-middle east bioequivalence conference. April 12& 13, 2010. Grand Hayat Hotel, Amman-Jordan.
65. CTD AUPAM training course, May 2010, ACDEMA – Amman.
66. First Saudi international regulatory & registration workshop 26-27 February 2012. Riyadh, kingdom of Saudi Arabia.
67. WHO prequalification of medicines program, 14 April 2012. Lectures hall, SFDA, Al lo'lo'a center, Riyadh-KSA.
68. Workshop for the GCC on the Protection of Inventions in the Pharmaceutical sector: Patents, undisclosed information and health Policies. October 15-16/2012. Conference Hall, building 36. King Abdulaziz City for Science and Technology. Riyadh
69. 4th annual generic medicine & biosimilar, 17-18 April 2013, Rotana Park, Abu Dhabi
70. 2nd Saudi international regulatory & registration conference, 06-08 May 2013, Ritz Carilton, Saudi Arabia
71. Certified professional trainer (CPT) programme, ILLAFTrain/29July-9 August 2017, Dubai, Dusit Thani hotel.

Professional experience

SPIMACO- ADAWAEIAH. (01/02/2012 – 31/10/2013)

ARRIYADH, KINGDOM OF SAUDI ARABIA

Registration Supervisor (Female section)

1. Works with the Regulatory Affairs Manager to ensure compliance with Regulatory Affairs policies and procedures.
2. Ensures timely submission of high quality dossiers in relation to processing of product registration.

3. Informed of regulatory requirements & emerging issues, which may affect the registration approval of product.
4. Provide reports and information according to regulatory requirements.
5. Monitor and report on the progress of product registration to the Regulatory Department and other concerned departments to ensure on time completion.
6. Oversee the compilation and submission of dossiers for registration of products in identified markets
7. Supervise all related product registration activities.
8. Ensure that all products registrations are kept up to date and renewals made on time.
9. Ensure that regulatory compliance for all products with the current laws and regulations.
10. Develop and/or review regulatory project plans/protocols and reports to meet regulatory requirements.

DAR AL DAWA PHARMACEUTICAL CO. (Sept. 1987 - July 2010)

AMMAN, JORDAN

Technical manager & Regulatory affairs manager, since 1/07/09 until 20/07/2010

Manager of Regulatory affairs & Registration department, since 1/1/08

1. Keeping up to date with all new EU and key FDA regulations, guidelines and points for information that will have an impact on any project.
2. Supervise preparation of CTD for new pharmaceutical products for local, regional and EU markets.
3. Ensure that these files are correct and complete and submitted in due time to the regulatory agency.
4. Keep company management up to date on status of specific product registration actions, problems, solutions and important new regulations.
5. Assure all products remain in compliance with applicable guidelines and competent authorities' requirements.
6. Supervise formulation/editing of local language texts, package leaflets, product profiles and other relevant product information for medical practitioners and pharmacists specifying indications, effects side effects, and interactions with other drugs.
7. Supervise compiling answers with respect to questions from registration authorities.
8. Is responsible for all contacts between the company and the registration authorities.

9. Is responsible to notify the competent authorities about any changes in the manufacture of the product that could affect quality, safety and/or efficacy of the product.
10. Represent regulatory affairs during company auditing.
11. To assist in ensuring that SOPs, QDs for all key departments processes are available and applicable.
12. To assist in identification and delivery of training for any other R&D department in any aspects of RA, Departmental SOPs and QDs.

Manager of Regulatory affairs & stability; Research and Development Department, 19/1/2006 – 1/1/08

RA section:

1. Keeping up to date with all new EU and key FDA regulations, guidelines and points for information that will have an impact on any project.
2. Supervise preparation of CTD for new pharmaceutical products for local, regional and EU markets.
3. Insure that these files are correct and complete and submitted in due time to the regulatory agency.
4. Keep company management up to date on status of specific product registration actions, problems, solutions and important new regulations.
5. Assure all products remain in compliance with applicable guidelines and competent authorities' requirements.
6. Supervise formulation/editing of local language texts, package leaflets, product profiles and other relevant product information for medical practitioners and pharmacists specifying indications, effects side effects, and interactions with other drugs.
7. Supervise compiling answers with respect to questions from registration authorities.
8. Is responsible for all contacts between the company and the registration authorities.
9. Is responsible to notify the competent authorities about any changes in the manufacture of the product that could affect quality, safety and/or efficacy of the product.
10. Represent regulatory affairs during company auditing.
11. To assist in ensuring that SOPs, QDs for all key departments processes are available and applicable.
12. To assist in identification and delivery of training for any other R&D department in any aspects of RA, Departmental SOPs and QDs.

Stability section:

1. Ensure compliance of stability group activities with GMP, international guidance documents as well as DAD corporate policies.
2. Represent the stability section during regulatory inspection.
3. Monitor industry and regulatory trends as related to stability and introduce them into practice in order to maintain and advance the state of the art in stability matters.
4. Prepare and/or review regulatory filing.
5. Participate in inter-department product task force teams.
6. Review and approval of stability technical reports, protocols, SOPs, specifications and investigations for accuracy and compliance.
7. Assist in the investigation of aberrant stability results. Provide written summary reports of such investigations, when necessary.
8. Serve as the stability liaison between RA, QC, and QA.
9. Establish, implement, and audit internal and external company stability programs and systems for sample storage and data retrieval.
10. Perform statistical analysis of historical stability data and make recommendations for the expiration date extensions, product improvements, and establishment of internal specification limits for finished product release.

Manager of stability studies & medical information; Research and Development Department, since 8/1998-19/1.2006.

Tasks & Responsibility:

1. Approve primary and secondary packaging specification, text specification, shelf life specification, finished product specification, stability reports & protocols and technical files.
2. Training of new staff.
3. Follow up problems encountered during stability & design output stages.
4. Follow up the registration requirements.
5. Supervise the documentation process related to R& D department.
6. Follow up the implementation of ISO in the R & D department.
7. Manage all activities related to the supervision of stability & Medical information sections.
8. Approve the needs of the stability & medical information sections.

Section head of stability & medical information sections, since 4/1996 - 8/1998:

1. Tasks & responsibility of medical information section head:

2. To make literature survey & collect the necessary medical information.
3. To supervise the technical files arrangement & preparation.
4. To follow up the registration requirements.
5. Compiling all the reports & information related to design in one file for each product.
6. To participate in documentation related to R & D activities.
7. To update the technical files each product.
8. Tasks & responsibility of stability section head:
9. Initiate the stability program for each product according to the R&D policy.
10. Participate in carrying out all the physical & chemical tests for products under stability, according to its protocol.
11. Supervise the stability analysis to fulfill the stability program requirements & to calculate the shelf life of each product.
12. Collect, study, analyzes & reports all results of stability to the R&D director.
13. To prepare the final stability report.
14. To participate in methods validation & documentation related to R&D department activities.
15. To decide on the final packaging components types & specifications.
16. Training of new & existing staff in the section.

Section head of stability section, since 2/93-4/96.

Tasks & responsibility:

Same as above.

Pharmacist in the R&D department, since 9/87-2/93.

Tasks & responsibility:

1. Development of a new formula for generic products.
2. Development of a new method of analysis, for nonofficial products.
3. Validation of the method of analysis.
4. Carrying out accelerated stability studies.
5. Writing the technical files & the reports related to the above activities.

Pharmacist in a private pharmacy, since 6/86-9/87.

Professional activities

Participate in training of others through lectures.

Time management, DAD employees.

Stability testing, DAD employees.

Physical test, DAD employees.

Toxicity of chemicals, DAD employees.

Stability Guidelines, MOH employees.

Validation Guidelines, stability employees

TQM, Islamic Hospital employees.

Self-development, Pharmacists

Lecture about CTD content in AUPAM conference

Aleppo training course

The most important courses in human development

Smart Step/as a doorway to self-development

The art of problem solving and decision-making

T r a v e l i n g

UAE visit 9-11/03/08 (MOH employees)

Syria visit 22-24/08/08 (AUPAM regarding CTD)

Egypt visit 31/08-02/09/08 (RA audit)

Training in Syria (Asia manufacturer) 11/09

UAE visit 16-17/12/09 (MOH)

Palestine to attend a Pharmaceutical conference 2009

UAE visit 2013(MOH)

Korea Tourism 2017

M e m b e r s h i p

Jordan Pharmaceutical Association, Since 1986.

Woman Affair in the Jordan Pharmaceutical Association, 1986 – 1990.

Institute of Packaging, since December 1998.

Internal Auditing Team, since September 1998.

Internal Specification Committee.

Internal Bioequivalence committee.

Internal Packaging committee.

AUPAM committee for updating the Arab Guidelines on Stability Testing of Pharmaceutical Products, during 1999/2000.

Process champion for design and development process / ISO 9000:2000.

AUPAM committee for updating the Arab Guidelines on GMP of Pharmaceutical Products, during 2006

GMP Internal Training team, since 09/2006.

AUPAM committee for updating the Arab Guidelines on Stability of Pharmaceutical Products, 06-07/07

AUPAM committee for putting system for inspection of Pharmaceutical manufacturer. Start at 07/07

AUPAM Technical committee for preparation conference (Arab CTD) 5/09

Member of Edutrapedia.com Council

Expert of Success Skills at Annajah.net

Member in ILLAFtrain (International Learning and Leadership Advanced Foundation Train).

My Scientific Paper

Alshaar, A. M. (2022). A Comparative Study of Managerial Control in Islamic Managerial Thought and Contemporary Managerial Thought. *Journal of Islamic Sciences and Law*, 1(5). <https://www.acjrs.com/Studies/113/>

Alshaar, A. M. (2022). Impact of Leadership Styles on Job Satisfaction: Case Study. *International Journal of Academic Research in Business and Social Sciences*. 12(7), 370 – 385. <http://dx.doi.org/10.6007/IJARBSS/v12-i7/13980>

Alshaar, A. M. K. (2023). The Impact of Creativity on Digital Entrepreneurship at the Academy of Refugee Studies. *International Journal of Academic Research in Business and Social Sciences*, 13(3), 1171 – 1186. <DOI: 10.6007/IJARBSS/v13-i3/16542>

Alshaar, A. M. K. (2023). Authentic Leadership and its Impact on Supporting Strategic Intelligence. *International Journal of Academic Research in Business and Social Sciences*, 13(3), 59 – 75. <DOI: 10.6007/IJARBSS/v13-i3/16438>

Interests and Hobbies

Updating pharmaceutical knowledge by utilizing a variety of available media.

Developing and improving interpersonal skills.

Developing and improving managerial skills.

Reading & Writing.

Teaching peoples and solving their problems.

Testing my aptitude and intellect in face of vocational challenges.

Skills

Computer Knowledge (Windows Applications, Internet Explorer).

Typing Skills.

Work efficiently and flexibly in a group/team or as individual.

Note: Have a valid driving license and a car.

Master in management from a distance

Languages

Good command of English

Arabic is the mother tongue

References

Dr. O. Jawan

Managing Director

Alkindi

Sahab- Jordan.

Dr. I. Kalefa

Manager of Formulation Section, R&D Department

Dar Al Dawa Development and Investment CO. LTD

Na'ur- Jordan.

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Hanan Sboul Ph. MBA, CAE

Secretary General

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Dr. Hayel Fakhoury

Associate Professor

Management

University of North Texas, (Denton-U.S.A.), (Denton-U.S.A.), May, 1990

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Ahmad AlQatamin

Director/ Professor

Professor

Strategic Management

University of Texas at Dallas, United State of America, 1989

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